

**Annotated Study Book for Study Design:**

**Study Design Version: 1.0**

**Sponsor: Novo Nordisk**

**Study Design**

**Generated by Central Designer™**

**May 26, 2023 10:29AM**



**NOT SUBMITTED**

: InForm Screening (Scr) [SCR]	
InForm Screening [SCR]	
Study ID:	
1. Subject initials [hidden] [Initials]	[INITIALS] A3
2. DoB - Legacy IVRS interface item. Do not change or transfer [hidden] [Date of birth]	[BIRTH_DATE_SCR] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (1900-2030)
3. Age {read-only} [Age]	[AGE] N3
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

Study Object Descriptions: InForm Screening		
Type	RefName	Description
Form	SCR	Visit: SCR
Item	INITIALS	Populated by IV/WRS or RTSM as '---' - please do not change the refname or format
Item	BIRTH_DATE_SCR	Populated by IV/WRS - please do not change the refname or format
Item	AGE	Populated by RTSM - please do not change the refname or format

RDE Analytics: RD_SCR		
Data Variable RefName	RD Column Name	Column Data Type
INITIALS	INITIALS	VARCHAR2
	INITIALS_ND	VARCHAR2
BIRTH_DATE_SCR	BIRTH_DATE_SCR	DATE
	BIRTH_DATE_SCR_DTS	VARCHAR2
	BIRTH_DATE_SCR_ND	VARCHAR2
AGE	AGE	NUMBER
	AGE_ND	VARCHAR2

**NOT SUBMITTED**

<b>: InForm Enrollment (Enr) [ENR]</b>		
<b>InForm Enrollment [ENR]</b>		
Study ID:		
1. Subject No. [read-only] [Subject No.]	[PATIENT] N6	
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		
<b>Study Object Descriptions: InForm Enrollment</b>		
Type	RefName	Description
Form	ENR	Visit: ENR
Item	PATIENT	Populated by IV/WRS or RTSM and mapped from ENR to Inf Cons/Demog Integrations: A, IV/WRS, I, RTSM - please do not change the refname or format
<b>RDE Analytics: RD_ENR</b>		
Data Variable RefName	RD Column Name	Column Data Type
PATIENT	PATIENT	NUMBER
	PATIENT_ND	VARCHAR2

**SV=Subject Visits**

: Date of visit (DoV) [VISIT_DATE_DOV]		
Study ID:		
1.* Date o [Date of visit]	[VISIT_DATE] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030)	<b>SVSTDTC</b> <b>SVENDTC</b>
2.* Contact type [Contact type]	[CONTACT_TYPE_CODE] [A:21] <input type="radio"/> Site visit [A:9] <input type="radio"/> Telephone contact [A:23] <input type="radio"/> Visit entered in error [A:28] <input type="radio"/> Remote video contact [A:29] <input type="radio"/> Off-site visit [A:30] <input type="radio"/> Visit missed	<b>SVCNTMOD</b>
3.* Was the visit impacted by COVID-19? [VISIT_IMPACT] Tick 'Yes' if the contact type was changed, the visit date was rescheduled outside the visit window or missed due to COVID-19 situation [Impacted by COVID-19]	[A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No	<b>SVEPCHGI</b>

Key: [\*] = Item is required  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

**Study Object Descriptions: Date of visit**

Type	RefName	Description
Form	VISIT_DATE_DOV	Visit: V1,V2,P3,V4,P5,V6,P7,V8,P9,V10,P11,V12,P13,V14,P15,V16,P17,V18,P19,V20,P21,V22,P23,V24,P25,V26,P27,V28,P29,V30,P31,P32,V33,P34,V35

**Codelist Values Tables: Date of visit**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cCONTACT_TYPE_CODE	String		Site visit	21	citmCONTACT_TYPE_CODE1	CONTACT_TYPE_CODE
			Telephone contact	9	citmCONTACT_TYPE_CODE2	
			Visit entered in error	23	citmCONTACT_TYPE_CODE3	
			Remote video contact	28	citmCONTACT_TYPE_CODE28	
			Off-site visit	29	citmCONTACT_TYPE_CODE29	
			Visit missed	30	citmCONTACT_TYPE_CODE30	
cVISIT_IMPACT	String		Yes	1	citmVISIT_IMPACT_Y	VISIT_IMPACT
			No	2	citmVISIT_IMPACT_N	

**RDE Analytics: RD\_VISIT\_DATE\_DOV**

Data Variable RefName	RD Column Name	Column Data Type
VISIT_DATE	VISIT_DATE	DATE
	VISIT_DATE_DTS	VARCHAR2
	VISIT_DATE_ND	VARCHAR2
CONTACT_TYPE_CODE	CONTACT_TYPE_CODE_C	VARCHAR2
	CONTACT_TYPE_CODE	VARCHAR2
	CONTACT_TYPE_CODE_ND	VARCHAR2
VISIT_IMPACT	VISIT_IMPACT_C	VARCHAR2
	VISIT_IMPACT	VARCHAR2
	VISIT_IMPACT_ND	VARCHAR2

**Note: If multiple Informed Consent dates are available, then the latest date is RFICDTC**

**DS=Disposition DM=Demographics**

: Informed Consent and Demography (Inf Cons/Demog) [SUBJECT_INFO_2]	
Study ID:	
<b>Informed</b> <b>IFORM_CONSENT</b>	
1.* Date child assent obtained [Date child assent obtained]	<b>DSSTDTC</b>
2. Date and time informed consent obtained [hidden] [Date & Time]	
3. Date informed consent obtained by Parents/Legally Acceptable Representative (LAR) [hidden] [LAR Date]	
4. Date and time informed consent obtained by Parents/Legally Acceptable Representative (LAR) [hidden] [LAR Date and Time]	
5.* Date informed consent obtained by Parents/Legally Acceptable Representative (LAR) [Date of LAR]	<b>DSSTDTC</b>
6. Date informed consent obtained by Parents/Legally Acceptable Representative (LAR) <i>Only to be completed in countries where Informed Consent from both parents is required</i> [Date and Time of LAR]	<b>DSSTDTC</b>
<b>Demography [sctDEMOGRAPHY]</b>	
7. Date of birth [hidden] [Date of birth]	
8.* Date of birth [Date of birth]	
9. Retired item - maintained on CRF due to legacy integration. Do not use [hidden] [Retired Item]	
10. Sex [read-only] [Sex]	<b>SEX</b>
11. Sex single - Legacy Argus interfaced item. Do not change, use or transfer [hidden] [Retired Item]	
12. Ethnicity [hidden] [Ethnicity]	
13.* Subject self-reported ethnicity [Self-reported ethnicity]	
14. Ethnicity - Argus [hidden] [Ethnicity - Argus]	
15. Race [hidden] [Race]	
16.* Subject self-reported race <i>Select all that apply, but at least one</i> [Self-reported race]	<b>Note: RACE, When more than one selected, RACE=MULTIPLE and individual responses are RACE1, RACE2, etc. in SUPPDM</b>
17. Race - Argus [hidden] [Race - Argus]	
18. Subject No. [read-only] [Subject No.]	
19. Hidden item - used for IMPACT interface for SCREEN visit (Visit 1) [hidden] [IMPACT - SCREEN Date]	
<b>Rescreening [sctRESCREEN]</b>	
20. Previous Subject No. [hidden] [Prev. Subject No.]	

Key: [\*] = Item is required [b] = Base Unit  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: Informed Consent and Demography		
Type	RefName	Description
Form	SUBJECT_INFO_2	Visit: V1
Item	INFORM_CONSENT_DATE	Integrations: A, I - please do not change the refname or format
Item	INFORM_CONSENT_DATE_TIME	**Item DEACTIVATED**
Item	LAR_CONSENT_DATE_1	**Item DEACTIVATED**
Item	LAR_CONSENT_DATE_TIME_1	**Item DEACTIVATED**
Item	BIRTH_DATE	Mapped from BIRTH_DATE_ENTRY Integrations: A, R - please do not change the refname or format
Item	AGE_DERIVED	**Item DEACTIVATED** Calculated in InForm via rule Reporting item - please do not change the refname or format
Item	SEX_CODE	Populated by IV/WRS or RTSM Integrations: A, R, IV/WRS, I, RTSM - please do not change the refname or format
Item	SINGLE_SEX_CODE	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	ETHNIC_DETAIL_CODE	**Item DEACTIVATED**
Item	ARGUS_ETHNIC_X	Mapped from ETHNIC1_JL Integrations: A - please do not change the refname or format
Item	RACE_CODE	**Item DEACTIVATED** Integrations: A, R - please do not change the refname or format
Item	CONSENT_SPECIFY_OTHER	Integrations: A - please do not change the refname or format

	X	Mapped from RACE1_IK Integrations: A - please do not change the rename or format
Item   PATI		Populated by IV/WRS or RTSM and mapped from ENR to Inf Cons/Demog Integrations: A, IV/WRS, I, RTSM - please do not change the rename or format
Item   IMPACT_SCREEN_DT		**Item DEACTIVATED**
Item   PREVSUBJ_IN		**Item DEACTIVATED** Bespoke IWRs interface component for rescreened screen failure subjects - populated with subject's immediate previous subject number (e.g. in the event of multiple SF and rescreens)

**Codelist Values Tables: Informed Consent and Demography**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cLAR_CONSENT_DATE_NA	String		Date	1	ctmLAR_CONSENT_DATE	LAR_CONSENT_DATE_1, LAR_CONSENT_DATE_TIME_1
			N/A	998	ctmLAR_CONSENT_NA	
cISUBJ_INF_CONS_DATE	String		Date	1	ctmSUBJ_INF_CONS_DATE	LAR_CONSENT_DATE_TIME_2
			N/A	998	ctmSUBJ_INF_CONS_DATE_NA	
		1 - cISUBJ_INF_CONS_DATE	Date	1	ctmSUBJ_INF_CONS_DATE	LAR_CONSENT_DATE_2
cISEX	String		Male	1	ctmSEX1	SEX_CODE
			Female	2	ctmSEX2	
cISINGLE_SEX_CODE	String		To be selected	1	ctmSINGLE_SEX_CODE	SINGLE_SEX_CODE
cETHNIC_DETAIL	String		Hispanic or Latino	8	ctmETHNIC_DETAIL8	ETHNIC_DETAIL_CODE
			Not Hispanic or Latino	9	ctmETHNIC_DETAIL9	
cETHNIC1	String		Hispanic or Latino	HISpanic OR LATINO	ctmETHNIC1_HL	ETHNIC1_IL
			Not Hispanic or Latino	NOT HISPANIC OR LATINO	ctmETHNIC1_NH	
cRACE_CODE	String		American Indian or Alaska Native	27	ctmRACE27	RACE_CODE
			Asian	4	ctmRACExxx	
			Black or African American	18	ctmRACE18	
			Native Hawaiian or Other Pacific Islander	24	ctmRACE24	
			White	11	ctmRACE11	
			Other, specify	999	ctmRACE999	
cRACE1_CODE	String		American Indian or Alaska Native	AMERICAN INDIAN OR ALASKA NATIVE	ctmRACE_AIAN	RACE1_IK
			Asian	ASIAN	ctmRACE_ASIAN	
			Black or African American	BLACK OR AFRICAN AMERICAN	ctmRACE_BAA	
			Native Hawaiian or Other Pacific Islander	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	ctmRACE_NHOPI	
			White	WHITE	ctmRACE_WHITE	

**RDE Analytics: RD SUBJECT\_INFO\_2**

Data Variable RefName	RD Column Name	Column Data Type
INFORM_CONSENT_DATE	INFORM_CONSENT_DATE	DATE
	INFORM_CONSENT_DATE_DTS	VARCHAR2
	INFORM_CONSENT_DATE_ND	VARCHAR2
INFORM_CONSENT_DATE_TIME	INFORM_CONSENT_DATE_TIME	DATE
	INFORM_CONSENT_DATE_TIME_DTS	VARCHAR2
	INFORM_CONSENT_DATE_TIME_ND	VARCHAR2
LAR_CONSENT_DATE_1	LAR_CONSENT_DATE_1_C	VARCHAR2
	LAR_CONSENT_DATE_1	VARCHAR2
	LAR_CONSENT_DATE_1_ND	VARCHAR2
LAR_CONSENT_DATE_1 - LAR_CONSENT_DATE_V1	LAR_CONSENT_DATE_V1	DATE
	LAR_CONSENT_DATE_V1_DTS	VARCHAR2
LAR_CONSENT_DATE_1	LAR_CONSENT_DATE_1_C	VARCHAR2
	LAR_CONSENT_DATE_TIME_1_C	VARCHAR2
	LAR_CONSENT_DATE_TIME_1	VARCHAR2
	LAR_CONSENT_DATE_TIME_1_ND	VARCHAR2
LAR_CONSENT_DATE_TIME_1 - LAR_CONSENT_DATE_TIME_V1	LAR_CONSENT_DATE_TIME_V1	DATE
	LAR_CONSENT_DATE_TIME_V1_DTS	VARCHAR2
LAR_CONSENT_DATE_2	LAR_CONSENT_DATE_2_C	VARCHAR2
	LAR_CONSENT_DATE_2	VARCHAR2
	LAR_CONSENT_DATE_2_ND	VARCHAR2
LAR_CONSENT_DATE_2 - LAR_CONSENT_DATE_V2	LAR_CONSENT_DATE_V2	DATE
	LAR_CONSENT_DATE_V2_DTS	VARCHAR2
LAR_CONSENT_DATE_2	LAR_CONSENT_DATE_2_C	VARCHAR2
	LAR_CONSENT_DATE_TIME_2	VARCHAR2
	LAR_CONSENT_DATE_TIME_2_ND	VARCHAR2
LAR_CONSENT_DATE_TIME_2 - LAR_CONSENT_DATE_TIME_V2	LAR_CONSENT_DATE_TIME_V2	DATE
	LAR_CONSENT_DATE_TIME_V2_DTS	VARCHAR2
BIRTH_DATE	BIRTH_DATE	DATE
	BIRTH_DATE_DTS	VARCHAR2
	BIRTH_DATE_ND	VARCHAR2
BIRTH_DATE_ENTRY	BIRTH_DATE_ENTRY	DATE
	BIRTH_DATE_ENTRY_DTS	VARCHAR2
	BIRTH_DATE_ENTRY_DTR	VARCHAR2
	BIRTH_DATE_ENTRY_ND	VARCHAR2
AGE_DERIVED	AGE_DERIVED	NUMBER
	AGE_DERIVED_U	VARCHAR2
	AGE_DERIVED_ND	VARCHAR2
SEX_CODE	SEX_CODE_C	VARCHAR2
	SEX_CODE	VARCHAR2
	SEX_CODE_ND	VARCHAR2
SINGLE_SEX_CODE	SINGLE_SEX_CODE_C	VARCHAR2
	SINGLE_SEX_CODE	VARCHAR2
	SINGLE_SEX_CODE_ND	VARCHAR2
ETHNIC_DETAIL_CODE	ETHNIC_DETAIL_CODE_C	VARCHAR2
	ETHNIC_DETAIL_CODE	VARCHAR2
	ETHNIC_DETAIL_CODE_ND	VARCHAR2
ETHNIC1_IL	ETHNIC1_IL_C	VARCHAR2
	ETHNIC1_IL	VARCHAR2
	ETHNIC1_IL_ND	VARCHAR2
ARGUS_ETHNIC_X	ARGUS_ETHNIC_X	VARCHAR2
	ARGUS_ETHNIC_X_ND	VARCHAR2
RACE_CODE	RACE_CODE_C	VARCHAR2
	RACE_CODE	VARCHAR2
	RACE_CODE_ND	VARCHAR2
RACE_CODE - CONSENT_SPECIFY_OTHER	CONSENT_SPECIFY_OTHER	VARCHAR2
RACE1_IK	RACE1_IK_ND	VARCHAR2

-	1 Indian or Alaska Native	RACE1_IK_CITMRACEIAN_C	VARCHAR2
		RACE1_IK_CITMRACEIAN	VARCHAR2
RACE1_IK - ^		RACE1_IK_CITMRACEASIAN_C	VARCHAR2
		RACE1_IK_CITMRACEASIAN	VARCHAR2
RACE1_IK - Black or African American		RACE1_IK_CITMRACEBAA_C	VARCHAR2
		RACE1_IK_CITMRACEBAA	VARCHAR2
RACE1_IK - Native Hawaiian or Other Pacific Islander		RACE1_IK_CITMRACENHOP1_C	VARCHAR2
		RACE1_IK_CITMRACENHOP1	VARCHAR2
RACE1_IK - White		RACE1_IK_CITMRACEWHITE_C	VARCHAR2
		RACE1_IK_CITMRACEWHITE	VARCHAR2
ARGUS_RACE_X		ARGUS_RACE_X	VARCHAR2
		ARGUS_RACE_X_ND	VARCHAR2
PATIENT		PATIENT	NUMBER
		PATIENT_ND	VARCHAR2
IMPACT_SCREEN_DT		IMPACT_SCREEN_DT	DATE
		IMPACT_SCREEN_DT_DTS	VARCHAR2
		IMPACT_SCREEN_DT_ND	VARCHAR2
PREVSUBJ_IN		PREVSUBJ_IN	NUMBER
		PREVSUBJ_IN_ND	VARCHAR2

**MH=Medical History****MHCAT=GENERAL**

: Medical History/Concomitant Illness (MedHx/ConIII) [MEDHIST_MEDDRA1]			
Study ID:			
1.* Does the subject previously had, or has the subject previously had, any relevant conditions/illnesses?	<input type="radio"/> [A:1] Yes <input type="radio"/> [A:2] No		
Seq. No.	Diagnosis	Date of Onset	Continuing
2.			
If Yes is answered to question above, fill in details below.			
2.1 Seq. No. [read-only] [Seq. No.]	[MH_SEQ_NO] N3	<b>MHREFID</b>	
2.2* Diagnosis (For subjects with Type 2 diabetes, please ensure to add the details on Diabetic retinopathy and neuropathy, if applicable) [Diagnosis]	<p>[DIAGCATEG_L] [A:WEIGHT_DISORDER]</p> <p><input type="radio"/> [MHTERM_WGT_L] Weight disorder            [A:OVERWEIGHT] Overweight            [A:OBESITY] Obesity            [A:OTHER WEIGHT DISORDER] <input type="radio"/> [MHTERM_WGOTH_X] Other weight disorder, not listed above            A200</p> <p><input type="radio"/> [MHTERM_DIAG_L] Diabetes            [A:TYPE 2 DIABETES MELLITUS] Type 2 diabetes mellitus            [A:OTHER TYPE OF DIABETES] <input type="radio"/> [MHTERM_DIAGOTH_X] Other type of diabetes, not listed above            A200</p> <p><input type="radio"/> [MHTERM_EYED_L] Eye disease            [A:DIABETIC RETINOPATHY] Diabetic retinopathy            [A:OTHER EYE DISORDER] <input type="radio"/> [MHTERM_EYEDOTH_X] Other eye disorder, not listed above            A200</p> <p><input type="radio"/> [MHTERM_NEURO_L] Neuropathy            [A:DIABETIC PERIPHERAL NEUROPATHY] Diabetic peripheral neuropathy            [A:DIABETIC AUTONOMIC NEUROPATHY] Diabetic autonomic neuropathy            [A:OTHER NEUROPATHY] <input type="radio"/> [MHTERM_NEUROTH_X] Other neuropathy, not listed above            A200</p> <p><input type="radio"/> [MHTERM_PSYCH_L] Psychiatric disorder            [A:DEPRESSIVE DISORDER] Depressive disorder            [A:POST TRAUMATIC STRESS DISORDER] Post-traumatic stress disorder            [A:ANXIETY DISORDER] Anxiety disorder            [A:SUICIDAL IDEATION] Suicidal ideation            [A:SLEEP DISORDER] Sleep disorder            [A:SUBSTANCE ABUSE] Substance abuse            [A:CONCENTRATION IMPAIRED] Concentration impaired            [A:OTHER PSYCHIATRIC DISORDER] <input type="radio"/> [MHTERM_PSYCHOTH_X] Other psychiatric disorder, not listed above            A200</p> <p><input type="radio"/> [MHTERM_DYSLIP_L] Dyslipidaemia            [A:HYPERCHOLESTROLAEMIA] Hypercholesterolaemia            [A:HYPERTRIGLYCERIDEAEMIA] Hypertriglyceridaemia            [A:COMBINED HYPERLIPIDAEMIA] Combined hyperlipidaemia            [A:OTHER LIPID METABOLISM DISORDER] <input type="radio"/> [MHTERM_DYSLIOTH_X] Other lipid metabolism disorder, not listed above            A200</p> <p><input type="radio"/> [MHTERM_GLUC_L] Glucose metabolism disorder            [A:GLUCOSE TOLERANCE IMPAIRED] Glucose tolerance impaired (e.g. 2-hour plasma glucose 7.8-11.0 mmol/l (140-199 mg/dl) after 75 g oral glucose tolerance test or HbA1c 5.7-6.4% (39-47 mmol/mol)            [A:IMPAIRED FASTING GLUCOSE] Impaired fasting glucose (e.g. fasting plasma glucose 5.6-6.9 mmol/l (100-125 mg/dl)            [A:OTHER GLUCOSE METABOLISM DISORDER] <input type="radio"/> [MHTERM_GLUCOTH_X] Other glucose metabolism disorder, not listed above            A200</p> <p><input type="radio"/> [MHTERM_RESPIR_L] Respiratory disorder            [A:ASTHMA] Asthma            [A:OBSTRUCTIVE SLEEP APNOEA SYNDROME] Obstructive sleep apnoea syndrome            [A:OTHER RESPIRATORY DISORDER] <input type="radio"/> [MHTERM_RESPIOTH_X] Other respiratory disorder, not listed above            A200</p> <p><input type="radio"/> [MHTERM_CV1_L] Cardiovascular disorder and procedure            [A:HYPERTENSION] Hypertension            [A:OTHER CARDIOVASCULAR DISORDER] <input type="radio"/> [MHTERM_CVOTH_X] Other cardiovascular disorder, not listed above            A200</p> <p><input type="radio"/> [MHTERM_LIVER_L] Liver disease            [A:NONALCOHOLIC FATTY LIVER DISEASE] Nonalcoholic fatty liver disease            [A:OTHER LIVER DISEASE] <input type="radio"/> [MHTERM_LIVEROTH_X] Other liver disease, not listed above            A200</p> <p><input type="radio"/> [MHTERM_OT_X] Other disease, not listed above            A200</p>		
		<b>NOT SUBMITTED</b>	
			<b>MHTERM</b>

**MH=Medical History****MHCAT=GENERAL**

[ten]		[DISEASE_MED_TEXT] A200
2.4	[Insert either 'Diabetes' or 'Bleeding'] Complications? [hidden] [Diabetes either bleeding complications?]	[COMPLICATIONS_YN] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No
2.5*	Date of onset [Date of Onset]	[START_DATE] (DD/MM/YYYY) Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1900-2030) <b>MHSTDTC</b>
2.6	Continuing? [hidden] [Continuing?]	[STOP_DATE] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No
2.7	Date of resolution [hidden] [Date of resolution]	[STOP_DATE_NHH] (DD/MM/YYYY) Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1900-2035)
2.8*	Continuing? [Continuing]	[CONTINUING_YN] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> STOP_DATE_2 (DD/MM/YYYY) No, Stop Date: Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (1900-2030) <b>MHENRF</b> <b>Note: If Yes, then MHENRF=ONGOING</b> <b>MHENDT</b>
2.9	CTCAE - Legacy Argus interfaced item. Do not change, use or transfer [hidden] [Retired Item]	[CTCAE_SEVERITY_CODE] [A:1] <input type="radio"/> 1 Mild AE [A:2] <input type="radio"/> 2 Moderate AE [A:3] <input type="radio"/> 3 Severe AE [A:4] <input type="radio"/> 4 Life-threatening or disabling AE [A:5] <input type="radio"/> 5 Death related to AE
2.10	Breast neoplasm [hidden] [Breast neoplasm]	[MHTERM_BREAST_L] [A:BREAST CANCER] <input type="radio"/> Breast cancer [A:CARCINOMA IN SITU OF BREAST] <input type="radio"/> Carcinoma in situ of breast [A:OTHER TYPE OF BREAST NEOPLASM] <input type="radio"/> [MHTERM_BRSTOTH_X] <input type="checkbox"/> Other type of breast neoplasm, not listed above A200
2.11	Coronary heart disease [hidden] [Coronary heart disease]	[MH_DIAGSUPL_CHD_L] [A:ISCHAEMIA DOCUMENTED BY STRESS TEST WITH IMAGING MODALITY] <input type="radio"/> Ischaemia documented by stress test with imaging modality [A:ISCHAEMIA NOT DOCUMENTED BY STRESS TEST WITH IMAGING MODALITY] <input type="radio"/> Ischaemia not documented by stress test with imaging modality
2.12	Coronary artery stenosis [hidden] [Coronary artery stenosis]	[MH_DIAGSUPL_STEN_L] [A:1 CORONARY VESSEL WITH >=50% STENOSIS] <input type="radio"/> 1 Coronary vessel with >=50% stenosis [A:2 CORONARY VESSELS WITH >=50% STENOSIS] <input type="radio"/> 2 Coronary vessels with >=50% stenosis [A:>3 CORONARY VESSELS WITH >=50% STENOSIS] <input type="radio"/> 3 Coronary vessels with >=50% stenosis [A:UNKNOWN NUMBER OF VESSELS WITH >=50% STENOSIS] <input type="radio"/> Unknown number of vessels with >=50% stenosis
2.13	Myocardial infarction [hidden] [Myocardial infarction]	[MH_DIAGSUPL_MI_L] [A:NSTEMI] <input type="radio"/> nSTEMI [A:STEMI] <input type="radio"/> STEMI [A:UNKNOWN IF NSTEMI OR STEMI] <input type="radio"/> Unknown if nSTEMI or STEMI
2.14	Stroke [hidden] [Stroke]	[MH_DIAGSUPL_STRK_L] [A:ISCHAEMIC STROKE] <input type="radio"/> Ischaemic stroke [A:HAEMORRHAGIC STROKE] <input type="radio"/> Haemorrhagic stroke [A:UNDETERMINED STROKE] <input type="radio"/> Undetermined stroke
2.15	Peripheral arterial disease (atherosclerotic disease) [hidden] [Peripheral arterial disease (atherosclerotic disease)]	[MH_DIAGSUPL_PAD_L] [A:STAGE I - ASYMPTOMATIC] <input type="radio"/> Stage I - asymptomatic [A:STAGE II - CLAUDICATION AFTER >200 M OF WALKING] <input type="radio"/> Stage II A - claudication after >200 m of walking [A:STAGE II B - CLAUDICATION AFTER <200 M OF WALKING] <input type="radio"/> Stage II B - claudication after <200 m of walking [A:STAGE III - REST PAIN] <input type="radio"/> Stage III - rest pain [A:STAGE IV - NECROSIS AND/OR GANGRENE OF THE LIMB] <input type="radio"/> Stage IV - necrosis and/or gangrene of the limb
2.16	Peripheral revascularisation [hidden] [Peripheral revascularisation]	[MH_DIAGSUPL_REVAS_L] [A:PERIPHERAL ARTERY ANGIOPLASTY INCLUDING STENT] <input type="radio"/> Peripheral artery angioplasty including stent [A:PERIPHERAL ARTERY SURGERY INCLUDING RECONSTRUCTION] <input type="radio"/> Peripheral artery surgery including reconstruction [A:UNKNOWN REVASCULARISATION] <input type="radio"/> Unknown revascularisation
2.17	Leg amputation (only due to atherosclerosis) [hidden] [Leg amputation (only due to atherosclerosis)]	[MH_DIAGSUPL_AMPUT_L] [A:AMPUTATION ABOVE KNEE] <input type="radio"/> Amputation above knee [A:AMPUTATION BELOW KNEE] <input type="radio"/> Amputation below knee [A:AMPUTATION AT OR ABOVE ANKLE] <input type="radio"/> Amputation at or above ankle [A:AMPUTATION BELOW ANKLE] <input type="radio"/> Amputation below ankle
2.18	Atrial fibrillation [hidden] [Atrial fibrillation]	[MH_DIAGSUPL_FIBR_L] [A:PAROXYSMAL ATRIAL FIBRILLATION] <input type="radio"/> Paroxysmal atrial fibrillation [A:PERSISTENT ATRIAL FIBRILLATION] <input type="radio"/> Persistent atrial fibrillation [A:PERMANENT ATRIAL FIBRILLATION] <input type="radio"/> Permanent atrial fibrillation
2.19	Cardiovascular disorder [hidden] [Cardiovascular disorder]	[MHTERM_CV2_L] [A:CORONARY HEART DISEASE] <input type="radio"/> Coronary heart disease [A:HYPERTENSION] <input type="radio"/> Hypertension [A:STABLE ANGINA PECTORIS] <input type="radio"/> Stable angina pectoris [A:ANGINA PECTORIS UNSTABLE] <input type="radio"/> Angina pectoris unstable [A:CORONARY ARTERY STENOSIS] <input type="radio"/> Coronary artery stenosis [A:MYOCARDIAL INFARCTION] <input type="radio"/> Myocardial infarction [A:PERCUTANEOUS CORONARY INTERVENTION] <input type="radio"/> Percutaneous coronary intervention [A:CORONARY ARTERY BYPASS GRAFT] <input type="radio"/> Coronary artery bypass graft [A:STROKE] <input type="radio"/> Stroke [A:TRANSIENT ISCHEMIC ATTACK] <input type="radio"/> Transient ischemic attack [A:CAROTID ARTERY STENOSIS (>=50% STENOSIS)] <input type="radio"/> Carotid artery stenosis (>=50% stenosis) [A:CAROTID REVASCULARISATION] <input type="radio"/> Carotid revascularisation [A:PERIPHERAL ARTERIAL DISEASE (ATHEROSCLEROTIC DISEASE)] <input type="radio"/> Peripheral arterial disease (atherosclerotic disease) [A:PERIPHERAL ARTERY STENOSIS (>=50% STENOSIS)] <input type="radio"/> Peripheral artery stenosis (>=50% stenosis) [A:PERIPHERAL REVASCULARISATION] <input type="radio"/> Peripheral revascularisation [A:LEG AMPUTATION (ONLY DUE TO ATHEROSCLEROSIS)] <input type="radio"/> Leg amputation (only due to atherosclerosis) [A:ATRIAL FIBRILLATION] <input type="radio"/> Atrial fibrillation [A:OTHER CARDIOVASCULAR DISORDER] <input type="radio"/> [MHTERM_CV2_X] <input type="checkbox"/> Other cardiovascular disorder, not listed above A200
2.20	Hypercholesterolaemia [hidden] [Hypercholesterolaemia]	[MH_DIAGSUPL_HYPCOL_L] [A:PRIMARY (GENETIC)] <input type="radio"/> Primary (genetic) [A:SECONDARY (ACQUIRED)] <input type="radio"/> Secondary (acquired) [A:UNKNOWN TYPE] <input type="radio"/> Unknown type
2.21	Hypertriglyceridaemia [hidden] [Hypertriglyceridaemia]	[MH_DIAGSUPL_HYPTRYG_L] [A:PRIMARY (GENETIC)] <input type="radio"/> Primary (genetic) [A:SECONDARY (ACQUIRED)] <input type="radio"/> Secondary (acquired) [A:UNKNOWN TYPE] <input type="radio"/> Unknown type
2.22	Combined hyperlipidaemia [hidden] [Combined hyperlipidaemia]	[MH_DIAGSUPL_HYPLIP_L] [A:PRIMARY (GENETIC)] <input type="radio"/> Primary (genetic) [A:SECONDARY (ACQUIRED)] <input type="radio"/> Secondary (acquired) [A:UNKNOWN TYPE] <input type="radio"/> Unknown type
2.23	Eating disorder [hidden] [Eating disorder]	[MHTERM_EATDIS_L] [A:BULIMIA NERVOSA] <input type="radio"/> Bulimia nervosa [A:ANOREXIA NERVOSA] <input type="radio"/> Anorexia nervosa

		<p>[A:BINGE EATING] [A:OTHER EATING DISORDER] [MHTERM_EATDISOTH_X] Other eating disorder, not listed above A200</p>
2.24	Diabetic retinopathy [hidden] [Diabetic retinopathy]	<p>[MH_DIAGSUPL_RETINO_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.25	Diabetic macular oedema [hidden] [Diabetic macular oedema]	<p>[MH_DIAGSUPL_MACODM_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.26	Vitreous haemorrhage [hidden] [Vitreous haemorrhage]	<p>[MH_DIAGSUPL_VITHAEM_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.27	Retinal tear [hidden] [Retinal tear]	<p>[MH_DIAGSUPL_RTEAR_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.28	Tractional retinal detachment [hidden] [Tractional retinal detachment]	<p>[MH_DIAGSUPL_RETDETCH_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.29	Retinal vein occlusion [hidden] [Retinal vein occlusion]	<p>[MH_DIAGSUPL_OCVL_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.30	Corneal opacity [hidden] [Corneal opacity]	<p>[MH_DIAGSUPL_OPAC_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.31	Glaucoma [hidden] [Glaucoma]	<p>[MH_DIAGSUPL_GLauc_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.32	Cataract [hidden] [Cataract]	<p>[MH_DIAGSUPL_CATR_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.33	Pseudophakia [hidden] [Pseudophakia]	<p>[MH_DIAGSUPL_PHAK_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.34	Eye injury [hidden] [Eye injury]	<p>[MH_DIAGSUPL_EYENJ_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.35	Age-related macular degeneration [hidden] [Age-related macular degeneration]	<p>[MH_DIAGSUPL_MACDEG_L] [A:RIGHT EYE] Right eye [A:LEFT EYE] Left eye</p>
2.36	Gallbladder disease and procedure [hidden] [Gallbladder disease and procedure]	<p>[MHTERM_GALL1_L] [A:CHOLELIITHIASIS] Cholelithiasis [A:CHOLECYSTITIS] Cholecystitis [A:BILARY COLIC] Biliary colic [A:CHOLECYSTECTOMY] Cholecystectomy [A:OTHER GALLBLADDER DISORDER] [MHTERM_GALLOTH_X] Other gallbladder disorder, not listed above A200</p>
2.37	Gallbladder disease [hidden] [Gallbladder disease]	<p>[MHTERM_GALL2_L] [A:CHOLELIITHIASIS] Cholelithiasis [A:CHOLECYSTITIS] Cholecystitis [A:BILARY COLIC] Biliary colic [A:CHOLECYSTECTOMY] Cholecystectomy [A:OTHER GALLBLADDER DISORDER] [MHTERM_GALL2OTH_X] Other gallbladder disorder, not listed above A200</p>
2.38	Gastrointestinal disorder and neoplasm [hidden] [Gastrointestinal disorder and neoplasm]	<p>[MHTERM_GASTRO_L] [A:GASTROESOPHAGEAL REFLUX DISEASE] Gastroesophageal reflux disease [A: BENIGN NEOPLASM OF COLON] Benign neoplasm of colon [A: CARCINOMA IN SITU OF COLON] Carcinoma in situ of colon [A: MALIGNANT NEOPLASM OF COLON] Malignant neoplasm of colon [A: CROHN'S DISEASE] Crohn's disease [A: ULCERATIVE COLITIS] Ulcerative colitis [A: GASTRIC ULCER] Gastric ulcer [A: OTHER GASTROINTESTINAL DISORDER OR NEOPLASM] [MHTERM_GASTROOTH_X] Other gastrointestinal disorder or neoplasm, not listed above A200</p>
2.39	Genitourinary tract disorder [hidden] [Genitourinary tract disorder]	<p>[MHTERM_GENURN_L] [A: INVOLUNTARY IMPAIRED FERTILITY] Involuntary impaired fertility (both male and female) [A: INFERTILITY] Infertility (both male and female) [A: URINARY INCONTINENCE] Urinary incontinence (both male and female) [A: MENSTRUAL DISORDER] Menstrual disorder Menstrual disorder: [A: OLIGOMENORRHOEA] Oligomenorrhea [A: POLYMMENORRHOEA] Polymenorrhea [A: AMENORRHOEA] Amenorrhea [A: PCOS] Polycystic ovarian syndrome [A: OTHER GENITOURINARY TRACT DISORDER] [MHTERM_GENURNOTH_X] Other genitourinary tract disorder, not listed above A200</p>
2.40	Heart failure [hidden] [Heart failure]	<p>[MHTERM_HRTFAIL_L] [A: HEART FAILURE WITH PRESERVED EJECTION FRACTION] [MH_DIAGSUPL_HPEF_L] Heart failure with preserved ejection fraction (HFpEF) [A: NYHA CLASS I] NYHA class I [A: NYHA CLASS II] NYHA class II [A: NYHA CLASS III] NYHA class III [A: NYHA CLASS IV] NYHA class IV [A: HEART FAILURE WITH REDUCED EJECTION FRACTION] [MH_DIAGSUPL_HREF_L] Heart failure with reduced ejection fraction (HFrEF) [A: NYHA CLASS I] NYHA class I [A: NYHA CLASS II] NYHA class II [A: NYHA CLASS III] NYHA class III [A: NYHA CLASS IV] NYHA class IV [A: HEART FAILURE (WITH UNKNOWN EJECTION FRACTION)] [MH_DIAGSUPL_HUNK_L] Heart failure (with unknown ejection fraction)</p>

			<p>[A:OTHER HEART FAILURE DISEASE]</p> <p>[MHTERM_HRTFLOTH_X] <input checked="" type="checkbox"/> Other heart failure disease, not listed above A200</p>
2.41	Kidney disease [hidden] [Kidney disease]		<p>[MHTERM_KIDNEY_L]</p> <p>[A:DIABETIC NEPHROPATHY] <input type="checkbox"/> Diabetic nephropathy (diabetic kidney disease)</p> <p>[A:CHRONIC KIDNEY DISEASE] <input type="checkbox"/> Chronic kidney disease (other than diabetic kidney disease and defined as estimated or measured GFR &lt;60 ml/min per 1.73 m<sup>2</sup> or markers of kidney damage for &gt; 3 months)</p> <p>[A:OTHER KIDNEY DISORDER] <input type="checkbox"/> [MHTERM_KIDNYOTH_X] <input checked="" type="checkbox"/> Other kidney disorder, not listed above A200</p>
2.42	Musculoskeletal system disorder [hidden] [Musculoskeletal system disorder]		<p>[MHTERM_MUSSKL_L]</p> <p>[A:KNEE OSTEOARTHRITIS] <input type="checkbox"/> Knee osteoarthritis</p> <p>[A:HIPS OSTEOARTHRITIS] <input type="checkbox"/> Hips osteoarthritis</p> <p>[A:HYPERURICAEMIA] <input type="checkbox"/> Hyperuricemia (Gout)</p> <p>[A:MUSCULOSKELETAL PAIN] <input type="checkbox"/> Musculoskeletal pain</p> <p>[A:OTHER MUSCULOSKELETAL SYSTEM DISORDER] <input type="checkbox"/> [MHTERM_MUSSKLOTH_X] <input checked="" type="checkbox"/> Other musculoskeletal system disorder, not listed above A200</p>
2.43	Pancreatic disease [hidden] [Pancreatic disease]		<p>[MHTERM_PANCREA_L]</p> <p>[A:ACUTE PANCREATITIS] <input type="checkbox"/> Acute pancreatitis</p> <p>[A:CHRONIC PANCREATITIS] <input type="checkbox"/> Chronic pancreatitis</p> <p>[A:OTHER PANCREATIC DISEASE] <input type="checkbox"/> [MHTERM_PANCROTH_X] <input checked="" type="checkbox"/> Other pancreatic disease, not listed above A200</p>
2.44	Skin cancer and skin disorder [hidden] [Skin cancer and skin disorder]		<p>[MHTERM_SKIN_L]</p> <p>[A:BASEL CELL CARCINOMA] <input type="checkbox"/> Basal cell carcinoma</p> <p>[A:SQAMOUS CELL CARCINOMA] <input type="checkbox"/> Squamous cell carcinoma</p> <p>[A:MALIGNANT MELANOMA] <input type="checkbox"/> Malignant melanoma</p> <p>[A:PSORIASIS] <input type="checkbox"/> Psoriasis</p> <p>[A:ATOPIC DERMATITIS] <input type="checkbox"/> Atopic dermatitis</p> <p>[A:ECZEMA] <input type="checkbox"/> Eczema</p> <p>[A:OTHER SKIN CANCER OR SKIN DISORDER] <input type="checkbox"/> [MHTERM_SKINOTH_X] <input checked="" type="checkbox"/> Other skin cancer or skin disorder, not listed above A200</p>
2.45	Thyroid disorder [hidden] [Thyroid disorder]		<p>[MHTERM_THYR_L]</p> <p>[A:HYPERTHYROIDISM] <input type="checkbox"/> Hyperthyroidism</p> <p>[A:HYPOTHYROIDISM] <input type="checkbox"/> Hypothyroidism</p> <p>[A:OTHER THYROID DISORDER] <input type="checkbox"/> [MHTERM_THYRTH_X] <input checked="" type="checkbox"/> Other thyroid disorder, not listed above A200</p>

Key: [\*] = Item is required    [ ] = Item is collapsible

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Note: Collapsible settings are only available to users who have the rights to edit the item.

Type	RefName	Description
Form	MEDHIST_MEDDRA1	Visit: V1
Item	MEDICAL_HISTORY_MEDDRA	Integrations: A, R - please do not change the refname or format
Item	MH_SEQ_NO	Calculated in InForm via rule Integrations: A, R - please do not change the refname or format
Item	DIAGCATEG_L	The MEDDRA code for the level 2 terms (MedDRA term x) and the free text fields (Other disorders) should be mapped to item DISEASE_MED_TEXT
Item	DISEASE_MED_TEXT	Integrations: A, R - please do not change the refname or format
Item	COMPLICATIONS_YN	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	START_DATE	Integrations: A, R - please do not change the refname or format
Item	STOP_DATE	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	STOP_DATE_NMH	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	CONTINUING_YN	Integrations: A, R - please do not change the refname or format
Item	CTCAE_SEVERITY_CODE	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	MHTERM_BREAST_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_CHD_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_STEN_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_MI_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_STRK_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_PAD_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_REVAS_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_AMPUT_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_FIBR_L	**Item DEACTIVATED**
Item	MHTERM_CV2_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_HYPCOL_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_HPYTRYG_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_HYPLIP_L	**Item DEACTIVATED**
Item	MHTERM_EATDIS_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_RETINO_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_MACODM_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_VITHAEM_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_RTEAR_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_RETDETCH_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_OCOL_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_OPAQ_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_GLAUC_L	**Item DEACTIVATED**

	CATR_L	**Item DEACTIVATED**
Item	MH_D_C2_HAK_L	**Item DEACTIVATED**
Item	MH_D_C2_VENJL_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_MACDEG_L	**Item DEACTIVATED**
Item	MHTERM_GALL1_L	**Item DEACTIVATED**
Item	MHTERM_GALL2_L	**Item DEACTIVATED**
Item	MHTERM_GASTRO_L	**Item DEACTIVATED**
Item	MHTERM_GENURN_L	**Item DEACTIVATED**
Item	MHTERM_HRTFAIL_L	**Item DEACTIVATED**
Item	MHTERM_KIDNEY_L	**Item DEACTIVATED**
Item	MHTERM_MUSSKL_L	**Item DEACTIVATED**
Item	MHTERM_PANCREA_L	**Item DEACTIVATED**
Item	MHTERM_SKIN_L	**Item DEACTIVATED**
Item	MHTERM_THYR_L	**Item DEACTIVATED**

**Codelist Values Tables: Medical History/Concomitant Illness**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cYESNO	String		Yes	1	citmYESNO1	MEDICAL_HISTORY_MEDDRA
			No	2	citmYESNO2	
cDIAGCATEG_L	String	1 - cDIAGCATEG_L	Weight disorder	WEIGHT DISORDER	citmMHTERM23_L	DIAGCATEG_L
			Diabetes	DIABETES	citmMHTERM4_L	
			Eye disease	EYE DISEASE	citmMHTERM7_L	
			Neuropathy	NEUROPATHY	citmMHTERM17_L	
			Psychiatric disorder	PSYCHIATRIC DISORDER	citmMHTERM19_L	
			Dyslipidaemia	DYSLIPIDAEMIA	citmMHTERM5_L	
			Glucose metabolism disorder	GLUCOSE METABOLISM DISORDER	citmMHTERM12_L	
			Respiratory disorder	RESPIRATORY DISORDER	citmMHTERM20_L	
			Cardiovascular disorder and procedure	CARDIOVASCULAR DISORDER AND PROCEDURE	citmMHTERM2_L	
			Liver disease	LIVER DISEASE	citmMHTERM15_L	
			Other disease, not listed above	OTHER DISEASE	citmMHTERM24_L	
cIMHTERM_WGT_L	String	1 - cIMHTERM_WGT_L	Overweight	OVERWEIGHT	citmMHTERM_WGT_L_2	MHTERM_WGT_L
			Obesity	OBESITY	citmMHTERM_WGT_L_3	
			Other weight disorder, not listed above	OTHER WEIGHT DISORDER	citmMHTERM_WGT_L_4	
CLMHTERM_DIAB_L	String	1 - CLMHTERM_DIAB_L	Type 2 diabetes mellitus	TYPE 2 DIABETES MELLITUS	citmMHTERM_DIAB_L_2	MHTERM_DIAB_L
			Other type of diabetes	OTHER TYPE OF DIABETES	citmMHTERM_DIAB_L_3	
cIMHTERM_EYED_L	String		Diabetic retinopathy	DIABETIC RETINOPATHY	citmMHTERM_EYED_L_1	
			Other eye disorder, not listed above	OTHER EYE DISORDER	citmMHTERM_EYED_L_13	
cIMHTERM_NEURO_L	String	1 - cIMHTERM_NEURO_L	Diabetic peripheral neuropathy	DIABETIC PERIPHERAL NEUROPATHY	citmMHTERM_NEURO_L_1	MHTERM_NEURO_L
			Diabetic autonomic neuropathy	DIABETIC AUTONOMIC NEUROPATHY	citmMHTERM_NEURO_L_2	
			Other neuropathy, not listed above	OTHER NEUROPATHY	citmMHTERM_NEURO_L_3	
cIMHTERM_PSYCH_L	String	1 - cIMHTERM_PSYCH_L	Depressive disorder	DEPRESSIVE DISORDER	citmMHTERM_PSYCH_L_1	MHTERM_PSYCH_L
			Post-traumatic stress disorder	POST TRAUMATIC STRESS DISORDER	citmMHTERM_PSYCH_L_4	
			Anxiety disorder	ANXIETY DISORDER	citmMHTERM_PSYCH_L_5	
			Suicidal ideation	SUICIDAL IDEATION	citmMHTERM_PSYCH_L_6	
			Sleep disorder	SLEEP DISORDER	citmMHTERM_PSYCH_L_8	
			Substance abuse	SUBSTANCE ABUSE	citmMHTERM_PSYCH_L_9	
			Concentration impaired	CONCENTRATION IMPAIRED	citmMHTERM_PSYCH_L_11	
			Other psychiatric disorder, not listed above	OTHER PSYCHIATRIC DISORDER	citmMHTERM_PSYCH_L_12	
cIMHTERM_DYSLIP_L	String		Hypercholesterolaemia	HYPERCHOLESTEROLAEMIA	citmMHTERM_DYSLIP_L_1	MHTERM_DYSLIP_L
			Hypertriglyceridaemia	HYPERTRIGLYCERIDEAEMIA	citmMHTERM_DYSLIP_L_2	
			Combined hyperlipidaemia	COMBINED HYPERLIPIDAEMIA	citmMHTERM_DYSLIP_L_3	
			Other lipid metabolism disorder, not listed above	OTHER LIPID METABOLISM DISORDER	citmMHTERM_DYSLIP_L_4	
cIMHTERM_GLUC_L	String		Glucose tolerance impaired (e.g. 2-hour plasma glucose 7.8-11.0 mmol/l (140-199 mg/dl) after 75 g oral glucose tolerance test or HbA1c 5.7-6.4% (39-47 mmol/mol)	GLUCOSE TOLERANCE IMPAIRED	citmMHTERM_GLUC_L_1	MHTERM_GLUC_L
			Impaired fasting glucose (e.g. fasting plasma glucose 5.6-6.9 mmol/l (100-125 mg/dl)	IMPAIRED FASTING GLUCOSE	citmMHTERM_GLUC_L_2	
			Other glucose metabolism disorder, not listed above	OTHER GLUCOSE METABOLISM DISORDER	citmMHTERM_GLUC_L_3	
cIMHTERM_RESPIR_L	String	1 - cIMHTERM_RESPIR_L	Asthma	ASTHMA	citmMHTERM_RESPIR_L_1	MHTERM_RESPIR_L
			Obstructive sleep apnoea syndrome	OBSTRUCTIVE SLEEP APNOEA SYNDROME	citmMHTERM_RESPIR_L_3	
			Other respiratory disorder, not listed above	OTHER RESPIRATORY DISORDER	citmMHTERM_RESPIR_L_4	
cIMHTERM_CV1_L	String	1 - cIMHTERM_CV1_L	Hypertension	HYPERTENSION	citmMHTERM_CV1_L_2	MHTERM_CV1_L
			Other cardiovascular disorder, not listed above	OTHER CARDIOVASCULAR DISORDER	citmMHTERM_CV1_L_18	
cIMHTERM_LIVER_L	String	1 - cIMHTERM_LIVER_L	Nonalcoholic fatty liver disease	NONALCOHOLIC FATTY LIVER DISEASE	citmMHTERM_LIVER_L_1	MHTERM_LIVER_L
			Other liver disease, not listed above	OTHER LIVER DISEASE	citmMHTERM_LIVER_L_3	
cICOMPLICATIONS_YN	String		Yes	1	citmCOMPLICATIONS_Y	COMPLICATIONS_YN
			No	2	citmCOMPLICATIONS_N	
cICONTINUING_YN	String		Yes	1	citmCONTINUING_Y	STOP_DATE
			No	2	citmCONTINUING_N	
cICONTINUING_YN_2	String		Yes	1	CONTINUING_Y_2	CONTINUING_YN
			No	2	CONTINUING_N_2	
cICTAE_SEVERITY_CODE	String		1 Mild AE	1	citmCTAE_SEVERITY_1	CTCAE_SEVERITY_CODE
			2 Moderate AE	2	citmCTAE_SEVERITY_2	
			3 Severe AE	3	citmCTAE_SEVERITY_3	
			4 Life-threatening or disabling AE	4	citmCTAE_SEVERITY_4	
			5 Death related to AE	5	citmCTAE_SEVERITY_5	
cIMHTERM_BREAST_L	String		Breast cancer	BREAST CANCER	citmMHTERM_BREAST_L_1	MHTERM_BREAST_L
			Carcinoma in situ of breast	CARCINOMA IN SITU OF BREAST	citmMHTERM_BREAST_L_2	
			Other type of breast neoplasm, not listed above	OTHER TYPE OF BREAST NEOPLASM	citmMHTERM_BREAST_L_3	
cIMH_DIAGSUPL_CHD_L	String		Ischaemia documented by stress test with imaging modality	ISCHAEMIA DOCUMENTED BY STRESS TEST WITH IMAGING MODALITY	citmMH_DIAGSUPL_CHD_L_1	MH_DIAGSUPL_CHD_L
			Ischaemia not documented by stress test with imaging modality	ISCHAEMIA NOT DOCUMENTED BY STRESS TEST WITH IMAGING MODALITY	citmMH_DIAGSUPL_CHD_L_2	
cIMH_DIAG_SUPL_STEN_L	String		1 Coronary vessel with >=50% stenosis	1 CORONARY VESSEL WITH >=50% STENOSIS	citmMH_DIAG_SUPL_STEN_L_1	MH_DIAGSUPL_STEN_L
			2 Coronary vessels with >=50% stenosis	2 CORONARY VESSELS WITH >=50% STENOSIS	citmMH_DIAG_SUPL_STEN_L_2	
			>=3 Coronary vessels with >=50% stenosis	>=3 CORONARY VESSELS WITH >=50% STENOSIS	citmMH_DIAG_SUPL_STEN_L_3	
			Unknown number of vessels with >=50% stenosis	UNKNOWN NUMBER OF VESSELS WITH >=50% STENOSIS	citmMH_DIAG_SUPL_STEN_L_4	
cIMH_DIAGSUPL_MI_L	String		nSTEMI	NSTEMI	citmMH_DIAGSUPL_MI_L_1	MH_DIAGSUPL_MI_L
			STEMI	STEMI	citmMH_DIAGSUPL_MI_L_2	
			Unknown if nSTEMI or STEMI	UNKNOWN IF NSTEMI OR STEMI	citmMH_DIAGSUPL_MI_L_3	
cIMH_DIAGSUPL_STRK_L	String		Ischaemic stroke	ISCHAEMIC STROKE	citmMH_DIAGSUPL_STRK_L_1	MH_DIAGSUPL_STRK_L
			Haemorrhagic stroke	HAEMORRHAGIC STROKE	citmMH_DIAGSUPL_STRK_L_2	
			Undetermined stroke	UNDETERMINED STROKE	citmMH_DIAGSUPL_STRK_L_3	
cIMH_DIAGSUPL_PAD_L	String		Stage I - asymptomatic	STAGE I - ASYMPTOMATIC	citmMH_DIAGSUPL_PAD_L_1	MH_DIAGSUPL_PAD_L

		Stage IIA - claudication after >200 m of walking	STAGE IIA - CLAUDICATION AFTER >200 M OF WALKING	ctmMH_DIAGSUPL_PAD_L_2	
		Stage IIB - claudication after <200 m of walking	STAGE IIB - CLAUDICATION AFTER <200 M OF WALKING	ctmMH_DIAGSUPL_PAD_L_3	
		Stage III - rest pain	STAGE III - REST PAIN	ctmMH_DIAGSUPL_PAD_L_4	
		Stage IV - necrosis and/or gangrene of the limb	STAGE IV - NECROSIS AND/OR GANGRENE OF THE LIMB	ctmMH_DIAGSUPL_PAD_L_5	
ctMH_DIAGSUPL_REVAS_L	String	Peripheral artery angioplasty including stent	PERIPHERAL ARTERY ANGIOPLASTY INCLUDING STENT	ctmMH_DIAGSUPL_REVAS_L_1	MH_DIAGSUPL_REVAS_L
		Peripheral artery surgery including reconstruction	PERIPHERAL ARTERY SURGERY INCLUDING RECONSTRUCTION	ctmMH_DIAGSUPL_REVAS_L_2	
		Unknown revascularisation	UNKNOWN REVASCULARISATION	ctmMH_DIAGSUPL_REVAS_L_3	
ctMH_DIAGSUPL_AMPUT_L	String	Amputation above knee	AMPUTATION ABOVE KNEE	ctmMH_DIAGSUPL_AMPUT_L_1	MH_DIAGSUPL_AMPUT_L
		Amputation below knee	AMPUTATION BELOW KNEE	ctmMH_DIAGSUPL_AMPUT_L_2	
		Amputation at or above ankle	AMPUTATION AT OR ABOVE ANKLE	ctmMH_DIAGSUPL_AMPUT_L_3	
		Amputation below ankle	AMPUTATION BELOW ANKLE	ctmMH_DIAGSUPL_AMPUT_L_4	
ctMH_DIAGSUPL_FIBR_L	String	Paroxysmal atrial fibrillation	PAROXYSMAL ATRIAL FIBRILLATION	ctmMH_DIAGSUPL_FIBR_L_1	MH_DIAGSUPL_FIBR_L
		Persistent atrial fibrillation	PERSISTENT ATRIAL FIBRILLATION	ctmMH_DIAGSUPL_FIBR_L_2	
		Permanent atrial fibrillation	PERMANENT ATRIAL FIBRILLATION	ctmMH_DIAGSUPL_FIBR_L_3	
ctMHTERM_CV2_L	String	Coronary heart disease	CORONARY HEART DISEASE	ctmMHTERM_CV2_L_1	MHTERM_CV2_L
		Hypertension	HYPERTENSION	ctmMHTERM_CV2_L_2	
		Stable angina pectoris	STABLE ANGINA PECTORIS	ctmMHTERM_CV2_L_3	
		Angina pectoris unstable	ANGINA PECTORIS UNSTABLE	ctmMHTERM_CV2_L_4	
		Coronary artery stenosis	CORONARY ARTERY STENOSIS	ctmMHTERM_CV2_L_5	
		Mycardial infarction	MYOCARDIAL INFARCTION	ctmMHTERM_CV2_L_6	
		Percutaneous coronary intervention	PERCUTANEOUS CORONARY INTERVENTION	ctmMHTERM_CV2_L_7	
		Coronary artery bypass graft	CORONARY ARTERY BYPASS GRAFT	ctmMHTERM_CV2_L_8	
		Stroke	STROKE	ctmMHTERM_CV2_L_9	
		Transient ischemic attack	TRANSIENT ISCHEMIC ATTACK	ctmMHTERM_CV2_L_10	
		Carotid artery stenosis (>50% stenosis)	CAROTID ARTERY STENOSIS (>=50% STENOSIS)	ctmMHTERM_CV2_L_11	
		Carotid revascularisation	CAROTID REVASCULARISATION	ctmMHTERM_CV2_L_12	
		Peripheral arterial disease (atherosclerotic disease)	PERIPHERAL ARTERIAL DISEASE (ATHEROSCLEROTIC DISEASE)	ctmMHTERM_CV2_L_13	
		Peripheral artery stenosis (>50% stenosis)	PERIPHERAL ARTERY STENOSIS (>=50% STENOSIS)	ctmMHTERM_CV2_L_14	
		Peripheral revascularisation	PERIPHERAL REVASCULARISATION	ctmMHTERM_CV2_L_15	
		Leg amputation (only due to atherosclerosis)	LEG AMPUTATION (ONLY DUE TO ATHEROSCLEROSIS)	ctmMHTERM_CV2_L_16	
		Atrial fibrillation	ATRIAL FIBRILLATION	ctmMHTERM_CV2_L_17	
		Other cardiovascular disorder, not listed above	OTHER CARDIOVASCULAR DISORDER	ctmMHTERM_CV2_L_18	
ctMH_DIAGSUPL_HYPCOL_L	String	Primary (genetic)	PRIMARY (GENETIC)	ctmMH_DIAGSUPL_HYPCOL_L_1	MH_DIAGSUPL_HYPCOL_L
		Secondary (acquired)	SECONDARY (ACQUIRED)	ctmMH_DIAGSUPL_HYPCOL_L_2	
		Unknown type	UNKNOWN TYPE	ctmMH_DIAGSUPL_HYPCOL_L_3	
ctMH_DIAGSUPL_HYPTRYG_L	String	Primary (genetic)	PRIMARY (GENETIC)	ctmMH_DIAGSUPL_HYPTRYG_L_1	MH_DIAGSUPL_HYPTRYG_L
		Secondary (acquired)	SECONDARY (ACQUIRED)	ctmMH_DIAGSUPL_HYPTRYG_L_2	
		Unknown type	UNKNOWN TYPE	ctmMH_DIAGSUPL_HYPTRYG_L_3	
ctMH_DIAGSUPL_HYPLIP_L	String	Primary (genetic)	PRIMARY (GENETIC)	ctmMH_DIAGSUPL_HYPLIP_L_1	MH_DIAGSUPL_HYPLIP_L
		Secondary (acquired)	SECONDARY (ACQUIRED)	ctmMH_DIAGSUPL_HYPLIP_L_2	
		Unknown type	UNKNOWN TYPE	ctmMH_DIAGSUPL_HYPLIP_L_3	
ctMHTERM_EATDIS_L	String	Bulimia nervosa	BULIMIA NERVOSA	ctmMHTERM_EATDIS_L_1	MHTERM_EATDIS_L
		Anorexia nervosa	ANOREXIA NERVOSA	ctmMHTERM_EATDIS_L_2	
		Binge eating	BINGE EATING	ctmMHTERM_EATDIS_L_3	
		Other eating disorder, not listed above	OTHER EATING DISORDER	ctmMHTERM_EATDIS_L_4	
ctMH_DIAGSUPL_RETINO_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_RETINO_L_1	MH_DIAGSUPL_RETINO_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_RETINO_L_2	
ctMH_DIAGSUPL_MACODM_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_MACODM_L_1	MH_DIAGSUPL_MACODM_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_MACODM_L_2	
ctMH_DIAGSUPL_VITHAEM_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_VITHAEM_L_1	MH_DIAGSUPL_VITHAEM_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_VITHAEM_L_2	
ctMH_DIAGSUPL_RTEAR_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_RTEAR_L_1	MH_DIAGSUPL_RTEAR_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_RTEAR_L_2	
ctMH_DIAGSUPL_RETDETCH_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_RETDETCH_L_1	MH_DIAGSUPL_RETDETCH_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_RETDETCH_L_2	
ctMH_DIAGSUPL_OCUL_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_OCUL_L_1	MH_DIAGSUPL_OCUL_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_OCUL_L_2	
ctMH_DIAGSUPL_OPAQ_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_OPAQ_L_1	MH_DIAGSUPL_OPAQ_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_OPAQ_L_2	
ctMH_DIAGSUPL_GLAUC_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_GLAUC_L_1	MH_DIAGSUPL_GLAUC_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_GLAUC_L_2	
ctMH_DIAGSUPL_CATR_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_CATR_L_1	MH_DIAGSUPL_CATR_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_CATR_L_2	
ctMH_DIAGSUPL_PHAK_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_PHAK_L_1	MH_DIAGSUPL_PHAK_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_PHAK_L_2	
ctMH_DIAGSUPL_EYEINJ_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_EYEINJ_L_1	MH_DIAGSUPL_EYEINJ_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_EYEINJ_L_2	
ctMH_DIAGSUPL_MACDEG_L	String	Right eye	RIGHT EYE	ctmMH_DIAGSUPL_MACDEG_L_1	MH_DIAGSUPL_MACDEG_L
		Left eye	LEFT EYE	ctmMH_DIAGSUPL_MACDEG_L_2	
ctMHTERM_GALL1_L	String	Cholelithiasis	CHOLELITHIASIS	ctmMHTERM_GALL1_L_1	MHTERM_GALL1_L
		Cholecystitis	CHOLECYSTITIS	ctmMHTERM_GALL1_L_2	
		Biliary colic	BILIARY COLIC	ctmMHTERM_GALL1_L_3	
		Cholecystectomy	CHOLECYSTECTOMY	ctmMHTERM_GALL1_L_4	
		Other gallbladder disorder, not listed above	OTHER GALLBLADDER DISORDER	ctmMHTERM_GALL1_L_5	
ctMHTERM_GALL2_L	String	Cholelithiasis	CHOLELITHIASIS	ctmMHTERM_GALL2_L_1	MHTERM_GALL2_L
		Cholecystitis	CHOLECYSTITIS	ctmMHTERM_GALL2_L_2	
		Biliary colic	BILIARY COLIC	ctmMHTERM_GALL2_L_3	
		Cholecystectomy	CHOLECYSTECTOMY	ctmMHTERM_GALL2_L_4	
		Other gallbladder disorder, not listed above	OTHER GALLBLADDER DISORDER	ctmMHTERM_GALL2_L_5	
ctMHTERM_GASTRO_L	String	Gastroesophageal reflux disease	GASTROESOPHAGEAL REFUX DISEASE	ctmMHTERM_GASTRO_L_1	MHTERM_GASTRO_L
		Benign neoplasm of colon	BENIGN NEOPLASM OF COLON	ctmMHTERM_GASTRO_L_2	
		Carcinoma in situ of colon	CARCINOMA IN SITU OF COLON	ctmMHTERM_GASTRO_L_3	
		Malignant neoplasm of colon	MALIGNANT NEOPLASM OF COLON	ctmMHTERM_GASTRO_L_4	
		Crohn's disease	CROHNS DISEASE	ctmMHTERM_GASTRO_L_5	
		Ulcerative colitis	ULCERATIVE COLITIS	ctmMHTERM_GASTRO_L_6	
		Gastric ulcer	GASTRIC ULCER	ctmMHTERM_GASTRO_L_7	
		Other gastrointestinal disorder or neoplasm, not listed above	OTHER GASTROINTESTINAL DISORDER OR NEOPLASM	ctmMHTERM_GASTRO_L_8	
ctMHTERM_GENURN_L	String	Involuntary impaired fertility (both male and female)	INVOLUNTARY IMPAIRED FERTILITY	ctmMHTERM_GENURN_L_1	MHTERM_GENURN_L
		Infertility (both male and female)	INFERTILITY	ctmMHTERM_GENURN_L_2	

		Urinary incontinence (both male and female)	URINARY INCONTINENCE	citmHTERM_GENURN_L_3	
		Menstrual disorder	MENSTRUAL DISORDER	citmHTERM_GENURN_L_4	
		Poly cystic ovarian syndrome	POLYCYSTIC OVARIAN SYNDROME	citmHTERM_GENURN_L_5	
		Other genitourinary tract disorder, not listed above	OTHER GENITOURINARY TRACT DISORDER	citmHTERM_GENURN_L_6	
cIMH_DIAGSUPL_MENSDIS_L	String	Oligomenorrhoea	OLIGOMENORRHOEA	citmH_DIAGSUPL_MENSDIS_L_1	MH_DIAGSUPL_MENSDIS_L
		Polymenorrhoea	POLYMENORRHOEA	citmH_DIAGSUPL_MENSDIS_L_2	
		Amenorrhoea	AMENORRHOEA	citmH_DIAGSUPL_MENSDIS_L_3	
cIMHTERM_HRTFAIL_L	String	Heart failure with preserved ejection fraction (HFpEF)	HEART FAILURE WITH PRESERVED EJECTION FRACTION	citmHTERM_HRTFAIL_L_1	MHTERM_HRTFAIL_L
		Heart failure with reduced ejection fraction (HFrEF)	HEART FAILURE WITH REDUCED EJECTION FRACTION	citmHTERM_HRTFAIL_L_2	
		Heart failure (with unknown ejection fraction)	HEART FAILURE (WITH UNKNOWN EJECTION FRACTION)	citmHTERM_HRTFAIL_L_3	
		Other heart failure disease, not listed above	OTHER HEART FAILURE DISEASE	citmHTERM_HRTFAIL_L_4	
cIMH_DIAGSUPL_HFPEF_L	String	NYHA class I	NYHA CLASS I	citmH_DIAGSUPL_HFPEF_L_1	MH_DIAGSUPL_HFPEF_L
		NYHA class II	NYHA CLASS II	citmH_DIAGSUPL_HFPEF_L_2	
		NYHA class III	NYHA CLASS III	citmH_DIAGSUPL_HFPEF_L_3	
		NYHA class IV	NYHA CLASS IV	citmH_DIAGSUPL_HFPEF_L_4	
cIMH_DIAGSUPL_HFREF_L	String	NYHA class I	NYHA CLASS I	citmH_DIAGSUPL_HFREF_L_1	MH_DIAGSUPL_HFREF_L
		NYHA class II	NYHA CLASS II	citmH_DIAGSUPL_HFREF_L_2	
		NYHA class III	NYHA CLASS III	citmH_DIAGSUPL_HFREF_L_3	
		NYHA class IV	NYHA CLASS IV	citmH_DIAGSUPL_HFREF_L_4	
cIMH_DIAGSUPL_HFUNK_L	String	NYHA class I	NYHA CLASS I	citmH_DIAGSUPL_HFUNK_L_1	MH_DIAGSUPL_HFUNK_L
		NYHA class II	NYHA CLASS II	citmH_DIAGSUPL_HFUNK_L_2	
		NYHA class III	NYHA CLASS III	citmH_DIAGSUPL_HFUNK_L_3	
		NYHA class IV	NYHA CLASS IV	citmH_DIAGSUPL_HFUNK_L_4	
cIMHTERM_KIDNEY_L	String	Diabetic nephropathy (diabetic kidney disease)	DIABETIC NEPHROPATHY	citmHTERM_KIDNEY_L_1	MHTERM_KIDNEY_L
		Chronic kidney disease (other than diabetic kidney disease and defined as estimated or measured GFR <60 ml/min per 1.73 m <sup>2</sup> or markers of kidney damage for > 3 months)	CHRONIC KIDNEY DISEASE	citmHTERM_KIDNEY_L_2	
		Other kidney disorder, not listed above	OTHER KIDNEY DISORDER	citmHTERM_KIDNEY_L_3	
cIMHTERM_MUSSKL_L	String	Knee osteoarthritis	KNEE OSTEOARTHRITIS	citmHTERM_MUSSKL_L_1	MHTERM_MUSSKL_L
		Hips osteoarthritis	HIPS OSTEOARTHRITIS	citmHTERM_MUSSKL_L_2	
		Hyperuricaemia (Gout)	HYPERURICAEMIA	citmHTERM_MUSSKL_L_3	
		Musculoskeletal pain	MUSCULOSKELETAL PAIN	citmHTERM_MUSSKL_L_4	
		Other musculoskeletal system disorder, not listed above	OTHER MUSCULOSKELETAL SYSTEM DISORDER	citmHTERM_MUSSKL_L_5	
cIMHTERM_PANCREA_L	String	Acute pancreatitis	ACUTE PANCREATITIS	citmHTERM_PANCREA_L_1	MHTERM_PANCREA_L
		Chronic pancreatitis	CHRONIC PANCREATITIS	citmHTERM_PANCREA_L_2	
		Other pancreatic disease, not listed above	OTHER PANCREATIC DISEASE	citmHTERM_PANCREA_L_3	
cIMHTERM_SKIN_L	String	Basal cell carcinoma	BASAL CELL CARCINOMA	citmHTERM_SKIN_L_1	MHTERM_SKIN_L
		Squamous cell carcinoma	SQUAMOUS CELL CARCINOMA	citmHTERM_SKIN_L_2	
		Malignant melanoma	MALIGNANT MELANOMA	citmHTERM_SKIN_L_3	
		Psoriasis	PSORIASIS	citmHTERM_SKIN_L_4	
		Atopic dermatitis	ATOPIC DERMATITIS	citmHTERM_SKIN_L_5	
		Eczema	ECZEMA	citmHTERM_SKIN_L_6	
		Other skin cancer or skin disorder, not listed above	OTHER SKIN CANCER OR SKIN DISORDER	citmHTERM_SKIN_L_7	
cIMHTERM_THYR_L	String	Hyperthyroidism	HYPERTHYROIDISM	citmHTERM_THYR_L_1	MHTERM_THYR_L
		Hypothyroidism	HYPOTHYROIDISM	citmHTERM_THYR_L_2	
		Other thyroid disorder, not listed above	OTHER THYROID DISORDER	citmHTERM_THYR_L_3	

RDE Analytics: RD_MEDHIST_MEDDRA1		
Data Variable RefName	RD Column Name	Column Data Type
MEDICAL_HISTORY_MEDDRA	MEDICAL_HISTORY_MEDDRA_C	VARCHAR2
	MEDICAL_HISTORY_MEDDRA	VARCHAR2
	MEDICAL_HISTORY_MEDDRA_ND	VARCHAR2
*RD_MEDHIST_MEDDRA1_SCTMEDICAL_HISTORY_MEDDRA1		
MH_SEQ_NO	MH_SEQ_NO	NUMBER
	MH_SEQ_NO_ND	VARCHAR2
DIAGCATEG_L	DIAGCATEG_L_C	VARCHAR2
	DIAGCATEG_L	VARCHAR2
	DIAGCATEG_L_ND	VARCHAR2
DIAGCATEG_L - MHTERM_WGT_L	MHTERM_WGT_L_C	VARCHAR2
	MHTERM_WGT_L	VARCHAR2
DIAGCATEG_L - MHTERM_WGTOOTH_X	MHTERM_WGTOOTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_DIAB_L	MHTERM_DIAB_L_C	VARCHAR2
	MHTERM_DIAB_L	VARCHAR2
DIAGCATEG_L - MHTERM_DIABOTH_X	MHTERM_DIABOTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_EYED_L	MHTERM_EYED_L_C	VARCHAR2
	MHTERM_EYED_L	VARCHAR2
DIAGCATEG_L - MHTERM_EYEDOTH_X	MHTERM_EYEDOTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_NEURO_L	MHTERM_NEURO_L_C	VARCHAR2
	MHTERM_NEURO_L	VARCHAR2
DIAGCATEG_L - MHTERM_NEUROTH_X	MHTERM_NEUROTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_PSYCH_L	MHTERM_PSYCH_L_C	VARCHAR2
	MHTERM_PSYCH_L	VARCHAR2
DIAGCATEG_L - MHTERM_PSYCHOTH_X	MHTERM_PSYCHOTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_DYSLIP_L	MHTERM_DYSLIP_L_C	VARCHAR2
	MHTERM_DYSLIP_L	VARCHAR2
DIAGCATEG_L - MHTERM_DYSLIPOTH_X	MHTERM_DYSLIPOTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_GLUC_L	MHTERM_GLUC_L_C	VARCHAR2
	MHTERM_GLUC_L	VARCHAR2
DIAGCATEG_L - MHTERM_GLUCOTH_X	MHTERM_GLUCOTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_RESPIR_L	MHTERM_RESPIR_L_C	VARCHAR2
	MHTERM_RESPIR_L	VARCHAR2
DIAGCATEG_L - MHTERM_RESPIROTH_X	MHTERM_RESPIROTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_CV1_L	MHTERM_CV1_L_C	VARCHAR2
	MHTERM_CV1_L	VARCHAR2
DIAGCATEG_L - MHTERM_CVOTH_X	MHTERM_CVOTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_LIVER_L	MHTERM_LIVER_L_C	VARCHAR2
	MHTERM_LIVER_L	VARCHAR2
DIAGCATEG_L - MHTERM_LIVEROTH_X	MHTERM_LIVEROTH_X	VARCHAR2
DIAGCATEG_L - MHTERM_OT_X	MHTERM_OT_X	VARCHAR2
DISEASE_MED_TEXT	DISEASE_MED_TEXT	VARCHAR2
	DISEASE_MED_TEXT_ND	VARCHAR2

	COMPLICATIONS_YN_C	VARCHAR2
	COMPLICATIONS_YN	VARCHAR2
	COMPLICATIONS_YN_ND	VARCHAR2
START_DATE	START_DATE	DATE
	START_DATE_DTS	VARCHAR2
	START_DATE_DTR	VARCHAR2
	START_DATE_ND	VARCHAR2
STOP_DATE	STOP_DATE_C	VARCHAR2
	STOP_DATE	VARCHAR2
	STOP_DATE_ND	VARCHAR2
STOP_DATE_NMH	STOP_DATE_NMH	DATE
	STOP_DATE_NMH_DTS	VARCHAR2
	STOP_DATE_NMH_DTR	VARCHAR2
	STOP_DATE_NMH_ND	VARCHAR2
CONTINUING_YN	CONTINUING_YN_C	VARCHAR2
	CONTINUING_YN	VARCHAR2
	CONTINUING_YN_ND	VARCHAR2
CONTINUING_YN - STOP_DATE_2	STOP_DATE_2	DATE
	STOP_DATE_2_DTS	VARCHAR2
	STOP_DATE_2_DTR	VARCHAR2
CTCAE_SEVERITY_CODE	CTCAE_SEVERITY_CODE_C	VARCHAR2
	CTCAE_SEVERITY_CODE	VARCHAR2
	CTCAE_SEVERITY_CODE_ND	VARCHAR2
MHTERM_BREAST_L	MHTERM_BREAST_L_C	VARCHAR2
	MHTERM_BREAST_L	VARCHAR2
	MHTERM_BREAST_L_ND	VARCHAR2
MHTERM_BREAST_L - MHTERM_BRSTOTH_X	MHTERM_BRSTOTH_X	VARCHAR2
MH_DIAGSUPL_CHD_L	MH_DIAGSUPL_CHD_L_C	VARCHAR2
	MH_DIAGSUPL_CHD_L	VARCHAR2
	MH_DIAGSUPL_CHD_L_ND	VARCHAR2
MH_DIAGSUPL_STEN_L	MH_DIAGSUPL_STEN_L_C	VARCHAR2
	MH_DIAGSUPL_STEN_L	VARCHAR2
	MH_DIAGSUPL_STEN_L_ND	VARCHAR2
MH_DIAGSUPL_MI_L	MH_DIAGSUPL_MI_L_C	VARCHAR2
	MH_DIAGSUPL_MI_L	VARCHAR2
	MH_DIAGSUPL_MI_L_ND	VARCHAR2
MH_DIAGSUPL_STRK_L	MH_DIAGSUPL_STRK_L_C	VARCHAR2
	MH_DIAGSUPL_STRK_L	VARCHAR2
	MH_DIAGSUPL_STRK_L_ND	VARCHAR2
MH_DIAGSUPL_PAD_L	MH_DIAGSUPL_PAD_L_C	VARCHAR2
	MH_DIAGSUPL_PAD_L	VARCHAR2
	MH_DIAGSUPL_PAD_L_ND	VARCHAR2
MH_DIAGSUPL_REVAS_L	MH_DIAGSUPL_REVAS_L_C	VARCHAR2
	MH_DIAGSUPL_REVAS_L	VARCHAR2
	MH_DIAGSUPL_REVAS_L_ND	VARCHAR2
MH_DIAGSUPL_AMPUT_L	MH_DIAGSUPL_AMPUT_L_C	VARCHAR2
	MH_DIAGSUPL_AMPUT_L	VARCHAR2
	MH_DIAGSUPL_AMPUT_L_ND	VARCHAR2
MH_DIAGSUPL_FIBR_L	MH_DIAGSUPL_FIBR_L_C	VARCHAR2
	MH_DIAGSUPL_FIBR_L	VARCHAR2
	MH_DIAGSUPL_FIBR_L_ND	VARCHAR2
MHTERM_CV2_L	MHTERM_CV2_L_C	VARCHAR2
	MHTERM_CV2_L	VARCHAR2
	MHTERM_CV2_L_ND	VARCHAR2
MHTERM_CV2_L - MHTERM_CV2_X	MHTERM_CV2_X	VARCHAR2
MH_DIAGSUPL_HYPCOL_L	MH_DIAGSUPL_HYPCOL_L_C	VARCHAR2
	MH_DIAGSUPL_HYPCOL_L	VARCHAR2
	MH_DIAGSUPL_HYPCOL_L_ND	VARCHAR2
MH_DIAGSUPL_HYPTRYG_L	MH_DIAGSUPL_HYPTRYG_L_C	VARCHAR2
	MH_DIAGSUPL_HYPTRYG_L	VARCHAR2
	MH_DIAGSUPL_HYPTRYG_L_ND	VARCHAR2
MH_DIAGSUPL_HYPLIP_L	MH_DIAGSUPL_HYPLIP_L_C	VARCHAR2
	MH_DIAGSUPL_HYPLIP_L	VARCHAR2
	MH_DIAGSUPL_HYPLIP_L_ND	VARCHAR2
MHTERM_EATDIS_L	MHTERM_EATDIS_L_C	VARCHAR2
	MHTERM_EATDIS_L	VARCHAR2
	MHTERM_EATDIS_L_ND	VARCHAR2
MHTERM_EATDIS_L - MHTERM_EATDISOTH_X	MHTERM_EATDISOTH_X	VARCHAR2
MH_DIAGSUPL_RETINO_L	MH_DIAGSUPL_RETINO_L_C	VARCHAR2
	MH_DIAGSUPL_RETINO_L	VARCHAR2
	MH_DIAGSUPL_RETINO_L_ND	VARCHAR2
MH_DIAGSUPL_MACODM_L	MH_DIAGSUPL_MACODM_L_C	VARCHAR2
	MH_DIAGSUPL_MACODM_L	VARCHAR2
	MH_DIAGSUPL_MACODM_L_ND	VARCHAR2
MH_DIAGSUPL_VITHAEM_L	MH_DIAGSUPL_VITHAEM_L_C	VARCHAR2
	MH_DIAGSUPL_VITHAEM_L	VARCHAR2
	MH_DIAGSUPL_VITHAEM_L_ND	VARCHAR2
MH_DIAGSUPL_RTEAR_L	MH_DIAGSUPL_RTEAR_L_C	VARCHAR2
	MH_DIAGSUPL_RTEAR_L	VARCHAR2
	MH_DIAGSUPL_RTEAR_L_ND	VARCHAR2
MH_DIAGSUPL_RETDETCH_L	MH_DIAGSUPL_RETDETCH_L_C	VARCHAR2
	MH_DIAGSUPL_RETDETCH_L	VARCHAR2
	MH_DIAGSUPL_RETDETCH_L_ND	VARCHAR2
MH_DIAGSUPL_OCUL_L	MH_DIAGSUPL_OCUL_L_C	VARCHAR2
	MH_DIAGSUPL_OCUL_L	VARCHAR2
	MH_DIAGSUPL_OCUL_L_ND	VARCHAR2
MH_DIAGSUPL_OPAQ_L	MH_DIAGSUPL_OPAQ_L_C	VARCHAR2
	MH_DIAGSUPL_OPAQ_L	VARCHAR2
	MH_DIAGSUPL_OPAQ_L_ND	VARCHAR2

..	IC_L	MH_DIAGSUPL_GLAUC_L_C	VARCHAR2
		MH_DIAGSUPL_GLAUC_L	VARCHAR2
		MH_DIAGSUPL_GLAUC_L_ND	VARCHAR2
MH_DIAGSUPL_CATR_L		MH_DIAGSUPL_CATR_L_C	VARCHAR2
		MH_DIAGSUPL_CATR_L	VARCHAR2
		MH_DIAGSUPL_CATR_L_ND	VARCHAR2
MH_DIAGSUPL_PHAK_L		MH_DIAGSUPL_PHAK_L_C	VARCHAR2
		MH_DIAGSUPL_PHAK_L	VARCHAR2
		MH_DIAGSUPL_PHAK_L_ND	VARCHAR2
MH_DIAGSUPL_EYEINJ_L		MH_DIAGSUPL_EYEINJ_L_C	VARCHAR2
		MH_DIAGSUPL_EYEINJ_L	VARCHAR2
		MH_DIAGSUPL_EYEINJ_L_ND	VARCHAR2
MH_DIAGSUPL_MACDEG_L		MH_DIAGSUPL_MACDEG_L_C	VARCHAR2
		MH_DIAGSUPL_MACDEG_L	VARCHAR2
		MH_DIAGSUPL_MACDEG_L_ND	VARCHAR2
MHTERM_GALL1_L		MHTERM_GALL1_L_C	VARCHAR2
		MHTERM_GALL1_L	VARCHAR2
		MHTERM_GALL1_L_ND	VARCHAR2
MHTERM_GALL1_L - MHTERM_GALLOTH_X		MHTERM_GALLOTH_X	VARCHAR2
MHTERM_GALL2_L		MHTERM_GALL2_L_C	VARCHAR2
		MHTERM_GALL2_L	VARCHAR2
		MHTERM_GALL2_L_ND	VARCHAR2
MHTERM_GALL2_L - MHTERM_GALL2OTH_X		MHTERM_GALL2OTH_X	VARCHAR2
MHTERM_GASTRO_L		MHTERM_GASTRO_L_C	VARCHAR2
		MHTERM_GASTRO_L	VARCHAR2
		MHTERM_GASTRO_L_ND	VARCHAR2
MHTERM_GASTRO_L - MHTERM_GASTROOTH_X		MHTERM_GASTROOTH_X	VARCHAR2
MHTERM_GENURN_L		MHTERM_GENURN_L_C	VARCHAR2
		MHTERM_GENURN_L	VARCHAR2
		MHTERM_GENURN_L_ND	VARCHAR2
MHTERM_GENURN_L - MH_DIAGSUPL_MENSDIS_L		MH_DIAGSUPL_MENSDIS_L_C	VARCHAR2
		MH_DIAGSUPL_MENSDIS_L	VARCHAR2
MHTERM_GENURN_L - MHTERM_GENURNOTH_X		MHTERM_GENURNOTH_X	VARCHAR2
MHTERM_HRTFAIL_L		MHTERM_HRTFAIL_L_C	VARCHAR2
		MHTERM_HRTFAIL_L	VARCHAR2
		MHTERM_HRTFAIL_L_ND	VARCHAR2
MHTERM_HRTFAIL_L - MH_DIAGSUPL_HFPEF_L		MH_DIAGSUPL_HFPEF_L_C	VARCHAR2
		MH_DIAGSUPL_HFPEF_L	VARCHAR2
MHTERM_HRTFAIL_L - MH_DIAGSUPL_HFREF_L		MH_DIAGSUPL_HFREF_L_C	VARCHAR2
		MH_DIAGSUPL_HFREF_L	VARCHAR2
MHTERM_HRTFAIL_L - MH_DIAGSUPL_HFUNK_L		MH_DIAGSUPL_HFUNK_L_C	VARCHAR2
		MH_DIAGSUPL_HFUNK_L	VARCHAR2
MHTERM_HRTFAIL_L - MHTERM_HRTFLOTH_X		MHTERM_HRTFLOTH_X	VARCHAR2
MHTERM_KIDNEY_L		MHTERM_KIDNEY_L_C	VARCHAR2
		MHTERM_KIDNEY_L	VARCHAR2
		MHTERM_KIDNEY_L_ND	VARCHAR2
MHTERM_KIDNEY_L - MHTERM_KIDNYOTH_X		MHTERM_KIDNYOTH_X	VARCHAR2
MHTERM_MUSSKL_L		MHTERM_MUSSKL_L_C	VARCHAR2
		MHTERM_MUSSKL_L	VARCHAR2
		MHTERM_MUSSKL_L_ND	VARCHAR2
MHTERM_MUSSKL_L - MHTERM_MUSSKLOTH_X		MHTERM_MUSSKLOTH_X	VARCHAR2
MHTERM_PANCREA_L		MHTERM_PANCREA_L_C	VARCHAR2
		MHTERM_PANCREA_L	VARCHAR2
		MHTERM_PANCREA_L_ND	VARCHAR2
MHTERM_PANCREA_L - MHTERM_PANCROTH_X		MHTERM_PANCROTH_X	VARCHAR2
MHTERM_SKIN_L		MHTERM_SKIN_L_C	VARCHAR2
		MHTERM_SKIN_L	VARCHAR2
		MHTERM_SKIN_L_ND	VARCHAR2
MHTERM_SKIN_L - MHTERM_SKINOTH_X		MHTERM_SKINOTH_X	VARCHAR2
MHTERM_THYR_L		MHTERM_THYR_L_C	VARCHAR2
		MHTERM_THYR_L	VARCHAR2
		MHTERM_THYR_L_ND	VARCHAR2
MHTERM_THYR_L - MHTERM_THYROTH_X		MHTERM_THYROTH_X	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

APMH=Associated Persons Medical History		FA=Findings About
<b>: Weight History (Weight_Hx) [WEIGHT_HIST]</b> Study ID: <small>This form is used to collect additional information to what would be recorded in the Medical History/Concomitant Illness eCRF. Please ensure that all relevant medical history related to weight related comorbidities is recorded in the below form.</small> <p>1.* What was subject's weight a year ago? [What was your weight a year ago]  <input type="radio"/> [A:220] kg [A:700] lb            xxx.x</p> <p>2.* What has been the subject's weight at birth? [What has been the subject's weight at birth]  <input type="radio"/> [A:1] [grpWGTHX_BIRTH]            [WGTHX_BIRTH] [WGTHX_BIRTH_UNIT]            xxx.x [A:220] kg [A:700] lb            [A:2] Unknown</p> <p>3.* What has been the subject's maximum weight? [What has been your maximum weight?  <input type="radio"/> [A:220] kg [A:700] lb            xxx.x</p> <p>4.* How old was the subject at that time when he/she gained maximum weight? [How old were you at that time?  <input type="radio"/> [A:2] years            N2</p> <p>5. In the subject's own opinion, was the subject overweight or obese when [hidden]  <small>[Subject overweight or obese]</small></p> <p>6. What is the least the subject has ever weighed as an adult? [hidden]  <small>[What is the least you have ever weighed as an adult? ]</small>  <input type="radio"/> [A:220] kg [A:700] lb            xxxx.</p> <p>7.* How many times has the subject intentionally lost ≥ 11 lb/5 kg?  <small>[How many times have you intentionally lost ≥ 10 pounds/5 kg?]</small>  <input type="radio"/> [A:59] Never  <input type="radio"/> [A:414] 1-2  <input type="radio"/> [A:415] 3-5  <input type="radio"/> [A:416] 6-10  <input type="radio"/> [A:417] &gt;10</p> <p>8.* Which of the following methods has the subject tried for weight loss (regardless of how much weight they lost)? (Tick all that apply)  <small>[Which of the following methods has the subject tried for weight loss (regardless of how much weight they lost)?]</small>  <b>FASCAT=METHODS FOR WEIGHT LOSS</b>  <input type="checkbox"/> self-directed (i.e., "on my own," using only books, websites, mobile apps, activity trackers or fitness monitors)  <input type="checkbox"/> weight loss program (e.g., Weight Watchers, insurance-offered program, dietary counselling, personal training, very-low-calorie diet, full meal replacement)  <input type="checkbox"/> over-the-counter weight loss aids  <input type="checkbox"/> off-label prescription medications for obesity  <input type="checkbox"/> prescription Anti-Obesity medications  <input type="checkbox"/> none of the above</p> <p>9.* Regarding bariatric surgery, has the subject ever  <small>[Regarding bariatric surgery, has the subject ever]</small>  <input type="checkbox"/> considered pursuing bariatric surgery  <input type="checkbox"/> discussed bariatric surgery with a healthcare provider  <input type="checkbox"/> begun preparations for bariatric surgery  <input type="checkbox"/> been offered bariatric surgery, but declined  <input type="checkbox"/> none of the above</p> <p>10.* Did any of the subject's first degree relatives ever have overweight or obesity?  <small>(First degree relative is defined as biological parent or sibling, if unknown select 'No')            [Obesity in first degree relatives?]</small>  <input type="checkbox"/> No  <input type="checkbox"/> Yes</p> <p>11. What has the subject's weight gain pattern been from age 18 to present: [hidden]  <small>[What has your weight gain pattern been from age 18 to present:]</small>  <b>MHTERM=FIRST DEGREE RELATIVES WITH OBESITY</b>  <input type="checkbox"/> No pattern  <input type="checkbox"/> Gradual increase of weight  <input type="checkbox"/> Sudden weight gain in relation to pregnancy  <input type="checkbox"/> Sudden weight gain in relation to pharmacological treatment  <input type="checkbox"/> Yo-yo pattern/weight cycling due to intermittent weight loss treatment (diet and exercise or pharmacological)</p> <p>12. Number of pregnancies  <small>If male just specify 0 (zero) [hidden]            [Number of pregnancies:]</small>  <input type="checkbox"/> N2</p> <p>13. Yes [hidden]  <small>[Yes]</small></p> <p>14. 18 years old [hidden]  <small>[18 years old]</small></p>		<b>MHCAT=WEIGHT HISTORY</b> <b>FACAT= WEIGHT HISTORY</b> <b>FAOBJ= WEIGHT</b> <b>FAORRES/FAORRESU when FATESTCD=SUBJWGYR</b> <b>FAORRES/FAORRESU when FATESTCD=SUWEBIRT</b> <b>FASCAT=MAXIMUM WEIGHT</b> <b>FAORRES/FAORRESU when FATESTCD=SUBMXWGT</b> <b>FAORRES when FATESTCD=SULOSWGT</b> <b>FAORRES when FATESTCD=SELFMETD</b> <b>FAORRES when FATESTCD=WEGLSPGM</b> <b>FAORRES when FATESTCD=CNTWEGLS</b> <b>FAORRES when FATESTCD=OFFLAPRE</b> <b>FAORRES when FATESTCD=PRSMEOBS</b> <b>FAORRES when FATESTCD=PRSUBASR</b> <b>FAORRES when FATESTCD=DISCBASR</b> <b>FAORRES when FATESTCD=PREPBASR</b> <b>FAORRES when FATESTCD=DECLBASR</b> <b>MHPRESP=Y</b> <b>MHOCCUR</b> <b>FAORRES when FATESTCD=OBSDREL</b> <b>FAORRES when FATESTCD=NONABBAR</b> <b>FAORRES when FATESTCD=NONOFABV</b> <b>FAORRES when FATESTCD=OBSESY</b> <b>WGTHX_OBESITY_YN</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>WGTHX_GAIN</b> <input type="checkbox"/> No pattern <input type="checkbox"/> Gradual increase of weight <input type="checkbox"/> Sudden weight gain in relation to pregnancy <input type="checkbox"/> Sudden weight gain in relation to pharmacological treatment <input type="checkbox"/> Yo-yo pattern/weight cycling due to intermittent weight loss treatment (diet and exercise or pharmacological) <b>WGTHX_PREG</b> <input type="checkbox"/> N2 <b>WGTHX_OBESITY</b> <small>If yes, whom:</small> <b>WGTHX_OBESYES</b> <input type="checkbox"/> Mother <input type="checkbox"/> Father <b>WGTHX_OBESYES2</b> <input type="checkbox"/> Any sibling(s) <small>If yes, please specify number:</small> <input type="checkbox"/> N2 <b>WGTHX_OBESYES3</b> <input type="checkbox"/> Any children <small>If yes, please specify number:</small> <input type="checkbox"/> N2 <b>WGTHX_OPN_OBAS3</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <small>Note: [*] = Item is required [ ✓ ] = Source verification required            Note: Source verification critical settings made in Inform will override any settings made in Central Designer.</small>

Study Object Descriptions: Weight History		
Type	RefName	Description
Form	WEIGHT_HIST	Visit: V2
Item	grpWGTHX_OPN_OBAS	**Item DEACTIVATED**
Item	grpWGTHX_LEAST	**Item DEACTIVATED**
Item	WGTHX_GAIN	**Item DEACTIVATED**
Item	WGTHX_PREG	**Item DEACTIVATED**
Item	grpWGTHX_OBESITY	**Item DEACTIVATED**
Item	WGTHX_OPN_OBAS3	**Item DEACTIVATED**

## Codelist Values Tables: Weight History

	<b>Codelist Data Type</b>	<b>Subset</b>	<b>Label</b>	<b>Code</b>	<b>Codelist Item RefName</b>	<b>Data Variable RefName</b>
cIWGTH	String		kg	220	ctmWGTH_X_UNIT1	WGTH_X_UNIT,
			lb	700	ctmWGTH_X_UNIT2	WGTH_X_UNIT1,
cIWGTHX_BIRTH1	String		Known	1	ctmWGTH_X_BIRTH1	WGTH_X_BIRTH1
			Unknown	2	ctmWGTH_X_BIRTH2	
cIWGTHX_BIRTH_UNIT	String		kg	220	ctmWGTH_X_BIRTH_UNIT1	WGTH_X_BIRTH_UNIT
			lb	700	ctmWGTH_X_BIRTH_UNIT2	
cIWGTHX_OPN_OBAS1	String		No	2	ctmWGTH_X_OPN_OBAS2	WGTH_X_OPN_OBAS1,
			Yes	1	ctmWGTH_X_OPN_OBAS1	WGTH_X_OPN_OBAS2,
cIWGTHX_LOSTLBS	String		Never	59	ctmWGTH_X_LOSTLBS1	WGTH_X_LOSTLBS
			1-2	414	ctmWGTH_X_LOSTLBS2	
			3-5	415	ctmWGTH_X_LOSTLBS3	
			6-10	416	ctmWGTH_X_LOSTLBS4	
			>10	417	ctmWGTH_X_LOSTLBS5	
cIWEIGHTLOSS1	String	self-directed (i.e., "on my own," using only books, websites, mobile apps, activity trackers or fitness monitors)			1	ctmWEIGHTLOSS1
cIWEIGHTLOSS2	String	weight loss program (e.g., Weight Watchers, insurance-offered program, dietary counselling, personal training, very-low-calorie diet, full meal replacement)			1	ctmWEIGHTLOSS2
cIWEIGHTLOSS3	String	over-the-counter weight loss aids			1	ctmWEIGHTLOSS3
cIWEIGHTLOSS4	String	Off-label prescription medications for obesity			1	ctmWEIGHTLOSS4
cIWEIGHTLOSS5	String	Prescription Anti-Obesity medications			1	ctmWEIGHTLOSS5
cIWEIGHTLOSS6	String	none of the above			1	ctmWEIGHTLOSS1_5
cIBARIATRIC1	String	considered pursuing bariatric surgery			1	ctmBARIATRIC1
cIBARIATRIC2	String	discussed bariatric surgery with a healthcare provider			1	ctmBARIATRIC2
cIBARIATRIC3	String	begun preparations for bariatric surgery			1	ctmBARIATRIC3
cIBARIATRIC4	String	been offered bariatric surgery, but declined			1	ctmBARIATRIC4
cIBARIATRICS	String	none of the above			1	ctmBARIATRICS
cINOYES_3_1	String		No	2	ctmNOYES2_3_1	
			Yes	1	ctmNOYES1_3_1	WGTH_X_OBESITY_YN
cIWGTHX_GAIN	String		No pattern	409	ctmWGTH_X_GAIN1	
			Gradual increase of weight	410	ctmWGTH_X_GAIN2	WGTH_X_GAIN
			Sudden weight gain in relation to pregnancy	411	ctmWGTH_X_GAIN3	
			Sudden weight gain in relation to pharmacological treatment	412	ctmWGTH_X_GAIN4	
			Yo-yo pattern/weight cycling due to intermittent weight loss treatment (diet and exercise or pharmacological)	413	ctmWGTH_X_GAIN5	
cIWGTHX_OBESYES	String	Mother	8	ctmWGTH_X_OBESYES1	WGTH_X_OBESYES	
		Father	9	ctmWGTH_X_OBESYES2		
cIWGTHX_OBESYES2	String	Any sibling(s)	2	ctmWGTH_X_OBESYES3	WGTH_X_OBESYES2	
cIWGTHX_OBESYES3	String	Any children	3	ctmWGTH_X_OBESYES4	WGTH_X_OBESYES3	

**RDE Analytics: RD\_WEIGHT\_HIST**

<b>Data Variable RefName</b>	<b>RD Column Name</b>	<b>Column Data Type</b>
grpWGTHX_YEAR	GRPWGTH_X_YEAR_ND	VARCHAR2
grpWGTHX_YEAR - WGTH_X_YEAR	WGTH_X_YEAR	FLOAT
grpWGTHX_YEAR - WGTH_X_UNIT	WGTH_X_UNIT_C	VARCHAR2
WGTH_X_BIRTH1	WGTH_X_UNIT	VARCHAR2
WGTH_X_BIRTH1 - WGTH_X_BIRTH	WGTH_X_BIRTH1_C	VARCHAR2
WGTH_X_BIRTH1 - WGTH_X_BIRTH_UNIT	WGTH_X_BIRTH1	VARCHAR2
WGTH_X_BIRTH1 - WGTH_X_BIRTH1_ND	WGTH_X_BIRTH1_ND	VARCHAR2
WGTH_X_BIRTH	WGTH_X_BIRTH	FLOAT
WGTH_X_BIRTH_UNIT_C	WGTH_X_BIRTH_UNIT	VARCHAR2
WGTH_X_BIRTH_UNIT	WGTH_X_BIRTH_UNIT	VARCHAR2
grpWGTHX_MAX	GRPWGTH_X_MAX_ND	VARCHAR2
grpWGTHX_MAX - WGTH_X_MAX	WGTH_X_MAX	FLOAT
grpWGTHX_MAX - WGTH_X_UNIT1	WGTH_X_UNIT1_C	VARCHAR2
WGTH_X_UNIT1	WGTH_X_UNIT1	VARCHAR2
WGTH_X_YEARS	WGTH_X_YEARS	NUMBER
WGTH_X_YEARS_ND	WGTH_X_YEARS_ND	VARCHAR2
grpWGTHX_OPN_OBAS	GRPWGTH_X_OPN_OBAS_ND	VARCHAR2
grpWGTHX_OPN_OBAS - WGTH_X_OPN_OBAS1	WGTH_X_OPN_OBAS1_C	VARCHAR2
WGTH_X_OPN_OBAS1	WGTH_X_OPN_OBAS1	VARCHAR2
grpWGTHX_OPN_OBAS - WGTH_X_OPN_OBAS2	WGTH_X_OPN_OBAS2_C	VARCHAR2
WGTH_X_OPN_OBAS2	WGTH_X_OPN_OBAS2	VARCHAR2
grpWGTHX_LEAST	GRPWGTH_X_LEAST_ND	VARCHAR2
grpWGTHX_LEAST - WGTH_X_LEAST	WGTH_X_LEAST	FLOAT
grpWGTHX_LEAST - WGTH_X_LEAST_UNIT	WGTH_X_LEAST_UNIT_C	VARCHAR2
WGTH_X_LEAST_UNIT	WGTH_X_LEAST_UNIT	VARCHAR2
WGTH_X_LOSTLBS	WGTH_X_LOSTLBS_C	VARCHAR2
WGTH_X_LOSTLBS	WGTH_X_LOSTLBS	VARCHAR2
WGTH_X_LOSTLBS_ND	WGTH_X_LOSTLBS_ND	VARCHAR2
grpWGTHX_WEIGHTLOSS	GRPWGTH_X_WEIGHTLOSS_ND	VARCHAR2
grpWGTHX_WEIGHTLOSS - self-directed (i.e., "on my own," using only books, websites, mobile apps, activity trackers or fitness monitors)	*WEIGHTLOSS1_CITMWEIGHTLOSS1_C	VARCHAR2
grpWGTHX_WEIGHTLOSS - weight loss program (e.g., Weight Watchers, insurance-offered program, dietary counselling, personal training, very-low-calorie diet, full meal replacement)	*WEIGHTLOSS1_CITMWEIGHTLOSS1	VARCHAR2
grpWGTHX_WEIGHTLOSS - over-the-counter weight loss aids	*WEIGHTLOSS2_CITMWEIGHTLOSS2_C	VARCHAR2
grpWGTHX_WEIGHTLOSS - Off-label prescription medications for obesity	*WEIGHTLOSS2_CITMWEIGHTLOSS2	VARCHAR2
grpWGTHX_WEIGHTLOSS - Prescription Anti-Obesity medications	*WEIGHTLOSS3_CITMWEIGHTLOSS3_C	VARCHAR2
grpWGTHX_WEIGHTLOSS - none of the above	*WEIGHTLOSS3_CITMWEIGHTLOSS3	VARCHAR2
grpWGTHX_WEIGHTLOSS - Off-label prescription medications for obesity	*WEIGHTLOSS4_CITMWEIGHTLOSS4_C	VARCHAR2
grpWGTHX_WEIGHTLOSS - Prescription Anti-Obesity medications	*WEIGHTLOSS4_CITMWEIGHTLOSS4	VARCHAR2
grpWGTHX_WEIGHTLOSS - none of the above	*WEIGHTLOSS5_CITMWEIGHTLOSS5_C	VARCHAR2
grpWGTHX_BARIATRIC	*WEIGHTLOSS5_CITMWEIGHTLOSS5	VARCHAR2
grpWGTHX_BARIATRIC - considered pursuing bariatric surgery	*WEIGHTLOSS6_CITMWEIGHTLOSS15_C	VARCHAR2
grpWGTHX_BARIATRIC - discussed bariatric surgery with a healthcare provider	*WEIGHTLOSS6_CITMWEIGHTLOSS15	VARCHAR2
grpWGTHX_BARIATRIC - begun preparations for bariatric surgery	BARIATRIC1_CITMBARIATRIC3_C	VARCHAR2
grpWGTHX_BARIATRIC - been offered bariatric surgery, but declined	BARIATRIC3_CITMBARIATRIC3	VARCHAR2
	BARIATRIC4_CITMBARIATRIC4_C	VARCHAR2
	BARIATRIC4_CITMBARIATRIC4	VARCHAR2

IC - none of the above	BARIATRICS_CITMBARIATRICS_C	VARCHAR2
WGTHX_OBEC_TV	BARIATRICS_CITMBARIATRICS	VARCHAR2
	WGTHX_OBESITY_YN_C	VARCHAR2
	WGTHX_OBESITY_YN	VARCHAR2
	WGTHX_OBESITY_YN_ND	VARCHAR2
	WGTHX_GAIN_C	VARCHAR2
	WGTHX_GAIN	VARCHAR2
	WGTHX_GAIN_ND	VARCHAR2
	WGTHX_PREG	NUMBER
	WGTHX_PREG_ND	VARCHAR2
	GRPWGTHX_OBESITY_ND	VARCHAR2
grpWGTHX_OBESITY	*WGTHX_OBESYES_CITMWGTHXOBESYES1_C	VARCHAR2
grpWGTHX_OBESITY - Mother	*WGTHX_OBESYES_CITMWGTHXOBESYES1	VARCHAR2
grpWGTHX_OBESITY - Father	*WGTHX_OBESYES_CITMWGTHXOBESYES2_C	VARCHAR2
grpWGTHX_OBESITY - Any sibling(s)	*WGTHX_OBESYES_CITMWGTHXOBESYES2	VARCHAR2
	*WGTHX_OBESYES2_WGTHX_OBESITY_NUM1_C	VARCHAR2
	*WGTHX_OBESYES2_WGTHX_OBESITY_NUM1	VARCHAR2
grpWGTHX_OBESITY - WGTHX_OBESITY_NUM1	WGTHX_OBESITY_NUM1	NUMBER
grpWGTHX_OBESITY - Any children	*WGTHX_OBESYES3_WGTHX_OBESITY_NUM2_C	VARCHAR2
grpWGTHX_OBESITY - WGTHX_OBESITY_NUM2	*WGTHX_OBESYES3_WGTHX_OBESITY_NUM2	VARCHAR2
WGTHX_OPN_OBAS3	WGTHX_OBESITY_NUM2	NUMBER
	WGTHX_OPN_OBAS3_C	VARCHAR2
	WGTHX_OPN_OBAS3	VARCHAR2
	WGTHX_OPN_OBAS3_ND	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**RP=Reproductive System Findings**

: Childbearing Potential (ChBrPot) [CHILDBEAR_POTENTIAL]						
Study ID:						
1.* Is the [Subject of childbearing potential?			[CHILDBEAR_POT_YN] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No		RPORRES when RPTESTCD=CHILDPOT	
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.						
Study Object Descriptions: Childbearing Potential						
Type	RefName	Description				
Form	CHILDBEAR_POTENTIAL	Visit: V1,V2,P3,V4,P5,V6,P7,V8,P9,V10,P11,V12,P13,V14,P15,V16,P17,V18,P19,V20,P21,V22,P23,V24,P25,V26,P27,V28,P29,V30,V31,P32,V33,P34,V35 Form to be dynamically triggered from the Inf Cons/Demog form for female subjects				
Codelist Values Tables: Childbearing Potential						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clCHILDBEAR_POT_YN	String		Yes	1	citmCHILDBEAR_POT_YN1	CHILDBEAR_POT_YN
			No	2	citmCHILDBEAR_POT_YN2	
RDE Analytics: RD_CHILDBEAR_POTENTIAL						
Data Variable RefName	RD Column Name	Column Data Type				
CHILDBEAR_POT_YN	CHILDBEAR_POT_YN_C	VARCHAR2				
	CHILDBEAR_POT_YN	VARCHAR2				
	CHILDBEAR_POT_YN_ND	VARCHAR2				

**LB=Laboratory Test Results****LBCAT=PREGNANCY TEST**

: Pregnancy Test (Preg) [PREGVIS]					
Study ID: If Positive, do not be discontinued from investigational medicinal product. The paper Pregnancy forms must also be completed.		Test done?		Medium	Result
#	Test	Test done?	Medium	Result	Date of test
1.a	PREGNANCY_TEST_RESULT		Urine		
1.1	Test [hidden] [Test]	[A:1] <input checked="" type="radio"/> PREGNANCY_TEST_RESULT			
1.2	Test done? [Test done?]	[A:1] <input type="checkbox"/> Not Done	<b>LBSTAT</b>		
1.3	Medium (read-only) [Medium]	[A:4] <input checked="" type="radio"/> Urine	<b>LBSPEC</b>		
1.4	Result [Result]	[A:1] <input checked="" type="radio"/> Positive <input type="radio"/> Negative	<b>LBORRES when LBTESTCD=HCG</b>		
1.5	Date of test [hidden] [Date of test]	[PREGVIS_LBDTC_D] (DD/MM/YYYY)	Req <input checked="" type="checkbox"/>	/ Req <input type="checkbox"/>	/ Req <input checked="" type="checkbox"/> (2023-2030)
Key: <input checked="" type="checkbox"/> = Fixed item Note: Source verification critical settings made in InForm will override any settings made in Central Designer.					

Study Object Descriptions: Pregnancy Test		
Type	RefName	Description
Form	PREGVIS	Visit: V1, V2, V4, V6, V8, V10, V12, V14, V16, V18, V20, V22, V24, V26, V28, V30, V31, V33, V35 Form is dynamically triggered from the Childbearing Potential form if the response is Yes
Item	PREGVIS_LBDTC_D	**Item DEACTIVATED**

Codelist Values Tables: Pregnancy Test						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIPREGVIS_LBTPCD	String	PREGNANCY_TEST_RESULT	1	citnPREGVIS_TEST	PREGVIS_LBTPCD_L	
cIPREGVIS_LBSTAT	String		Not Done	1	citnPREGVIS_ND	PREGVIS_LBSTAT_K
cIPREGVIS_LSPEC	String		Urine	4	citnPREGVIS_U	PREGVIS_LSPEC_L
cIPREGVIS_LBORRES	String		Positive	1	citnPREGVIS_POS	PREGVIS_LBORRES_L
			Negative	2	citnPREGVIS_NEG	

RDE Analytics: RD_PREGVIS		
Data Variable RefName	RD Column Name	Column Data Type
<b>RD_PREGVIS_SCTPREGVIS</b>		
PREGVIS_LBTPCD_L	PREGVIS_LBTPCD_L_C	VARCHAR2
	PREGVIS_LBTPCD_L	VARCHAR2
	PREGVIS_LBTPCD_L_ND	VARCHAR2
PREGVIS_LBSTAT_K	PREGVIS_LBSTAT_K_ND	VARCHAR2
PREGVIS_LBSTAT_K - Not Done	*PREGVIS_LBSTAT_K_CITMPREGVISND_C	VARCHAR2
	*PREGVIS_LBSTAT_K_CITMPREGVISND	VARCHAR2
PREGVIS_LSPEC_L	PREGVIS_LSPEC_L_C	VARCHAR2
	PREGVIS_LSPEC_L	VARCHAR2
	PREGVIS_LSPEC_L_ND	VARCHAR2
PREGVIS_LBORRES_L	PREGVIS_LBORRES_L_C	VARCHAR2
	PREGVIS_LBORRES_L	VARCHAR2
	PREGVIS_LBORRES_L_ND	VARCHAR2
PREGVIS_LBDTC_D	PREGVIS_LBDTC_D	DATE
	PREGVIS_LBDTC_D_DTS	VARCHAR2
	PREGVIS_LBDTC_D_ND	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**RP=Reproductive System Findings****RPCAT=CONTRACEPTIVE COUNSELLING**

: Contraceptive counselling (Contraceptive counselling) [CONTRACEPTIVES_1]	
Study ID:	
1.* Has the subject provided contraceptive counselling at this visit? [contraceptive counselling]	<input type="radio"/> [A:1] Yes <input type="radio"/> [A:2] No <input type="radio"/> [A:998] N/A, due to pregnancy
2. Has the subject used contraception meeting the definition of highly effective (<1% failure rate) since last visit: [hidden] [subject used contraception]	<input checked="" type="radio"/> [CONTRA_COUNS_L] <small>[A:1] [METH_CONTRA_L]</small> <small>Yes</small> <small>[A:2] Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation</small> <small>[A:2] Progestogen-only hormone contraception associated with inhibition of ovulation</small> <small>[A:3] Intrauterine device (IUD)</small> <small>[A:4] Intrauterine hormone-releasing system (IUS)</small> <small>[A:5] Bilateral tubal occlusion</small> <small>[A:6] Vasectomized partner</small> <small>[A:7] Sexual abstinence</small> <small>[A:999] [CONTRA_METHOD_X]</small> <small>Other (according to local legislation)</small> <small>Please specify:</small> <small>A200</small>
<small>Key: [*] = Item is required</small> <small>Note: Source verification critical settings made in Inform will override any settings made in Central Designer.</small>	

Study Object Descriptions: Contraceptive counselling		
Type	RefName	Description
Form	CONTRACEPTIVES_1	Visit: V1, V2, V4, V6, V8, V10, V12, V14, V16, V18, V20, V22, V24, V26, V28, V30, V31
Item	CONTRA_METHOD_YN_L	**Item DEACTIVATED**
Item	METH_CONTRA_L	**Item DEACTIVATED**
Item	CONTRA_METHOD_X	**Item DEACTIVATED**

Codelist Values Tables: Contraceptive counselling						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clCONTRA_COUNS_YN_NA	String		Yes	1	cltmCOTRA_COUNS_Y	CONTRA_COUNS_L
			No	2	cltmCOTRA_COUNS_N	
			N/A, due to pregnancy	998	cltmCOTRA_COUNS_NA	
cYESNO_5	String		Yes	1	cltmYESNO1_5	CONTRA_METHOD_YN_L
			No	2	cltmYESNO2_5	
cMETH_CONTRA	String		Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation	1	cltmMETH_CONTRA_1	METH_CONTRA_L
			Progestogen-only hormone contraception associated with inhibition of ovulation	2	cltmMETH_CONTRA_2	
			Intrauterine device (IUD)	3	cltmMETH_CONTRA_3	
			Intrauterine hormone-releasing system (IUS)	4	cltmMETH_CONTRA_4	
			Bilateral tubal occlusion	5	cltmMETH_CONTRA_5	
			Vasectomized partner	6	cltmMETH_CONTRA_6	
			Sexual abstinence	7	cltmMETH_CONTRA_7	
			Other (according to local legislation)	999	cltmMETH_CONTRA_8	

RDE Analytics: RD_CONTRACEPTIVES_1		
Data Variable RefName	RD Column Name	Column Data Type
CONTRA_COUNS_L	CONTRA_COUNS_L_C	VARCHAR2
	CONTRA_COUNS_L	VARCHAR2
	CONTRA_COUNS_L_ND	VARCHAR2
CONTRA_METHOD_YN_L	CONTRA_METHOD_YN_L_C	VARCHAR2
	CONTRA_METHOD_YN_L	VARCHAR2
	CONTRA_METHOD_YN_L_ND	VARCHAR2
CONTRA_METHOD_YN_L - Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation	*METH_CONTRA_L_CITMMETHODCONTR1_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHODCONTR1	VARCHAR2
CONTRA_METHOD_YN_L - Progestogen-only hormone contraception associated with inhibition of ovulation	*METH_CONTRA_L_CITMMETHODCONTR2_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHODCONTR2	VARCHAR2
CONTRA_METHOD_YN_L - Intrauterine device (IUD)	*METH_CONTRA_L_CITMMETHODCONTR3_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHODCONTR3	VARCHAR2
CONTRA_METHOD_YN_L - Intrauterine hormone-releasing system (IUS)	*METH_CONTRA_L_CITMMETHODCONTR4_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHODCONTR4	VARCHAR2
CONTRA_METHOD_YN_L - Bilateral tubal occlusion	*METH_CONTRA_L_CITMMETHODCONTR5_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHODCONTR5	VARCHAR2
CONTRA_METHOD_YN_L - Vasectomized partner	*METH_CONTRA_L_CITMMETHODCONTR6_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHODCONTR6	VARCHAR2
CONTRA_METHOD_YN_L - Sexual abstinence	*METH_CONTRA_L_CITMMETHODCONTR7_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHODCONTR7	VARCHAR2
CONTRA_METHOD_YN_L - Other (according to local legislation)	*METH_CONTRA_L_CONTRA_METHOD_X_C	VARCHAR2
	*METH_CONTRA_L_CONTRA_METHOD_X	VARCHAR2
CONTRA_METHOD_YN_L - CONTRA_METHOD_X	CONTRA_METHOD_X	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**VS=Vital Signs**

**VSCAT=VITAL SIGNS**

<b>: Vital Signs (VS) [VITAL_SIGN_SINGLE]</b>	
<b>Study ID:</b> Any clinical deterioration of a pre-existing condition as well as any new clinically significant sign, symptom or illness is considered an adverse event. Complete an Adverse Event form (AE). If medication is taken remember to record in the Concomitant Medication form (CM).	
1. Date of examination [hidden] [Date of examination]	[ACTUAL_DATE_VS_SINGLE] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030)
<b>Blood pressure and pulse [sctVS_SINGLE]</b>	
2.* Blood pressure (Measurements should be preceded by at least 5 minutes of rest for the participant in a quiet setting without distractions and with a completely automated device) [BP]	[grpBP_SINGLE] [BP_SYSTOLIC_SINGLE] [BP_DIASTOLIC_SINGLE] Systolic N3 mmHg <sup>[b]</sup> Diastolic N3 mmHg <sup>[b]</sup>
3.* Pulse (Measurements should be preceded by at least 5 minutes of rest for the participant in a quiet setting without distractions and with a completely automated device) [Pulse]	[PULSE_SINGLE] N3 beats/min <sup>[b]</sup>
Note: [*] = Item is required    [ ] = Source verification required    [b] = Base Unit Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

<b>Study Object Descriptions: Vital Signs</b>		
Type	RefName	Description
Form	VITAL_SIGN_SINGLE	Visit: V1, V2, V6, V10, V14, V20, V24, V30, V31, V35
Item	ACTUAL_DATE_VS_SINGLE	**Item DEACTIVATED**

<b>RDE Analytics: RD_VITAL_SIGN_SINGLE</b>		
Data Variable RefName	RD Column Name	Column Data Type
ACTUAL_DATE_VS_SINGLE	ACTUAL_DATE_VS_SINGLE	DATE
	ACTUAL_DATE_VS_SINGLE_DTS	VARCHAR2
	ACTUAL_DATE_VS_SINGLE_ND	VARCHAR2
grpBP_SINGLE	GRPBP_SINGLE_ND	VARCHAR2
grpBP_SINGLE - BP_SYSTOLIC_SINGLE	BP_SYSTOLIC_SINGLE	NUMBER
	BP_SYSTOLIC_SINGLE_U	VARCHAR2
grpBP_SINGLE - BP_DIASTOLIC_SINGLE	BP_DIASTOLIC_SINGLE	NUMBER
	BP_DIASTOLIC_SINGLE_U	VARCHAR2
PULSE_SINGLE	PULSE_SINGLE	NUMBER
	PULSE_SINGLE_U	VARCHAR2
	PULSE_SINGLE_ND	VARCHAR2

**LB=Laboratory Test Results**

Collection of Samples for Laboratory (Lab) [LAB_SAMPLE_TAKEN_3]		LBCAT=COLLECTION OF SAMPLES	LBSPEC=BLOOD
<p><b>Study ID:</b> Collect bloc<sup>a</sup> ~ving the procedures detailed in the laboratory manual. When result, ..., sign and date all pages and file with the subjects notes. For all values outside the normal range, indicate on the lab report whether they are Clinically Significant (CS) or Not Clinically Significant (NS).</p> <p>1. Sample collection date [hidden] [Sample Collection Date] <b>[ALL_SAMPLE_DATE_4] (DD/MM/YYYY)</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Rev <input type="checkbox"/> (2020-2030)</p> <p>2. Sample collection date and time [hidden] [Sample Collection Date] <b>[ALL_SAMPLE_DATE_TIME_4] (DD/MM/YYYY hh:mm)</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Rev <input type="checkbox"/> (2020-2030) Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> 24-hour clock</p> <p>Blood [sctSAMPLE_TAKEN_YN_3_1] 3.* Have all blood samples been taken? [Blood Sample] <b>[SAMPLE_TAKEN_YN_4]</b> [A:1] <input checked="" type="radio"/> Yes [A:2] <input type="radio"/> [COMMENT_TEXT_YN_4] No, comment A200</p>			
		<b>LBSTAT=NOT DONE</b>	<b>Note: If result is 'Yes' no record is submitted.</b> <b>If result is 'No' LBSTAT='NOT DONE'</b>
		<b>LBREASND when LBTESTCD=LBALL</b>	

Key: [\*] = Item is required  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

**Study Object Descriptions: Collection of Samples for Laboratory**

Type	RefName	Description
Form	LAB_SAMPLE_TAKEN_3	Visit: V1, V6, V10, V14, V20, V28, V31, V35
Item	ALL_SAMPLE_DATE_4	**Item DEACTIVATED**
Item	ALL_SAMPLE_DATE_TIME_4	**Item DEACTIVATED**

**Codelist Values Tables: Collection of Samples for Laboratory**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cSAMPLE_TAKEN_YN_4	String		Yes	1	ctmSAMPLE_TAKEN_Y1_2	SAMPLE_TAKEN_YN_4

**RDE Analytics: RD\_LAB\_SAMPLE\_TAKEN\_3**

Data Variable RefName	RD Column Name	Column Data Type
ALL_SAMPLE_DATE_4	ALL_SAMPLE_DATE_4	DATE
	ALL_SAMPLE_DATE_4_DTS	VARCHAR2
	ALL_SAMPLE_DATE_4_ND	VARCHAR2
ALL_SAMPLE_DATE_TIME_4	ALL_SAMPLE_DATE_TIME_4	DATE
	ALL_SAMPLE_DATE_TIME_4_DTS	VARCHAR2
	ALL_SAMPLE_DATE_TIME_4_ND	VARCHAR2
SAMPLE_TAKEN_YN_4	SAMPLE_TAKEN_YN_4_C	VARCHAR2
	SAMPLE_TAKEN_YN_4	VARCHAR2
	SAMPLE_TAKEN_YN_4_ND	VARCHAR2
SAMPLE_TAKEN_YN_4 - COMMENT_TEXT_YN_4	COMMENT_TEXT_YN_4	VARCHAR2

SU=Substance Use

SUCAT=TOBACCO

: Tobacco Use (Tobacco) [TOBACCO_SU]			
Study ID:		<b>SUOCUR=N</b>	<b>SMOKSTAT in SUPPSU</b>
1.* Smoki Smoking is defined as smoking at least one cigarette or equivalent daily [Smoking Status]		<b>SUOCUR=Y</b>	
2. Previous smoker, Smoking stop date: [hidden] [Smoke stop date]		<b>SUOCUR=Y</b>	<b>SUENDTC</b>
3. Type of tobacco [hidden] [Type of tobacco]		<b>SUOCUR=Y</b>	
4. Average number per day [hidden] [Ave. no. per day]		<b>SUOCUR=Y</b>	
5. Approximate years of smoking Round down to the year, e.g. Smoking less than 1 year: enter 0 years (e.g. if subject smoked for 8 months) Smoking between 1 and 2 years: enter 1 year (e.g. if subject smoked for 1 year and 11 months) [hidden] [Approx. years smoking]		<b>SUOCUR=Y</b>	<b>SUDUR</b>
6. Nicotine product status Nicotine products include nicotine patches, gum etc [hidden] [Nicotine product status]		<b>SUOCUR=Y</b>	
Key: [*] = Item is required [b] = Base Unit		Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

**Study Object Descriptions: Tobacco Use**

Type	RefName	Description
Form	TOBACCO_SU	Visit: V1
Item	SMOKER_STOP_DATE	**Item DEACTIVATED**
Item	STIMULANT_CODE	**Item DEACTIVATED**
Item	STIMULANT_NO	**Item DEACTIVATED**
Item	STIMULANT_DURATION	**Item DEACTIVATED**
Item	NICOTINE_STATUS_CODE	**Item DEACTIVATED**
Item	NICOTINE_STOP_DATE	**Item DEACTIVATED**

**Codelist Values Tables: Tobacco Use**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cSMOKER_STATUS_CODE	String		Never smoked	68	citmSMOKER_STATUS_CODE68	SMOKER_STATUS_CODE
			Previous smoker	69	citmSMOKER_STATUS_CODE69	
			Current smoker	6	citmSMOKER_STATUS_CODE6	
cSTIMULANT_CODE	String		Cigarettes	3	citmSTIMULANT_CODE3	STIMULANT_CODE
			Cigars	4	citmSTIMULANT_CODE4	
			Pipes	5	citmSTIMULANT_CODES	
			Cheroots	17	citmSTIMULANT_CODE17	
			Cigarillos	18	citmSTIMULANT_CODE18	
cNICOTINE_STATUS_CODE	String		Never used nicotine products	68	citmNICOTINE_STATUS_CODE68	NICOTINE_STATUS_CODE
			Previously used nicotine products	69	citmNICOTINE_STATUS_CODE69	
			Currently uses nicotine products	6	citmNICOTINE_STATUS_CODE6	

**RDE Analytics: RD\_TOBACCO\_SU**

Data Variable RefName	RD Column Name	Column Data Type
SMOKER_STATUS_CODE	SMOKER_STATUS_CODE_C	VARCHAR2
	SMOKER_STATUS_CODE	VARCHAR2
	SMOKER_STATUS_CODE_ND	VARCHAR2
SMOKER_STOP_DATE	SMOKER_STOP_DATE	DATE
	SMOKER_STOP_DATE_DTS	VARCHAR2
	SMOKER_STOP_DATE_DTR	VARCHAR2
	SMOKER_STOP_DATE_ND	VARCHAR2
STIMULANT_CODE	STIMULANT_CODE_C	VARCHAR2
	STIMULANT_CODE	VARCHAR2
	STIMULANT_CODE_ND	VARCHAR2
STIMULANT_NO	STIMULANT_NO	NUMBER
	STIMULANT_NO_U	VARCHAR2
	STIMULANT_NO_ND	VARCHAR2
STIMULANT_DURATION	STIMULANT_DURATION	NUMBER
	STIMULANT_DURATION_U	VARCHAR2
	STIMULANT_DURATION_ND	VARCHAR2
NICOTINE_STATUS_CODE	NICOTINE_STATUS_CODE_C	VARCHAR2
	NICOTINE_STATUS_CODE	VARCHAR2
	NICOTINE_STATUS_CODE_ND	VARCHAR2
NICOTINE_STATUS_CODE - NICOTINE_STOP_DATE	NICOTINE_STOP_DATE	DATE
	NICOTINE_STOP_DATE_DTS	VARCHAR2
	NICOTINE_STOP_DATE_DTR	VARCHAR2

**EG=ECG Test Results****EGCAT=ECG**

: ECG (ECG) [ECG_2]	
<b>Study ID:</b> Visit 1: If <input checked="" type="checkbox"/> clinically significant, record in the Medical History/Concomitant Illness form (MedHx/ConIll). If medication is taken remember to record in the Concomitant Medication form (CM). Visit V24, if <input checked="" type="checkbox"/> significantly deteriorate of a pre-existing condition as well as any new clinically significant sign, symptom or illness is considered an adverse event. Complete an Adverse Event form (AE). If medication is taken remember to record in the Concomitant Medication form (CM).	
1. Date of examination [hidden] [Date of examination]	[EXAM_DATE_ECG_2] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2022-2035)
2. Date and time of examination [hidden] [Date and time of examination]	[EXAM_DATE_TIME_ECG_2] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2022-2035) Req/Unk <input type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock
<b>ECG Examination [sctECG_Exam2]</b>	
3.* Overall interpretation of ECG [Interpretation]	<b>[ECG_NORMAL_ABNORMAL_2]</b> [A:1] <input checked="" type="radio"/> Normal [A:2] <input type="radio"/> <b>grpNORMAL_ABNORMAL_CODE_EC2</b> <input checked="" type="checkbox"/> Abnormal <b>[ABNORMAL_TEXT_EC2]</b> Specify abnormality: A200
<b>EGORRES when EGTESTCD=INTP</b> <b>Note: If result is Abnormal then EGORRES=Specify</b>  <b>CLSIG in SUPPEG</b>	
Key: [*] = Item is required    [ ] = Source verification required    [ ] = Item is collapsible Note: Source verification critical settings made in InForm will override any settings made in Central Designer. Note: Collapsible settings are only available to users who have the rights to edit the item.	

**Study Object Descriptions: ECG**

Type	RefName	Description
Form	ECG_2	Visit: V1, V24, V30
Item	EXAM_DATE_ECG_2	**Item DEACTIVATED**
Item	EXAM_DATE_TIME_ECG_2	**Item DEACTIVATED**

**Codelist Values Tables: ECG**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIECG_ABNORMAL_NORMAL_1	String		Normal	1	ctmECG_NORMAL_2	ECG_NORMAL_ABNORMAL_2
			Abnormal	2	ctmECG_ABNORMAL1_2	

  

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cICLIN_SIG_YN_1	String		Yes	1	ctmCLIN_SIG_Y	CLIN_SIG_YN_5
			No	2	ctmCLIN_SIG_N	

**RDE Analytics: RD\_ECG\_2**

Data Variable RefName	RD Column Name	Column Data Type
EXAM_DATE_ECG_2	EXAM_DATE_ECG_2	DATE
	EXAM_DATE_ECG_2_DTS	VARCHAR2
	EXAM_DATE_ECG_2_ND	VARCHAR2
EXAM_DATE_TIME_ECG_2	EXAM_DATE_TIME_ECG_2	DATE
	EXAM_DATE_TIME_ECG_2_DTS	VARCHAR2
	EXAM_DATE_TIME_ECG_2_DTR	VARCHAR2
	EXAM_DATE_TIME_ECG_2_ND	VARCHAR2
ECG_NORMAL_ABNORMAL_2	ECG_NORMAL_ABNORMAL_2_C	VARCHAR2
	ECG_NORMAL_ABNORMAL_2	VARCHAR2
	ECG_NORMAL_ABNORMAL_2_ND	VARCHAR2
ECG_NORMAL_ABNORMAL_2 - ABNORMAL_TEXT_EC2	ABNORMAL_TEXT_EC2	VARCHAR2
ECG_NORMAL_ABNORMAL_2 - CLIN_SIG_YN_5	CLIN_SIG_YN_5_C	VARCHAR2
	CLIN_SIG_YN_5	VARCHAR2

**OE=Ophthalmic Examinations**

: Eye Examination (Eye Exam) [OPHTHALMOSCOPY_1]	
Study ID: Note: Exam... 1. * Date of examination [Date of Exam]	[EXAM_DATE1] (DD/MM/YYYY) Req <input type="button" value="▼"/> / Req <input type="button" value="▼"/> / Req <input type="button" value="▼"/> (2023-2030)
2.* Right eye Interpretation of eye examination [Right Eye]	<b>OELAT=RIGHT</b> <b>OELOC=EYE</b>
	<b>OEDTC</b>
	<b>OEORRES when OETESTCD=OEEXAM</b>
3.* Left eye Interpretation of eye examination [Left Eye]	<b>OELAT=LEFT</b> <b>OELOC=EYE</b>
	<b>CLSIG in SUPPOE</b>
	<b>OEORRES when OETESTCD=OEEXAM</b>
	<b>Note: If result is Abnormal then OEORRES=Specify</b>
	<b>CLSIG in SUPPOE</b>

Key: [\*] = Item is required [ ✓ ] = Source verification required  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: Eye Examination		
Type	RefName	Description
Form	OPHTHALMOSCOPY_1	Visit: V1 (Fundus examination can be performed up to 90 days prior to screening), V24, V30

Codelist Values Tables: Eye Examination						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIRIGHT_NORM_ABN_1	String		Normal	1	ctmRIGHT_NORMAL_1	RIGHT_NORM_ABN_1
			Abnormal, Specify Abnormality	2	ctmRIGHT_ANORMAL_1	
cYESNO_3	String		Yes	1	ctmYESNO1_3	RIGHT_CLIN_SIG_YN,
			No	2	ctmYESNO2_3	LEFT_CLIN_SIG_YN
cILEFT_NORM_ABN_1	String		Normal	1	ctmLEFT_NORMAL1	LEFT_NORM_ABN_1
			Abnormal, Specify Abnormality:	2	ctmLEFT_ANORMAL1	

RDE Analytics: RD_OPHTHALMOSCOPY_1		
Data Variable RefName	RD Column Name	Column Data Type
EXAM_DATE1	EXAM_DATE1	DATE
	EXAM_DATE1_DTS	VARCHAR2
	EXAM_DATE1_IND	VARCHAR2
RIGHT_NORM_ABN_1	RIGHT_NORM_ABN_1_C	VARCHAR2
	RIGHT_NORM_ABN_1	VARCHAR2
	RIGHT_NORM_ABN_1_IND	VARCHAR2
RIGHT_NORM_ABN_1 - ABNORMAL_TEXT3_3	ABNORMAL_TEXT3_3	VARCHAR2
RIGHT_NORM_ABN_1 - RIGHT_CLIN_SIG_YN	RIGHT_CLIN_SIG_YN_C	VARCHAR2
	RIGHT_CLIN_SIG_YN	VARCHAR2
LEFT_NORM_ABN_1	LEFT_NORM_ABN_1_C	VARCHAR2
	LEFT_NORM_ABN_1	VARCHAR2
	LEFT_NORM_ABN_1_IND	VARCHAR2
LEFT_NORM_ABN_1 - ABNORMAL_TEXT3_1	ABNORMAL_TEXT3_1	VARCHAR2
LEFT_NORM_ABN_1 - LEFT_CLIN_SIG_YN	LEFT_CLIN_SIG_YN_C	VARCHAR2
	LEFT_CLIN_SIG_YN	VARCHAR2

**VS=Vital Signs****VSCAT=BODY MEASUREMENT**

: Body measurements 1 (Body Meas) [BODY_MEASUREMENT_1]	
<p><b>Study ID:</b> Preferably, ~~nts should be taken by the investigator, or the same qualified delegate, throughout the duration of the study.</p> <p>1. Date of examination [hidden] [Exam Date]</p> <p>2. Date and time of examination [hidden] [Exam Date &amp; Time]</p> <p>3. Was the subject fasting when the body measurement was done? [hidden] [Fasting?]</p> <p><b>VSTPT=FIRST</b> <b>VSTPTNUM=1</b></p> <p>4. Height 1 (Before measuring linear growth, remove shoes, hats, hair ornaments, and braids whenever possible because these items interfere with accurate growth measurement. The participant must be repositioned between the measurements.) [Height 1]</p> <p><b>VSTPT=SECOND</b> <b>VSTPTNUM=2</b></p> <p>5. Height 2 (Before measuring linear growth, remove shoes, hats, hair ornaments, and braids whenever possible because these items interfere with accurate growth measurement. The participant must be repositioned between the measurements.) [Height 2]</p> <p><b>VSTPT=THIRD</b> <b>VSTPTNUM=3</b></p> <p>6. Height 3 (Before measuring linear growth, remove shoes, hats, hair ornaments, and braids whenever possible because these items interfere with accurate growth measurement. The participant must be repositioned between the measurements.) [Height 3]</p> <p>7. Mean Height (System calculated mean) [read-only] [Mean Height]</p> <p>8.* Body weight ✓ (Measured at site visits without shoes, with an empty bladder and only wearing light clothing) [Body weight]</p> <p>9. Body weight derived (calculated) [hidden] [Body Weight]</p> <p>10. Retired item - maintained on CRF due to legacy integration. Do not use [hidden] [retired item]</p> <p>11. BMI (System calculated) [read-only] [BMI]</p> <p>12. Waist circumference [hidden] [Waist]</p> <p>13. Hip circumference [hidden] [Hip]</p>	
<p>[BODY_MEAS_DATE3] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2022-2035)</p> <p>[BODY_MEAS_DATE_TIME3] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2022-2035)</p> <p>Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock</p> <p>[BM_FASTING] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No</p> <p>[grpHEIGHT1_4] [BODY_HEIGHT1_4] [HEIGHT_UNIT1_4] 0 &lt;= xxx.x [A:340] <input type="radio"/> cm</p> <p><b>VSORRES/VSORRESU when VTESTCD=HEIGHT</b></p> <p>[grpHEIGHT1_5] [BODY_HEIGHT1_5] [HEIGHT_UNIT1_5] 0 &lt;= xxx.x [A:340] <input type="radio"/> cm</p> <p><b>VSORRES/VSORRESU when VTESTCD=HEIGHT</b></p> <p>[grpHEIGHT1_6] [BODY_HEIGHT1_6] [HEIGHT_UNIT1_6] 0 &lt;= xxx.x [A:340] <input type="radio"/> cm</p> <p><b>VSORRES/VSORRESU when VTESTCD=HEIGHT</b></p> <p>[grpHEIGHT] [BODY_HEIGHT] [HEIGHT_UNIT] xxx.x [A:340] <input type="radio"/> cm</p> <p><b>VSORRES/VSORRESU when VTESTCD=HGHTMEAN</b></p> <p>[grpBODY_WEIGHT] [BODY_WEIGHT] [BODY_WEIGHT_UNIT] xxx.x [A:220] <input type="radio"/> kg [A:700] <input type="radio"/> lb</p> <p>[BODY_WEIGHT_DERIVE] xxxxx. <input type="radio"/> kg<sup>[b]</sup></p> <p>[BMI_DERIVED] xxx.xxxx <input type="radio"/> kg/m<sup>2</sup><sup>[b]</sup></p> <p>[BMI_DERIVED_N] xxx.x <input type="radio"/> kg/m<sup>2</sup><sup>[b]</sup></p> <p><b>VSORRES/VSORRESU when VTESTCD=BMI</b></p> <p>[grpWAIST_CIRCUMFERENCE] [WAIST_CIRCUMFERENCE] [WAIST_CIRCUM_UNIT] xxxxxx. [A:340] <input type="radio"/> cm</p> <p>[grpHIP_CIRCUMFERENCE] [HIP] [HIP_CIRCUM_UNIT] xxxxxx. [A:340] <input type="radio"/> cm</p>	

Key: [\*] = Item is required [ ] = Source verification required [b] = Base Unit

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: Body measurements 1		
Type	RefName	Description
Form	BODY_MEASUREMENT_1	Visit: V1,V16, V20, V26, V28, V31, V33
Item	BODY_MEAS_DATE3	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	BODY_MEAS_DATE_TIME3	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	BM_FASTING	**Item DEACTIVATED**
Item	grpHEIGHT	Integrations: A, R - please do not change the refname or format
Item	grpBODY_WEIGHT	Integrations: A, R - please do not change the refname or format
Item	BODY_WEIGHT_DERIVE	**Item DEACTIVATED**Integrations: A - please do not change the refname or format
Item	BMI_DERIVED	**Item DEACTIVATED**  Calculated in InForm via rule Integrations: A - please do not change the refname or format
Item	grpWAIST_CIRCUMFERENCE	**Item DEACTIVATED**
Item	grpHIP_CIRCUMFERENCE	**Item DEACTIVATED**

Codelist Values Tables: Body measurements 1						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cFAST_YN	String		Yes	1	citmFAST_YN1	BM_FASTING
			No	2	citmFAST_YN2	
cHEIGHT_UNIT_1_4	String		cm	340	citmHEIGHT_UNIT_CM_1_1	HEIGHT_UNIT1_4
cHEIGHT_UNIT_1_3	String		cm	340	citmHEIGHT_UNIT_CM_1_2	HEIGHT_UNIT1_5
cHEIGHT_UNIT_1_6	String		cm	340	citmHEIGHT_UNIT_CM_1_3	HEIGHT_UNIT1_6
cHEIGHT_UNIT	String		cm	340	citmHEIGHT_UNIT_CM	HEIGHT_UNIT, WAIST_CIRCUM_UNIT, HIP_CIRCUM_UNIT
cBODY_WEIGHT_UNIT	String		kg	220	citmBODY_WEIGHT_UNIT_KG	BODY_WEIGHT_UNIT
			lb	700	citmBODY_WEIGHT_UNIT_LB	

RDE Analytics: RD_BODY_MEASUREMENT_1		
Data Variable RefName	RD Column Name	Column Data Type
BODY_MEAS_DATE3	BODY_MEAS_DATE3	DATE
	BODY_MEAS_DATE3_DTS	VARCHAR2
	BODY_MEAS_DATE3_ND	VARCHAR2
BODY_MEAS_DATE_TIME3	BODY_MEAS_DATE_TIME3	DATE
	BODY_MEAS_DATE_TIME3_DTS	VARCHAR2
	BODY_MEAS_DATE_TIME3_DTR	VARCHAR2
	BODY_MEAS_DATE_TIME3_ND	VARCHAR2
BM_FASTING	BM_FASTING_C	VARCHAR2
	BM_FASTING	VARCHAR2
	BM_FASTING_ND	VARCHAR2
grpHEIGHT1_4	GRPHIGHT1_4_ND	VARCHAR2
grpHEIGHT1_4 - BODY_HEIGHT1_4	BODY_HEIGHT1_4	FLOAT
grpHEIGHT1_4 - HEIGHT_UNIT1_4	HEIGHT_UNIT1_4_C	VARCHAR2
	HEIGHT_UNIT1_4	VARCHAR2
grpHEIGHT1_5	GRPHIGHT1_5_ND	VARCHAR2
grpHEIGHT1_5 - BODY_HEIGHT1_5	BODY_HEIGHT1_5	FLOAT
grpHEIGHT1_5 - HEIGHT_UNIT1_5	HEIGHT_UNIT1_5_C	VARCHAR2
	HEIGHT_UNIT1_5	VARCHAR2
grpHEIGHT1_6	GRPHIGHT1_6_ND	VARCHAR2
grpHEIGHT1_6 - BODY_HEIGHT1_6	BODY_HEIGHT1_6	FLOAT
grpHEIGHT1_6 - HEIGHT_UNIT1_6	HEIGHT_UNIT1_6_C	VARCHAR2

	HEIGHT_UNIT1_6	VARCHAR2
grpHEIGHT_GH	GRPHEIGHT_ND	VARCHAR2
grpHEIGHT - ON HEIGHT	BODY_HEIGHT	FLOAT
grpHEIGHT - HEIGHT_UNIT	HEIGHT_UNIT_C	VARCHAR2
	HEIGHT_UNIT	VARCHAR2
grpBODY_WEIGHT	GRPBODY_WEIGHT_ND	VARCHAR2
grpBODY_WEIGHT - BODY_WEIGHT	BODY_WEIGHT	FLOAT
grpBODY_WEIGHT - BODY_WEIGHT_UNIT	BODY_WEIGHT_UNIT_C	VARCHAR2
	BODY_WEIGHT_UNIT	VARCHAR2
BODY_WEIGHT_DERIVE	BODY_WEIGHT_DERIVE	FLOAT
	BODY_WEIGHT_DERIVE_U	VARCHAR2
	BODY_WEIGHT_DERIVE_ND	VARCHAR2
BMI_DERIVED	BMI_DERIVED	FLOAT
	BMI_DERIVED_U	VARCHAR2
	BMI_DERIVED_ND	VARCHAR2
BMI_DERIVED_N	BMI_DERIVED_N	FLOAT
	BMI_DERIVED_N_U	VARCHAR2
	BMI_DERIVED_N_ND	VARCHAR2
grpWAIST_CIRCUMFERENCE	GRPWAIT_CIRCUMFERENCE_ND	VARCHAR2
grpWAIST_CIRCUMFERENCE - WAIST_CIRCUMFERENCE	WAIST_CIRCUMFERENCE	FLOAT
grpWAIST_CIRCUMFERENCE - WAIST_CIRCUM_UNIT	WAIST_CIRCUM_UNIT_C	VARCHAR2
	WAIST_CIRCUM_UNIT	VARCHAR2
grpHIP_CIRCUMFERENCE	GRPHIP_CIRCUMFERENCE_ND	VARCHAR2
grpHIP_CIRCUMFERENCE - HIP	HIP	FLOAT
grpHIP_CIRCUMFERENCE - HIP_CIRCUM_UNIT	HIP_CIRCUM_UNIT_C	VARCHAR2
	HIP_CIRCUM_UNIT	VARCHAR2

**NOT SUBMITTED**

Physical Examination (PE) [PHYSICAL_EXAM_4]	
<p>Study ID: Visit 1: If clinically significant, record in the Medical History/Concomitant Illness form (MedHx/ConIll). If medication is taken remember to record in the Concomitant Medication form (CM).</p> <p>Visits V14, V24, V30, V35 Any clinically significant deterioration of a pre-existing condition as well as any new clinically significant sign, symptom or illness is considered an adverse event. Complete an Adverse Event form (AE). If medication is taken remember to record in the Concomitant Medication form (CM).</p> <p>1.* Was the physical examination performed? [PE Performed]</p>	
<p>Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</p>	
<p>[PE_EXAM_YN]  <input type="radio"/> Yes  <input type="radio"/> No         </p>	

**Study Object Descriptions: Physical Examination**

Type	RefName	Description
Form	PHYSICAL_EXAM_4	Visit: V1, V14, V24, V30, V35

**Codelist Values Tables: Physical Examination**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clPE_YN	String			Yes	1	ctmPE_Y
				No	2	ctmPE_N

**RDE Analytics: RD\_PHYSICAL\_EXAM\_4**

Data Variable RefName	RD Column Name	Column Data Type
PE_EXAM_YN	PE_EXAM_YN_C	VARCHAR2
	PE_EXAM_YN	VARCHAR2
	PE_EXAM_YN_ND	VARCHAR2

**RP=Reproductive System Findings** **RS=Disease Response and Clin Classification**

: Tanner Staging Male (Tanner Staging Male) [TAN_STAG_MALE]		RSCAT=TANNER SCALE BOY	
Study ID: 1			
1.* Genita [Genital Development]	<b>Note : If result is 'Not Done' RSSTAT='NOT DONE'</b>	[GENIT_DEV] [A:1] <input type="radio"/> 1 [A:2] <input type="radio"/> 2 [A:3] <input type="radio"/> 3 [A:4] <input type="radio"/> 4 [A:5] <input type="radio"/> 5 [A:997] <input type="radio"/> [GEN_REA] Not Done Specify Reason: A200	<b>RSORRES when RSTESTCD=TANN0201</b> <b>RSREASND</b>
2.* Left Testicular Volume [Left Testicular Volume]	<b>RPCAT=PUBERTAL STATUS</b>	[TESTI_VOL_LEFT] 0 < N2 ml[b]	<b>RPORRES/RPORRESU when RPTESTCD=PUBTELVL</b>
3.* Right Testicular Volume [Right Testicular Volume]		[TESTI_VOL_RIGHT] 0 < N2 ml[b]	<b>RPORRES/RPORRESU when RPTESTCD=PUBTERVL</b>
4.* Pubic Hair Development [Pubic Hair Development]		[PUBIC_HAIR_DEV1] [A:1] <input type="radio"/> 1 [A:2] <input type="radio"/> 2 [A:3] <input type="radio"/> 3 [A:4] <input type="radio"/> 4 [A:5] <input type="radio"/> 5 [A:997] <input type="radio"/> [HAIR_REA] Not Done Specify Reason: A200	<b>RSORRES when RSTESTCD=TANN0202</b> <b>RSREASND</b>

Key: [\*] = Item is required [b] = Base Unit  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: Tanner Staging Male						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clGEN_DEV_2	String		1	1	citmGEN_DEV1	GENIT_DEV
			2	2	citmGEN_DEV2	
			3	3	citmGEN_DEV3	
			4	4	citmGEN_DEV4	
			5	5	citmGEN_DEV5	
			Not Done	997	citmGEN_DEV99	
clGEN_DEV_1	String		1	1	citmGEN_DEV1	PUBLIC_HAIR_DEV1
			2	2	citmGEN_DEV2	
			3	3	citmGEN_DEV3	
			4	4	citmGEN_DEV4	
			5	5	citmGEN_DEV5	
			Not Done	997	citmGEN_DEV99	

RDE Analytics: RD_TAN_STAG_MALE		
Data Variable RefName	RD Column Name	Column Data Type
GENIT_DEV	GENIT_DEV_C	VARCHAR2
	GENIT_DEV_U	VARCHAR2
	GENIT_DEV_ND	VARCHAR2
GENIT_DEV - GEN_REA	GEN_REA	VARCHAR2
TESTI_VOL_LEFT	TESTI_VOL_LEFT	NUMBER
	TESTI_VOL_LEFT_U	VARCHAR2
	TESTI_VOL_LEFT_ND	VARCHAR2
TESTI_VOL_RIGHT	TESTI_VOL_RIGHT	NUMBER
	TESTI_VOL_RIGHT_U	VARCHAR2
	TESTI_VOL_RIGHT_ND	VARCHAR2
PUBLIC_HAIR_DEV1	PUBLIC_HAIR_DEV1_C	VARCHAR2
	PUBLIC_HAIR_DEV1_U	VARCHAR2
	PUBLIC_HAIR_DEV1_ND	VARCHAR2
PUBLIC_HAIR_DEV1 - HAIR_REA	HAIR_REA	VARCHAR2

**RS=Disease Response and Clin Classification**

: Tanner Staging Female (Tanner Staging Female) [TAN_STAG_FEMA]		RSCAT=TANNER SCALE GIRL
Study ID: 1		
1.*	Breast	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input checked="" type="radio"/> [BREAST_REA] Not Done Specify Reason: A200
		<b>RSORRES when RSTESTCD=TANN0101</b>
		<b>RSREASND</b>
2.*	Pubic Hair Development [Pubic Hair Development]	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input checked="" type="radio"/> [HAIR_REA1] Not Done Specify Reason: A200
		<b>RSORRES when RSTESTCD=TANN0102</b>
		<b>RSREASND</b>

Key: [\*] = Item is required  
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: Tanner Staging Female		
Type	RefName	Description
Form	TAN_STAG_FEMA	Visit: V1, V14, V24, V30, V35

Codelist Values Tables: Tanner Staging Female						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clGEN_DEV	String		1	1	citmGEN_DEV1	BREAST_DEVELOPMENT
			2	2	citmGEN_DEV2	
			3	3	citmGEN_DEV3	
			4	4	citmGEN_DEV4	
			5	5	citmGEN_DEV5	
			Not Done	997	citmGEN_DEV99	
clGEN_DEV_3	String		1	1	citmGEN_DEV1	PUBIC_HAIR_DEV
			2	2	citmGEN_DEV2	
			3	3	citmGEN_DEV3	
			4	4	citmGEN_DEV4	
			5	5	citmGEN_DEV5	
			Not Done	997	citmGEN_DEV99	

RDE Analytics: RD_TAN_STAG_FEMA		
Data Variable RefName	RD Column Name	Column Data Type
BREAST_DEVELOPMENT	BREAST_DEVELOPMENT_C	VARCHAR2
	BREAST_DEVELOPMENT	VARCHAR2
	BREAST_DEVELOPMENT_ND	VARCHAR2
BREAST_DEVELOPMENT - BREAST_REA	BREAST_REA	VARCHAR2
PUBLIC_HAIR_DEV	PUBLIC_HAIR_DEV_C	VARCHAR2
	PUBLIC_HAIR_DEV	VARCHAR2
	PUBLIC_HAIR_DEV_ND	VARCHAR2
PUBLIC_HAIR_DEV - HAIR_REA1	HAIR_REA1	VARCHAR2

**PR=Procedures****PRCAT=DXA SCAN**

: DXA_SCAN (DXA_SCAN) [DXA_SCAN]		PROCUR	PRPRES=Y
Study ID:	1.* Has an <input type="checkbox"/> performed? [Has an DXA Scan been performed?]	<b>PRTRT=DXA</b>	<b>PRDTC</b>
		<b>COMMENT IN SUPPR</b>	

Key: [\*] = Item is required  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: DXA_SCAN		
Type	RefName	Description
Form	DXA_SCAN	VISIT: V1, V24, V30

Codelist Values Tables: DXA_SCAN						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cYESNOUNK_1	String		Yes	1	ctmYESNOUNK1_1	DXA_QUEST1
			No	2	ctmYESNOUNK2_1	

RDE Analytics: RD_DXA_SCAN		
Data Variable RefName	RD Column Name	Column Data Type
DXA_QUEST1	DXA_QUEST1_C	VARCHAR2
	DXA_QUEST1	VARCHAR2
	DXA_QUEST1_ND	VARCHAR2
DXA_QUEST1 - DXA_QUEST2	DXA_QUEST2	DATE
	DXA_QUEST2_DTS	VARCHAR2
DXA_QUEST1 - DXA_OTH	DXA_OTH	VARCHAR2

**QS=QUESTIONNAIRES****QSCAT=CSSRS PARENTAL CARD**

: C-SSRS parental card (CSSRSparentalcard) [CSSRS_Parental_card]	
Study ID: If the subject to any question on the questionnaire the subject must be evaluated as soon as possible by a Mental Health Professional. <b>CSSRS [setCSSRS1]</b> 1. Have you wished you were dead or wished you could go to sleep and not wake up? [Have you wished you were dead or wished you could go to sleep and not wake up?]	
[CSSRS1] <input type="radio"/> Yes <input checked="" type="radio"/> No <b>QSORRES when QTESTCD=CSSPC101</b>	
2. Have you actually had any thoughts about killing yourself? [Have you actually had any thoughts about killing yourself?]	
[CSSRS2] <input type="radio"/> Yes <input checked="" type="radio"/> No <b>QSORRES when QTESTCD=CSSPC102</b>	
<b>If Yes to 2, answer question 3, 4, 5 and 6 [setCSSRS2]</b>	
3. Have you thought about how you might do this? [Have you thought about how you might do this?]	
[CSSRS3] <input type="radio"/> Yes <input checked="" type="radio"/> No <b>QSORRES when QTESTCD=CSSPC103</b>	
4. Have you had any intention of acting on these thoughts of killing yourself, as opposed to you have the thoughts but you definitely would not act on them? [Have you had any intention of acting on these thoughts of killing yourself, as opposed to you have the thoughts but you definitely would not act on them?]	
[CSSRS4] <input type="radio"/> Yes <input checked="" type="radio"/> No <b>QSORRES when QTESTCD=CSSPC104</b>	
5. Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan? [Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?]	
[CSSRS5] <input type="radio"/> Yes <input checked="" type="radio"/> No <b>QSORRES when QTESTCD=CSSPC105</b>	
6. Have you done anything, started to do anything, or prepared to do anything to end your life? [Have you done anything, started to do anything, or prepared to do anything to end your life?]	
[CSSRS6] <input type="radio"/> Yes <input checked="" type="radio"/> No <b>QSORRES when QTESTCD=CSSPC106</b>	
7. Has an immediate evaluation of the subject by a Mental Health Professional been arranged? [Has an immediate evaluation of the subject by a Mental Health Professional been arranged?]	
[CSSRS7] <input type="radio"/> Yes <input checked="" type="radio"/> No <b>QSORRES when QTESTCD=CSSPC107</b>	

Key: [\*] = Item is required  
 Note: Source verification critical settings made in Inform will override any settings made in Central Designer.

Study Object Descriptions: C-SSRS parental card		
Type	RefName	Description
Form	CSSRS_Parental_card	Visit: : V1, V2, V4, V6, V8, V10, V12, V14, V16, V18, V20, V22, V24, V26, V28, V30, V33, V35

Codelist Values Tables: C-SSRS parental card						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cYESNO_1	String		Yes	1	citmYESNO1_1	CSSRS1, CSSRS2, CSSRS3, CSSRS4, CSSRS5, CSSRS6, CSSRS7
					citmYESNO2_1	

RDE Analytics: RD_CSSRS_PARENTAL_CARD		
Data Variable RefName	RD Column Name	Column Data Type
CSSRS1	CSSRS1_C	VARCHAR2
	CSSRS1	VARCHAR2
	CSSRS1_ND	VARCHAR2
CSSRS2	CSSRS2_C	VARCHAR2
	CSSRS2	VARCHAR2
	CSSRS2_ND	VARCHAR2
CSSRS3	CSSRS3_C	VARCHAR2
	CSSRS3	VARCHAR2
	CSSRS3_ND	VARCHAR2
CSSRS4	CSSRS4_C	VARCHAR2
	CSSRS4	VARCHAR2
	CSSRS4_ND	VARCHAR2
CSSRS5	CSSRS5_C	VARCHAR2
	CSSRS5	VARCHAR2
	CSSRS5_ND	VARCHAR2
CSSRS6	CSSRS6_C	VARCHAR2
	CSSRS6	VARCHAR2
	CSSRS6_ND	VARCHAR2
CSSRS7	CSSRS7_C	VARCHAR2
	CSSRS7	VARCHAR2
	CSSRS7_ND	VARCHAR2

**QS=QUESTIONNAIRES****QSCAT=C-SSRS BASELINE**

C-SSRS Baseline (C-SSRS Baseline) [CSSRSBASELINE]	
Study ID: # Note: Grom... <b>SUICIDAL IDEATION [sctCSSRSBaseline]</b> Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.	<b>QNAM=EVLINTTX QSSCAT=SUICIDAL IDEATION</b>
1.* Wish to be Dead [Wish to be Dead]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSBASE_1_DESC] Yes If yes, describe: A200 <b>QSORRES when QTESTCD=CSS0101</b> <b>QSORRES when QTESTCD=CSS0101A</b>
2.* Non-Specific Active Suicidal Thoughts [Non-Specific Active Suicidal Thoughts]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSBASE_2_DESC] Yes If yes, describe: A200 <b>QSORRES when QTESTCD=CSS0102</b> <b>QSORRES when QTESTCD=CSS0102A</b>
3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act [Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSBASE_3_DESC] Yes If yes, describe: A200 <b>QSORRES when QTESTCD=CSS0103</b> <b>QSORRES when QTESTCD=CSS0103A</b>
4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan [Active Suicidal Ideation with Some Intent to Act, without Specific Plan]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSBASE_4_DESC] Yes If yes, describe: A200 <b>QSORRES when QTESTCD=CSS0104</b> <b>QSORRES when QTESTCD=CSS0104A</b>
5. Active Suicidal Ideation with Specific Plan and Intent [Active Suicidal Ideation with Specific Plan and Intent]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSBASE_5_DESC] Yes If yes, describe: A200 <b>QSORRES when QTESTCD=CSS0105</b> <b>QSORRES when QTESTCD=CSS0105A</b>
<b>QSSCAT=INTENSITY OF IDEATION</b>	
The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe). Ask about time he/she was feeling the most suicidal.	
6. Most Severe Ideation: [Most Severe Ideation:]	<input type="radio"/> 1. Wish to be dead <input type="radio"/> 2. Non-Specific Active Suicidal Thoughts <input type="radio"/> 3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act <input type="radio"/> 4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan <input type="radio"/> 5. Active Suicidal Ideation with Specific Plan and Intent <b>QSORRES when QTESTCD=CSS0106</b>
7. Frequency [Frequency]	<input type="radio"/> Less than once a week <input type="radio"/> Once a week <input type="radio"/> 2-5 times in week <input type="radio"/> Daily or almost daily <input type="radio"/> Many times each day <b>QSORRES when QTESTCD=CSS0107</b>
8. Duration [Duration]	<input type="radio"/> Fleeting - few seconds or minutes <input type="radio"/> Less than 1 hour/some of the time <input type="radio"/> 1-4 hours/a lot of time <input type="radio"/> 4-8 hours/most of day <input type="radio"/> More than 8 hours/persistent or continuous <b>QSORRES when QTESTCD=CSS0108</b>
9. Controllability [Controllability]	<input type="radio"/> Easily able to control thoughts <input type="radio"/> Can control thoughts with little difficulty <input type="radio"/> Can control thoughts with some difficulty <input type="radio"/> Can control thoughts with a lot of difficulty <input type="radio"/> Unable to control thoughts <input type="radio"/> Does not attempt to control thoughts <b>QSORRES when QTESTCD=CSS0109</b>
10. Deterrents [Deterrents]	<input type="radio"/> Deterrents definitely stopped you from attempting suicide <input type="radio"/> Deterrents probably stopped you <input type="radio"/> Uncertain that deterrents stopped you <input type="radio"/> Deterrents most likely did not stop you <input type="radio"/> Deterrents definitely did not stop you <input type="radio"/> Does not apply <b>QSORRES when QTESTCD=CSS0110</b>
11. Reasons for Ideation [Reasons for Ideation]	<input type="radio"/> Completely to get attention, revenge or a reaction from others <input type="radio"/> Mostly to get attention, revenge or a reaction from others <input type="radio"/> Equally to get attention, revenge or a reaction from others and to end/stop the pain. <input type="radio"/> Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) <input type="radio"/> Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) <input type="radio"/> Does not apply <b>QSORRES when QTESTCD=CSS0111</b>
<b>QSSCAT=SUICIDAL BEHAVIOR</b>	
(Check all that apply, so long as these are separate events; must ask about all types)	
12. Actual Attempt [Actual Attempt]	<input type="radio"/> No <input checked="" type="radio"/> [grpCSSRSBASE_ATTEMPT] Yes If yes, describe: <b>[CSSRSBASE_TOT_ATTEMPT]</b> Total # of Attempts N2 <b>[CSSRSBASE_TEXT_ATTEMPT]</b> describe: A200 <b>QSORRES when QTESTCD=CSS0112</b> <b>QSORRES when QTESTCD=CSS0113</b> <b>QSORRES when QTESTCD=CSS0113A</b> <b>[CSSRSBASE_ENGAGED]</b> Has subject engaged in Non-Suicidal Self-Injurious Behavior? <input type="radio"/> No <input checked="" type="radio"/> Yes <b>QSORRES when QTESTCD=CSS0114</b>

		[CSSRSBASE_INTERRUPTED] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpCSSRSBASE_INTER] <input type="checkbox"/> Yes If yes, describe: [CSSRSBASE_INTER] Total # of interrupted: N2 [CSSRSBASE_INTER_TEXT] describe: A200	<b>QSORRES when QTESTCD=CSS0115</b> <b>QSORRES when QTESTCD=CSS0116</b>  <b>QSORRES when QTESTCD=CSS0116A</b>
14. Aborted Attempt: [Aborted Attempt:]		[CSSRSBASE_ABORTED] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpCSSRSBASE_ABORTED] <input type="checkbox"/> Yes If yes, describe: [CSSRSBASE_NO_ABORTED] Total # of interrupted: N2 [CSSRSBASE_ABORTED_TEXT] describe: A200	<b>QSORRES when QTESTCD=CSS0117</b> <b>QSORRES when QTESTCD=CSS0118</b> <b>QSORRES when QTESTCD=CSS0118A</b>
15. Preparatory Acts or Behavior: [Suicide]		[CSSRSBASE_BEHAVIOR] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [CSSRSBASE_BEHAVIOR_TEXT] <input type="checkbox"/> Yes If yes, describe: A200	<b>QSORRES when QTESTCD=CSS0119</b> <b>QSORRES when QTESTCD=CSS0119A</b>
16. Suicidal Behavior: [Suicidal Behavior:]		[CSSRSBASE_SUICIDE_BEH] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> Yes	<b>QSORRES when QTESTCD=CSS0120</b>
<b>Answer for Actual Attempts Only [sctCSSRSBaseline4]</b>			
17. Most Recent Attempt Actual Lethality/Medical Damage: [Most Recent]		[grpCSSRSBASE_ATTEMPT_1] Most Recent Attempt: [CSSRSBASE_ATTEM_DATE_1] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Ref <input checked="" type="checkbox"/> (2023-2030) [CSSRSBASE_ATTEM_DAMAGE_1] [A:0] <input checked="" type="radio"/> [CSSRSBASE_POTENTIAL_1] <input type="checkbox"/> No physical damage or very minor physical damage [A:0] <input type="radio"/> Behavior not likely to result in injury [A:1] <input type="radio"/> Behavior likely to result in injury but not likely to cause death [A:2] <input type="radio"/> Behavior likely to result in death despite available medical care [A:1] <input type="radio"/> Minor physical damage [A:2] <input type="radio"/> Moderate physical damage; medical attention needed [A:3] <input type="radio"/> Moderately severe physical damage; medical hospitalization and likely intensive care required [A:4] <input type="radio"/> Severe physical damage; medical hospitalization with intensive care required [A:5] <input type="radio"/> Death	<b>QSORRES when QTESTCD=CSS0121A</b> <b>QSORRES when QTESTCD=CSS0122A</b> <b>QSORRES when QTESTCD=CSS0123A</b>  <b>QSORRES when QTESTCD=CSS0121B</b>
18. Most Lethal Attempt Actual Lethality/Medical Damage: [Most Lethal]		[grpCSSRSBASE_ATTEMPT_2] Most Lethal Attempt: [CSSRSBASE_ATTEM_DATE_2] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Ref <input checked="" type="checkbox"/> (2023-2030) [CSSRSBASE_ATTEM_DAMAGE_2] [A:0] <input checked="" type="radio"/> [CSSRSBASE_POTENTIAL_2] <input type="checkbox"/> No physical damage or very minor physical damage [A:0] <input type="radio"/> Behavior not likely to result in injury [A:1] <input type="radio"/> Behavior likely to result in injury but not likely to cause death [A:2] <input type="radio"/> Behavior likely to result in death despite available medical care [A:1] <input type="radio"/> Minor physical damage [A:2] <input type="radio"/> Moderate physical damage; medical attention needed [A:3] <input type="radio"/> Moderately severe physical damage; medical hospitalization and likely intensive care required [A:4] <input type="radio"/> Severe physical damage; medical hospitalization with intensive care required [A:5] <input type="radio"/> Death	<b>QSORRES when QTESTCD=CSS0121C</b> <b>QSORRES when QTESTCD=CSS0122C</b> <b>QSORRES when QTESTCD=CSS0123C</b>
19. Initial/First Attempt Actual Lethality/Medical Damage: [Initial/First]		[grpCSSRSBASE_ATTEMPT_3] Initial/First Attempt: [CSSRSBASE_ATTEM_DATE_3] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Ref <input checked="" type="checkbox"/> (2023-2030) [CSSRSBASE_ATTEM_DAMAGE_3] [A:0] <input checked="" type="radio"/> [CSSRSBASE_POTENTIAL_3] <input type="checkbox"/> No physical damage or very minor physical damage [A:0] <input type="radio"/> Behavior not likely to result in injury [A:1] <input type="radio"/> Behavior likely to result in injury but not likely to cause death [A:2] <input type="radio"/> Behavior likely to result in death despite available medical care [A:1] <input type="radio"/> Minor physical damage [A:2] <input type="radio"/> Moderate physical damage; medical attention needed [A:3] <input type="radio"/> Moderately severe physical damage; medical hospitalization and likely intensive care required [A:4] <input type="radio"/> Severe physical damage; medical hospitalization with intensive care required [A:5] <input type="radio"/> Death	<b>QSORRES when QTESTCD=CSS0420A</b> <b>QSORRES when QTESTCD=CSS0420B</b>  <b>QSORRES when QTESTCD=CSS0421A</b> <b>QSORRES when QTESTCD=CSS0422A</b> <b>QSORRES when QTESTCD=CSS0423A</b>

Key: [\*] = Item is required    [✓] = Source verification required    [□] = Item is collapsible  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: C-SSRS Baseline		
Type	RefName	Description
Form	CSSRSBASELINE	Visit : V1

Codelist Values Tables: C-SSRS Baseline			
Codelist RefName	Codelist Data Type	Subset	Label
cICSSRSBASE_1	String	No	2 citmCSSRSBASE_2 CSSRSBASE_1
cICSSRSBASE_1	String	Yes	1 citmCSSRSBASE_1
cICSSRSBASE_2	String	No	2 citmCSSRSBASE_2_1 CSSRSBASE_2
cICSSRSBASE_2	String	Yes	1 citmCSSRSBASE_2_1_1
cICSSRSBASE_1_2	String	No	2 citmCSSRSBASE_1_2_2 CSSRSBASE_3
cICSSRSBASE_1_2	String	Yes	1 citmCSSRSBASE_1_2_1
cICSSRSBASE_1_3	String	No	2 citmCSSRSBASE_2_3 CSSRSBASE_4
cICSSRSBASE_1_3	String	Yes	1 citmCSSRSBASE_1_3
cICSSRSBASE_1_4	String	No	2 citmCSSRSBASE_2_4 CSSRSBASE_5
cICSSRSBASE_1_4	String	Yes	1 citmCSSRSBASE_1_4
cICSSRSBASE_MSIDEATION	String	1. Wish to be dead 2. Non-Specific Active Suicidal Thoughts 3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act	1 citmCSSRSBASE_MSIDEATION1 2 citmCSSRSBASE_MSIDEATION2 3 citmCSSRSBASE_MSIDEATION3

		4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan	4	ctmCSSRSBASE_MSIDEATION4	
		5. Active Suicidal Ideation with Specific Plan and Intent	5	ctmCSSRSBASE_MSIDEATIONS5	
cICSSRSBASE_1C	String	Less than once a week	1	ctmCSSRSBASE_IDEA_1	CSSRSBASE_IDEA_1
		Once a week	2	ctmCSSRSBASE_IDEA_2	
		2-5 times in week	3	ctmCSSRSBASE_IDEA_3	
		Daily or almost daily	4	ctmCSSRSBASE_IDEA_4	
		Many times each day	5	ctmCSSRSBASE_IDEA_5	
cICSSRSBASE_IDEA_2	String	Fleeting - few seconds or minutes	1	ctmCSSRSBASE_IDEA_2_1	CSSRSBASE_IDEA_2
		Less than 1 hour/some of the time	2	ctmCSSRSBASE_IDEA_2_2	
		1-4 hours/a lot of time	3	ctmCSSRSBASE_IDEA_2_3	
		4-8 hours/most of day	4	ctmCSSRSBASE_IDEA_2_4	
		More than 8 hours/persistent or continuous	5	ctmCSSRSBASE_IDEA_2_5	
cICSSRSBASE_IDEA_3	String	Easily able to control thoughts	1	ctmCSSRSBASE_IDEA_3_1	CSSRSBASE_IDEA_3
		Can control thoughts with little difficulty	2	ctmCSSRSBASE_IDEA_3_2	
		Can control thoughts with some difficulty	3	ctmCSSRSBASE_IDEA_3_3	
		Can control thoughts with a lot of difficulty	4	ctmCSSRSBASE_IDEA_3_4	
		Unable to control thoughts	5	ctmCSSRSBASE_IDEA_3_5	
		Does not attempt to control thoughts	0	ctmCSSRSBASE_IDEA_3_0	
cICSSRSBASE_IDEA_4	String	Deterrents definitely stopped you from attempting suicide	1	ctmCSSRSBASE_IDEA_4_1	CSSRSBASE_IDEA_4
		Deterrents probably stopped you	2	ctmCSSRSBASE_IDEA_4_2	
		Uncertain that deterrent stopped you	3	ctmCSSRSBASE_IDEA_4_3	
		Deterrents most likely did not stop you	4	ctmCSSRSBASE_IDEA_4_4	
		Deterrents definitely did not stop you	5	ctmCSSRSBASE_IDEA_4_5	
		Does not apply	0	ctmCSSRSBASE_IDEA_4_0	
cICSSRSBASE_IDEA_5	String	Completely to get attention, revenge or a reaction from others	1	ctmCSSRSBASE_IDEA_5_1	CSSRSBASE_IDEA_5
		Mostly to get attention, revenge or a reaction from others	2	ctmCSSRSBASE_IDEA_5_2	
		Equally to get attention, revenge or a reaction from others and to end/stop the pain.	3	ctmCSSRSBASE_IDEA_5_3	
		Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)	4	ctmCSSRSBASE_IDEA_5_4	
		Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)	5	ctmCSSRSBASE_IDEA_5_5	
		Does not apply	0	ctmCSSRSBASE_IDEA_5_0	
cICSSRLAST_SUICIDE	String	No	2	ctmCSSRLAST_SUICIDE_2	CSSRSBASE_ATTEMPT, CSSRSBASE_ENGAGED, CSSRSBASE_INTERRUPTED, CSSRSBASE_ABORTED, CSSRSBASE_SUICIDE_BEH
		Yes	1	ctmCSSRLAST_SUICIDE_1	
cICSSRLAST_SUICIDE_2	String	No	2	ctmCSSRLAST_SUICIDE_2	CSSRSBASE_BEHAVIOR
		Yes	1	ctmCSSRLAST_SUICIDE_1	
cICSSRSBASE_ATTEM_DAMAGE_1	String	No physical damage or very minor physical damage	0	ctmCSSRSBASE_ATTEM_DAMAGE_1_0	CSSRSBASE_ATTEM_DAMAGE_1,
		Minor physical damage	1	ctmCSSRSBASE_ATTEM_DAMAGE_1_1	CSSRSBASE_ATTEM_DAMAGE_2,
		Moderate physical damage; medical attention needed	2	ctmCSSRSBASE_ATTEM_DAMAGE_1_2	CSSRSBASE_ATTEM_DAMAGE_3
		Moderately severe physical damage; medical hospitalization and likely intensive care required	3	ctmCSSRSBASE_ATTEM_DAMAGE_1_3	
		Severe physical damage; medical hospitalization with intensive care required	4	ctmCSSRSBASE_ATTEM_DAMAGE_1_4	
		Death	5	ctmCSSRSBASE_ATTEM_DAMAGE_1_5	
cICSSRSBASE_ATTEM_DAMAGE_2_1	String	Behavior not likely to result in injury	0	ctmCSSRSLAST_ATTEM_DAMAGE_3_0	CSSRSBASE_POTENTIAL_1,
		Behavior likely to result in injury but not likely to cause death	1	ctmCSSRSLAST_ATTEM_DAMAGE_3_1	CSSRSBASE_POTENTIAL_2,
		Behavior likely to result in death despite available medical care	2	ctmCSSRSLAST_ATTEM_DAMAGE_3_2	CSSRSBASE_POTENTIAL_3

RDE Analytics: RD_CSSRSBASELINE		
Data Variable RefName	RD Column Name	Column Data Type
CSRSBASE_1	CSRSBASE_1_C	VARCHAR
	CSRSBASE_1	VARCHAR
	CSRSBASE_1_ND	VARCHAR
CSRSBASE_1 - CSRSBASE_1_DESC	CSRSBASE_1_DESC	VARCHAR
CSRSBASE_2	CSRSBASE_2_C	VARCHAR
	CSRSBASE_2	VARCHAR
	CSRSBASE_2_ND	VARCHAR
CSSRSBASE_2 - CSSRSBASE_2_DESC	CSSRSBASE_2_DESC	VARCHAR
CSRSBASE_3	CSRSBASE_3_C	VARCHAR
	CSRSBASE_3	VARCHAR
	CSRSBASE_3_ND	VARCHAR
CSSRSBASE_3 - CSSRSBASE_3_DESC	CSSRSBASE_3_DESC	VARCHAR
CSRSBASE_4	CSRSBASE_4_C	VARCHAR
	CSRSBASE_4	VARCHAR
	CSRSBASE_4_ND	VARCHAR
CSSRSBASE_4 - CSSRSBASE_4_DESC	CSSRSBASE_4_DESC	VARCHAR
CSRSBASE_5	CSRSBASE_5_C	VARCHAR
	CSRSBASE_5	VARCHAR
	CSRSBASE_5_ND	VARCHAR
CSSRSBASE_5 - CSSRSBASE_5_DESC	CSSRSBASE_5_DESC	VARCHAR
grpCSSRSBASE_MSIDEATION	GRPCSSRSBASE_MSIDEATION_ND	VARCHAR
grpCSSRSBASE_MSIDEATION - CSRSBASE_MSIDEATION	CSSRSBASE_MSIDEATION_C	VARCHAR
	CSSRSBASE_MSIDEATION	VARCHAR
CSSRSBASE_IDEA_1	CSSRSBASE_IDEA_1_C	VARCHAR
	CSSRSBASE_IDEA_1	VARCHAR
	CSSRSBASE_IDEA_1_ND	VARCHAR
CSSRSBASE_IDEA_2	CSSRSBASE_IDEA_2_C	VARCHAR
	CSSRSBASE_IDEA_2	VARCHAR
	CSSRSBASE_IDEA_2_ND	VARCHAR
CSSRSBASE_IDEA_3	CSSRSBASE_IDEA_3_C	VARCHAR
	CSSRSBASE_IDEA_3	VARCHAR
	CSSRSBASE_IDEA_3_ND	VARCHAR
CSSRSBASE_IDEA_4	CSSRSBASE_IDEA_4_C	VARCHAR
	CSSRSBASE_IDEA_4	VARCHAR
	CSSRSBASE_IDEA_4_ND	VARCHAR
CSSRSBASE_IDEA_5	CSSRSBASE_IDEA_5_C	VARCHAR
	CSSRSBASE_IDEA_5	VARCHAR
	CSSRSBASE_IDEA_5_ND	VARCHAR
CSSRSBASE_ATTEMPT	CSSRSBASE_ATTEMPT_C	VARCHAR
	CSSRSBASE_ATTEMPT	VARCHAR
	CSSRSBASE_ATTEMPT_ND	VARCHAR
CSSRSBASE_ATTEMPT - CSRSBASE_TOT_ATTEMPT	CSSRSBASE_TOT_ATTEMPT	NUMBER

	'T - CSSRSBASE_TEXT_ATTEMPT	CSSRSBASE_TEXT_ATTEMPT	VARCHAR2
CSSRSBA	TTEMPT - CSSRSBASE_ENGAGED	CSSRSBASE_ENGAGED_C	VARCHAR2
	CSSRSBASE_ENGAGED	CSSRSBASE_ENGAGED	VARCHAR2
CSSRSBASE_INTERRUPTED		CSSRSBASE_INTERRUPTED_C	VARCHAR2
	CSSRSBASE_INTERRUPTED	CSSRSBASE_INTERRUPTED	VARCHAR2
	CSSRSBASE_INTERRUPTED_ND	CSSRSBASE_INTERRUPTED_ND	VARCHAR2
CSSRSBASE_INTERRUPTED - CSSRSBASE_INTER	CSSRSBASE_INTER	NUMBER	
CSSRSBASE_INTERRUPTED - CSSRSBASE_INTER_TEXT	CSSRSBASE_INTER_TEXT	VARCHAR2	
CSSRSBASE_ABORTED	CSSRSBASE_ABORTED_C	VARCHAR2	
	CSSRSBASE_ABORTED	CSSRSBASE_ABORTED	VARCHAR2
	CSSRSBASE_ABORTED_ND	CSSRSBASE_ABORTED_ND	VARCHAR2
CSSRSBASE_ABORTED - CSSRSBASE_NO_ABORTED	CSSRSBASE_NO_ABORTED	NUMBER	
CSSRSBASE_ABORTED - CSSRSBASE_ABORTED_TEXT	CSSRSBASE_ABORTED_TEXT	VARCHAR2	
CSSRSBASE_BEHAVIOR	CSSRSBASE_BEHAVIOR_C	VARCHAR2	
	CSSRSBASE_BEHAVIOR	CSSRSBASE_BEHAVIOR	VARCHAR2
	CSSRSBASE_BEHAVIOR_ND	CSSRSBASE_BEHAVIOR_ND	VARCHAR2
CSSRSBASE_BEHAVIOR - CSSRSBASE_BEHAVIOR_TEXT	CSSRSBASE_BEHAVIOR_TEXT	VARCHAR2	
CSSRSBASE_SUICIDE_BEH	CSSRSBASE_SUICIDE_BEH_C	VARCHAR2	
	CSSRSBASE_SUICIDE_BEH	CSSRSBASE_SUICIDE_BEH	VARCHAR2
	CSSRSBASE_SUICIDE_BEH_ND	CSSRSBASE_SUICIDE_BEH_ND	VARCHAR2
grpCSSRSBASE_ATTEMPT_1	GRPCSSRSBASE_ATTEMPT_1_ND	VARCHAR2	
grpCSSRSBASE_ATTEMPT_1 - CSSRSBASE_ATTEM_DATE_1	CSSRSBASE_ATTEM_DATE_1	DATE	
	CSSRSBASE_ATTEM_DATE_1_DTS	VARCHAR2	
grpCSSRSBASE_ATTEMPT_1 - CSSRSBASE_ATTEM_DAMAGE_1	CSSRSBASE_ATTEM_DAMAGE_1_C	VARCHAR2	
	CSSRSBASE_ATTEM_DAMAGE_1	VARCHAR2	
grpCSSRSBASE_ATTEMPT_1 - CSSRSBASE_POTENTIAL_1	CSSRSBASE_POTENTIAL_1_C	VARCHAR2	
	CSSRSBASE_POTENTIAL_1	VARCHAR2	
grpCSSRSBASE_ATTEMPT_2	GRPCSSRSBASE_ATTEMPT_2_ND	VARCHAR2	
grpCSSRSBASE_ATTEMPT_2 - CSSRSBASE_ATTEM_DATE_2	CSSRSBASE_ATTEM_DATE_2	DATE	
	CSSRSBASE_ATTEM_DATE_2_DTS	VARCHAR2	
grpCSSRSBASE_ATTEMPT_2 - CSSRSBASE_ATTEM_DAMAGE_2	CSSRSBASE_ATTEM_DAMAGE_2_C	VARCHAR2	
	CSSRSBASE_ATTEM_DAMAGE_2	VARCHAR2	
grpCSSRSBASE_ATTEMPT_2 - CSSRSBASE_POTENTIAL_2	CSSRSBASE_POTENTIAL_2_C	VARCHAR2	
	CSSRSBASE_POTENTIAL_2	VARCHAR2	
grpCSSRSBASE_ATTEMPT_3	GRPCSSRSBASE_ATTEMPT_3_ND	VARCHAR2	
grpCSSRSBASE_ATTEMPT_3 - CSSRSBASE_ATTEM_DATE_3	CSSRSBASE_ATTEM_DATE_3	DATE	
	CSSRSBASE_ATTEM_DATE_3_DTS	VARCHAR2	
grpCSSRSBASE_ATTEMPT_3 - CSSRSBASE_ATTEM_DAMAGE_3	CSSRSBASE_ATTEM_DAMAGE_3_C	VARCHAR2	
	CSSRSBASE_ATTEM_DAMAGE_3	VARCHAR2	
grpCSSRSBASE_ATTEMPT_3 - CSSRSBASE_POTENTIAL_3	CSSRSBASE_POTENTIAL_3_C	VARCHAR2	
	CSSRSBASE_POTENTIAL_3	VARCHAR2	

**QS=Questionnaires****QSCAT=PHQ-9**

: PHQ-9 (PHQ9) [PHQ9]		
Study ID: 1	Note: Group 1	
sctPHQ9 [sctPHQ9]		
1.* Little interest or pleasure in doing things [Little interest or pleasure in doing things]	[PHQ_1] [N:0] 0 - Not at all [N:1] 1 - Several days [N:2] 2 - More than half the days [N:3] 3 - Nearly every day	<b>QSORRES when QSTESTCD=PHQ0101</b>
2.* Feeling down, depressed, or hopeless [Feeling down, depressed, or hopeless]	[PHQ_2] [N:0] 0 - Not at all [N:1] 1 - Several days [N:2] 2 - More than half the days [N:3] 3 - Nearly every day	<b>QSORRES when QSTESTCD=PHQ0102</b>
3.* Trouble falling or staying asleep, or sleeping too much [Trouble falling or staying asleep, or sleeping too much]	[PHQ_3] [N:0] 0 - Not at all [N:1] 1 - Several days [N:2] 2 - More than half the days [N:3] 3 - Nearly every day	<b>QSORRES when QSTESTCD=PHQ0103</b>
4.* Feeling tired or having little energy [Feeling tired or having little energy]	[PHQ_4] [N:0] 0 - Not at all [N:1] 1 - Several days [N:2] 2 - More than half the days [N:3] 3 - Nearly every day	<b>QSORRES when QSTESTCD=PHQ0104</b>
5.* Poor appetite or overeating [Poor appetite or overeating]	[PHQ_5] [N:0] 0 - Not at all [N:1] 1 - Several days [N:2] 2 - More than half the days [N:3] 3 - Nearly every day	<b>QSORRES when QSTESTCD=PHQ0105</b>
6.* Feeling bad about yourself - or that you are a failure or have let yourself or your family down [Feeling bad about yourself - or that you are a failure or have let yourself or your family down]	[PHQ_6] [N:0] 0 - Not at all [N:1] 1 - Several days [N:2] 2 - More than half the days [N:3] 3 - Nearly every day	<b>QSORRES when QSTESTCD=PHQ0106</b>
7.* Trouble concentrating on things, such as reading the newspaper or watching television [Trouble concentrating on things, such as reading the newspaper or watching television]	[PHQ_7] [N:0] 0 - Not at all [N:1] 1 - Several days [N:2] 2 - More than half the days [N:3] 3 - Nearly every day	<b>QSORRES when QSTESTCD=PHQ0107</b>
8.* Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual [Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual]	[PHQ_8] [N:0] 0 - Not at all [N:1] 1 - Several days [N:2] 2 - More than half the days [N:3] 3 - Nearly every day	<b>QSORRES when QSTESTCD=PHQ0108</b>
9.* Thoughts that you would be better off dead or of hurting yourself in some way [Thoughts that you would be better off dead or of hurting yourself in some way]	[PHQ_9] [N:0] 0 - Not at all [N:1] 1 - Several days [N:2] 2 - More than half the days [N:3] 3 - Nearly every day	<b>QSORRES when QSTESTCD=PHQ0109</b>
10.* For office coding: [For office coding:]	[grpPHQ_OFFICE] [PHQ_OFFICE_0] [PHQ_OFFICE_1] [PHQ_OFFICE_2] [PHQ_OFFICE_3] 0 N2 1 N2   2 N2 3 N2	
11.* Total Score [Total Score]	[PHQ_TOTAL_SCORE] N2	<b>QSORRES when QSTESTCD=PHQ0111</b>
12.* If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people? [If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?]	[PHQ_10] [N:1] 0 - Not difficult at all [N:2] 1 - Somewhat difficult [N:3] 2 - Very difficult [N:4] 3 - Extremely difficult	<b>QSORRES when QSTESTCD=PHQ0110</b>

Key: [\*] = Item is required    [✓] = Source verification required  
Note: Source verification critical settings made in Inform will override any settings made in Central Designer.

**Study Object Descriptions: PHQ-9**

Type	RefName	Description
Form	PHQ9	Visit: V1, V14, V24, V30, V33, V35

**Codelist Values Tables: PHQ-9**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cPHQ	Integer		0 - Not at all	0	citmPHQ_0	PHQ_1, PHQ_2, PHQ_3, PHQ_4, PHQ_5, PHQ_6, PHQ_7, PHQ_8, PHQ_9
			1 - Several days	1	citmPHQ_1	
			2 - More than half the days	2	citmPHQ_2	
			3 - Nearly every day	3	citmPHQ_3	
cPHQ_10	Integer		Not difficult at all	1	citmPHQ_1_1	PHQ_10
			Somewhat difficult	2	citmPHQ_1_2	
			Very difficult	3	citmPHQ_1_3	
			Extremely difficult	4	citmPHQ_1_4	

**RDE Analytics: RD\_PHQ9**

Data Variable RefName	RD Column Name	Column Data Type
PHQ_1	PHQ_1_C	NUMBER
	PHQ_1	VARCHAR2
	PHQ_1_ND	VARCHAR2
PHQ_2	PHQ_2_C	NUMBER
	PHQ_2	VARCHAR2
	PHQ_2_ND	VARCHAR2
PHQ_3	PHQ_3_C	NUMBER
	PHQ_3	VARCHAR2
	PHQ_3_ND	VARCHAR2
PHQ_4	PHQ_4_C	NUMBER
	PHQ_4	VARCHAR2
	PHQ_4_ND	VARCHAR2
PHQ_5	PHQ_5_C	NUMBER
	PHQ_5	VARCHAR2
	PHQ_5_ND	VARCHAR2
PHQ_6	PHQ_6_C	NUMBER
	PHQ_6	VARCHAR2

	PHQ_6_CD	VARCHAR2
PHQ_7	PHQ_7_C	NUMBER
	PHQ_7_V	VARCHAR2
	PHQ_7_CD	VARCHAR2
PHQ_8	PHQ_8_C	NUMBER
	PHQ_8_V	VARCHAR2
	PHQ_8_CD	VARCHAR2
PHQ_9	PHQ_9_C	NUMBER
	PHQ_9_V	VARCHAR2
	PHQ_9_CD	VARCHAR2
grpPHQ_OFFICE	GRPHQ_OFFICE_CD	VARCHAR2
grpPHQ_OFFICE - PHQ_OFFICE_0	PHQ_OFFICE_0	NUMBER
grpPHQ_OFFICE - PHQ_OFFICE_1	PHQ_OFFICE_1	NUMBER
grpPHQ_OFFICE - PHQ_OFFICE_2	PHQ_OFFICE_2	NUMBER
grpPHQ_OFFICE - PHQ_OFFICE_3	PHQ_OFFICE_3	NUMBER
PHQ_TOTAL_SCORE	PHQ_TOTAL_SCORE_CD	NUMBER
	PHQ_TOTAL_SCORE_CD	VARCHAR2
PHQ_10	PHQ_10_C	NUMBER
	PHQ_10_V	VARCHAR2
	PHQ_10_CD	VARCHAR2

**Note: If result is 'No' no record is submitted**

**DS=Disposition**

**DSCAT=OTHER EVENT**

: Collection of Consent to Biosamples for Future Research (Collection Future Research) [COLLECTION_FUTURE_RESEARCH]		Study ID:
1.*	Child assent for biosamples for future analysis [Child assent for biosamples for future analysis]	<input type="radio"/> No <input checked="" type="radio"/> Yes <b>[grpDSTERM_1]</b> <small>[A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpDSTERM_1] ☐</small> <small>Yes</small> <small>[DSSTDTC_1] (DD/MM/YYYY)</small> <small>Req ✓ / Req ✓ / Req ✓ (2023-2030)</small>
2.	Consent for biosamples for future analysis obtained by Parents/Legally Acceptable Representative (LAR) [Consent for biosamples for future analysis obtained by Parents/Legally Acceptable Representative (LAR)]	<input type="radio"/> No <input checked="" type="radio"/> Yes <b>[DSSTDTC_2]</b> <small>[A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpDSTERM_2] ☐</small> <small>Yes</small> <small>[DSSTDTC_2] (DD/MM/YYYY)</small> <small>Req ✓ / Req ✓ / Req ✓ (2023-2030)</small>
3.	Consent for biosamples for future analysis obtained by Parents/Legally Acceptable Representative (LAR) Only to be completed in countries where Informed Consent from both parents is required [Consent for biosamples for future analysis obtained by Parents/Legally Acceptable Representative (LAR)]	<input type="radio"/> No <input checked="" type="radio"/> Yes <b>[DSSTDTC_3]</b> <small>[A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpDSTERM_3] ☐</small> <small>Yes</small> <small>[DSSTDTC_3] (DD/MM/YYYY)</small> <small>Req ✓ / Req ✓ / Req ✓ (2023-2030)</small>

Key: [\*] = Item is required   [ ] = Item is collapsible  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.

#### Study Object Descriptions: Collection of Consent to Biosamples for Future Research

Type	RefName	Description
Form	COLLECTION_FUTURE_RESEARCH	Visit: V1

#### Codelist Values Tables: Collection of Consent to Biosamples for Future Research

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDSTERM_YN_1	String	No	2	ctmDSTERM_1N	DSTERM_1	
		Yes	1	ctmDSTERM_1Y		
clDSTERM_YN_2	String	No	2	ctmDSTERM_2N	DSTERM_2	
		Yes	1	ctmDSTERM_2Y		
clDSTERM_YN_3	String	No	2	ctmDSTERM_3N	DSTERM_3	
		Yes	1	ctmDSTERM_3Y		

#### RDE Analytics: \*RD\_COLLECTION\_FUTURE\_RESEARCH

Data Variable RefName	RD Column Name	Column Data Type
DSTERM_1	DSTERM_1_C	VARCHAR2
	DSTERM_1	VARCHAR2
	DSTERM_1_ND	VARCHAR2
DSTERM_1 - DSSTDTC_1	DSSTDTC_1_DATE	
	DSSTDTC_1_DTS	VARCHAR2
DSTERM_2	DSTERM_2_C	VARCHAR2
	DSTERM_2	VARCHAR2
	DSTERM_2_ND	VARCHAR2
DSTERM_2 - DSSTDTC_2	DSSTDTC_2_DATE	
	DSSTDTC_2_DTS	VARCHAR2
DSTERM_3	DSTERM_3_C	VARCHAR2
	DSTERM_3	VARCHAR2
	DSTERM_3_ND	VARCHAR2
DSTERM_3 - DSSTDTC_3	DSSTDTC_3_DATE	
	DSSTDTC_3_DTS	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**Note: For protocol specified inclusion criteria IETESTCD is I1 - In. For protocol specified exclusion criteria IETESTCD is E1 - En.**

**IE=Inclusion/Exclusion Criteria Not Met DS=Disposition**

<b>: Eligibility Criteria (Elig) [ELIG_CRIT_2]</b>		<b>DSCAT=PROTOCOL MILESTONE</b>	
<p>To qualify for participation all eligibility criteria must be met by subject. The screening status should not be updated once the subject is randomised.</p> <p>1. Screening status: Having evaluated all criteria, is the subject eligible to continue in the study?  <input checked="" type="radio"/> [A:1] [ELIG_STAT_1] Subject is eligible (Meets all eligibility requirements)  <input type="radio"/> [A:2] [ELIG_STAT_2] Subject failed one or more eligibility requirements (Subject is a screen failure)  <input type="radio"/> [A:3] [ELIG_STAT_3] Eligibility evaluation was not completed</p> <p>If subject is not eligible, complete the End of Study form  Complete the applicable sections below if the subject failed one or more eligibility requirements (Subject is a screen failure)  [Eligibility status]</p>			
<b>DSSTDTC</b>		<b>[ELIG_STATUS]</b>	
<b>NOT SUBMITTED</b>		<b>[A:1] [ELIG_STAT_1] Subject is eligible (Meets all eligibility requirements) Date subject is confirmed eligible Req ✓ / Red ✓ / Req ✓ (2023-2030)</b>	
		<b>[A:2] [ELIG_STAT_2] Subject failed one or more eligibility requirements (Subject is a screen failure)</b>	
		<b>[A:3] [ELIG_STAT_3] Eligibility evaluation was not completed</b>	
<b>Failed inclusion criterion</b>			
<b>NOT SUBMITTED</b>			
		<b>DSDECOD=ELIGIBILITY CRITERIA MET</b>	
		<b>DSTERM=ELIGIBILITY CRITERIA MET</b>	
<p>2. Failed inclusion criteria Entry [sctELIG_INCL]</p> <p>2.1 Failed inclusion criterion  <input checked="" type="checkbox"/> [Failed inclusion criterion]</p>			
<b>IECAT=INCLUSION</b>		<b>[ELIG_FAIL_INCL] [cFAIL_INCL] ✓</b>	
<b>IETESTCD</b>			
Met exclusion criterion			
<p>3. Met exclusion criteria Entry [sctELIG_EXCL]</p> <p>3.1 Met exclusion criterion  <input checked="" type="checkbox"/> [Met exclusion criterion]</p>			
<b>IECAT=EXCLUSION</b>		<b>[ELIG_MET_EXCL] [cMET_EXCL] ✓</b>	
<b>IETESTCD</b>			
<p><b>Eligibility criteria [sctELIG_CRITERIA]</b></p> <p><b>Inclusion Criteria</b></p> <p>1. Informed consent of parent(s) or legally acceptable representative (LAR) of participant and child assent, obtained before any study-related activities. Study-related activities are any procedures that are carried out as part of the study, including activities to determine suitability for the study.  a. The parent(s) or LAR of the child must sign and date the Informed Consent Form (according to local requirements)  b. The parent(s) or LAR of the child must sign and date the Child Assent Form or provide oral assent (according to local requirements)  2. Age at the time of signing informed consent, of:  a. Group Kids: 6 to &lt; 12 years  b. Group Teens: 12 to &lt; 18 years, and Tanner stage &gt; 1  3. BMI, at screening and randomisation, corresponding to:  a. Group Kids: ≥95th percentile<sup>a</sup>  b. Group Teens: ≥95th percentile<sup>a</sup> or ≥85th percentile<sup>b</sup> with the presence of at least 1 weight-related comorbidity (treated or untreated): hypertension, dyslipidaemia, obstructive sleep apnoea or T2D  4. History of at least one unsuccessful effort to lose sufficient body weight after participation in a structured lifestyle modification programme (diet and exercise counselling) for at least 3 months<sup>b</sup>  5. Body weight of &gt;45 kg at screening and randomisation.</p> <p><b>For participants with T2D at screening the following inclusion criteria apply in addition to criteria 1-5:</b>  6. Treatment with either lifestyle intervention, or treatment with metformin according to local label. Treatment with metformin should be stable (same drug(s), dose, and dosing frequency) for at least 90 days before screening  7. HbA1c ≤10.0% (86 mmol/mol) as measured by central laboratory at screening</p> <p><b>For participants assessed by DXA scan the following additional criteria must apply:</b>  8. Evaluation of the quality of the DXA scan must be performed and found acceptable by the imaging laboratory prior to randomisation  9. BMI ≤ 40.0 kg/m<sup>2</sup> at screening</p> <p><b>Exclusion Criteria</b></p> <p><b>Obesity related</b></p> <p>1. Treatment with any medication prescribed for the indication of obesity or weight management within 90 days before screening  2. Previous or planned (during the study period) obesity treatment with surgery or a weight loss device. However, the following are allowed: (1) liposuction and/or abdominoplasty, if performed &gt;1 year prior to screening, (2) adjustable gastric banding, if the band has been removed &gt;1 year prior to screening, (3) intragastric balloon, if the balloon has been removed &gt;1 year prior to screening or (4) duodenal-jejunal bypass liner (e.g., EndobARRIER), if the sleeve has been removed &gt;1 year prior to screening.  3. Uncontrolled thyroid disease  4. Participants with endocrine, hypothalamic, or syndromic obesity  5. A self-reported (or by parent(s)/LAR where applicable) change in body weight &gt;5% within 90 days before screening irrespective of medical records</p> <p><b>Mental health</b></p> <p>6. History of major depressive disorder within 2 years before screening<sup>b</sup>  7. Diagnosis of other severe psychiatric disorders (e.g., schizophrenia, bipolar disorder)<sup>b</sup>  8. A lifetime history of suicidal attempt<sup>b</sup>  9. Suicidal behaviour within 30 days before screening  <b>Additional mental health for Group Teens</b>  10. A Patient Health Questionnaire-9 (PHQ-9) score of ≥15 at screening  11. Suicidal ideation corresponding to type 4 or 5 based on the Columbia-Suicide Severity Rating Scale (C-SSRS) within 30 days before screening</p> <p><b>General Safety</b></p> <p>12. History or presence of chronic pancreatitis<sup>b</sup>  13. Presence of acute pancreatitis within 180 days before screening  14. Calcitonin ≥50 ng/L  15. Personal, or first-degree relative's, history of multiple endocrine neoplasia type 2 or medullary thyroid carcinoma<sup>b</sup>  16. Type 1 diabetes mellitus or monogenic diabetes  17. Renal impairment with estimated glomerular filtration rate (eGFR) &lt; 60 mL/min/1.73 m<sup>2</sup>, as calculated by the Bedside Schwartz equation<sup>c</sup>  18. Presence or history of malignant neoplasms within the past 5 years prior to the day of screening<sup>b</sup>  19. Severe, uncontrolled hypertension or minor surgical procedures, in the opinion of the investigator  20. Known or suspected abuse of alcohol or recreational drugs  21. Use of any medication with unknown or unspecified content within 90 days before screening  22. Known or suspected hypersensitivity to trial product(s) or related products  23. Previous participation in this study. Participation defined as signed informed consent  24. Participation (i.e., signed informed consent) in any interventional, clinical study of an approved or non-approved investigational medicinal product within 90 days before screening  25. Other participant(s) from the same household in any semipanlitude study  26. Known or suspected history of arrhythmias, significant bradycardia, or conduction delays on ECG within 180 days before screening, new clinically significant arrhythmias or conduction delays on ECG identified at screening  27. Female who is pregnant, breast feeding, intends to become pregnant or is of child-bearing potential and not using a highly effective contraceptive method, as defined in Appendix 4, Section 10.4  28. Any disorder, unwillingness, or inability, not covered by any of the other exclusion criteria, which in the investigator's opinion, might jeopardise the participant's safety or compliance with the protocol</p> <p><b>Glycaemia-related</b></p> <p>29. Treatment with glucose-lowering agent(s) within 90 days before screening (except for metformin)  30. Treatment with a GLP-1 receptor agonist within 180 days before screening</p> <p><b>Diabetes related for participants with T2D</b></p> <p>31. Uncontrolled and potentially unstable diabetic retinopathy or maculopathy. Verified by a fundus examination performed within the past 90 days before screening or in the period between screening and randomisation. Pharmacological pupil-dilation is a requirement unless using a digital fundus photography camera specified for non-dilated examination  32. Positive insulinoma associated-protein 2 (IA-2) antibodies or anti-glutamic acid decarboxylase (anti-GAD) antibodies</p>			
<p>4. End of the form [read-only]  <input checked="" type="checkbox"/> [Eligibility status]</p>			
<p>Key: [*] = Item is required  Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</p>			

<b>Study Object Descriptions: Eligibility Criteria</b>		
Type	RefName	Description
Form	ELIG_CRIT_2	Visit: Eligibility
Item	ELIG_END	Item does not collect data. Item is present in order to display full text of the criteria in the section note

<b>Codelist Values Tables: Eligibility Criteria</b>						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cELIG_STATUS	String		Subject is eligible (Meets all eligibility requirements)	1	citmELIG_STAT_1	ELIG_STATUS
			Subject failed one or more eligibility requirements (Subject is a screen failure)	2	citmELIG_STAT_2	
			Eligibility evaluation was not completed	3	citmELIG_STAT_3	
cFAIL_INCL	String		Inclusion Criteria 1	11	citmFAIL_INCL_1	ELIG_FAIL_INCL
			Inclusion Criteria 2	12	citmFAIL_INCL_2	
			Inclusion Criteria 3	13	citmFAIL_INCL_3	
			Inclusion Criteria 4	14	citmFAIL_INCL_4	
			Inclusion Criteria 5	15	citmFAIL_INCL_5	
			Inclusion Criteria 6	16	citmFAIL_INCL_6	
			Inclusion Criteria 7	17	citmFAIL_INCL_7	
			Inclusion Criteria 8	18	citmFAIL_INCL_8	
			Inclusion Criteria 9	19	citmFAIL_INCL_9	
cIMET_EXCL	String		Exclusion Criteria 1	E1	citmMET_EXCL_1	ELIG_MET_EXCL
			Exclusion Criteria 2	E2	citmMET_EXCL_2	
			Exclusion Criteria 3	E3	citmMET_EXCL_3	

		E4	citmMET_EXCL_4
		E5	citmMET_EXCL_5
		E6	citmMET_EXCL_6
		E7	citmMET_EXCL_7
		E8	citmMET_EXCL_8
		E9	citmMET_EXCL_9
		E10	citmMET_EXCL_10
		E11	citmMET_EXCL_11
		E12	citmMET_EXCL_12
		E13	citmMET_EXCL_13
		E14	citmMET_EXCL_14
		E15	citmMET_EXCL_15
		E16	citmMET_EXCL_16
		E17	citmMET_EXCL_17
		E18	citmMET_EXCL_18
		E19	citmMET_EXCL_19
		E20	citmMET_EXCL_20
		E21	citmMET_EXCL_21
		E22	citmMET_EXCL_22
		E23	citmMET_EXCL_23
		E24	citmMET_EXCL_24
		E25	citmMET_EXCL_25
		E26	citmMET_EXCL_26
		E27	citmMET_EXCL_27
		E28	citmMET_EXCL_28
		E29	citmMET_EXCL_29
		E30	citmMET_EXCL_30
		E31	citmMET_EXCL_31
		E32	citmMET_EXCL_32
cELIG_END	String	1	citmELIG_END
			ELIG_END

<b>RDE Analytics: RD_ELIG_CRIT_2</b>		
Data Variable RefName	RD Column Name	Column Data Type
ELIG_STATUS	ELIG_STATUS_C	VARCHAR2
	ELIG_STATUS	VARCHAR2
	ELIG_STATUS_ND	VARCHAR2
ELIG_STATUS - ELIG_DT	ELIG_DT	DATE
	ELIG_DT_DTS	VARCHAR2
ELIG_END	ELIG_END_C	VARCHAR2
	ELIG_END	VARCHAR2
	ELIG_END_ND	VARCHAR2
<b>*RD_ELIG_CRIT_2_SCTELIG_INCL</b>		
ELIG_FAIL_INCL	ELIG_FAIL_INCL_C	VARCHAR2
	ELIG_FAIL_INCL	VARCHAR2
	ELIG_FAIL_INCL_ND	VARCHAR2
<b>*RD_ELIG_CRIT_2_SCTELIG_EXCL</b>		
ELIG_MET_EXCL	ELIG_MET_EXCL_C	VARCHAR2
	ELIG_MET_EXCL	VARCHAR2
	ELIG_MET_EXCL_ND	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

: Randomisation (Rand) [RANDOMIS_CRIT]		DM=Demographics		DS=Disposition	
Study ID:		DSSTDTC	[RANDOMISATION_DATE] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2023-2030)	DSDECOD=RANDOMIZED	DSCAT=PROTOCOL MILESTONE
1. Date of [Date of randomisation] read-only]			[RANDOMISATION_NO]	N6	DTERM=RANDOMIZED
2. Randomisation No [hidden] [Randomisation No]			[RAND_TRIAL_DRUG_CODE]	<input type="radio"/> Pseudo/blinded arm 1 <input type="radio"/> Pseudo/blinded arm 2 <input type="radio"/> Pseudo/blinded arm 3 <input type="radio"/> Pseudo/blinded arm 4 <input type="radio"/> Pseudo/blinded arm 5	
3. Randomised to intervention arm [hidden] [Randomised to arm]			[STRATUM_CODE]	<input type="radio"/> Group Kids,Male, Tanner Stage 1 <input type="radio"/> Group Kids,Male, Tanner Stage 2-3 <input type="radio"/> Group Kids,Male, Tanner Stage 4-5 <input type="radio"/> Group Kids,Female, Tanner Stage 1 <input type="radio"/> Group Kids,Female, Tanner Stage 2-3 <input type="radio"/> Group Kids,Female, Tanner Stage 4-5 <input type="radio"/> Group Teens,Male <input type="radio"/> Group Teens,Female	
4. Stratification [read-only] [Stratification]			STRATUM in SUPPDM		
5. Cohort No. [hidden] [Cohort No.]			COHORT	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10 <input type="radio"/> 1A <input type="radio"/> 2A <input type="radio"/> 3A <input type="radio"/> 4A <input type="radio"/> 5A <input type="radio"/> 6A <input type="radio"/> 7A <input type="radio"/> 8A <input type="radio"/> 9A <input type="radio"/> 10A <input type="radio"/> 1B <input type="radio"/> 2B <input type="radio"/> 3B <input type="radio"/> 4B <input type="radio"/> 5B <input type="radio"/> 6B <input type="radio"/> 7B <input type="radio"/> 8B <input type="radio"/> 9B <input type="radio"/> 10B	

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: Randomisation		
Type	RefName	Description
Form	RANDOMIS_CRIT	Visit: V2  See CRF guidance for instructions on RTSM-InForm integrations
Item	RANDOMISATION_DATE	Populated by IV/WRS or RTSM - please do not change the refname or format
Item	RANDOMISATION_NO	**Item DEACTIVATED**
Item	RAND_TRIAL_DRUG_CODE	Populated by IV/WRS or RTSM - please do not change the refname or format
Item	STRATUM_CODE	Integrations: RTSM - please do not change the refname or format
Item	COHORT	**Item DEACTIVATED** Integrations: RTSM - please do not change the refname or format

Codelist Values Tables: Randomisation						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clRAND_TRIAL_DRUG_CODE	String		Pseudo/blinded arm 1	P	clRAND_TRIAL_DRUG_A	RAND_TRIAL_DRUG_CODE
			Pseudo/blinded arm 2	PP	clRAND_TRIAL_DRUG_B	
			Pseudo/blinded arm 3	PPP	clRAND_TRIAL_DRUG_C	
			Pseudo/blinded arm 4	PPPP	clRAND_TRIAL_DRUG_D	
			Pseudo/blinded arm 5	PPPPP	clRAND_TRIAL_DRUG_E	
clSTRATUM_CODE	String		Group Kids,Male, Tanner Stage 1	1	ctmSTRATUM_CODE_A	STRATUM_CODE
			Group Kids,Male, Tanner Stage 2-3	2	ctmSTRATUM_CODE_B	
			Group Kids,Male, Tanner Stage 4-5	3	ctmSTRATUM_CODE_C	
			Group Kids,Female, Tanner Stage 1	4	ctmSTRATUM_CODE_D	
			Group Kids,Female, Tanner Stage 2-3	5	ctmSTRATUM_CODE_E	
			Group Kids,Female, Tanner Stage 4-5	6	ctmSTRATUM_CODE_F	
			Group Teens,Male	7	ctmSTRATUM_CODE_G	
			Group Teens,Female	8	ctmSTRATUM_CODE_H	
clCOHORT	String		1	12	ctmCOHORT_1	COHORT
			2	13	ctmCOHORT_2	
			3	14	ctmCOHORT_3	
			4	15	ctmCOHORT_4	
			5	16	ctmCOHORT_5	
			6	17	ctmCOHORT_6	
			7	18	ctmCOHORT_7	
			8	19	ctmCOHORT_8	
			9	20	ctmCOHORT_9	
			10	21	ctmCOHORT_10	
			1A	22	ctmCOHORT_1A	
			2A	23	ctmCOHORT_2A	
			3A	24	ctmCOHORT_3A	
			4A	25	ctmCOHORT_4A	
			5A	26	ctmCOHORT_5A	
			6A	27	ctmCOHORT_6A	
			7A	28	ctmCOHORT_7A	

8A	29	citmCOHORT_8A
9A	30	citmCOHORT_9A
10A	31	citmCOHORT_10A
1B	32	citmCOHORT_1B
2B	33	citmCOHORT_2B
3B	34	citmCOHORT_3B
4B	35	citmCOHORT_4B
5B	36	citmCOHORT_5B
6B	37	citmCOHORT_6B
7B	38	citmCOHORT_7B
8B	39	citmCOHORT_8B
9B	40	citmCOHORT_9B
10B	41	citmCOHORT_10B

RDE Analytics: RD_RANDOMIS_CRIT		
Data Variable RefName	RD Column Name	Column Data Type
RANDOMISATION_DATE	RANDOMISATION_DATE	DATE
	RANDOMISATION_DATE_DTS	VARCHAR2
	RANDOMISATION_DATE_ND	VARCHAR2
RANDOMISATION_NO	RANDOMISATION_NO	NUMBER
	RANDOMISATION_NO_ND	VARCHAR2
RAND_TRIAL_DRUG_CODE	RAND_TRIAL_DRUG_CODE_C	VARCHAR2
	RAND_TRIAL_DRUG_CODE	VARCHAR2
	RAND_TRIAL_DRUG_CODE_ND	VARCHAR2
STRATUM_CODE	STRATUM_CODE_C	VARCHAR2
	STRATUM_CODE	VARCHAR2
	STRATUM_CODE_ND	VARCHAR2
COHORT	COHORT_C	VARCHAR2
	COHORT	VARCHAR2
	COHORT_ND	VARCHAR2

**RP=Reproductive System Findings****RPCAT=MENSTRUAL PERIOD**

<b>: First Date of Last Menstrual Cycle (Menstrual cycle) [MENSTRUAL_CYCLE]</b>	
Study ID: ---'s only Note: Fem <b>sctMENSTRUAL_CYCLE [sctMENSTRUAL_CYCLE]</b> 1. Did the subject menstruate? [Did the subject menstruate?]	
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	
[A:1] <input checked="" type="radio"/> [MENSTRUAL_CYCLE_DATE] (DD/MM/YYYY) Yes <input checked="" type="checkbox"/> / <input type="checkbox"/> Req / <input type="checkbox"/> / <input checked="" type="checkbox"/> Req (2023-2030) [A:2] <input type="radio"/> No	
<b>RPORRES when RPTESTCD=MENSYN</b> <b>RPORRES when RPTESTCD=LMPSTDTC</b>	

Study Object Descriptions: First Date of Last Menstrual Cycle		
Type	RefName	Description
Form	MENSTRUAL_CYCLE	Visit: V2, V14, V24, V30

Codelist Values Tables: First Date of Last Menstrual Cycle						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cMENSTRUAL_CYCLE	String			Yes	1	ctmMENSTRUAL_CYCLE_1 MENSTRUAL_CYCLE_1
				No	2	ctmMENSTRUAL_CYCLE_2

RDE Analytics: RD_MENSTRUAL_CYCLE		
Data Variable RefName	RD Column Name	Column Data Type
MENSTRUAL_CYCLE_1	MENSTRUAL_CYCLE_1_C	VARCHAR2
	MENSTRUAL_CYCLE_1	VARCHAR2
	MENSTRUAL_CYCLE_1_ND	VARCHAR2
MENSTRUAL_CYCLE_1 - MENSTRUAL_CYCLE_DATE	MENSTRUAL_CYCLE_DATE	DATE
	MENSTRUAL_CYCLE_DATE_DTS	VARCHAR2

**LB=Laboratory Test Results****LBCAT=COLLECTION OF SAMPLES****LBSPEC=BLOOD**

<b>: Collection of Samples for Laboratory_2 (Lab) [LAB_SAMPLE_TAKEN_4]</b>	
<b>Study ID:</b> Collect sam... ~ the procedures detailed in the laboratory manual.	<b>[ALL_SAMPLE_DATE_3] (DD/MM/YYYY)</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2020-2030)
1. Sample collection date and time [hidden] [Sample Collection Date]	<b>[ALL_SAMPLE_DATE_TIME_3] (DD/MM/YYYY hh:mm)</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2020-2030) Req <input checked="" type="checkbox"/> : Req <input checked="" type="checkbox"/> 24-hour clock
<b>Blood [sctSAMPLE_TAKEN_YN_3]</b>	<b>[SAMPLE_TAKEN_YN_1_3]</b> [A:1] <input type="radio"/> Yes [A:2] <input checked="" type="radio"/> [COMMENT_TEXT_YN_3] No, comment A200
3.* Have all blood samples been taken? [Blood Sample]	<b>LBSTAT=NOT DONE</b> <b>Note: If result is 'Yes' no record is submitted. If result is 'No' LBSTAT='NOT DONE'</b>
<b>Biosamples for future analysis [sctSAMPLE_TAKEN_YN_4]</b>	<b>[SAMPLE_TAKEN_YN_2]</b> [A:1] <input type="radio"/> Yes [A:2] <input checked="" type="radio"/> [COMMENT_TEXT_YN_3_1] No, comment A200
4. Have biosamples for future analysis been taken? [Have biosamples for future analysis been taken?]	<b>NOT SUBMITTED</b>
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

**Study Object Descriptions: Collection of Samples for Laboratory\_2**

Type	RefName	Description
Form	LAB_SAMPLE_TAKEN_4	Visit: V2,V24,V30
Item	ALL_SAMPLE_DATE_3	**Item DEACTIVATED**
Item	ALL_SAMPLE_DATE_TIME_3	**Item DEACTIVATED**

**Codelist Values Tables: Collection of Samples for Laboratory\_2**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cSAMPLE_TAKEN_YN_V1_1	String		Yes	1	citmSAMPLE_TAKEN_Y1	SAMPLE_TAKEN_YN_1_3
			No, comment	2	citmSAMPLE_TAKEN_N1	
cSAMPLE_TAKEN_YN_V1_2	String		Yes	1	citmSAMPLE_TAKEN_Y1_1	SAMPLE_TAKEN_YN_2
			No, comment	2	citmSAMPLE_TAKEN_N1_1	

**RDE Analytics: RD\_LAB\_SAMPLE\_TAKEN\_4**

Data Variable RefName	RD Column Name	Column Data Type
ALL_SAMPLE_DATE_3	ALL_SAMPLE_DATE_3	DATE
	ALL_SAMPLE_DATE_3_DTS	VARCHAR2
	ALL_SAMPLE_DATE_3_ND	VARCHAR2
ALL_SAMPLE_DATE_TIME_3	ALL_SAMPLE_DATE_TIME_3	DATE
	ALL_SAMPLE_DATE_TIME_3_DTS	VARCHAR2
	ALL_SAMPLE_DATE_TIME_3_ND	VARCHAR2
SAMPLE_TAKEN_YN_1_3	SAMPLE_TAKEN_YN_1_3_C	VARCHAR2
	SAMPLE_TAKEN_YN_1_3	VARCHAR2
	SAMPLE_TAKEN_YN_1_3_ND	VARCHAR2
SAMPLE_TAKEN_YN_1_3 - COMMENT_TEXT_YN_3	COMMENT_TEXT_YN_3	VARCHAR2
SAMPLE_TAKEN_YN_2	SAMPLE_TAKEN_YN_2_C	VARCHAR2
	SAMPLE_TAKEN_YN_2	VARCHAR2
	SAMPLE_TAKEN_YN_2_ND	VARCHAR2
SAMPLE_TAKEN_YN_2 - COMMENT_TEXT_YN_3_1	COMMENT_TEXT_YN_3_1	VARCHAR2

**VS=Vital Signs****VSCAT=BODY MEASUREMENT**

: Body measurements (Body Meas) [BODY_MEASUREMENT_2]		
<b>Study ID:</b> Preferably, measurements should be taken by the investigator, or the same qualified delegate, throughout the duration of the study.		
1. Date of examination [hidden] [Exam Date]	[BODY_MEAS_DATE_2] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2016-2025)	
2. Date and time of examination [hidden] [Exam Date & Time]	[BODY_MEAS_DATE_TIME1] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2021-2030) Req/Unk <input type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock	
3.* Height 1 (Before measuring linear growth, remove shoes, hats, hair ornaments, and braids whenever possible because these items interfere with accurate growth measurement. The participant must be repositioned between the measurements.) [Height 1]	[grpHEIGHT1] [BODY_HEIGHT1] [HEIGHT_UNIT1] 0 <= xxx.x [A:340] cm	VSORRES/VSORRESU when VTESTCD=HEIGHT
4.* Height 2 (Before measuring linear growth, remove shoes, hats, hair ornaments, and braids whenever possible because these items interfere with accurate growth measurement. The participant must be repositioned between the measurements.) [Height 2]	[grpHEIGHT1_2] [BODY_HEIGHT1_1] [HEIGHT_UNIT1_1] 0 <= xxx.x [A:340] cm	VSORRES/VSORRESU when VTESTCD=HEIGHT
5.* Height 3 (Before measuring linear growth, remove shoes, hats, hair ornaments, and braids whenever possible because these items interfere with accurate growth measurement. The participant must be repositioned between the measurements.) [Height 3]	[grpHEIGHT1_3] [BODY_HEIGHT1_2] [HEIGHT_UNIT1_2] 0 <= xxx.x [A:340] cm	VSORRES/VSORRESU when VTESTCD=HEIGHT
6. Mean height (System calculated mean) [read-only] [Mean height]	[grpHEIGHT_MEAN1] [BODY_HEIGHT_MEAN1] [HEIGHT_MEAN_UNIT1] xxx.x [A:340] cm	VSORRES/VSORRESU when VTESTCD=HGHTMEAN
7.* Body weight (Measured at site visits without shoes, with an empty bladder and only wearing light clothing) [Body weight]	[grpBODY_WEIGHT1] [BODY_WEIGHT1] [BODY_WEIGHT_UNIT1] 0 <= xxx.x [A:220] kg [A:700] lb	VSORRES/VSORRESU when VTESTCD=WEIGHT
8.* Waist circumference(Nearest 0.5 centimetre) (Defined as abdominal circumference located midway between the lower rib margin and the iliac crest. Measures must be obtained in standing position with a non-stretchable measuring tape. The tape should touch the skin but not compress soft tissue and twists in the tape should be avoided.) [Waist]	[grpWAIST_CIRCUMFERENCE1] [WAIST_CIRCUMFERENCE1] [WAIST_CIRCUM_UNIT1] xxx.x [A:340] cm	VSORRES/VSORRESU when VTESTCD=WSTCIR
9. Body weight derived (calculated) [hidden] [Body Weight]	[BODY_WEIGHT_DERIVE_2] xxxx. kg <sup>b</sup>	
10. BMI (System Calculated) [BMI]	[BMI_DERIVED_V2] xxx.x kg/m <sup>2</sup>	VSORRES/VSORRESU when VTESTCD=BMI

Key: [\*] = Item is required [ ] = Source verification required [ ] = Base Unit

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

**Study Object Descriptions: Body measurements**

Type	RefName	Description
Form	BODY_MEASUREMENT_2	Visit: V2, V8, V12, V24, V30, V35
Item	BODY_MEAS_DATE_2	**Item DEACTIVATED**
Item	BODY_WEIGHT_DERIVE_2	**Item DEACTIVATED**
Item	BMI_DERIVED_V2	Calculated in InForm via rule

**Codelist Values Tables: Body measurements**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cHEIGHT_UNIT_1	String		cm	340	ctmHEIGHT_UNIT_CM_1	HEIGHT_UNIT1, HEIGHT_MEAN_UNIT1
cHEIGHT_UNIT2_2	String		cm	340	ctmHEIGHT_UNIT_CM_1	HEIGHT_UNIT1_1, HEIGHT_UNIT1_2
cBODY_WEIGHT_UNIT_1	String		kg	220	ctmBODY_WEIGHT_UNIT_KG_1	BODY_WEIGHT_UNIT1
cBODY_WEIGHT_UNIT_1	String		lb	700	ctmBODY_WEIGHT_UNIT_LB_1	
cHEIGHT_UNIT1	String		cm	340	ctmHEIGHT_UNIT_CM_2	WAIST_CIRCUM_UNIT1

**RDE Analytics: RD\_BODY\_MEASUREMENT\_2**

Data Variable RefName	RD Column Name	Column Data Type
BODY_MEAS_DATE_2	BODY_MEAS_DATE_2	DATE
	BODY_MEAS_DATE_2_DTS	VARCHAR2
	BODY_MEAS_DATE_2_ND	VARCHAR2
BODY_MEAS_DATE_TIME1	BODY_MEAS_DATE_TIME1	DATE
	BODY_MEAS_DATE_TIME1_DTS	VARCHAR2
	BODY_MEAS_DATE_TIME1_DTR	VARCHAR2
	BODY_MEAS_DATE_TIME1_ND	VARCHAR2
grpHEIGHT1	GRPHEIGHT1_ND	VARCHAR2
grpHEIGHT1 - BODY_HEIGHT1	BODY_HEIGHT1	FLOAT
grpHEIGHT1 - HEIGHT_UNIT1	HEIGHT_UNIT1_C	VARCHAR2
	HEIGHT_UNIT1	VARCHAR2
grpHEIGHT1_2	GRPHEIGHT1_2_ND	VARCHAR2
grpHEIGHT1_2 - BODY_HEIGHT1_1	BODY_HEIGHT1_1	FLOAT
grpHEIGHT1_2 - HEIGHT_UNIT1_1	HEIGHT_UNIT1_1_C	VARCHAR2
	HEIGHT_UNIT1_1	VARCHAR2
grpHEIGHT1_3	GRPHEIGHT1_3_ND	VARCHAR2
grpHEIGHT1_3 - BODY_HEIGHT1_2	BODY_HEIGHT1_2	FLOAT
grpHEIGHT1_3 - HEIGHT_UNIT1_2	HEIGHT_UNIT1_2_C	VARCHAR2
	HEIGHT_UNIT1_2	VARCHAR2
grpHEIGHT_MEAN1	GRPHEIGHT_MEAN1_ND	VARCHAR2
grpHEIGHT_MEAN1 - BODY_HEIGHT_MEAN1	BODY_HEIGHT_MEAN1	FLOAT
grpHEIGHT_MEAN1 - HEIGHT_MEAN_UNIT1	HEIGHT_MEAN_UNIT1_C	VARCHAR2
	HEIGHT_MEAN_UNIT1	VARCHAR2
grpBODY_WEIGHT1	GRPBODY_WEIGHT1_ND	VARCHAR2
grpBODY_WEIGHT1 - BODY_WEIGHT1	BODY_WEIGHT1	FLOAT
grpBODY_WEIGHT1 - BODY_WEIGHT_UNIT1	BODY_WEIGHT_UNIT1_C	VARCHAR2
	BODY_WEIGHT_UNIT1	VARCHAR2
grpWAIST_CIRCUMFERENCE1	GRPWAIST_CIRCUMFERENCE1_ND	VARCHAR2
grpWAIST_CIRCUMFERENCE1 - WAIST_CIRCUMFERENCE1	WAIST_CIRCUMFERENCE1	FLOAT
grpWAIST_CIRCUMFERENCE1 - WAIST_CIRCUM_UNIT1	WAIST_CIRCUM_UNIT1_C	VARCHAR2
	WAIST_CIRCUM_UNIT1	VARCHAR2
BODY_WEIGHT_DERIVE_2	BODY_WEIGHT_DERIVE_2	FLOAT
	BODY_WEIGHT_DERIVE_2_U	VARCHAR2
	BODY_WEIGHT_DERIVE_2_ND	VARCHAR2
BMI_DERIVED_V2	BMI_DERIVED_V2	FLOAT
	BMI_DERIVED_V2_ND	VARCHAR2

**Note: If multiple first dose dates are available then the first date is DSSTDTC**

**EC=Exposure as Collected**

**DS=Disposition**

<b>: First Dose (First Dose) [DOSAGE_1]</b>				<b>ECCAT=ADMINISTRATION OF TRIAL PRODUCT</b>		<b>DSCAT=PROTOCOL MILESTONE</b>	
Study ID:							
1.	Date of investigational medicinal product [Semaglutide/Semaglutide placebo] [Date of first dose]	<b>ECTRT=SEMAGLUTIDE/PLACEBO</b>		<b>ECSTDTC</b>	<b>DSSTDTC</b>	<b>[START_DATE_DOSE]</b> <input type="radio"/> <b>[START_DATE_DOSE] (DD/MM/YYYY)</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2023-2030) <input type="radio"/> N/A	
2.	Date and time of first dose of investigational medicinal product [hidden] [Date and time of first dose]					<b>[START_DATE_TIME_DOSE]</b> <input type="radio"/> <b>[START_DATE_TIME_FDOSE] (DD/MM/YYYY hh:mm)</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2022-2035) Req <input type="checkbox"/> : Req <input checked="" type="checkbox"/> 24-hour clock <input type="radio"/> N/A	
3.	First date and dose of investigational medicinal product [hidden] [First date and dose]					<b>[START_DATE_DOSE_1]</b> <input type="radio"/> <b>[grpDRUG_TYPE_DATE_DOSE]</b> <b>[START_DATE_DOSE_1] (DD/MM/YYYY)</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2022-2035) <b>[grpDOSE_UNIT]</b> <b>[DOSE_2]</b> <b>[DOSE_UNIT]</b> 0 < xxxx. <input type="radio"/> Unit 1 <input type="radio"/> N/A <input type="radio"/> Unit 2 <input type="radio"/> N/A	
4.	Injection site [hidden] [Injection site]					<b>[INJ_LOCATION_CODE_1]</b> <input type="radio"/> <b>Upper Arm (Arm)</b> <input type="radio"/> <b>Stomach (Abdominal skin)</b> <input type="radio"/> <b>Thigh</b>	

Key: [\*] = Item is required    [✓] = Source verification required

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

<b>Study Object Descriptions: First Dose</b>		
Type	RefName	Description
Form	DOSAGE_1	Visit: V2
Item	START_DATE_TIME_DOSE	**Item DEACTIVATED**
Item	START_DATE_DOSE_1	**Item DEACTIVATED**
Item	INJ_LOCATION_CODE_1	**Item DEACTIVATED**

<b>Codelist Values Tables: First Dose</b>						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cSTART_DATE_DOSE	String		Date	1	citmSTART_DATE_DOSE	START_DATE_DOSE,
			N/A	998	citmSTART_DATE_NA	START_DATE_TIME_DOSE,
cFDOSE_UNIT	String		Unit 1	T1	citmFDOSE_UNIT1	DOSE_UNIT
			Unit 2	T2	citmFDOSE_UNIT2	
cINJ_LOC	String		Upper Arm (Arm)	5	citmINJ_LOC_117	INJ_LOCATION_CODE_1
			Stomach (Abdominal skin)	151	citmINJ_LOC_3	
			Thigh	3	citmINJ_LOC_4	

<b>RDE Analytics: RD_DOSAGE_1</b>		
Data Variable RefName	RD Column Name	Column Data Type
START_DATE_DOSE	START_DATE_DOSE_C	VARCHAR2
	START_DATE_DOSE	VARCHAR2
	START_DATE_DOSE_ND	VARCHAR2
START_DATE_DOSE - START_DATE_FDOSE	START_DATE_FDOSE	DATE
	START_DATE_FDOSE_DTS	VARCHAR2
START_DATE_TIME_DOSE	START_DATE_TIME_DOSE_C	VARCHAR2
	START_DATE_TIME_DOSE	VARCHAR2
	START_DATE_TIME_DOSE_ND	VARCHAR2
START_DATE_TIME_DOSE - START_DATE_TIME_FDOSE	START_DATE_TIME_FDOSE	DATE
	START_DATE_TIME_FDOSE_DTS	VARCHAR2
START_DATE_DOSE_1	START_DATE_DOSE_1_C	VARCHAR2
	START_DATE_DOSE_1	VARCHAR2
	START_DATE_DOSE_1_ND	VARCHAR2
START_DATE_DOSE_1 - START_DATE_FDOSE_1	START_DATE_FDOSE_1	DATE
	START_DATE_FDOSE_1_DTS	VARCHAR2
START_DATE_DOSE_1 - DOSE_2	DOSE_2	FLOAT
START_DATE_DOSE_1 - DOSE_UNIT	DOSE_UNIT_C	VARCHAR2
	DOSE_UNIT	VARCHAR2
INJ_LOCATION_CODE_1	INJ_LOCATION_CODE_1_C	VARCHAR2
	INJ_LOCATION_CODE_1	VARCHAR2
	INJ_LOCATION_CODE_1_ND	VARCHAR2

**ECCAT=DRUG ADMIN DETAILS****ECTRT=SEMAGLUTIDE/PLACEBO****EC=Exposure as Collected****ECCAT=ADMINISTRATION OF TRIAL PRODUCT**

<b>: Drug administration-Baseline (Drug Admin-Baseline) [DRUG_ADMIN_BASE]</b>	
Study ID: I To be completed by participants 10 years old and above.	
1.* Who administered the drug [Who administered the drug]	
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

[DRUG\_ADMIN\_BASE1]  
 Participant  
 Parent(s)/LAR (Legally Acceptable Representative)  
 Investigator/Site staff

**PARTY1 in SUPPEC**

<b>Study Object Descriptions: Drug administration-Baseline</b>		
Type	RefName	Description
Form	DRUG_ADMIN_BASE	Visit: V2

**Codelist Values Tables: Drug administration-Baseline**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cDRUG_ADMIN_1	String		Participant	1	citmDRUG_ADMIN1_1	DRUG_ADMIN_BASE1
			Parent(s)/LAR (Legally Acceptable Representative)	2	citmDRUG_ADMIN2_1	
			Investigator/Site staff	3	citmDRUG_ADMIN3_1	

**RDE Analytics: RD\_DRUG\_ADMIN\_BASE**

Data Variable RefName	RD Column Name	Column Data Type
DRUG_ADMIN_BASE1	DRUG_ADMIN_BASE1_C	VARCHAR2
	DRUG_ADMIN_BASE1	VARCHAR2
	DRUG_ADMIN_BASE1_ND	VARCHAR2

**SS=Subject Status****SSCAT=GLUCOSE METABOLISM**

: Evaluation of glycaemic status (Eval Glycaemic Status) [EVAL_GLY_STAT]	
<b>Study ID:</b> Note: ONLY Please eval_.....'t T2D. .'s glycaemic status based on all available information	
1. Glycaemic status [Glycaemic status]	<b>[GLYCAEMIC_1_L]</b> [A-418] <input type="radio"/> Normo-glycaemia [A-419] <input type="radio"/> Pre-diabetes
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

**SSORRES when STESTCD=GLYCAEST****Study Object Descriptions: Evaluation of glycaemic status**

Type	RefName	Description
Form	EVAL_GLY_STAT	Visit: V2

**Codelist Values Tables: Evaluation of glycaemic status**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cGLYCAEMIC_STATUS1	String		Normo-glycaemia	418	citmGLYCAEMIC_STATUS1_2	GLYCAEMIC_1_L

**RDE Analytics: RD\_EVAL\_GLY\_STAT**

Data Variable RefName	RD Column Name	Column Data Type
GLYCAEMIC_1_L	GLYCAEMIC_1_L_C	VARCHAR2
	GLYCAEMIC_1_L	VARCHAR2
	GLYCAEMIC_1_L_ND	VARCHAR2

**LB=Laboratory Test Results**

<b>: Self Measured Fasting Glucose (Home) (Fasting Glucose) [GLUCOSE_FASTING_3]</b> Study ID: NOTE: • Only 1 or 1 • SMBG measurements should be taken fasting (at least 8 hours overnight before the visit), and prior to taking any diabetes medication. • Only values obtained by the BG meter supplied by Novo Nordisk should be entered in the CRF. • All data from the diary must be transcribed into the CRF.		<b>LBCAT=SELF MEASURED PLASMA GLUCOSE</b> <b>LBSPEC=PLASMA</b> <b>LBSCAT=1-POINT PROFILE</b>	
1. Glucose Unit [Glucose Unit]	[A:56] <input type="radio"/> mmol/L [A:162] <input type="radio"/> mg/dL	<b>LBORRESU</b>	
2.* 0-1 days before current visit [0-1 Days]	<b>LBTP</b> <b>LBTPNUM</b>  <b>LBELTM=-PnD</b>	<b>LBDT</b>	
3. xx days before current visit [hidden] [XX Days]		<b>LBFAST</b>  <b>LBORRES when LBTESTCD=GLUC</b>	

Key: [\*] = Item is required. [✓] = Source verification required.  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: Self Measured Fasting Glucose (Home)		
Type	RefName	Description
Form	GLUCOSE_FASTING_3	Visit: V2, V4, V6, V8, V10, V12, V14, V16, V18, V20, V22, V24, V26, V28, V30, V31, V33, V35
Item	GLUCO_TIME_POINT_V3_2	**Item DEACTIVATED**

Codelist Values Tables: Self Measured Fasting Glucose (Home)						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIGLUCE_UNIT	String		mmol/L	561	citmGLUC_UNIT2	GLUCOSE_UNIT_V3
			mg/dL	162	citmGLUC_UNIT1	
cIGLUCO_TIME_POINT	String		1	citmGLUCO_1	GLUCO_TIME_POINT_V3_1	
			Not done	997	citmGLUCO_997	GLUCO_TIME_POINT_V3_2
cYESNO_2	String		Yes	1	citmYESNO1_2	GLUCO_FASTING_YN_V3_1
			No	2	citmYESNO2_2	GLUCO_FASTING_YN_V3_2

RDE Analytics: RD_GLUCOSE_FASTING_3		
Data Variable RefName	RD Column Name	Column Data Type
GLUCOSE_UNIT_V3	GLUCOSE_UNIT_V3_C	VARCHAR2
	GLUCOSE_UNIT_V3	VARCHAR2
	GLUCOSE_UNIT_V3_ND	VARCHAR2
GLUCO_TIME_POINT_V3_1	GLUCO_TIME_POINT_V3_1_C	VARCHAR2
	GLUCO_TIME_POINT_V3_1	VARCHAR2
	GLUCO_TIME_POINT_V3_1_ND	VARCHAR2
GLUCO_TIME_POINT_V3_1 - GLUCO_ACTUAL_DATE_V3_1	GLUCO_ACTUAL_DATE_V3_1	DATE
	GLUCO_ACTUAL_DATE_V3_1_DTS	VARCHAR2
	GLUCO_ACTUAL_DATE_V3_1_DTR	VARCHAR2
GLUCO_TIME_POINT_V3_1 - GLUCO_FASTING_YN_V3_1	GLUCO_FASTING_YN_V3_1_C	VARCHAR2
	GLUCO_FASTING_YN_V3_1	VARCHAR2
GLUCO_TIME_POINT_V3_1 - GLUCOSE_VALUE_V3_1	GLUCOSE_VALUE_V3_1	FLOAT
GLUCO_TIME_POINT_V3_2	GLUCO_TIME_POINT_V3_2_C	VARCHAR2
	GLUCO_TIME_POINT_V3_2	VARCHAR2
	GLUCO_TIME_POINT_V3_2_ND	VARCHAR2
GLUCO_TIME_POINT_V3_2 - GLUCO_ACTUAL_DATE_V3_2	GLUCO_ACTUAL_DATE_V3_2	DATE
	GLUCO_ACTUAL_DATE_V3_2_DTS	VARCHAR2
	GLUCO_ACTUAL_DATE_V3_2_DTR	VARCHAR2
GLUCO_TIME_POINT_V3_2 - GLUCO_FASTING_YN_V3_2	GLUCO_FASTING_YN_V3_2_C	VARCHAR2
	GLUCO_FASTING_YN_V3_2	VARCHAR2
GLUCO_TIME_POINT_V3_2 - GLUCOSE_VALUE_V3_2	GLUCOSE_VALUE_V3_2	FLOAT

**QS=Questionnaires****QSCAT=MENTAL HEALTH EVALUATION**

: Mental Health Evaluation (Mental Health Evaluation ) [MENTAL_HEALTH]	
<p>Study ID: If Question answered "YES" and event is clinically relevant fulfilling the criteria for adverse event reporting, report the event in AE form.</p> <p>sctMENTAL_HEALTH [sctMENTAL_HEALTH]</p> <p>1. Has the subject experienced or shown any clinically relevant mood changes since last evaluation? (Investigator question to both Subject AND subject's parent(s)/LAR) [Has the subject experienced or shown any clinically relevant mood changes since last evaluation? ]</p> <p><b>QSORRES when QTESTCD=MHE011A</b></p>	
<p>[sctMENTALHEALTH1] [MENTALHEALTH1] Subject [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No</p> <p>[MENTALHEALTH1LAR] Subject's parent(s)/LAR [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No</p> <p>[MENTALHEALTH2] [MENTALHEALTH2] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No</p> <p><b>QSEVAL=STUDY SUBJECT</b></p> <p><b>QSEVAL=SUBJECT'S PARENT(S)/LAR</b></p> <p><b>QSEVAL=SUBJECT'S PARENT(S)/LAR</b></p>	
<p>2. Have the subject's parent(s)/LAR witnessed any clinically relevant changes in behaviour and/or school performance since last evaluation? (Investigator question to s [Have the subject's parent(s)/LAR witnessed any clinically relevant changes in behaviour and/or school performance since last evaluation? (Investigator question to s</p> <p><b>QSORRES when QTESTCD=MHE012</b></p>	
<p>sctMENTALHEALTH2 [sctMENTALHEALTH2]</p> <p>If Questions 1 and /or 2 is answered "YES", Please complete questions 3 and 4</p> <p>3. Will the C-SSRS (parental card version) be completed? (Investigator discretion) If Yes, complete C-SSRS parental card [C-SSRS (parental card version)] [Will the C-SSRS (parental card version) be completed? (Investigator discretion)]</p> <p><b>QSORRES when QTESTCD=MHE0103</b></p>	
<p><b>QSORRES when QTESTCD=MHE014</b></p>	
<p>[MENTALHEALTH3] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No</p> <p>[MENTALHEALTH4] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> [MENTALOTH] <input type="checkbox"/> No Please provide reason A200</p>	

Key: [\*] = Item is required [✓] = Source verification required [□] = Item is collapsible  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Mental Health Evaluation		
Type	RefName	Description
Form	MENTAL_HEALTH	Visit : V2, V4, V6, V8, V10, V12, V14, V16, V18, V20, V22, V24, V26, V28, V30, V31, V33, V35

Codelist Values Tables: Mental Health Evaluation						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cYESNO	String		Yes	1	ctmYESNO1	MENTALHEALTH1S, MENTALHEALTH1LAR, MENTALHEALTH2
			No	2	ctmYESNO2	
cYESNO_1	String		Yes	1	ctmYESNO1_1	MENTALHEALTH3, MENTALHEALTH4
			No	2	ctmYESNO2_1	

RDE Analytics: RD_MENTAL_HEALTH		
Data Variable RefName	RD Column Name	Column Data Type
grpMENTALHEALTH1	GRPMENTALHEALTH1_ND	VARCHAR2
grpMENTALHEALTH1 - MENTALHEALTH1S	MENTALHEALTH1S_C	VARCHAR2
	MENTALHEALTH1S	VARCHAR2
grpMENTALHEALTH1 - MENTALHEALTH1LAR	MENTALHEALTH1LAR_C	VARCHAR2
	MENTALHEALTH1LAR	VARCHAR2
MENTALHEALTH2	MENTALHEALTH2_C	VARCHAR2
	MENTALHEALTH2	VARCHAR2
	MENTALHEALTH2_ND	VARCHAR2
MENTALHEALTH3	MENTALHEALTH3_C	VARCHAR2
	MENTALHEALTH3	VARCHAR2
	MENTALHEALTH3_ND	VARCHAR2
MENTALHEALTH4	MENTALHEALTH4_C	VARCHAR2
	MENTALHEALTH4	VARCHAR2
	MENTALHEALTH4_ND	VARCHAR2
MENTALHEALTH4 - MENTALOTH	MENTALOTH	VARCHAR2

**PR=Procedures**

: X-Ray for Bone Age Assessment (X-ray bone age) [X_RAY]		PRCAT=X-RAY BONE AGE MEASUREMENT
Study ID:		
1.* Has an age assessment been taken? [Has an X-ray for bone age assessment been taken?]	<b>PRTRT=X-RAY</b>	<b>PROCCUR</b> <b>PRPRESP=Y</b>
		<b>PRDTC</b>
		<b>PRREASND</b>
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Study Object Descriptions: X-Ray for Bone Age Assessment		
Type	RefName	Description
Form	X_RAY	Visit: V2, V24, V30

Codelist Values Tables: X-Ray for Bone Age Assessment						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cYESNO_2_1	String		Yes	1	ctmYESNO1_2_1	XRAY_TAKEN
			No	2	ctmYESNO2_2_1	
cIXRAY_REASON	String		Epiphyseal closure	1	ctmXRAY_REASON1	XRAY_REASON
			Specify reason	2	ctmXRAY_REASON2	

RDE Analytics: RD_X_RAY		
Data Variable RefName	RD Column Name	Column Data Type
XRAY_TAKEN	XRAY_TAKEN_C	VARCHAR2
	XRAY_TAKEN	VARCHAR2
	XRAY_TAKEN_ND	VARCHAR2
XRAY_TAKEN - XRAY_DATE	XRAY_DATE	DATE
	XRAY_DATE_DTS	VARCHAR2
XRAY_TAKEN - XRAY_REASON	XRAY_REASON_C	VARCHAR2
	XRAY_REASON	VARCHAR2
XRAY_TAKEN - XRAY_TEXT	XRAY_TEXT	VARCHAR2

**LB=Laboratory Test Results** | **PR=Procedures** | **VS=Vital Signs**

: Missed Assessment due to COVID-19 (Missed Assessment) [MISSD_ASSMNT]			
Study ID: <b>sctMISSD_</b> <b>MISSD_ASSMNT</b>			
1.* Were any of the below assessments not done? [Any assessments not done]		[MISSD_ASSMNT_YN] [A:1] <input checked="" type="radio"/> Yes [A:2] <input type="radio"/> No	<b>NOT SUBMITTED</b>
<b>sctDOMAIN_1</b> [sctDOMAIN_1]			
#	Domain 1	Assessment	Status
2.a	VS	Body measurement	COVID-19
2.b	VS	Waist circumference	COVID-19
2.c	VS	Blood pressure	COVID-19
2.d	VS	Height	COVID-19
<b>sctDOMAIN_1 Entry</b> [sctDOMAIN_1]			
2.1	Domain 1 [hidden] [Domain 1]	<b>VTEST</b>	<b>[DOMAIN_1] [cIDOMAIN_1]</b> <b>[ASSESSMENT_1] [cMISSSED_ASSESSMENTS_1]</b> <b>[STAT_1] [A:1] <input type="checkbox"/> Not done</b> <b>[REASND_1] [A:1] <input checked="" type="radio"/> COVID-19</b>
2.2	Assessment [Assessment]		
2.3	Status [Status]		
2.4	REASND [hidden] [REASND]		
<b>[sctDOMAIN_2]</b>			
#	Domain 2	Assessment	Status
3.a	PR	DXA Scan	REASND
<b>Entry</b> [sctDOMAIN_2]			
3.1	Domain 2 [hidden] [Domain 2]	<b>PRTT</b>	<b>[DOMAIN_2] [cIDOMAIN_1]</b> <b>[ASSESSMENT_2] [cMISSSED_ASSESSMENTS_1]</b> <b>[STAT_1] [A:1] <input type="checkbox"/> Not done</b> <b>[REASND] [A:1] <input checked="" type="radio"/> COVID-19</b>
3.2	Assessment [Assessment]		
3.3	Status [Status]		
3.4	REASND [hidden] [REASND]		
<b>[sctDOMAIN_3]</b>			
#	Domain 2	Assessment	Status
4.a	QS	Lab	REASND
<b>Entry</b> [sctDOMAIN_3]			
4.1	Domain 2 [hidden] [Domain 2]	<b>LBTEST</b>	<b>[DOMAIN_3] [cIDOMAIN_1]</b> <b>[ASSESSMENT_3] [cMISSSED_ASSESSMENTS_1]</b> <b>[STAT_3] [A:1] <input type="checkbox"/> Not done</b> <b>[REASND_3] [A:1] <input checked="" type="radio"/> COVID-19</b>
4.2	Assessment [Assessment]		
4.3	Status [Status]		
4.4	REASND [hidden] [REASND]		
Key: [*] = Item is required  = Fixed item Note: Source verification critical settings made in Inform will override any settings made in Central Designer.			

**Study Object Descriptions: Missed Assessment due to COVID-19**

Type	RefName	Description
Form	MISSD_ASSMNT	Visit: V2,V24, V20

**Codelist Values Tables: Missed Assessment due to COVID-19**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cYESNO_1	String		Yes	1	citmYESNO1_1	MISSD_ASSMNT_YN
			No	2	citmYESNO2_1	
cIDOMAIN_1	String		FA	1	NewCodelistItem_5	DOMAIN_1, DOMAIN_2, DOMAIN_3
			FT	2	NewCodelistItem2_1	
			QS	3	NewCodelistItem3_2	
			DS	4	NewCodelistItem4_2	
			HO	5	NewCodelistItem5	
			VS	6	NewCodelistItem6	
			EG	7	NewCodelistItem7	
			PR	8	NewCodelistItem8	
cMISSSED_ASSESSMENTS_1	String		Vital Signs	1	citmMISSSED_ASSESSMENTS1	ASSESSMENT_1, ASSESSMENT_2, ASSESSMENT_3
			Body measurement	2	citmMISSSED_ASSESSMENTS2	
			First Dose	3	citmMISSSED_ASSESSMENTS3	
			ECG	4	citmMISSSED_ASSESSMENTS4	
			Last Dose	5	citmMISSSED_ASSESSMENTS5	
			IWQOL-Lite-CT Physical Function	6	citmMISSSED_ASSESSMENTS6	
			Short Form-36 (SF-36)	7	citmMISSSED_ASSESSMENTS7	
			Waist circumference	8	citmMISSSED_ASSESSMENTS8	
			Blood pressure	9	citmMISSSED_ASSESSMENTS9	
			Height	10	citmMISSSED_ASSESSMENTS10	
			DXA Scan	11	citmMISSSED_ASSESSMENTS11	
			Lab	12	citmMISSSED_ASSESSMENTS12	
cISTAT	String		Not done	1	NewCodelistItem_6	STAT, STAT_1, STAT_3
cREASND_1	String		COVID-19	1	COVID19	REASND_1, REASND_2, REASND_3

**RDE Analytics: RD\_MISSD\_ASSMNT**

Data Variable RefName	RD Column Name	Column Data Type
MISSD_ASSMNT_YN	MISSD_ASSMNT_YN_C	VARCHAR2
	MISSD_ASSMNT_YN	VARCHAR2
	MISSD_ASSMNT_YN_ND	VARCHAR2
<b>*RD_MISSD_ASSMNT_SCTDOMAIN_1</b>		
DOMAIN_1	DOMAIN_1_C	VARCHAR2
	DOMAIN_1	VARCHAR2
	DOMAIN_1_ND	VARCHAR2

	ASSESSMENT_1_C	VARCHAR2
	ASSESSMENT_1	VARCHAR2
	'ASSESSMENT_1_ND	VARCHAR2
STAT	STAT_ND	VARCHAR2
STAT - Not done	STAT_NEWCODELISTITEM6_C	VARCHAR2
	STAT_NEWCODELISTITEM6	VARCHAR2
REASND_1	REASND_1_C	VARCHAR2
	REASND_1	VARCHAR2
	REASND_1_ND	VARCHAR2
<b>*RD_MISSD_ASSMNT_SCTDOMAIN_2</b>		
DOMAIN_2	DOMAIN_2_C	VARCHAR2
	DOMAIN_2	VARCHAR2
	DOMAIN_2_ND	VARCHAR2
ASSESSMENT_2	ASSESSMENT_2_C	VARCHAR2
	ASSESSMENT_2	VARCHAR2
	ASSESSMENT_2_ND	VARCHAR2
STAT_1	STAT_1_ND	VARCHAR2
STAT_1 - Not done	STAT_1_NEWCODELISTITEM6_C	VARCHAR2
	STAT_1_NEWCODELISTITEM6	VARCHAR2
REASND	REASND_C	VARCHAR2
	REASND	VARCHAR2
	REASND_ND	VARCHAR2
<b>*RD_MISSD_ASSMNT_SCTDOMAIN_3</b>		
DOMAIN_3	DOMAIN_3_C	VARCHAR2
	DOMAIN_3	VARCHAR2
	DOMAIN_3_ND	VARCHAR2
ASSESSMENT_3	ASSESSMENT_3_C	VARCHAR2
	ASSESSMENT_3	VARCHAR2
	ASSESSMENT_3_ND	VARCHAR2
STAT_3	STAT_3_ND	VARCHAR2
STAT_3 - Not done	STAT_3_NEWCODELISTITEM6_C	VARCHAR2
	STAT_3_NEWCODELISTITEM6	VARCHAR2
REASND_3	REASND_3_C	VARCHAR2
	REASND_3	VARCHAR2
	REASND_3_ND	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**VS=Vital Signs**

: Height-Repeated by 2nd personnel (HEIGHT_REPEAT) [HEIGHT_REPEAT]		VSSCAT=REPEATED BY SECOND PERSONNEL	VSCAT=BODY MEASUREMENT
<b>Study ID:</b> The height ... * as to be performed by the second qualified person at site, who does not have the access to the previous measurements.			
1.* Repeated Height 1 ✓ (The height measurements must be performed by a second qualified person at site, who is blinded to the previous measurements.)	VSTPT=FIRST	VSTPTNUM=1	[grpHEIGHT2_1] [BODY_HEIGHT2_1] [HEIGHT_UNIT2_1] 0 <= xxx.x [A:1] cm <b>VSORRES/VSORRESU when VTESTCD=HEIGHT</b>
2.* Repeated Height 2 ✓ (The height measurements must be performed by a second qualified person at site, who is blinded to the previous measurements.)	VSTPT=SECOND	VSTPTNUM=2	[grpHEIGHT2_2] [BODY_HEIGHT2_2] [HEIGHT_UNIT2_2] 0 <= xxx.x [A:1] cm <b>VSORRES/VSORRESU when VTESTCD=HEIGHT</b>
3.* Repeated Height 3 ✓ (The height measurements must be performed by a second qualified person at site, who is blinded to the previous measurements.)	VSTPT=THIRD	VSTPTNUM=3	[grpHEIGHT2_3] [BODY_HEIGHT2_3] [HEIGHT_UNIT2_3] 0 <= xxx.x [A:1] cm <b>VSORRES/VSORRESU when VTESTCD=HEIGHT</b>
4. Mean Repeated Height (System calculated mean) [read-only] [Mean height]			[grpHEIGHT_MEAN2] [BODY_HEIGHT_MEAN2] [HEIGHT_MEAN_UNIT2] 0 < xxx.x [A:1] cm <b>VSORRES/VSORRESU when VTESTCD=HGHTMEAN</b>

Key: [\*] = Item is required    [ ✓ ] = Source verification required  
Note: Source verification critical settings made in Inform will override any settings made in Central Designer.

Study Object Descriptions: Height-Repeated by 2nd personnel		
Type	RefName	Description
Form	HEIGHT_REPEAT	Visit: V2,V24,V35

Codelist Values Tables: Height-Repeated by 2nd personnel						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cHEIGHT_UNIT2_1	String		cm	1	ctmHEIGHT_UNIT_CM_2_1	HEIGHT_UNIT2_1, HEIGHT_UNIT2_2, HEIGHT_UNIT2_3, HEIGHT_MEAN_UNIT2

RDE Analytics: RD_HEIGHT_REPEAT		
Data Variable RefName	RD Column Name	Column Data Type
grpHEIGHT2_1	GRPHEIGHT2_1_ND	VARCHAR2
grpHEIGHT2_1 - BODY_HEIGHT2_1	BODY_HEIGHT2_1	FLOAT
grpHEIGHT2_1 - HEIGHT_UNIT2_1	HEIGHT_UNIT2_1_C	VARCHAR2
	HEIGHT_UNIT2_1	VARCHAR2
grpHEIGHT2_2	GRPHEIGHT2_2_ND	VARCHAR2
grpHEIGHT2_2 - BODY_HEIGHT2_2	BODY_HEIGHT2_2	FLOAT
grpHEIGHT2_2 - HEIGHT_UNIT2_2	HEIGHT_UNIT2_2_C	VARCHAR2
	HEIGHT_UNIT2_2	VARCHAR2
grpHEIGHT2_3	GRPHEIGHT2_3_ND	VARCHAR2
grpHEIGHT2_3 - BODY_HEIGHT2_3	BODY_HEIGHT2_3	FLOAT
grpHEIGHT2_3 - HEIGHT_UNIT2_3	HEIGHT_UNIT2_3_C	VARCHAR2
	HEIGHT_UNIT2_3	VARCHAR2
grpHEIGHT_MEAN2	GRPHEIGHT_MEAN2_ND	VARCHAR2
grpHEIGHT_MEAN2 - BODY_HEIGHT_MEAN2	BODY_HEIGHT_MEAN2	FLOAT
grpHEIGHT_MEAN2 - HEIGHT_MEAN_UNIT2	HEIGHT_MEAN_UNIT2_C	VARCHAR2
	HEIGHT_MEAN_UNIT2	VARCHAR2

**DS=Disposition****DSCAT=OTHER EVENT**

Treatment Discontinuation (Discontinuation) [TREAT_DISCONT]	
<b>DSDECOD=TEMPORARY DISCONTINUATION OF TRIAL TREATMENT</b>	
Study ID: Complete this field. If IMP is present, the IMP is temporarily discontinued. continued use the End of IMP treatment form instead.	
1.* Discontinuation date [Discontinuation date]	<input type="text" value="DSSTDTC"/> [DISCONT_DATE] (DD/MM/YYYY) <input checked="" type="checkbox"/> Req / <input type="checkbox"/> Req / <input type="checkbox"/> Ref (2023-2030)
2.* Reasons for discontinuation [Reasons for discontinuation]	<input type="checkbox"/> [DISCONT_REASON] [A:1] <input type="checkbox"/> Safety concern as judged by the investigator [A:2] <input type="checkbox"/> Suspicion of acute pancreatitis [A:3] <input type="checkbox"/> Pregnancy [A:5] <input type="checkbox"/> Intention of becoming pregnant [A:8] <input type="checkbox"/> Tolerability not resolved by lowering dose [A:20] <input type="checkbox"/> [DISCONT_OTHER] Other A200

Key: [\*] = Item is required  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: Treatment Discontinuation						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cDISCONT_REASON	String		Safety concern as judged by the investigator	1	citmDISCONT_REASON1	DISCONT_REASON
			Suspicion of acute pancreatitis	2	citmDISCONT_REASON2	
			Pregnancy	3	citmDISCONT_REASON3	
			Intention of becoming pregnant	5	citmDISCONT_REASON4	
			Tolerability not resolved by lowering dose	8	citmDISCONT_REASON5	
			Other	20	citmDISCONT_REASON11	

RDE Analytics: RD_TREAT_DISCONT		
Data Variable RefName	RD Column Name	Column Data Type
DISCONT_DATE	DISCONT_DATE	DATE
	DISCONT_DATE_DTS	VARCHAR2
	DISCONT_DATE_ND	VARCHAR2
DISCONT_REASON	DISCONT_REASON_ND	VARCHAR2
DISCONT_REASON - Safety concern as judged by the investigator	*DISCONT_REASON_CITMDISCONTREASON1_C	VARCHAR2
	*DISCONT_REASON_CITMDISCONTREASON1	VARCHAR2
DISCONT_REASON - Suspicion of acute pancreatitis	*DISCONT_REASON_CITMDISCONTREASON2_C	VARCHAR2
	*DISCONT_REASON_CITMDISCONTREASON2	VARCHAR2
DISCONT_REASON - Pregnancy	*DISCONT_REASON_CITMDISCONTREASON3_C	VARCHAR2
	*DISCONT_REASON_CITMDISCONTREASON3	VARCHAR2
DISCONT_REASON - Intention of becoming pregnant	*DISCONT_REASON_CITMDISCONTREASON4_C	VARCHAR2
	*DISCONT_REASON_CITMDISCONTREASON4	VARCHAR2
DISCONT_REASON - Tolerability not resolved by lowering dose	*DISCONT_REASON_CITMDISCONTREASONS_C	VARCHAR2
	*DISCONT_REASON_CITMDISCONTREASONS	VARCHAR2
DISCONT_REASON - Other	*DISCONT_REASON_DISCONT_OTHER_C	VARCHAR2
	*DISCONT_REASON_DISCONT_OTHER	VARCHAR2
DISCONT_REASON - DISCONT_OTHER	DISCONT_OTHER	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**VS=Vital Signs****VSCAT=BODY MEASUREMENT**

: Body measurements 3 (Body Meas) [BODY_MEASUREMENT_3]	
Study ID:	
1. Date o [Exam Date]	<b>[BODY_MEAS_DATE_3] (DD/MM/YYYY)</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2022-2035)
2. Date and time of examination [hidden] [Exam Date & Time]	<b>[BODY_MEAS_DATE_TIME2] (DD/MM/YYYY hh:mm)</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) Req/Unk <input type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock
3.* Body weight ✓ (Measured at site visits without shoes, with an empty bladder and only wearing light clothing) [Body weight]	<b>[grpBODY_WEIGHT2]</b> <b>[BODY_WEIGHT2] [BODY_WEIGHT_UNIT2]</b> xxx.x <input type="radio"/> kg <input checked="" type="radio"/> lb
4. Body weight derived (calculated) [hidden] [Body Weight]	<b>[BODY_WEIGHT_DERIVE_3]</b> xxx.x <input type="radio"/> kg <input checked="" type="radio"/> lb
Key: [*] = Item is required    [✓] = Source verification required    [b] = Base Unit Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

**VSORRES/VSORRESU when VTESTCD=WEIGHT**

Study Object Descriptions: Body measurements 3		
Type	RefName	Description
Form	BODY_MEASUREMENT_3	Visit: V4, V6, V10, V14, V18, V22
Item	BODY_MEAS_DATE_3	**Item DEACTIVATED**
Item	BODY_MEAS_DATE_TIME2	**Item DEACTIVATED**
Item	BODY_WEIGHT_DERIVE_3	**Item DEACTIVATED**

Codelist Values Tables: Body measurements 3						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIBODY_WEIGHT_UNIT_2	String		kg	220	citmBODY_WEIGHT_UNIT_KG_2	BODY_WEIGHT_UNIT2
			lb	700	citmBODY_WEIGHT_UNIT_LB_2	

RDE Analytics: RD_BODY_MEASUREMENT_3		
Data Variable RefName	RD Column Name	Column Data Type
BODY_MEAS_DATE_3	BODY_MEAS_DATE_3	DATE
	BODY_MEAS_DATE_3_DTS	VARCHAR2
	BODY_MEAS_DATE_3_ND	VARCHAR2
BODY_MEAS_DATE_TIME2	BODY_MEAS_DATE_TIME2	DATE
	BODY_MEAS_DATE_TIME2_DTS	VARCHAR2
	BODY_MEAS_DATE_TIME2_DTR	VARCHAR2
	BODY_MEAS_DATE_TIME2_ND	VARCHAR2
grpBODY_WEIGHT2	GRPBODY_WEIGHT2_ND	VARCHAR2
grpBODY_WEIGHT2 - BODY_WEIGHT2	BODY_WEIGHT2	FLOAT
grpBODY_WEIGHT2 - BODY_WEIGHT_UNIT2	BODY_WEIGHT_UNIT2_C	VARCHAR2
	BODY_WEIGHT_UNIT2	VARCHAR2
BODY_WEIGHT_DERIVE_3	BODY_WEIGHT_DERIVE_3	FLOAT
	BODY_WEIGHT_DERIVE_3_U	VARCHAR2
	BODY_WEIGHT_DERIVE_3_ND	VARCHAR2

DOSECOLLECTION (Dose Collection Form) - Repeating Form [DOSECOLLECTION]			What date was taken	What date was the dose taken	Rationale for the dose
#	Seq. No.	What dose was taken			
1					
<p><b>Study ID: NN9536-4512</b>  Transcribe Dosing Diaries detail in this form.  Each dose taken including missed dose must be recorded in separate forms-use ADD ENTRY button.  In case of missed dose, please report the planned dose date.</p> <p><b>Dosing collection from last visit [scDOSE]</b></p> <p>1. Seq. No. [read-only]  [Seq. No.]</p> <p>2. What dose was taken  [What dose was taken]</p> <p>3. What date was the dose taken  [What date was the dose taken]</p> <p>4. Rationale for the dose  [Rationale for the dose]</p>					
<b>ECSCAT= DOSING COLLECTION FROM LAST VISIT</b>			<b>ECTRT=SEMAGLUTIDE/PLACEBO</b> <b>ECREFID</b> <b>ECDOSE/ECDOSU ECPRESP=Y ECOCCUR=Y</b> <b>ECREASOC ECPRESP=Y ECOCCUR=N</b> <b>ECREASOC ECPRESP=Y ECOCCUR=N</b> <b>ECSTDTC</b> <b>ECADJ</b>		
<p>Key: [*] = Item is required    [✓] = Source verification required  Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</p>					

**Study Object Descriptions: DOSECOLLECTION**

Type	RefName	Description
Form	DOSECOLLECTION	Visits: V4, V8, V12, V16, V18, V22, V26

**Codelist Values Tables: DOSECOLLECTION**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDOSE	String		0.25 mg	1	citmDOSE1	DOSE1
			0.50 mg	2	citmDOSE2	
			1.0 mg	3	citmDOSE3	
			1.7 mg	4	citmDOSE4	
			2.4 mg	5	citmDOSE5	
			Missed dose	6	citmDOSE6	
			Took study drug, do not remember dose	7	citmDOSE7	
			Other, specify	999	citmDOSE9	
Rational_1	String		Dose escalation	1	Rational1_1	RATIONALE
			Target dose/Maximum Tolerated Dose (MTD) reached	2	Rational2_1	
			Re-initiate previous dose	3	Rational3_1	
			Dose reduction due to tolerability/Adverse Event	4	Rational4_1	
			Other, specify	999	Rational5_1	

**RDE Analytics: RD\_DOSECOLLECTION**

Data Variable RefName	RD Column Name	Column Data Type
DOSE_SEQ_NO	DOSE_SEQ_NO	NUMBER
	DOSE_SEQ_NO_ND	VARCHAR2
DOSETAKENinmg	DOSETAKENINMG_ND	VARCHAR2
DOSETAKENinmg - DOSE1	DOSE1_C	VARCHAR2
	DOSE1	VARCHAR2
DOSETAKENinmg - DOSETAKENOTHER_1	DOSETAKENOTHER_1	FLOAT
DOSESTARTDATE	DOSESTARTDATE	DATE
	DOSESTARTDATE_DTS	VARCHAR2
	DOSESTARTDATE_ND	VARCHAR2
RATIONALE	RATIONALE_C	VARCHAR2
	RATIONALE	VARCHAR2
	RATIONALE_ND	VARCHAR2
RATIONALE - RATIONALEOTHER	RATIONALEOTHER	VARCHAR2

Dose Collection with PK data (Dose Collection with PK data) [DOSECOLLECTION_WITHPK]			
Study ID: 1	Seq. No.	What dose was taken	What date was the dose taken
1.			
Dosing collection from last visit			
1.1	Seq. No. [read-only] [Seq. No.]	ECSCAT= DOSING COLLECTION FROM LAST VISIT	
1.2*	What dose was taken [What dose was taken]	[DOSEPK_SEQ_NO] N2	ECREFID
		[grpPKDOSETAKEN] [DOSE2] [A:1] <input type="radio"/> 0.25 mg [A:2] <input type="radio"/> 0.50 mg [A:3] <input type="radio"/> 1.0 mg [A:4] <input type="radio"/> 1.7 mg [A:5] <input type="radio"/> 2.4 mg [A:6] <input type="radio"/> Missed dose [A:7] Took study drug [A:999] [PK_DOSE_OTHER_1] Other, specify xx.xx	ECDOSE/ECDOSU ECPRESP=Y ECOCCUR=Y ECREASOC ECPRESP=Y ECOCCUR=Y ECREASOC ECPRESP=Y ECOCCUR=N ECREASOC ECPRESP=Y ECOCCUR=N
1.3*	What date was the dose taken [What date was the dose taken]	[PKDOSESTARTDATE] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030)	ECSTDTC
1.4*	Rationale for the dose [Rationale for the dose]	[PKRATIONALE] [A:1] <input type="radio"/> Dose escalation [A:2] <input type="radio"/> Target dose/Maximum Tolerated Dose (MTD) reached [A:3] <input type="radio"/> Re-initiate previous dose [A:4] <input type="radio"/> Dose reduction due to tolerability/Adverse Event [A:999] [PK_RATIONAL_OTHER] Other, Specify A200	ECADJ
ECSCAT= SECOND LAST INJECTION BEFORE THE CLINIC VISIT			
Dosing collection for PK visit [sctDOSECOLLECTION_WITHPK_1]			
Second last injection before the participant's clinic visit	2.* What dose was taken [What dose was taken]	[grpPKDOSETAKEN2] [DOSE3] [A:1] <input type="radio"/> 0.25 mg [A:2] <input type="radio"/> 0.50 mg [A:3] <input type="radio"/> 1.0 mg [A:4] <input type="radio"/> 1.7 mg [A:5] <input type="radio"/> 2.4 mg [A:6] <input type="radio"/> Missed dose [A:7] Took study drug, do not remember dose [A:999] [PK_DOSE_OTHER_2] Other, specify xx.xx	ECDOSE/ECDOSU ECPRESP=Y ECOCCUR=Y ECREASOC ECPRESP=Y ECOCCUR=N ECREASOC ECPRESP=Y ECOCCUR=N
3.* What date and time was the dose taken Time of dosing (required for doses taken prior to PK sampling) [What date and time was the dose taken]	[PKDOSESTARTDATE2] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) NReq <input type="checkbox"/> : NReq <input checked="" type="checkbox"/> 24-hour clock	ECSTDTC	
4.* Rationale for the dose [Rationale for the dose]	[PKRATIONALE2] [A:1] <input type="radio"/> Dose escalation [A:2] <input type="radio"/> Target dose/Maximum Tolerated Dose (MTD) reached [A:3] <input type="radio"/> Re-initiate previous dose [A:4] <input type="radio"/> Dose reduction due to tolerability/Adverse Event [A:999] [PK_RATIONAL_OTHER2] Other, Specify A200	ECADJ	
ECSCAT= LAST INJECTION BEFORE THE CLINIC VISIT			
Last injection before your child's Clinic Visit [sctDOSECOLLECTION_WITHPK_2]			
Last injection before the participant's clinic visit	5.* What dose was taken [What dose was taken]	[grpPKDOSETAKEN3] [DOSE4] [A:1] <input type="radio"/> 0.25 mg [A:2] <input type="radio"/> 0.50 mg [A:3] <input type="radio"/> 1.0 mg [A:4] <input type="radio"/> 1.7 mg [A:5] <input type="radio"/> 2.4 mg [A:6] <input type="radio"/> Missed dose [A:7] Took study drug [A:999] [PK_DOSE_OTHER_3] Other, specify xx.xx	ECDOSE/ECDOSU ECPRESP=Y ECOCCUR=Y ECREASOC ECPRESP=Y ECOCCUR=N ECREASOC ECPRESP=Y ECOCCUR=N
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7.* Rationale for the dose [Rationale for the dose]	[PKRATIONALE3] [A:1] <input type="radio"/> Dose escalation [A:2] <input type="radio"/> Target dose/Maximum Tolerated Dose (MTD) reached [A:3] <input type="radio"/> Re-initiate previous dose [A:4] <input type="radio"/> Dose reduction due to tolerability/Adverse Event [A:999] [PK_RATIONAL_OTHER3] Other, Specify A200	ECADJ	

Key: [\*] = Item is required    [!] = Source verification required  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

## Study Object Descriptions: Dose Collection with PK data

Type	RefName	Description
Form   DOSECOLLECTION_WITHPK   Visits: V6, V10, V14, V20, V24, V28, V30, V31		

## Codelist Values Tables: Dose Collection with PK data

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cDOSE_3	String		0.25 mg	1	citmDOSE1	DOSE2
			0.50 mg	2	citmDOSE2	
			1.0 mg	3	citmDOSE3	
			1.7 mg	4	citmDOSE4	
			2.4 mg	5	citmDOSE5	
			Missed dose	6	citmDOSE6	
			Took study drug, do not remember dose	7	citmDOSE7	

Rationale		Other, specify	999	citmDOSE9	
	nn	Dose escalation	1	Rational1	PKRATIONALE
		Target dose/Maximum Tolerated Dose (MTD) reached	2	Rational2	
		Re-initiate previous dose	3	Rational3	
		Dose reduction due to tolerability/Adverse Event	4	Rational4	
		Other, specify	999	Rational5	
clDOSE_2	String	0.25 mg	1	citmDOSE1	DOSE3
		0.50 mg	2	citmDOSE2	
		1.0 mg	3	citmDOSE3	
		1.7 mg	4	citmDOSE4	
		2.4 mg	5	citmDOSE5	
		Missed dose	6	citmDOSE6	
		Took study drug, do not remember dose	7	citmDOSE7	
		Other, specify	999	citmDOSE9	
Rational_1	String	Dose escalation	1	Rational1_1	PKRATIONALE2
		Target dose/Maximum Tolerated Dose (MTD) reached	2	Rational2_1	
		Re-initiate previous dose	3	Rational3_1	
		Dose reduction due to tolerability/Adverse Event	4	Rational4_1	
		Other, specify	999	Rational5_1	
clDOSE_4	String	0.25 mg	1	citmDOSE1	DOSE4
		0.50 mg	2	citmDOSE2	
		1.0 mg	3	citmDOSE3	
		1.7 mg	4	citmDOSE4	
		2.4 mg	5	citmDOSE5	
		Missed dose	6	citmDOSE6	
		Took study drug, do not remember dose	7	citmDOSE7	
		Other, specify	999	citmDOSE9	
clRATIONAL	String	Dose escalation	1	citmRATIONAL1	PKRATIONALE3
		Target dose/Maximum Tolerated Dose (MTD) reached	2	citmRATIONAL2	
		Re-initiate previous dose	3	citmRATIONAL3	
		Dose reduction due to tolerability/Adverse Event	4	citmRATIONAL4	
		Other, specify	999	citmRATIONAL5	

**RDE Analytics: RD\_DOSECLECTION\_WITHPK**

Data Variable RefName	RD Column Name	Column Data Type
grpPKDOSETAKEN2	GRPPKDOSETAKEN2_ND	VARCHAR2
grpPKDOSETAKEN2 - DOSE3	DOSE3_C	VARCHAR2
	DOSE3	VARCHAR2
grpPKDOSETAKEN2 - PK_DOSE_OTHER_2	PK_DOSE_OTHER_2	FLOAT
PKDOSESTARTDATE2	PKDOSESTARTDATE2	DATE
	PKDOSESTARTDATE2_DTS	VARCHAR2
	PKDOSESTARTDATE2_DTR	VARCHAR
	PKDOSESTARTDATE2_ND	VARCHAR2
PKRATIONALE2	PKRATIONALE2_C	VARCHAR2
	PKRATIONALE2	VARCHAR2
	PKRATIONALE2_ND	VARCHAR2
PKRATIONALE2 - PK_RATIONAL_OTHER2	PK_RATIONAL_OTHER2	VARCHAR2
grpPKDOSETAKEN3	GRPPKDOSETAKEN3_ND	VARCHAR2
grpPKDOSETAKEN3 - DOSE4	DOSE4_C	VARCHAR2
	DOSE4	VARCHAR2
grpPKDOSETAKEN3 - PK_DOSE_OTHER_3	PK_DOSE_OTHER_3	FLOAT
PKDOSESTARTDATE3	PKDOSESTARTDATE3	DATE
	PKDOSESTARTDATE3_DTS	VARCHAR2
	PKDOSESTARTDATE3_DTR	VARCHAR2
	PKDOSESTARTDATE3_ND	VARCHAR
PKRATIONALE3	PKRATIONALE3_C	VARCHAR2
	PKRATIONALE3	VARCHAR2
	PKRATIONALE3_ND	VARCHAR2
PKRATIONALE3 - PK_RATIONAL_OTHER3	PK_RATIONAL_OTHER3	VARCHAR2
<b>*RD_DOSECLECTION_WITHPK_SCTDOSECLECTION_WITHPK</b>		
DOSEPK_SEQ_NO	DOSEPK_SEQ_NO	NUMBER
	DOSEPK_SEQ_NO_ND	VARCHAR2
grpPKDOSETAKEN	GRPPKDOSETAKEN_ND	VARCHAR2
grpPKDOSETAKEN - DOSE2	DOSE2_C	VARCHAR2
	DOSE2	VARCHAR2
grpPKDOSETAKEN - PK_DOSE_OTHER_1	PK_DOSE_OTHER_1	FLOAT
PKDOSESTARTDATE	PKDOSESTARTDATE	DATE
	PKDOSESTARTDATE_DTS	VARCHAR2
	PKDOSESTARTDATE_ND	VARCHAR2
PKRATIONALE	PKRATIONALE_C	VARCHAR2
	PKRATIONALE	VARCHAR2
	PKRATIONALE_ND	VARCHAR2
PKRATIONALE - PK_RATIONAL_OTHER	PK_RATIONAL_OTHER	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

ECSCAT=DRUG ADMIN DETAILS	ECTRT=SEMAGLUTIDE/PLACEBO	EC=Exposure as Collected																																																																										
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**SS=Subject Status****SSCAT=GLUCOSE METABOLISM**

<b>: Evaluation of glycaemic status (Eval glycaemic status) [EVAL_GLY_STAT_2]</b>																													
<b>Study ID:</b> Note: ONLY without T2D. Please eval_`s glycaemic status based on all available information																													
1. Glycaemic status [Glycaemic status]																													
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[GLYCAEMIC\_2]  
[A-418]  Normo-glycaemia  
[A-419]  Pre-diabetes  
[A-420]  Diagnosed with type 2 diabetes

**SSORRES when STESTCD=GLYCAEST**

**QS=Questionnaires****QSCAT=C-SSRS SINCE LAST VISIT**

: C-SSRS Since Last Visit (C-SSRS Since Last Visit) [CSSRSLAST]			
Study ID: 1 Note: Grou... <b>SUICIDAL IDEATION [sctCSSRSLAST_1]</b> Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.			
<b>QSSCAT=SUICIDAL IDEATION</b>			
1.* Wish to be Dead [Wish to be Dead]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSLAST_1_DESC] Yes If yes, describe: A200		
<b>QSORRES when QTESTCD=CSS0201</b>			
2.* Non-Specific Active Suicidal Thoughts [Non-Specific Active Suicidal Thoughts]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSLAST_2_DESC] Yes If yes, describe: A200		
<b>QSORRES when QTESTCD=CSS0201A</b>			
3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act [Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSLAST_3_DESC] Yes If yes, describe: A200		
<b>QSORRES when QTESTCD=CSS0203</b>			
4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan [Active Suicidal Ideation with Some Intent to Act, without Specific Plan]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSLAST_4_DESC] Yes If yes, describe: A200		
<b>QSORRES when QTESTCD=CSS0204</b>			
5. Active Suicidal Ideation with Specific Plan and Intent [Active Suicidal Ideation with Specific Plan and Intent]	<input type="radio"/> No <input checked="" type="radio"/> [CSSRSLAST_5_DESC] Yes If yes, describe: A200		
<b>QSORRES when QTESTCD=CSS0205</b>			
<b>INTENSITY OF IDEATION [sctCSSRSLAST_2]</b> The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).			
6. Most Severe Ideation [Most Severe Ideation:]	<input type="radio"/> 1. Wish to be dead <input type="radio"/> 2. Non-Specific Active Suicidal Thoughts <input type="radio"/> 3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act <input type="radio"/> 4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan <input type="radio"/> 5. Active Suicidal Ideation with Specific Plan and Intent		
<b>QSORRES when QTESTCD=CSS0206</b>			
7. Frequency [Frequency]	<input type="radio"/> Less than once a week <input type="radio"/> Once a week <input type="radio"/> 2-5 times in week <input type="radio"/> Daily or almost daily <input type="radio"/> Many times each day		
<b>QSORRES when QTESTCD=CSS0207</b>			
8. Duration [Duration]	<input type="radio"/> Fleeting - few seconds or minutes <input type="radio"/> Less than 1 hour/some of the time <input type="radio"/> 1-4 hours/a lot of time <input type="radio"/> 4-8 hours/most of day <input type="radio"/> More than 8 hours/persistent or continuous		
<b>QSORRES when QTESTCD=CSS0208</b>			
9. Controllability [Controllability]	<input type="radio"/> Easily able to control thoughts <input type="radio"/> Can control thoughts with little difficulty <input type="radio"/> Can control thoughts with some difficulty <input type="radio"/> Can control thoughts with a lot of difficulty <input type="radio"/> Unable to control thoughts <input type="radio"/> Does not attempt to control thoughts		
<b>QSORRES when QTESTCD=CSS0209</b>			
10. Deterrents [Deterrents]	<input type="radio"/> Deterrents definitely stopped you from attempting suicide <input type="radio"/> Deterrents probably stopped you <input type="radio"/> Uncertain that deterrents stopped you <input type="radio"/> Deterrents most likely did not stop you <input type="radio"/> Deterrents definitely did not stop you <input type="radio"/> Does not apply		
<b>QSORRES when QTESTCD=CSS0210</b>			
11. Reasons for Ideation [Reasons for Ideation]	<input type="radio"/> Completely to get attention, revenge or a reaction from others <input type="radio"/> Mostly to get attention, revenge or a reaction from others <input type="radio"/> Equally to get attention, revenge or a reaction from others and to end/stop the pain. <input type="radio"/> Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) <input type="radio"/> Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) <input type="radio"/> Does not apply		
<b>QSORRES for QTESTCD=CSS0211</b>			
<b>SUICIDAL BEHAVIOR [sctCSSRSLAST_2_1]</b> (Check all that apply, so long as these are separate events; must ask about all types)			
12. Actual Attempt: [Actual Attempt]	<input type="radio"/> No <input checked="" type="radio"/> [grpCSSRSLAST_ATTEMPT] Yes If yes, describe: <b>[CSSRSLAST_SU_ATTEMPT]</b> Total # of Attempts N2 <b>[CSSRSLAST_SU_ATTEMPT_TEXT]</b> If yes, describe: A200		
<b>QSORRES when QTESTCD=CSS0212</b>			
<b>QSORRES when QTESTCD=CSS0213</b>			
<b>QSORRES when QTESTCD=CSS0213A</b>			
<b>[CSSRSLAST_SUCIDE]</b> Has subject engaged in Non-Suicidal Self-Injurious Behavior? <input type="radio"/> No <input checked="" type="radio"/> Yes			
<b>QSORRES when QTESTCD=CSS0214</b>			

		[CSSRLAST_INTERRUPT]	<b>QSORRES when QTESTCD=CSS0215</b>
14. Aborted Attempt: [Aborted Attempt:]		[CSSRLAST_ABORT]	<b>QSORRES when QTESTCD=CSS0216</b>
		[CSSRLAST_BEHAVIOR]	<b>QSORRES when QTESTCD=CSS0216A</b>
		[CSSRLAST_BEHAVIOR_TEXT]	<b>QSORRES when QTESTCD=CSS0217</b>
15. Preparatory Acts or Behavior: [Suicide]		[CSSRLAST_BEHAVIOR]	<b>QSORRES when QTESTCD=CSS0218</b>
		[CSSRLAST_BEHAVIOR_TEXT]	<b>QSORRES when QTESTCD=CSS0218A</b>
16. Suicidal Behavior: [Suicidal Behavior:]		[CSSRLAST_SUICIDE_BEH]	<b>QSORRES when QTESTCD=CSS0220</b>
17. Suicide: [Suicide:]		[CSSRLAST_SUICIDE_1]	<b>QSORRES when QTESTCD=CSS0221</b>
<b>Answer for Actual Attempts Only [sctCSSRSLAST_4]</b>			
18. Most Lethal Attempt Actual Lethality/Medical Damage: [Most Lethal]		[grpCSSRSLAST_ATTEMPT_1] [CSSRSLAST_ATTEM_DATE_1] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030)	<b>QSORRES when QTESTCD=CSS0222A</b>
		[CSSRSLAST_ATTEM_DAMAGE_1] [A:0] <input checked="" type="radio"/> [CSSRSLAST_ATTEM_DAMAGE_2] No physical damage or very minor physical damage [A:0] Behavior not likely to result in injury [A:1] Behavior likely to result in injury but not likely to cause death [A:2] Behavior likely to result in death despite available medical care [A:3] Minor physical damage [A:2] Moderate physical damage; medical attention needed [A:3] Moderately severe physical damage; medical hospitalization and likely intensive care required [A:4] Severe physical damage; medical hospitalization with intensive care required [A:5] Death	<b>QSORRES when QTESTCD=CSS0222B</b>

Key: [\*] = Item is required [ ✓ ] = Source verification required [ ☐ ] = Item is collapsible  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.

Type	RefName	Description
Form	CSSRSLAST	Visit: V14,V24,V30,V33,V35

Codelist Values Tables: C-SSRS Since Last Visit						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cICSSRSLAST_1	String		No	2	ctmCSSRSLAST_2_2	CSSRSLAST_1, CSSRSLAST_2, CSSRSLAST_3, CSSRSLAST_4, CSSRSLAST_5
			Yes	1	ctmCSSRSLAST_2_1	
cICSSRSLAST_MSIDEATION	String		1. Wish to be dead 2. Non-Specific Active Suicidal Thoughts 3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act 4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan 5. Active Suicidal Ideation with Specific Plan and Intent	1	ctmCSSRSLAST_MSIDEATION1	CSSRSLAST_MSIDEATION
cICSSRSLAST_IDEA_1	String		Less than once a week Once a week 2-5 times in week Daily or almost daily Many times each day	1	ctmCSSRSLAST_IDEA_1	CSSRSLAST_IDEA_1
cICSSRSLAST_IDEA_2	String		Fleeting - few seconds or minutes Less than 1 hour/some of the time 1-4 hours/a lot of time 4-8 hours/most of day More than 8 hours/persistent or continuous	1	ctmCSSRSLAST_IDEA_2_1	CSSRSLAST_IDEA_2
cICSSRSLAST_IDEA_3	String		Easily able to control thoughts Can control thoughts with little difficulty Can control thoughts with some difficulty Can control thoughts with a lot of difficulty Unable to control thoughts Does not attempt to control thoughts	1	ctmCSSRSLAST_IDEA_3_1	CSSRSLAST_IDEA_3
cICSSRSLAST_IDEA_4	String		Deterrents definitely stopped you from attempting suicide Deterrents probably stopped you Uncertain that deterrents stopped you Deterrents most likely did not stop you Deterrents definitely did not stop you Does not apply	1	ctmCSSRSLAST_IDEA_4_1	CSSRSLAST_IDEA_4
cICSSRSLAST_IDEA_5	String		Completely to get attention, revenge or a reaction from others Mostly to get attention, revenge or a reaction from others Equally to get attention, revenge or a reaction from others and to end/stop the pain. Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) Does not apply	1	ctmCSSRSLAST_IDEA_5_1	CSSRSLAST_IDEA_5

IPT	String	No	2	itmCSSRSLAST_2_2_1	CSSRSLAST_ATTEMPT
		Yes	1	itmCSSRSLAST_2_1_1	
clCSSRSLAST	String	No	2	itmCSSRSLAST_SUICIDE_2	CSSRSLAST_SUICIDE, CSSRSLAST_ABORT, CSSRSLAST_BEH
		Yes	1	itmCSSRSLAST_SUICIDE_1	
clCSSRSLAST_INTER	String	No	2	itmCSSRSLAST_SUICIDE_2_1	CSSRSLAST_INTER
		Yes	1	itmCSSRSLAST_SUICIDE_1_1	
clCSSRSLAST_SUICIDE_2	String	No	2	itmCSSRSLAST_SUICIDE_2	CSSRSLAST_BEHAVIOR
		Yes	1	itmCSSRSLAST_SUICIDE_1	
clCSSRSLAST_SUICIDE_1	String	No	2	itmCSSRSLAST_SUICIDE_2_1_1	CSSRSLAST_SUICIDE_1
		Yes	1	itmCSSRSLAST_SUICIDE_1_1_1	
clCSSRSLAST_ATTEM_DAMAGE_1	String	No physical damage or very minor physical damage	0	itmCSSRSLAST_ATTEM_DAMAGE_1_0	CSSRSLAST_ATTEM_DAMAGE_1
		Minor physical damage	1	itmCSSRSLAST_ATTEM_DAMAGE_1_1	
		Moderate physical damage; medical attention needed	2	itmCSSRSLAST_ATTEM_DAMAGE_1_2	
		Moderately severe physical damage; medical hospitalization and likely intensive care required	3	itmCSSRSLAST_ATTEM_DAMAGE_1_3	
		Severe physical damage; medical hospitalization with intensive care required	4	itmCSSRSLAST_ATTEM_DAMAGE_1_4	
		Death	5	itmCSSRSLAST_ATTEM_DAMAGE_1_5	
clCSSRSBASE_ATTEM_DAMAGE_2_1	String	Behavior not likely to result in injury	0	itmCSSRSLAST_ATTEM_DAMAGE_3_0	CSSRSLAST_ATTEM_DAMAGE_2
		Behavior likely to result in injury but not likely to cause death	1	itmCSSRSLAST_ATTEM_DAMAGE_3_1	
		Behavior likely to result in death despite available medical care	2	itmCSSRSLAST_ATTEM_DAMAGE_3_2	

RDE Analytics: RD_CSSRSLAST		
Data Variable RefName	RD Column Name	Column Data Type
CSSRSLAST_1	CSSRSLAST_1_C	VARCHAR2
	CSSRSLAST_1_I	VARCHAR2
	CSSRSLAST_1_ND	VARCHAR2
CSSRSLAST_1 - CSSRSLAST_1_DESC	CSSRSLAST_1_DESC	VARCHAR2
CSSRSLAST_2	CSSRSLAST_2_C	VARCHAR2
	CSSRSLAST_2_I	VARCHAR2
	CSSRSLAST_2_ND	VARCHAR2
CSSRSLAST_2 - CSSRSLAST_2_DESC	CSSRSLAST_2_DESC	VARCHAR2
CSSRSLAST_3	CSSRSLAST_3_C	VARCHAR2
	CSSRSLAST_3_I	VARCHAR2
	CSSRSLAST_3_ND	VARCHAR2
CSSRSLAST_3 - CSSRSLAST_3_DESC	CSSRSLAST_3_DESC	VARCHAR2
CSSRSLAST_4	CSSRSLAST_4_C	VARCHAR2
	CSSRSLAST_4_I	VARCHAR2
	CSSRSLAST_4_ND	VARCHAR2
CSSRSLAST_4 - CSSRSLAST_4_DESC	CSSRSLAST_4_DESC	VARCHAR2
CSSRSLAST_5	CSSRSLAST_5_C	VARCHAR2
	CSSRSLAST_5_I	VARCHAR2
	CSSRSLAST_5_ND	VARCHAR2
CSSRSLAST_5 - CSSRSLAST_5_DESC	CSSRSLAST_5_DESC	VARCHAR2
grpCSSRSLAT_MSIDEATION	GRPCSSRSLAT_MSIDEATION_ND	VARCHAR2
grpCSSRSLAT_MSIDEATION - CSSRSLAT_MSIDEATION	CSSRSLAT_MSIDEATION_C	VARCHAR2
	CSSRSLAT_MSIDEATION_I	VARCHAR2
CSSRSLAST_IDEA_1	CSSRSLAST_IDEA_1_C	VARCHAR2
	CSSRSLAST_IDEA_1_I	VARCHAR2
	CSSRSLAST_IDEA_1_ND	VARCHAR2
CSSRSLAST_IDEA_2	CSSRSLAST_IDEA_2_C	VARCHAR2
	CSSRSLAST_IDEA_2_I	VARCHAR2
	CSSRSLAST_IDEA_2_ND	VARCHAR2
CSSRSLAST_IDEA_3	CSSRSLAST_IDEA_3_C	VARCHAR2
	CSSRSLAST_IDEA_3_I	VARCHAR2
	CSSRSLAST_IDEA_3_ND	VARCHAR2
CSSRSLAST_IDEA_4	CSSRSLAST_IDEA_4_C	VARCHAR2
	CSSRSLAST_IDEA_4_I	VARCHAR2
	CSSRSLAST_IDEA_4_ND	VARCHAR2
CSSRSLAST_IDEA_5	CSSRSLAST_IDEA_5_C	VARCHAR2
	CSSRSLAST_IDEA_5_I	VARCHAR2
	CSSRSLAST_IDEA_5_ND	VARCHAR2
CSSRSLAST_ATTEMPT	CSSRSLAST_ATTEMPT_C	VARCHAR2
	CSSRSLAST_ATTEMPT_I	VARCHAR2
	CSSRSLAST_ATTEMPT_ND	VARCHAR2
CSSRSLAST_ATTEMPT - CSSRSLAST_SU_ATTEMPT	CSSRSLAST_SU_ATTEMPT	NUMBER
CSSRSLAST_ATTEMPT - CSSRSLAST_SU_ATTEMPT_TEXT	CSSRSLAST_SU_ATTEMPT_TEXT	VARCHAR2
CSSRSLAST_ATTEMPT - CSSRSLAST_SUICIDE	CSSRSLAST_SUICIDE_C	VARCHAR2
	CSSRSLAST_SUICIDE_I	VARCHAR2
CSSRSLAST_INTER	CSSRSLAST_INTER_C	VARCHAR2
	CSSRSLAST_INTER_I	VARCHAR2
	CSSRSLAST_INTER_ND	VARCHAR2
CSSRSLAST_INTER - CSSRSLAST_INTERRUPTED	CSSRSLAST_INTERRUPTED	NUMBER
CSSRSLAST_INTER - CSSRSLAST_ABORTED_TEXT	CSSRSLAST_ABORTED_TEXT	VARCHAR2
CSSRSLAST_ABORT	CSSRSLAST_ABORT_C	VARCHAR2
	CSSRSLAST_ABORT_I	VARCHAR2
	CSSRSLAST_ABORT_ND	VARCHAR2
CSSRSLAST_ABORT - CSSRSLAST_NO_ABORT	CSSRSLAST_NO_ABORT	NUMBER
CSSRSLAST_ABORT - CSSRSLAST_ABORT_TEXT	CSSRSLAST_ABORT_TEXT	VARCHAR2
CSSRSLAST_BEHAVIOR	CSSRSLAST_BEHAVIOR_C	VARCHAR2
	CSSRSLAST_BEHAVIOR_I	VARCHAR2
	CSSRSLAST_BEHAVIOR_ND	VARCHAR2
CSSRSLAST_BEHAVIOR - CSSRSLAST_BEHAVIOR_TEXT	CSSRSLAST_BEHAVIOR_TEXT	VARCHAR2
CSSRSLAST_SUICIDE_BEH	CSSRSLAST_SUICIDE_BEH_C	VARCHAR2
	CSSRSLAST_SUICIDE_BEH_I	VARCHAR2
	CSSRSLAST_SUICIDE_BEH_ND	VARCHAR2
CSSRSLAST_SUICIDE_1	CSSRSLAST_SUICIDE_1_C	VARCHAR2
	CSSRSLAST_SUICIDE_1_I	VARCHAR2
	CSSRSLAST_SUICIDE_1_ND	VARCHAR2
grpCSSRSLAST_ATTEMPT_1	GRPCSSRSLAST_ATTEMPT_1_ND	VARCHAR2
grpCSSRSLAST_ATTEMPT_1 - CSSRSLAST_ATTEM_DATE_1	CSSRSLAST_ATTEM_DATE_1	DATE

grpCSSR_ATTEMPT_1 - CSSRSLAST_ATTEM_DAMAGE_1	CSSRSLAST_ATTEM_DATE_1_DTS	VARCHAR2
	CSSRSLAST_ATTEM_DAMAGE_1_C	VARCHAR2
grpCSSRSLAST_ATTEMPT_1 - CSSRSLAST_ATTEM_DAMAGE_2	CSSRSLAST_ATTEM_DAMAGE_1_C	VARCHAR2
	CSSRSLAST_ATTEM_DAMAGE_2_C	VARCHAR2
	CSSRSLAST_ATTEM_DAMAGE_2	VARCHAR2

: Adverse Events (AE) - Repeating Form [AE_MEDDRA3]						HO=Healthcare Encounters		AE=Adverse Events			
#	AE Onset Date	AE Symptoms	SAE	Severity	Outcome of AE	Details of investigational medicinal product (IMP) given before AE onset		Related hypoglycaemic episodes (if any)			
1						[AE_NO_SEQ_NO] 0 < N3 [AE No.]	<b>AEREFID</b>	<b>HOREFID</b>	<b>RELREC: AE.HO</b>		
1.	Study ID: NN9536-4512 1. Adverse event number [read-only] [AE No.]					[AE_START_DATE] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030)					
2.*	Onset date of AE [AE Onset Date]					[AE_START_DATE_TIME] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2022-2035) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock					
3.	Onset date and time of AE [hidden] [AE Onset Date & Time]					[MEDDRA_AE_TEXT] A200	<b>AETERM</b>				
4.*	AE diagnosis (if known) or sign/symptom Report only one sign/symptom per AE form [AE Symptoms]										
Please refer to the protocol for detailed instructions on reporting requirements and timelines for Serious Adverse Events (SAEs).											
5.*	Is the AE serious? If Yes, complete a SIF [SAE]					[AE_SERIOUS_YN] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpAE_SERIOUS] <input type="checkbox"/> Yes Seriousness criteria: [DEATH_YN] Death [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpAUTOPSY_YN] <input type="checkbox"/> Yes [AUTOPSY_YN] Was an autopsy performed/planned? [A:2] <input type="radio"/> No [A:1] <input checked="" type="checkbox"/> Yes [LIFE_THREATENING_YN] Life-threatening [A:2] <input type="radio"/> No [A:1] <input checked="" type="checkbox"/> Yes [HOSPITAL_YN] In-patient hospitalisation/prolongation of existing hospitalisation [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpADM_DISCH_DATE] <input type="checkbox"/> Yes [HOSP_ADMISSION_DATE] (DD/MM/YYYY) Date of admission: Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) [HOSP_DISCHARGE_DATE] (DD/MM/YYYY) Date of discharge: Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030)	<b>AE SER</b>	<b>AEAUTOPS in SUPPAE</b>	<b>AESHOSP</b>	<b>HOSTDTC</b>	<b>HOTERM=HOSPITAL</b>
									<b>HOENDTC</b>		
						[DISABIL_INCAPACITY_YN] Persistent or significant disability/incapacity [A:2] <input type="radio"/> No [A:1] <input checked="" type="checkbox"/> Yes [CONGENI_BIRTH_DEF_YN] Congenital anomaly/birth defect [A:2] <input type="radio"/> No [A:1] <input checked="" type="checkbox"/> Yes [MEDICAL_EVENT_IMP_YN] Important medical event [A:2] <input type="radio"/> No [A:1] <input checked="" type="checkbox"/> Yes	<b>AESCONG</b>				
6.	Seriousness - Previous Item is used for an electronic check that downgrading of seriousness does not occur. [hidden] [Previous SAE]					[AE_SERIOUS_PREVIOUS_YN] A20					
7.*	Severity [Severity]					[AE_SEVERITY_CODE] [A:1] <input type="radio"/> Mild [A:2] <input type="radio"/> Moderate [A:3] <input type="radio"/> Severe	<b>AESEV</b>				
8.	Severity - Previous Item is used for an electronic check that downgrading of severity does not occur. [hidden] [Previous Severity]					[AE_SEVERITY_PREVIOUS] A20					
9.*	Outcome of adverse event If the adverse event has fatal outcome or if the sequelae meets a seriousness criterion, the adverse event must be reported as a serious adverse event by also completing a SIF [hidden] [Outcome of AE]					[AE_OUTCOME_CODE] [A:1] <input type="radio"/> [grpAE_OUTCOME_CODE1] <input type="checkbox"/> Recovered/resolved [AE_OUTCOME_CODE1] (DD/MM/YYYY) Date: Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) [A:11] <input type="radio"/> [grpAE_OUTCOME_CODE11] <input type="checkbox"/> Recovering/resolving [AE_OUTCOME_CODE11] (DD/MM/YYYY) Date: Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) [A:2] <input type="radio"/> [grpAE_OUTCOME_CODE2] <input type="checkbox"/> Recovered/resolved with sequelae [AE_SEQUELAE_DATE] (DD/MM/YYYY) Date: Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) [AE_SEQUELAE_TEXT] Describe sequelae A200	<b>AEOUT</b>	<b>AEENDTC</b>	<b>AESSQLAE in SUPPAE</b>		
10.	Outcome of adverse event If the adverse event has fatal outcome or if the sequelae meets a seriousness criterion, the adverse event must be reported as a serious adverse event by also completing a SIF [hidden] [Outcome of AE]					[AE_OUTCOME_CODE_A] [A:1] <input type="radio"/> [grpAE_OUTCOME_CODE1A] <input type="checkbox"/> Recovered/resolved [AE_OUTCOME_CODE1A] (DD/MM/YYYY hh:mm) Date and time: Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2022-2035) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock [A:11] <input type="radio"/> [grpAE_OUTCOME_CODE11A] <input type="checkbox"/> Recovering/resolving [AE_OUTCOME_CODE11A] (DD/MM/YYYY hh:mm) Date and time: Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2022-2035) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock [A:2] <input type="radio"/> [grpAE_OUTCOME_CODE2A] <input type="checkbox"/> Recovered/resolved with sequelae [AE_SEQUELAE_DATE_TIME_A] (DD/MM/YYYY hh:mm) Date and time: Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2022-2035) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock [AE_SEQUELAE_TEXT_A] Describe sequelae A200					
						[A:12] <input type="radio"/> Not recovered/not resolved [A:9] <input type="radio"/> [grpAE_OUTCOME_CODE9] <input type="checkbox"/> Fatal [AE_OUTCOME_CODE9] (DD/MM/YYYY hh:mm) Date and time: Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2022-2035) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input type="checkbox"/> 24-hour clock [A:5] <input type="radio"/> Unknown					

**AE=Adverse Events**

1. Is this event an adverse event for adjudication as defined in protocol?		<b>NOT SUBMITTED</b>	
If Yes, additional information in dedicated form(s) [hidden]		<input type="checkbox"/> [A:2] No <input checked="" type="checkbox"/> [A:1] <b>[AE_TYPE_CODE]</b> <input type="checkbox"/> Yes <input type="checkbox"/> [A:ACUTE CORONARY SYNDROME] <input type="checkbox"/> [A:PANCREATITIS] <input type="checkbox"/> [A:CEREBROVASCULAR EVENT] <input type="checkbox"/> [A:CORONARY ARTERY REVASCULARISATION] <input type="checkbox"/> [A:HEART FAILURE] <input type="checkbox"/> [A:HYPOLYCAEMIC EPISODE] <input type="checkbox"/> [A:EVT1] <input type="checkbox"/> [A:EVT2] <input type="checkbox"/> Acute coronary syndrome <input type="checkbox"/> Acute pancreatitis <input type="checkbox"/> Cerebrovascular event <input type="checkbox"/> Coronary revascularisation procedure <input type="checkbox"/> Heart failure <input type="checkbox"/> Hypoglycaemic episode <input type="checkbox"/> <Event type 1> <input type="checkbox"/> <Event type 2>	
12. Does the AE fulfil an AE of special interest (AESI) criterion as defined in protocol? If Yes, complete a SIF according to the required timelines. [hidden]			
<b>[AESI]</b> If the AE PT search resulted in a match, select adverse event category [hidden] <b>[PT search]</b>			
<b>Details of investigational medicinal product (IMP) given before AE onset [sctTRIAL_DRUG_INFO]</b> Action taken to IMP: Drug interrupted means temporary discontinuation of IMP. Drug withdrawn means permanent discontinuation of IMP. Technical complaint: If the adverse event is related to a technical complaint remember to complete the technical complaint form			
#	IMP	Product given?*	Causality
14.1	Semaglutide/ Semaglutide placebo		Action taken to product
14.2	Investigational Medicinal Product [IMP]		Tech complaint related AE?
14.2'	Product given? [Product given?]		Action taken to product – Previous
14.3	Causality [Causality]		
14.4	Action taken to product [Action taken to product]		
14.5	Is the AE related to a technical complaint? If yes, fill in the Technical Complaint form. [Tech complaint related AE?]		
14.6	Action taken to product due to AE - Previous  Item is used for an electronic check that downgrading of action taken to IMP does not occur. [hidden] [Action taken to product – Previous ]		
15.	Sequence number		Hypoglycaemic episode no.
<b>Related hypoglycaemic episodes (if any) Entry [sct_REL_HYPO]</b> 15.1 Sequence number [read-only] [Sequence number] 15.2 Hypoglycaemic episode no. [Hypoglycaemic episode no.] 16. Office use only Item used for SAE notification [hidden] [Office Use] 17. Office use only Item used to track changes in severity, action taken to product and seriousness. [hidden] [Office Use] 18. Office use only Item used to track changes in severity, action taken to product and seriousness. [hidden] [Office Use]			
Key: [*] = Item is required   [ ] = Source verification required   [ ] = Item is collapsible   [ ] = Key item   [ ] = Fixed item Note: Source verification critical settings made in InForm will override any settings made in Central Designer. Note: Collapsible settings are only available to users who have the rights to edit the item.			

Study Object Descriptions: Adverse Events		
Type	RefName	Description
Form	AE_MEDDRA3	Item 2 is a key item Visit: AE
Item	AE_NO_SEQ_NO	Calculated in InForm via rule Integrations: A, R - please do not change the refname or format
Item	AE_START_DATE	Integrations: A, R - please do not change the refname or format
Item	AE_START_DATE_TIME	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	MEDDRA_AE_TEXT	Integrations: A, R - please do not change the refname or format
Item	AE_SERIOUS_YN	Integrations: A, R - please do not change the refname or format
Item	AE_SERIOUS_PREVIOUS_YN	Item used to track changes in Seriousness
Item	AE_SEVERITY_CODE	Integrations: A, R - please do not change the refname or format
Item	AE_SEVERITY_PREVIOUS	Item used to track changes in Severity
Item	AE_OUTCOME_CODE	Integrations: A, R - please do not change the refname or format
Item	AE_OUTCOME_CODE_A	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	AE_CATEGORY_MATCH_YN	**Item DEACTIVATED**
Item	AESI_YN	**Item DEACTIVATED** Integrations: A, R - please do not change the refname or format
Item	PT_TRIAGE_YN	**Item DEACTIVATED**
Item	TRIAL_DRUG_CODE	Integrations: A, R - please do not change the refname or format
Item	PROD ADM YN	Integrations: A, R - please do not change the refname or format
Item	AE_RELATION_CODE	Integrations: A, R - please do not change the refname or format

	ANGE_CODE	Integrations: A, R - please do not change the refname or format
Item	A FRH TFD YN	Integrations: A - please do not change the refname or format
Item	AE_NO_C_CHG_CF PREVIOUS	Item used to track changes in Action taken to trial product due to AE
		Integrations: A - please do not change the refname or format
Item	SAE_OFFICE	Item used for SAE notification
Item	SAE_OFFICE2	Item used to track changes in Severity, Action taken to trial product due to AE & Seriousness
Item	SAE_OFFICE3	Item used to track changes in Severity, Action taken to trial product due to AE & Seriousness

**Keys (navigation)/Uniqueness: Adverse Events**

Item	Unique	Order #
AE_MEDDRA3 (Repeating form)		
scAE_START		

AE_START_DATE	None	1
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**Codelist Values Tables: Adverse Events**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clAE_SERIOUS_YN	String		No	2	citmAE_SERIOUS_N	AE_SERIOUS_YN
			Yes	1	citmAE_SERIOUS_Y	
cINOYES	String		No	2	citmNOYES2	DEATH_YN, AUTOPSY_YN, HOSPITAL_YN, DISABI_INCAPACITY_YN, CONGENI_BIRTH_DEF_YN, MEDICAL_EVENT_IMP_YN
			Yes	1	citmNOYES1	LIFE_THREAT_YN
clLIFE_THREATENING_YN	String		No	2	citmLIFE_THREATENING_N	
			Yes	1	citmLIFE_THREATENING_Y	
clAE_SEVERITY_CODE	String		Mild	1	citmAE_SEVERITY_CODE1	AE_SEVERITY_CODE
			Moderate	2	citmAE_SEVERITY_CODE2	
			Severe	3	citmAE_SEVERITY_CODE3	
clAE_OUTCOME_CODE	String		Recovered/resolved, date	1	citmAE_DRUG_CHANGE_CODE1	AE_OUTCOME_CODE, AE_OUTCOME_CODE_A
			Recovering/resolving, date	11	citmAE_DRUG_CHANGE_CODE11	
			Recovered/resolved with sequelae, date	2	citmAE_DRUG_CHANGE_CODE2	
			Not recovered/not resolved	12	citmAE_DRUG_CHANGE_CODE12	
			Fatal, date	9	citmAE_DRUG_CHANGE_CODE9	
			Unknown	5	citmAE_DRUG_CHANGE_CODES	
cINOYES_1_1_1	String		No	2	citmNOYES2_1_1_1	AE_CATEGORY_MATCH_YN
			Yes	1	citmNOYES1_1_1_1	
clAE_EVTADJ_EVT	String		Acute coronary syndrome	ACUTE CORONARY SYNDROME	citmEVTADJ_EVT_ACES	AE_TYPE_CODE
			Acute pancreatitis	PANCREATITIS	citmEVTADJ_EVT_PANC	
			Cerebrovascular event	CEREBROVASCULAR EVENT	citmEVTADJ_EVT_CEREB	
			Coronary revascularisation procedure	CORONARY ARTERY REVASCULARISATION	citmEVTADJ_EVT_CAR	
			Heart failure	HEART FAILURE	citmEVTADJ_EVT_HF	
			Hypoglycaemic episode	HYPOLYCAEMIC EPISODE	citmEVTADJ_EVT_HYPO	
			<Event type 1>	EVT1	citmEVTADJ_EVT_1	
			<Event type 2>	EVT2	citmEVTADJ_EVT_2	
clAESI_YN	String		No	2	citmAESI_N	AESI_YN
			Yes	1	citmAESI_Y	
clAE_TRIAGE_CODE_1	String		Acute coronary syndrome	CAT1	citmAE_TYPE_CODE_C1	PT_TRIAGE_YN
			Acute pancreatitis	CAT2	citmAE_TYPE_CODE_C2	
			Cerebrovascular event	CAT3	citmAE_TYPE_CODE_C3	
			Coronary revascularisation procedure	CAT4	citmAE_TYPE_CODE_C4	
			Heart failure	CAT5	citmAE_TYPE_CODE_C5	
			Hypoglycaemic episode	CAT6	citmAE_TYPE_CODE_C6	
			Category 1	CAT14	citmAE_TYPE_CODE_CAT1_1	
			Category 2	CAT15	citmAE_TYPE_CODE_CAT2_1	
cITRIAL_DRUG_CODE	Integer		Semaglutide/ Semaglutide placebo	1	citmTRIAL_DRUG_CODE1	TRIAL_DRUG_CODE
clPRODUCT_GIVEN_YN	String		Yes	1	citmPRODUCT_GIVEN_Y	PROD ADM_YN
			No	2	citmPRODUCT_GIVEN_N	
clAE_CAUSALITY	String		Probable	1	citmAE_CAUSALITY1	AE_RELATION_CODE
			Possible	2	citmAE_CAUSALITY2	
			Unlikely	3	citmAE_CAUSALITY3	
clAE_DRUG_CHANGE_CODE	String		Drug interrupted	24	citmAE_DRUG_CHANGE_24	AE_DRUG_CHANGE_CODE
			Drug withdrawn	25	citmAE_DRUG_CHANGE_25	
			Dose reduced	19	citmAE_DRUG_CHANGE_19	
			Dose increased	20	citmAE_DRUG_CHANGE_20	
			Dose not changed	21	citmAE_DRUG_CHANGE_21	
			Unknown	996	citmAE_DRUG_CHANGE_996	
			Not applicable	998	citmAE_DRUG_CHANGE_998	
clAE_TECH RELATED_YN	String		No	2	citmAE_TECH RELATED_N	AE_TECH RELATED_YN
			Yes	1	citmAE_TECH RELATED_Y	

**RDE Analytics: RD\_AE\_MEDDRA3**

Data Variable RefName	RD Column Name	Column Data Type
AE_NO_SEQ_NO	AE_NO_SEQ_NO	NUMBER
	AE_NO_SEQ_NO_ND	VARCHAR2
AE_START_DATE	AE_START_DATE	DATE
	AE_START_DATE_DTS	VARCHAR2
	AE_START_DATE_ND	VARCHAR2
AE_START_DATE_TIME	AE_START_DATE_TIME	DATE
	AE_START_DATE_TIME_DTS	VARCHAR2
	AE_START_DATE_TIME_DTR	VARCHAR2
	AE_START_DATE_TIME_ND	VARCHAR2
MEDDRA_AE_TEXT	MEDDRA_AE_TEXT	VARCHAR2
	MEDDRA_AE_TEXT_ND	VARCHAR2
AE_SERIOUS_YN	AE_SERIOUS_YN_C	VARCHAR2
	AE_SERIOUS_YN	VARCHAR2
	AE_SERIOUS_YN_ND	VARCHAR2
AE_SERIOUS_YN - DEATH_YN	DEATH_YN_C	VARCHAR2
	DEATH_YN	VARCHAR2
AE_SERIOUS_YN - AUTOPSY_YN	AUTOPSY_YN_C	VARCHAR2
	AUTOPSY_YN	VARCHAR2

FE_THREAT_YN	LIFE_THREAT_YN_C	VARCHAR2
	LIFE_THREAT_YN	VARCHAR2
AE_SERIOUS_YN_HOSPITAL_YN	HOSPITAL_YN_C	VARCHAR2
	HOSPITAL_YN	VARCHAR2
AE_SERIOUS_YN - HOSP_ADMISSION_DATE	HOSP_ADMISSION_DATE	DATE
	HOSP_ADMISSION_DATE_DTS	VARCHAR2
	HOSP_ADMISSION_DATE_DTR	VARCHAR2
AE_SERIOUS_YN - HOSP_DISCHARGE_DATE	HOSP_DISCHARGE_DATE	DATE
	HOSP_DISCHARGE_DATE_DTS	VARCHAR2
	HOSP_DISCHARGE_DATE_DTR	VARCHAR2
AE_SERIOUS_YN - DISABIL_INCAPACITY_YN	DISABIL_INCAPACITY_YN_C	VARCHAR2
	DISABIL_INCAPACITY_YN	VARCHAR2
AE_SERIOUS_YN - CONGENI_BIRTH_DEF_YN	CONGENI_BIRTH_DEF_YN_C	VARCHAR2
	CONGENI_BIRTH_DEF_YN	VARCHAR2
AE_SERIOUS_YN - MEDICAL_EVENT_IMP_YN	MEDICAL_EVENT_IMP_YN_C	VARCHAR2
	MEDICAL_EVENT_IMP_YN	VARCHAR2
AE_SERIOUS_PREVIOUS_YN	AE_SERIOUS_PREVIOUS_YN	VARCHAR2
	AE_SERIOUS_PREVIOUS_YN_ND	VARCHAR2
AE_SEVERITY_CODE	AE_SEVERITY_CODE_C	VARCHAR2
	AE_SEVERITY_CODE	VARCHAR2
	AE_SEVERITY_CODE_ND	VARCHAR2
AE_SEVERITY_PREVIOUS	AE_SEVERITY_PREVIOUS	VARCHAR2
	AE_SEVERITY_PREVIOUS_ND	VARCHAR2
AE_OUTCOME_CODE	AE_OUTCOME_CODE_C	VARCHAR2
	AE_OUTCOME_CODE	VARCHAR2
	AE_OUTCOME_CODE_ND	VARCHAR2
AE_OUTCOME_CODE - AE_OUTCOME_CODE1	AE_OUTCOME_CODE1	DATE
	AE_OUTCOME_CODE1_DTS	VARCHAR2
AE_OUTCOME_CODE - AE_OUTCOME_CODE11	AE_OUTCOME_CODE11	DATE
	AE_OUTCOME_CODE11_DTS	VARCHAR2
AE_OUTCOME_CODE - AE_SEQUELAE_DATE	AE_SEQUELAE_DATE	DATE
	AE_SEQUELAE_DATE_DTS	VARCHAR2
AE_OUTCOME_CODE - AE_SEQUELAE_TEXT	AE_SEQUELAE_TEXT	VARCHAR2
AE_OUTCOME_CODE - AE_OUTCOME_CODE9	AE_OUTCOME_CODE9	DATE
	AE_OUTCOME_CODE9_DTS	VARCHAR2
AE_OUTCOME_CODE_A	AE_OUTCOME_CODE_A_C	VARCHAR2
	AE_OUTCOME_CODE_A	VARCHAR2
	AE_OUTCOME_CODE_A_ND	VARCHAR2
AE_OUTCOME_CODE_A - AE_OUTCOME_CODE1A	AE_OUTCOME_CODE1A	DATE
	AE_OUTCOME_CODE1A_DTS	VARCHAR2
	AE_OUTCOME_CODE1A_DTR	VARCHAR2
AE_OUTCOME_CODE_A - AE_OUTCOME_CODE11A	AE_OUTCOME_CODE11A	DATE
	AE_OUTCOME_CODE11A_DTS	VARCHAR2
	AE_OUTCOME_CODE11A_DTR	VARCHAR2
AE_OUTCOME_CODE_A - AE_SEQUELAE_DATE_TIME_A	AE_SEQUELAE_DATE_TIME_A	DATE
	AE_SEQUELAE_DATE_TIME_A_DTS	VARCHAR2
	AE_SEQUELAE_DATE_TIME_A_DTR	VARCHAR2
AE_OUTCOME_CODE_A - AE_SEQUELAE_TEXT_A	AE_SEQUELAE_TEXT_A	VARCHAR2
AE_OUTCOME_CODE_A - AE_OUTCOME_CODE9A	AE_OUTCOME_CODE9A	DATE
	AE_OUTCOME_CODE9A_DTS	VARCHAR2
	AE_OUTCOME_CODE9A_DTR	VARCHAR2
AE_CATEGORY_MATCH_YN	AE_CATEGORY_MATCH_YN_C	VARCHAR2
	AE_CATEGORY_MATCH_YN	VARCHAR2
	AE_CATEGORY_MATCH_YN_ND	VARCHAR2
AE_CATEGORY_MATCH_YN - AE_TYPE_CODE	AE_TYPE_CODE_C	VARCHAR2
	AE_TYPE_CODE	VARCHAR2
AESI_YN	AESI_YN_C	VARCHAR2
	AESI_YN	VARCHAR2
	AESI_YN_ND	VARCHAR2
PT_TRIAGE_YN	PT_TRIAGE_YN_C	VARCHAR2
	PT_TRIAGE_YN	VARCHAR2
	PT_TRIAGE_YN_ND	VARCHAR2
SAE_OFFICE	SAE_OFFICE	NUMBER
	SAE_OFFICE_ND	VARCHAR2
SAE_OFFICE2	SAE_OFFICE2	NUMBER
	SAE_OFFICE2_ND	VARCHAR2
SAE_OFFICE3	SAE_OFFICE3	NUMBER
	SAE_OFFICE3_ND	VARCHAR2
<b>*RD_AE_MEDDRA3_SCTTRIAL_DRUG_INFO</b>		
TRIAL_DRUG_CODE	TRIAL_DRUG_CODE_C	NUMBER
	TRIAL_DRUG_CODE	VARCHAR2
	TRIAL_DRUG_CODE_ND	VARCHAR2
PROD ADM_YN	PROD ADM_YN_C	VARCHAR2
	PROD ADM_YN	VARCHAR2
	PROD ADM_YN_ND	VARCHAR2
AE_RELATION_CODE	AE_RELATION_CODE_C	VARCHAR2
	AE_RELATION_CODE	VARCHAR2
	AE_RELATION_CODE_ND	VARCHAR2
AE_DRUG_CHANGE_CODE	AE_DRUG_CHANGE_CODE_C	VARCHAR2
	AE_DRUG_CHANGE_CODE	VARCHAR2
	AE_DRUG_CHANGE_CODE_ND	VARCHAR2
AE_TECH RELATED_YN	AE TECH RELATED_YN_C	VARCHAR2
	AE TECH RELATED_YN	VARCHAR2
	AE TECH RELATED_YN_ND	VARCHAR2
AE_DRUG_CHANGE_PREVIOUS	AE DRUG CHANGE PREVIOUS	VARCHAR2
	AE DRUG CHANGE PREVIOUS_ND	VARCHAR2
<b>*RD_AE_MEDDRA3_SCT_REL_HYPO</b>		
AE_HYPO_NO	AE_HYPO_NO	NUMBER
	AE_HYPO_NO_ND	VARCHAR2

..	HYP0_NO	NUMBER
	HYP0_NO_ND	VARCHAR2

Key: [\*] :  
\*or table name in the actual RDE extract may be different.

NOT SUBMITTED

Safety Information Form (SIF) - Repeating Form [SIF]														
#	SIF ID	AE number(s)	Investigator name	Date of awareness	Condition recorded at baseline?	Any treatment for subject?	Alternative Aetiology	Relevant concomitant medication at the time of onset of AE	Event description	Was the randomisation code broken?	Pregnant at onset	Investigational medicinal product details	Relevant assessments and laboratory data/vital signs (performed to confirm the event and/or its outcome)	
1														
Study ID: NN9536-4512														
Safety Information Form [sctSIF_SEQ_NO]														
1.	Safety Information Form (SIF) number [read-only] [SIF No.]			[SIF_SEQ_NO] 0 < N3										
2.*	Related AE number(s) Multiple adverse event numbers may be added if several SAEs occur as part of the same clinical picture or within the same hospitalisation period [Related AE number(s)]													
[grpAE_NO_SIF] [AE_NO_SIF1] [AE_NO_SIF2] [AE_NO_SIF3] [AE_NO_SIF4] [AE_NO_SIF5] [AE_NO_SIF6] [AE_NO_SIF7] [AE_NO_SIF8] [AE_NO_SIF9] [AE_NO_SIF10] [AE_NO_SIF11] [AE_NO_SIF12] 0 < N3   0 < N3														
Investigator Information [sctSIP_INV_INFO]														
3.*	Investigator name [Investigator name]			[grpSIF_INV_NAME] [SIF_INV_NAME_1] Given name: A35 [SIF_INV_NAME_2] Middle name: A15 [SIF_INV_NAME_3] Family name: A50										
4.*	Date of awareness Date site became aware of this event [Date of awareness]			[DATE_AWARE_SIF] (DD/MM/YYYY) Req/Unk / Req / Req (2023-2030)										
AE Information [sctSIF_AE_INFO]														
5.*	Was the condition recorded at baseline? [Condition recorded at baseline?]			[CONDITION_BL_YNUK] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpINCR_EXAC_SYMPT] <input type="checkbox"/> Yes [INCR_EXAC_SYMPT] Did the condition worsen? [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No [A:996] <input type="radio"/> Unknown [A:996] <input type="radio"/> Unknown										
6.*	Did the subject receive any treatment for the event? If Yes, consider to associate treatment drugs in the concomitant medication section below. [Any treatment for subject?]			[SIF_TMT_FOR_EVENT] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> Yes [A:996] <input type="radio"/> Unknown										
Investigators Alternative Aetiology [sctINV_AETIOLOGY]														
7.	Alternative Aetiology Alternative aetiology is any other factor, including concomitant drug(s), that could have contributed to the event.  Only to be completed if the causal relationship to investigational medicinal product has been stated as Unlikely or Possible on the AE form. [Alternative Aetiology]			[AETIOLOGY] [A:1] <input type="checkbox"/> [grpAETIOLOGY_DISEASE] <input type="checkbox"/> Underlying disease [AETIOLOGY_DISEASE] Specify: A200  [A:2] <input type="checkbox"/> [grpAETIOLOGY_CONCOMMED] <input type="checkbox"/> Concomitant medication [AETIOLOGY_CONCOMMED] Specify: A200  [A:3] <input type="checkbox"/> [grpAETIOLOGY_OTHER] <input type="checkbox"/> Other [AETIOLOGY_OTHER] Specify: A200  [A:996] <input type="checkbox"/> Unknown										
Concomitant medications [sctSIF_CM]														
8.*	Did the subject take any relevant concomitant medication at the time of onset of AE (recent or ongoing treatments)?  Associate relevant concomitant medications for this event in the concomitant medication form below. [Relevant concomitant medication at the time of onset of AE]			[SIF_CM_AE] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> Yes [A:996] <input type="radio"/> Unknown										
Event Description (incl. treatment of event) Description of the event with signs/symptoms, treatment, course of the event and previous adverse events found relevant for the event being reported														
9.*	Event description [Event description]			[grpSIF_EVENT_DESC] [SIF_EVENT_DESC] A2000  [SIF_EVENT_DESC_2] A2000										
Randomisation [sctSIF_RAND]														
10.	Retired item - maintained on CRF due to legacy integration. Do not use [hidden] [Retired Item]													[DUN_ID] 0 < N7
11.	Randomisation Number [hidden] [Randomisation No]													[RANDOMISATION_NO_SIF] 0 < N6
12.*	Was the randomisation code broken by the Investigator? [Was the randomisation code broken?]													[SIF_RAND] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpSIF_RAND_DATE] <input type="checkbox"/> Yes [SIF_RAND_DATE] (DD/MM/YYYY) Date: Req / Req / Req (2023-2030) [A:998] <input type="radio"/> N/A
Pregnancy [sctSIF_PREG]														
13.*	Was the subject pregnant at onset of the event? If yes, fill in the Pregnancy Forms [Pregnant at onset]													[PREG_ONSET_YNUNK] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> Yes [A:996] <input type="radio"/> Unknown
Investigational medicinal product details [sctTRIAL_DRUG_INFO_SIF]														
#	Drug Index number	IMP	Was Product Given?	Dose	Route	Start date of product	Stop date, if product was interrupted / withdrawn	Start date and time of product	Stop date and time, if product was interrupted / withdrawn	If product was interrupted / withdrawn due to the event, did the AE abate?	Was product reintroduced?	Product name in Argus		
14.a		Semaglutide/Semaglutide placebo												
Investigational medicinal product details Entry [sctTRIAL_DRUG_INFO_SIF]														
14.1	Drug index number [hidden] [Drug index number]			[SIF_DRUG_INDEX]										

			<b>NOT SUBMITTED</b>
14.2	Inv [IMPI] Was product given at or prior to AE onset? [Was Product Given?]	[SIF_TRIAL_DRUG_CODE] [N:1] <input checked="" type="radio"/> Semaglutide/Semaglutide placebo  [PRODUCT_GIVEN_YN_SIF] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No	
14.3*	Dose [Dose]	[grpSIF_DOSE] [SIF_DOSE] Dose: xxxx.  [SIF_UNIT] Unit: <input checked="" type="radio"/> [cSIF_UNIT]  [SIF_FREQ] Frequency: <input checked="" type="radio"/> [cSIF_FREQ_CODE]	
14.4	Route [Route]	[SIF_ROUTE_CODE] [cSIF_ROUTE_CODE]	
14.5	Start date of product [Start date of product]	[SIF_TMT_STDT] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Rec <input checked="" type="checkbox"/> / Req <input type="checkbox"/> (2023-2030)	
14.6	Stop date, if product was interrupted / withdrawn [Stop date, if product was interrupted / withdrawn]	[SIF_DC_TMT_DT] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Rec <input checked="" type="checkbox"/> / Req <input type="checkbox"/> (2023-2030)	
14.7	Start date and time of product [hidden] [Start date and time of product]	[SIF_TMT_STDT_STTM] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Rec <input checked="" type="checkbox"/> / Req <input type="checkbox"/> (2023-2030) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock	
14.8	Stop date and time, if product was interrupted / withdrawn [hidden] [Stop date and time, if product was interrupted / withdrawn]	[SIF_DC_TMT_DT_TM] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Rec <input checked="" type="checkbox"/> / Req <input type="checkbox"/> (2023-2030) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock	
14.9	If product was interrupted / withdrawn due to the event, did the AE abate? [If product was interrupted / withdrawn due to the event, did the AE abate?]	[AE_WD_AE_ABATE_YNNAK] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No [A:998] <input type="radio"/> N/A [A:996] <input type="radio"/> Unknown	
14.10	Was product reintroduced? [Was product reintroduced?]	[TP_REINTRODUCED_YNNAUK] [A:1] <input checked="" type="radio"/> [grpSIF_DOSE_INFO] Yes [TP_REINTRODUCED_DATE] (DD/MM/YYYY) Date: Req <input checked="" type="checkbox"/> / Rec <input checked="" type="checkbox"/> / Req <input type="checkbox"/> (2023-2030) [SIF_REINTRO_DOSE_INFO] Specify the dose after reintroduction: [A:10] <input type="radio"/> Dose not changed [A:11] <input checked="" type="radio"/> [grpSIF_REINTRO_DOSE_RED] Dose reduced Reduced dose: xxxx.  [SIF_REINTRO_UNIT_RED] Unit: <input checked="" type="radio"/> [cSIF_UNIT_1]  [SIF_REINTRO_FREQ_RED] Frequency: <input checked="" type="radio"/> [cSIF_FREQ_CODE]  [A:12] <input checked="" type="radio"/> [grpSIF_REINTRO_DOSE_INCR] Dose increased [SIF_REINTRO_DOSE_INCR] Increased dose: xxxx.  [SIF_REINTRO_UNIT_INCR] Unit: <input checked="" type="radio"/> [cSIF_UNIT_1]  [SIF_REINTRO_FREQ_INCR] Frequency: <input checked="" type="radio"/> [cSIF_FREQ_CODE]  [AE_REAPPEAR_YNNAUK] Did the adverse event reappear after reintroduction? [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No [A:998] <input type="radio"/> N/A [A:996] <input type="radio"/> Unknown  [A:2] <input type="radio"/> No [A:998] <input type="radio"/> N/A [A:996] <input type="radio"/> Unknown	
14.11	Product name in Argus [hidden] [Product name in Argus]	[SIF_TRIAL_DRUG_CODE_ARG] [N:1] <input checked="" type="radio"/> Blinded Semaglutide	
15.	Date of assessment	Description of assessment	Result of assessment
15.1	Relevant assessments and laboratory data/vital signs (performed to confirm the event and/or its outcome) Entry [sctSIF_LAB]		
15.2*	Assessment index number [hidden] [Assessment index number]	[SIF_ASSESSMENT_INDEX] N3	
15.3*	Date of assessment [Date of assessment]	[SIF_ASSESSMENT_DATE] (DD/MM/YYYY) Req/Unk <input checked="" type="checkbox"/> / Rec <input checked="" type="checkbox"/> / Req <input type="checkbox"/> (2023-2030)	
15.4*	Description of assessment [Description of assessment]	[SIF_ASSESSMENT_DESC] A80	
15.5	Result of assessment [Result of assessment]	[grpSIF_ASSESSMENT_RESULT] [SIF_ASSESS_UNIT_RESULT] 0 < xxxx.  [SIF_ASSESS_UNIT] [A:1] <input checked="" type="radio"/> [SIF_ASSESS_UNIT_LIST] [cSIF_ASSESS_UNIT_LIST] [A:999] <input checked="" type="radio"/> [SIF_ASSESS_UNIT_OTHER] Other unit, specify: A25  [SIF_ASSESS_RESULT] Specify if non-numeric result: A600	
15.6	Reference range Use same unit for reference ranges as the reported result. If result of assessment is non-numeric N/A should be selected [Reference range]	[grpSIF_ASSESS_REF_RANGE] [SIF_ASSESS_REF_RANGE_L] Lower normal limit: A50 [SIF_ASSESS_REF_RANGE_H] Upper normal limit: A50 [SIF_ASSESS_NA] [A:996] <input type="radio"/> N/A	
16.	Office use only Item used for SAE notification [hidden] [Office Use]	[SAE_OFFICE] N3	
17.	Trial drug indication [hidden] [Indication]	[STUDY_INDICAT] A200	

quired [ ✓ ] = Source verification required [ ] = Item is collapsible [ ] = Fixed item  
 in = Concomitant Medication / Concomitant Medication.  
 Note: Some settings made in InForm will override any settings made in Central Designer.  
 Note: Collapsible items are only available to users who have the rights to edit the item.

**Study Object Descriptions: Safety Information Form**

Type	RefName	Description
Form	SIF	Visit: AE
Item	SIF_SEQ_NO	Calculated in InForm via rule Integrations: A, R - please do not change the refname or format
Item	grpSIF_NO_SIF	Integrations: A, R - please do not change the refname or format
Item	grpSIF_INV_NAME	Integrations: A, R - please do not change the refname or format
Item	DATE_AWARE_SIF	Integrations: A, R - please do not change the refname or format
Item	CONDITION_BL_YNUK	Integrations: A, R - please do not change the refname or format
Item	SIF_TMT_FOR_EVENT	Integrations: A, R - please do not change the refname or format
Item	AETIOLOGY	Integrations: A, R - please do not change the refname or format
Item	grpSIF_EVENT_DESC	Integrations: A, R - please do not change the refname or format
Item	DUN_ID	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	RANDOMISATION_NO_SIF	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	SIF_RAND	Integrations: A, R - please do not change the refname or format
Item	PREG_ONSET_YNUNK	Integrations: A, R - please do not change the refname or format
Item	SIF_DRUG_INDEX	**Item DEACTIVATED** Populated with a rule, used in Argus integration
Item	SIF_TRIAL_DRUG_CODE	Integrations: A, R - please do not change the refname or format
Item	PRODUCT_GIVEN_YN_SIF	Integrations: A, R - please do not change the refname or format
Item	grpSIF_DOSE	Integrations: A, R - please do not change the refname or format
Item	SIF_ROUTE_CODE	Integrations: A, R - please do not change the refname or format
Item	SIF_TMT_STDT	Integrations: A, R - please do not change the refname or format
Item	SIF_DC_TMT_DT	Integrations: A, R - please do not change the refname or format
Item	SIF_TMT_STDT_STTM	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	SIF_DC_TMT_DT_TM	**Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	AE_WD_AE_ABATE_YNNA	Integrations: A, R - please do not change the refname or format
Item	TP_REINTRODUCED_YNNAUNK	Integrations: A, R - please do not change the refname or format
Item	SIF_TRIAL_DRUG_CODE_ARG	Trial product name in Argus to be mapped based on entry in SIF_TRIAL_DRUG_CODE
Item	SIF_ASSESSMENT_INDEX	Populated with a rule, used in Argus integration
Item	SIF_ASSESSMENT_DATE	Integrations: A, R - please do not change the refname or format
Item	SIF_ASSESSMENT_DESC	Integrations: A, R - please do not change the refname or format
Item	grpSIF_ASSESSMENT_RESULT	Integrations: A, R - please do not change the refname or format
Item	grpSIF_ASSESSMENT_REF_RANGE	Integrations: A, R - please do not change the refname or format
Item	SAE_OFFICE	Item used for SAE notification
Item	STUDY_INDICAT	Populated by a rule in InForm

**Codelist Values Tables: Safety Information Form**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cCONDITION_BL_YNUK	String		No	2	citmCONDITION_BL_N	CONDITION_BL_YNUK
			Yes	1	citmCONDITION_BL_Y	
			Unknown	996	citmCONDITION_BL_UK	
cINCR_EXAC_SYMPT	String		Yes	1	citmINCR_EXAC_SYMPT_Y	INCR_EXAC_SYMPT
			No	2	citmINCR_EXAC_SYMPT_N	
			Unknown	996	citmINCR_EXAC_SYMPT_UK	
cSIF_TMT_FOR_EVENT	String		No	2	citmSIF_TMT_FOR_EVENT_N	SIF_TMT_FOR_EVENT
			Yes	1	citmSIF_TMT_FOR_EVENT_Y	
			Unknown	996	citmSIF_TMT_FOR_EVENT_UNK	
cAETIOLOGY	String		Underlying disease, specify:	1	citmAETIOLOGY_1	AETIOLOGY
			Concomitant medication, specify:	2	citmAETIOLOGY_2	
			Other, specify:	3	citmAETIOLOGY_3	
			Unknown	996	citmAETIOLOGY_4	
cSIF_CM_AE	String		No	2	citmSIF_CM2	SIF_CM_AE
			Yes	1	citmSIF_CM1	
			Unknown	996	citmSIF_CM996	
cSIF RAND_YNNA	String		No	2	citmSIF RAND_N	SIF RAND
			Yes	1	citmSIF RAND_Y	
			N/A	998	citmSIF RAND_NA	
cPREG_ONSET_YNNAUNK	String		No	2	citmPREG_ONSET_N	PREG_ONSET_YNUNK
			Yes	1	citmPREG_ONSET_Y	
			Unknown	996	citmPREG_ONSET_UNK	
cSIF_TRIAL_DRUG_CODE	Integer	1 - cSIF_TRIAL_DRUG_CODE	Semaglutide/Semaglutide placebo	1	citmSIF_TRIAL_DRUG_CODE1	SIF_TRIAL_DRUG_CODE
cPRODUCT_GIVEN_YN	String		Yes	1	citmPRODUCT_GIVEN_Y	PRODUCT_GIVEN_YN_SIF
cSIF_UNIT	String		No	2	citmPRODUCT_GIVEN_N	
cSIF_FREQ_CODE	String		mg	160	citmSIF_UNIT13	SIF_UNIT
cSIF_ROUTE_CODE	String	1 - cSIF_ROUTE_CODE	Once per week	21	citmSIF_FREQ_CODE_21	SIF_FREQ
cSIF_ROUTE_CODE	String		Subcutaneous	058	citmSIF_ROUTE_CODE58	SIF_ROUTE_CODE
cAE_WD_AE_ABATE_YNNA	String		Yes	1	citmAE_WD_AE_ABATE_Y	AE_WD_AE_ABATE_YNNA
cTP_REINTRODUCED_YNNAUNK	String		No	2	citmTP_REINTRODUCED_N	
cTP_REINTRODUCED_YNNAUNK			N/A	998	citmTP_REINTRODUCED_NA	
cTP_REINTRODUCED_YNNAUNK			Unknown	996	citmTP_REINTRODUCED_UNK	
cSIF REINTRO DOSE_INFO	String		Dose not changed	10	citmSIF REINTRO DOSE_INFO SAME	SIF REINTRO DOSE_INFO
cSIF REINTRO DOSE_INFO			Dose reduced	11	citmSIF REINTRO DOSE_INFO_RED	
cSIF REINTRO DOSE_INFO			Dose increased	12	citmSIF REINTRO DOSE_INFO_INCR	
cSIF UNIT_1	String		mg	160	citmNEW_DAILY_DOSE4	SIF REINTRO UNIT_RED, SIF REINTRO UNIT_INCR
cAE REAPPEAR YNNAUNK	String		Yes	1	citmAE REAPPEAR_Y	AE REAPPEAR_YNNAUNK
cAE REAPPEAR YNNAUNK			No	2	citmAE REAPPEAR_N	

			N/A	998	ctmAE_REAPPEAR_NA	
			Unknown	996	ctmAE_REAPPEAR_UNK	
cSIF_TRIAL_CODE_ARG	Integer	1 - cSIF_TRIAL_DRUG_CODE_ARG	Blinded Semaglutide	1	ctmSIF_TRIAL_DRUG_CODE_ARG1	SIF_TRIAL_DRUG_CODE_ARG
cSIF_ASSESSMENT_UNIT	String		Unit pull down list 2	1	ctmSIF_ASSESSMENT_UNIT_1	SIF_ASSESSMENT_UNIT
			OTHER	999	ctmSIF_ASSESSMENT_UNIT_OTHER	
cSIF_ASSESSMENT_UNIT_LIST	String		pg	100	ctmSIF_ASSESSMENT_UNIT_100	SIF_ASSESSMENT_UNIT_LIST
			pg/mL	101	ctmSIF_ASSESSMENT_UNIT_101	
			pg/L	102	ctmSIF_ASSESSMENT_UNIT_102	
			ng	120	ctmSIF_ASSESSMENT_UNIT_120	
			ng/mL	121	ctmSIF_ASSESSMENT_UNIT_121	
			ng/dL	122	ctmSIF_ASSESSMENT_UNIT_122	
			ng/L	123	ctmSIF_ASSESSMENT_UNIT_123	
			ug	140	ctmSIF_ASSESSMENT_UNIT_140	
			ug/mL	141	ctmSIF_ASSESSMENT_UNIT_141	
			ug/dL	142	ctmSIF_ASSESSMENT_UNIT_142	
			ug/L	143	ctmSIF_ASSESSMENT_UNIT_143	
			ug/100 mL	149	ctmSIF_ASSESSMENT_UNIT_149	
			mg	160	ctmSIF_ASSESSMENT_UNIT_160	
			mg/mL	161	ctmSIF_ASSESSMENT_UNIT_161	
			mg/dL	162	ctmSIF_ASSESSMENT_UNIT_162	
			mg/L	163	ctmSIF_ASSESSMENT_UNIT_163	
			mg/g	169	ctmSIF_ASSESSMENT_UNIT_169	
			mg/mmol	170	ctmSIF_ASSESSMENT_UNIT_170	
			mg%	171	ctmSIF_ASSESSMENT_UNIT_171	
			mg/uL	177	ctmSIF_ASSESSMENT_UNIT_177	
			g	200	ctmSIF_ASSESSMENT_UNIT_200	
			g/mL	201	ctmSIF_ASSESSMENT_UNIT_201	
			g/dL	202	ctmSIF_ASSESSMENT_UNIT_202	
			g/L	203	ctmSIF_ASSESSMENT_UNIT_203	
			g/uL	208	ctmSIF_ASSESSMENT_UNIT_208	
			g%	211	ctmSIF_ASSESSMENT_UNIT_211	
			mmHg	321	ctmSIF_ASSESSMENT_UNIT_321	
			uL	400	ctmSIF_ASSESSMENT_UNIT_400	
			mL	420	ctmSIF_ASSESSMENT_UNIT_420	
			dL	460	ctmSIF_ASSESSMENT_UNIT_460	
			L	480	ctmSIF_ASSESSMENT_UNIT_480	
			pmol	500	ctmSIF_ASSESSMENT_UNIT_500	
			pmol/L	501	ctmSIF_ASSESSMENT_UNIT_501	
			pmol/min	502	ctmSIF_ASSESSMENT_UNIT_502	
			nmol	520	ctmSIF_ASSESSMENT_UNIT_520	
			nmol/L	521	ctmSIF_ASSESSMENT_UNIT_521	
			umol	540	ctmSIF_ASSESSMENT_UNIT_540	
			umol/L	541	ctmSIF_ASSESSMENT_UNIT_541	
			umol/mL	544	ctmSIF_ASSESSMENT_UNIT_544	
			mmol	560	ctmSIF_ASSESSMENT_UNIT_560	
			mmol/L	561	ctmSIF_ASSESSMENT_UNIT_561	
			mmol/dL	564	ctmSIF_ASSESSMENT_UNIT_564	
			nmol/mL	566	ctmSIF_ASSESSMENT_UNIT_566	
			miU/L	806	ctmSIF_ASSESSMENT_UNIT_806	
			U/mol	809	ctmSIF_ASSESSMENT_UNIT_809	
			U	810	ctmSIF_ASSESSMENT_UNIT_810	
			U/L	811	ctmSIF_ASSESSMENT_UNIT_811	
			U/mL	812	ctmSIF_ASSESSMENT_UNIT_812	
			U/IU	814	ctmSIF_ASSESSMENT_UNIT_814	
			U/mL	819	ctmSIF_ASSESSMENT_UNIT_819	
			miU/mL	826	ctmSIF_ASSESSMENT_UNIT_826	
			IU	830	ctmSIF_ASSESSMENT_UNIT_830	
			IU/L	831	ctmSIF_ASSESSMENT_UNIT_831	
			IU/mL	832	ctmSIF_ASSESSMENT_UNIT_832	
			miU/mL	835	ctmSIF_ASSESSMENT_UNIT_835	
			miU/L	833	ctmSIF_ASSESSMENT_UNIT_833	
			%	850	ctmSIF_ASSESSMENT_UNIT_850	
			NK	996	ctmSIF_ASSESSMENT_UNIT_996	
			ND	997	ctmSIF_ASSESSMENT_UNIT_997	
			NA	998	ctmSIF_ASSESSMENT_UNIT_998	
cSIF_ASSESSMENT_NA	String		Dose Step	798	ctmSIF_ASSESSMENT_UNIT_798	
				996	ctmSIF_ASSESSMENT_NA	SIF_ASSESSMENT_NA

RDE Analytics: RD_SIF		
Data Variable RefName	RD Column Name	Column Data Type
SIF_SEQ_NO	SIF_SEQ_NO	NUMBER
	SIF_SEQ_NO_ND	VARCHAR2
grpAE_NO_SIF	GRPAE_NO_SIF_ND	VARCHAR2
grpAE_NO_SIF - AE_NO_SIF1	AE_NO_SIF1	NUMBER
grpAE_NO_SIF - AE_NO_SIF2	AE_NO_SIF2	NUMBER
grpAE_NO_SIF - AE_NO_SIF3	AE_NO_SIF3	NUMBER
grpAE_NO_SIF - AE_NO_SIF4	AE_NO_SIF4	NUMBER
grpAE_NO_SIF - AE_NO_SIF5	AE_NO_SIF5	NUMBER
grpAE_NO_SIF - AE_NO_SIF6	AE_NO_SIF6	NUMBER
grpAE_NO_SIF - AE_NO_SIF7	AE_NO_SIF7	NUMBER
grpAE_NO_SIF - AE_NO_SIF8	AE_NO_SIF8	NUMBER
grpAE_NO_SIF - AE_NO_SIF9	AE_NO_SIF9	NUMBER
grpAE_NO_SIF - AE_NO_SIF10	AE_NO_SIF10	NUMBER
grpAE_NO_SIF - AE_NO_SIF11	AE_NO_SIF11	NUMBER
grpAE_NO_SIF - AE_NO_SIF12	AE_NO_SIF12	NUMBER
grpSIF_INV_NAME	GRPSIF_INV_NAME_ND	VARCHAR2
grpSIF_INV_NAME - SIF_INV_NAME_1	SIF_INV_NAME_1	VARCHAR2
grpSIF_INV_NAME - SIF_INV_NAME_2	SIF_INV_NAME_2	VARCHAR2
grpSIF_INV_NAME - SIF_INV_NAME_3	SIF_INV_NAME_3	VARCHAR2

-	DATE_AWARE_SIF	DATE
	DATE_AWARE_SIF_DTS	VARCHAR2
	DATE_AWARE_SIF_DTR	VARCHAR2
	DATE_AWARE_SIF_ND	VARCHAR2
CONDITION_BL_YNUK	CONDITION_BL_YNUK_C	VARCHAR2
	CONDITION_BL_YNUK	VARCHAR2
	CONDITION_BL_YNUK_ND	VARCHAR2
CONDITION_BL_YNUK - INCR_EXAC_SYMPT	INCR_EXAC_SYMPT_C	VARCHAR2
	INCR_EXAC_SYMPT	VARCHAR2
SIF_TMT_FOR_EVENT	SIF_TMT_FOR_EVENT_C	VARCHAR2
	SIF_TMT_FOR_EVENT	VARCHAR2
	SIF_TMT_FOR_EVENT_ND	VARCHAR2
AETIOLOGY	AETIOLOGY_ND	VARCHAR2
AETIOLOGY - Underlying disease, specify:	*AETIOLOGY_GPAETIOLOGY_DISEASE_C	VARCHAR2
	*AETIOLOGY_GPAETIOLOGY_DISEASE	VARCHAR2
AETIOLOGY - AETIOLOGY_DISEASE	AETIOLOGY_DISEASE	VARCHAR2
AETIOLOGY - Concomitant medication, specify:	*AETIOLOGY_GPAETIOLOGY_CONCOMMED_C	VARCHAR2
	*AETIOLOGY_GPAETIOLOGY_CONCOMMED	VARCHAR2
AETIOLOGY - AETIOLOGY_CONCOMMED	AETIOLOGY_CONCOMMED	VARCHAR2
AETIOLOGY - Other, specify:	*AETIOLOGY_GPAETIOLOGY_OTHER_C	VARCHAR2
	*AETIOLOGY_GPAETIOLOGY_OTHER	VARCHAR2
AETIOLOGY - AETIOLOGY_OTHER	AETIOLOGY_OTHER	VARCHAR2
AETIOLOGY - Unknown	AETIOLOGY_CITMAETIOLOGY4_C	VARCHAR2
	AETIOLOGY_CITMAETIOLOGY4	VARCHAR2
SIF_CM_AE	SIF_CM_AE_C	VARCHAR2
	SIF_CM_AE	VARCHAR2
	SIF_CM_AE_ND	VARCHAR2
grpSIF_EVENT_DESC	GRPSIF_EVENT_DESC_ND	VARCHAR2
grpSIF_EVENT_DESC - SIF_EVENT_DESC	SIF_EVENT_DESC	VARCHAR2
grpSIF_EVENT_DESC - SIF_EVENT_DESC_2	SIF_EVENT_DESC_2	VARCHAR2
DUN_ID	DUN_ID	NUMBER
	DUN_ID_ND	VARCHAR2
RANDOMISATION_NO_SIF	RANDOMISATION_NO_SIF	NUMBER
	RANDOMISATION_NO_SIF_ND	VARCHAR2
SIF_RAND	SIF_RAND_C	VARCHAR2
	SIF_RAND	VARCHAR2
	SIF_RAND_ND	VARCHAR2
SIF_RAND - SIF_RAND_DATE	SIF_RAND_DATE	DATE
	SIF_RAND_DATE_DTS	VARCHAR2
PREG_ONSET_YNUNK	PREG_ONSET_YNUNK_C	VARCHAR2
	PREG_ONSET_YNUNK	VARCHAR2
	PREG_ONSET_YNUNK_ND	VARCHAR2
SAE_OFFICE	SAE_OFFICE	NUMBER
	SAE_OFFICE_ND	VARCHAR2
STUDY_INDICAT	STUDY_INDICAT	VARCHAR2
	STUDY_INDICAT_ND	VARCHAR2
<b>*RD_SIF_SCTTRIAL_DRUG_INFO_SIF</b>		
SIF_DRUG_INDEX	SIF_DRUG_INDEX	NUMBER
	SIF_DRUG_INDEX_ND	VARCHAR2
SIF_TRIAL_DRUG_CODE	SIF_TRIAL_DRUG_CODE_C	NUMBER
	SIF_TRIAL_DRUG_CODE	VARCHAR2
	SIF_TRIAL_DRUG_CODE_ND	VARCHAR2
PRODUCT_GIVEN_YN_SIF	PRODUCT_GIVEN_YN_SIF_C	VARCHAR2
	PRODUCT_GIVEN_YN_SIF	VARCHAR2
	PRODUCT_GIVEN_YN_SIF_ND	VARCHAR2
grpSIF_DOSE	GRPSIF_DOSE_ND	VARCHAR2
grpSIF_DOSE - SIF_DOSE	SIF_DOSE	FLOAT
grpSIF_DOSE - SIF_UNIT	SIF_UNIT_C	VARCHAR2
	SIF_UNIT	VARCHAR2
grpSIF_DOSE - SIF_FREQ	SIF_FREQ_C	VARCHAR2
	SIF_FREQ	VARCHAR2
SIF_ROUTE_CODE	SIF_ROUTE_CODE_C	VARCHAR2
	SIF_ROUTE_CODE	VARCHAR2
	SIF_ROUTE_CODE_ND	VARCHAR2
SIF_TMT_STDT	SIF_TMT_STDT	DATE
	SIF_TMT_STDT_DTS	VARCHAR2
	SIF_TMT_STDT_ND	VARCHAR2
SIF_DC_TMT_DT	SIF_DC_TMT_DT	DATE
	SIF_DC_TMT_DT_DTS	VARCHAR2
	SIF_DC_TMT_DT_ND	VARCHAR2
SIF_TMT_STDT_STTM	SIF_TMT_STDT_STTM	DATE
	SIF_TMT_STDT_STTM_DTS	VARCHAR2
	SIF_TMT_STDT_STTM_DTR	VARCHAR2
	SIF_TMT_STDT_STTM_ND	VARCHAR2
SIF_DC_TMT_DT_TM	SIF_DC_TMT_DT_TM	DATE
	SIF_DC_TMT_DT_TM_DTS	VARCHAR2
	SIF_DC_TMT_DT_TM_DTR	VARCHAR2
	SIF_DC_TMT_DT_TM_ND	VARCHAR2
AE_WD_AE_ABATE_YNNA	AE_WD_AE_ABATE_YNNA_C	VARCHAR2
	AE_WD_AE_ABATE_YNNA	VARCHAR2
	AE_WD_AE_ABATE_YNNA_ND	VARCHAR2
TP_REINTRODUCED_YNNAUNK	TP_REINTRODUCED_YNNAUNK_C	VARCHAR2
	TP_REINTRODUCED_YNNAUNK	VARCHAR2
	TP_REINTRODUCED_YNNAUNK_ND	VARCHAR2
TP_REINTRODUCED_YNNAUNK - TP_REINTRODUCED_DATE	TP_REINTRODUCED_DATE	DATE
	TP_REINTRODUCED_DATE_DTS	VARCHAR2
TP_REINTRODUCED_YNNAUNK - SIF_REINTRO_DOSE_INFO	SIF_REINTRO_DOSE_INFO_C	VARCHAR2
	SIF_REINTRO_DOSE_INFO	VARCHAR2
TP_REINTRODUCED_YNNAUNK - SIF_REINTRO_DOSE_RED	SIF_REINTRO_DOSE_RED	FLOAT

-	YNNNAUNK - SIF_REINTRO_UNIT_RED	SIF_REINTRO_UNIT_RED_C SIF_REINTRO_UNIT_RED	VARCHAR2 VARCHAR2
TP_REINTROD <sup>n</sup> CEN YNNNAUNK - SIF_REINTRO_FREQ_RED	SIF_REINTRO_FREQ_RED_C SIF_REINTRO_FREQ_RED	VARCHAR2 VARCHAR2	
TP_REINTRODUCED_YNNNAUNK - SIF_REINTRO_DOSE_INCR	SIF_REINTRO_DOSE_INCR	FLOAT	
TP_REINTRODUCED_YNNNAUNK - SIF_REINTRO_UNIT_INCR	SIF_REINTRO_UNIT_INCR	VARCHAR2	
TP_REINTRODUCED_YNNNAUNK - SIF_REINTRO_FREQ_INCR	SIF_REINTRO_FREQ_INCR_C SIF_REINTRO_FREQ_INCR	VARCHAR2 VARCHAR2	
TP_REINTRODUCED_YNNNAUNK - AE_REAPPEAR_YNNNAUNK	AE_REAPPEAR_YNNNAUNK_C AE_REAPPEAR_YNNNAUNK	VARCHAR2 VARCHAR2	
SIF_TRIAL_DRUG_CODE_ARG	SIF_TRIAL_DRUG_CODE_ARG_C SIF_TRIAL_DRUG_CODE_ARG SIF_TRIAL_DRUG_CODE_ARG_ND	NUMBER VARCHAR2 VARCHAR2	
<b>RD_SIF_SCTSIF_LAB</b>			
SIF_ASSMENT_INDEX	SIF_ASSMENT_INDEX SIF_ASSMENT_INDEX_ND	NUMBER VARCHAR2	
SIF_ASSMENT_DATE	SIF_ASSMENT_DATE SIF_ASSMENT_DATE_DTS SIF_ASSMENT_DATE_DTR SIF_ASSMENT_DATE_ND	DATE VARCHAR2 VARCHAR2 VARCHAR2	
SIF_ASSMENT_DESC	SIF_ASSMENT_DESC SIF_ASSMENT_DESC_ND	VARCHAR2 VARCHAR2	
grpSif_ASSMENT_RESULT	GRPSIF_ASSMENT_RESULT_ND	VARCHAR2	
grpSif_ASSMENT_RESULT - SIF_ASSMENT_UNIT_RESULT	SIF_ASSMENT_UNIT_RESULT	FLOAT	
grpSif_ASSMENT_RESULT - SIF_ASSMENT_UNIT	SIF_ASSMENT_UNIT_C SIF_ASSMENT_UNIT	VARCHAR2 VARCHAR2	
grpSif_ASSMENT_RESULT - SIF_ASSMENT_UNIT_LIST	SIF_ASSMENT_UNIT_LIST_C SIF_ASSMENT_UNIT_LIST	VARCHAR2 VARCHAR2	
grpSif_ASSMENT_RESULT - SIF_ASSMENT_UNIT_OTHER	SIF_ASSMENT_UNIT_OTHER	VARCHAR2	
grpSif_ASSMENT_RESULT - SIF_ASSMENT_RESULT	SIF_ASSMENT_RESULT	VARCHAR2	
grpSif_ASSMENT_REF_RANGE	GRPSIF_ASSMENT_REF_RANGE_ND	VARCHAR2	
grpSif_ASSMENT_REF_RANGE - SIF_ASSMENT_REF_RANGE_L	SIF_ASSMENT_REF_RANGE_L	VARCHAR2	
grpSif_ASSMENT_REF_RANGE - SIF_ASSMENT_REF_RANGE_H	SIF_ASSMENT_REF_RANGE_H	VARCHAR2	
grpSif_ASSMENT_REF_RANGE - SIF_ASSMENT_REF_RANGE_NA	SIF_ASSMENT_NA_C SIF_ASSMENT_NA	VARCHAR2 VARCHAR2	

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

COREF=MISADMINISTRATION COMMENT			CO=Comments	FA=Findings About	CE=Clinical Events		
			FACAT=AE REQUIRING ADDITIONAL DATA	CECAT=AE REQUIRING ADDITIONAL DATA			
: Medication Error, Misuse and Abuse (Misadministration) - Repeating Form [MISADMIN]							
#	Io.	Related AE No.	Investigational medicinal product(s)	Type and reason	Other AE(s)		
1					Any hypo(s)		
Study ID: NN9536-4512							
1.	Event number [read-only] [Event No.]					[MISADM_SEQ_NO] N2	<b>CEREFID FAREFID COREFID RELREC:CE.FA</b>
2.*	Related adverse event number [Related AE No.]					[MISADM_AE_NO] N3	<b>CELNKID FALNKID RELREC:CE.AE</b>
3.*	Investigational medicinal product(s) involved in the misadministration [Investigational medicinal product(s)]					[grpMISADM_IMP] [MISADM_IMP] A:1 [Semaglutide/Semaglutide placebo]	<b>FAORRES when FATESTCD=MISADM1</b>
4.*	Type of misadministration and the reason [Type and reason]					[MISADM_TYP] A:1 [MISADM_ACRES] Accidental misadministration: [A:1] Distraction [A:2] Poor eyesight [A:3] Miscalculation [A:4] Mix-up of products [A:5] Dispensing error [A:6] Incorrect handling of product [A:7] [MISADM_ACCOM] Communication issues: [A:11] Misunderstanding of 'instructions for use' [A:12] Misunderstanding of training/verbal instruction [A:999] [MISADM_ACOTH] Other, specify A200	<b>FAORRES when FATESTCD=MISREAS MISCOM in SUPPFA MISREAOT in SUPPFA</b>
	<b>CETERM=ACCIDENTAL MISADMINISTRATION</b>					[A:2] [MISADM_INTRAES] Intentional misadministration (Specify the subject's reason) [A:8] For physical effect [A:9] For psychological effect [A:10] To cause harm [A:999] [MISADM_INTOTH] Other, specify A200	<b>FAORRES when FATESTCD=MISREAS MISREAOT in SUPPFA</b>
	<b>FAOBJ=ACCIDENTAL MISADMINISTRATION</b>						
	<b>FAOBJ=INTENTIONAL MISADMINISTRATION</b>						
	<b>CETERM=INTENTIONAL MISADMINISTRATION</b>						
5.*	Did the subject experience any other adverse event(s) as a result of the misadministration? [Other AE(s)]					[MISADM_AE_YN] A:2 [MISADM_AENO] No [A:1] [grpMISADM_AENO] Yes Adverse Event No.: N3 N3 N3 N3	<b>NOT SUBMITTED RELREC:CE,AE</b>
6.*	Did the subject experience any hypoglycaemic episode(s) as a result of the misadministration? [Any hypo(s)]					[MISADM_HYPO_YN] A:2 [MISADM_HYPONO] No [A:1] [grpMISADM_HYPONO] Yes Hypoglycaemic Episode No.: N3 N3 N3 N3	<b>NOT SUBMITTED RELREC:CE,XH</b>
7.*	Classification <i>Incorrect dose due to mix-up of products should be reported under 'Wrong product(s) administered/used' Incorrect dose due to wrong frequency of administration should be reported under 'Wrong frequency' [Classification]</i>					[MISADM_CLASS] A:1 [MISADM_PROD] Wrong products administered/used [A:999] [MISADM_PRODOTH] Other, specify A200	<b>MISWPROD in SUPPFA</b>
	<b>FAORRES when FATESTCD=MISCLASS</b>					[A:2] [MISADM_FREQ] Wrong frequency of administration [A:1] [MISADM_FREQIOTH] Higher frequency, specify A200	<b>MISWFRRH in SUPPFA</b>
						[A:3] [MISADM_DOSE] Wrong dose administered [A:1] [MISADM_OVERDOSEOTH] Overdose, specify A200	<b>MISWDOD in SUPPFA</b>
						[A:4] [MISADM_RUT] Wrong route of administration [A:1] Intravenous [A:3] Intramuscular [A:999] [MISADM_RUTOOTH] Other, specify A200	<b>MISWRROUT in SUPPFA</b>
						[A:999] [MISADM_CLASSOTH] Other, specify A200	<b>MISCLAOT in SUPPFA</b>
8.	Trial Products [hidden] [Trial Products]					[MISADM_PRODLST] [CMISADM_PRODLST] ✓	
9.	Lower frequency, specify [hidden] [Lower frequency, specify]					[MISADM_FREQLOOTH] A200	
10.	Underdose, specify [hidden] [Underdose, specify]					[MISADM_UNDERDOSEOTH] A200	
11.	Investigational Medicinal product 2 [hidden]					[MISADM_IMP2] A:2 [Investigational Medicinal product 2]	
12.	Investigational Medicinal product 3 [hidden]					[MISADM_IMP3] A:3 [Investigational Medicinal product 3]	
13.						Comment	
13.1	Other relevant information Entry [sctMISADMINCOMM] Comment [Comment]					[MISADM_COMM] A200	<b>COVAL</b>

quired [ ] = Source verification required  
ion critical settings made in InForm will override any settings made in Central Designer.

<b>Study C - Options: Medication Error, Misuse and Abuse</b>		
Type	RefName	Description
Form	MISADMIN	Visit: AE
Item	MISADM_SEQ_NO	Calculated in InForm via a rule
Item	MISADM_AE_NO	Integrations: A - please do not change the refname or format
Item	MISADM_PRODLIST	**Item DEACTIVATED**
Item	MISADM_FREQLOOTH	**Item DEACTIVATED**
Item	MISADM_UNDERDOSEOTH	**Item DEACTIVATED**
Item	MISADM_IMP2	**Item DEACTIVATED**
Item	MISADM_IMP3	**Item DEACTIVATED**

<b>Codelist Values Tables: Medication Error, Misuse and Abuse</b>						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
c MISADM_IMP1	String		Semaglutide/Semaglutide placebo	1	citmMISADM_IMP1	MISADM_IMP1
c MISADM_TYP	String		Accidental misadministration: Intentional misadministration (Specify the subject's reason)	1	citmMISADM_TYP_1	MISADM_TYP
c MISADM_ACCREAS	String		Distraction Poor eyesight Miscalculation Mix-up of products Dispensing error Incorrect handling of product Communication issues Other, specify	1	citmMISADM_ACCREAS1	MISADM_ACCREAS
c MISADM_ACCCOM	String		Misunderstanding of 'instructions for use' Misunderstanding of training/verbal instruction	11	citmMISADM_ACCCOM_1	MISADM_ACCCOM
c MISADM_INTREAS	String		For physical effect For psychological effect To cause harm Other, specify	8	citmMISADM_INTREA1	MISADM_INTREAS
c MISADM_AE_YN	String		No Yes	2	citmMISADM_AE_N	MISADM_AE_YN
c MISADM_HYPO_YN	String		No Yes	2	citmMISADM_HYPO_N	MISADM_HYPO_YN
c MISADM_CLASS	String		Wrong products administered/used Wrong frequency of administration Wrong dose administered Wrong route of administration Other, specify	1	citmMISADM_CLASS_1	MISADM_CLASS
c MISADM_PROD	String		Other, specify	999	citmMISADM_PROD_999	MISADM_PROD
c MISADM_FREQ	String		Higher frequency	1	citmMISADM_FREQ_1	MISADM_FREQ
c MISADM_DOSE	String		Overdose	1	citmMISADM_DOSE1	MISADM_DOSE
c MISADM_RUT	String		Intravenous Intramuscular Other	1	citmMISADM_RUT_1	MISADM_RUT
c MISADM_PRODLIST	String		Product 2 instead of product 1 Product 1 instead of product 2	1	citmMISADM_PRODLIST_1	MISADM_PRODLIST
c MISADM_IMP2	String		Investigational Medicinal product 2	2	citmMISADM_IMP2	MISADM_IMP2
c MISADM_IMP3	String		Investigational Medicinal product 3	3	citmMISADM_IMP3	MISADM_IMP3

<b>RDE Analytics: RD_MISADMIN</b>		
Data Variable RefName	RD Column Name	Column Data Type
MISADM_SEQ_NO	MISADM_SEQ_NO	NUMBER
	MISADM_SEQ_NO_ND	VARCHAR2
MISADM_AE_NO	MISADM_AE_NO	NUMBER
	MISADM_AE_NO_ND	VARCHAR2
grp MISADM_IMP	GRPMISADM_IMP_NO	VARCHAR2
grp MISADM_IMP - Semaglutide/Semaglutide placebo	*MISADM_IMP1_CITMMISADMIMP1_C	VARCHAR2
	*MISADM_IMP1_CITMMISADMIMP1	VARCHAR2
MISADM_TYP	MISADM_TYP_C	VARCHAR2
	MISADM_TYP	VARCHAR2
	MISADM_TYP_ND	VARCHAR2
MISADM_TYP - MISADM_ACCREAS	MISADM_ACCREAS_C	VARCHAR2
	MISADM_ACCREAS	VARCHAR2
MISADM_TYP - MISADM_ACCCOM	MISADM_ACCCOM_C	VARCHAR2
	MISADM_ACCCOM	VARCHAR2
MISADM_TYP - MISADM_ACOTH	MISADM_ACOTH	VARCHAR2
MISADM_TYP - MISADM_INTREAS	MISADM_INTREAS_C	VARCHAR2
	MISADM_INTREAS	VARCHAR2
MISADM_TYP - MISADM_INTOOTH	MISADM_INTOOTH	VARCHAR2
MISADM_AE_YN	MISADM_AE_YN_C	VARCHAR2
	MISADM_AE_YN	VARCHAR2
	MISADM_AE_YN_ND	VARCHAR2
MISADM_AE_YN - MISADM_AE1	MISADM_AE1	NUMBER
MISADM_AE_YN - MISADM_AE2	MISADM_AE2	NUMBER
MISADM_AE_YN - MISADM_AE3	MISADM_AE3	NUMBER
MISADM_AE_YN - MISADM_AE4	MISADM_AE4	NUMBER
MISADM_HYPO_YN	MISADM_HYPO_YN_C	VARCHAR2
	MISADM_HYPO_YN	VARCHAR2
	MISADM_HYPO_YN_ND	VARCHAR2
MISADM_HYPO_YN - MISADM_HYPO1	MISADM_HYPO1	NUMBER
MISADM_HYPO_YN - MISADM_HYPO2	MISADM_HYPO2	NUMBER
MISADM_HYPO_YN - MISADM_HYPO3	MISADM_HYPO3	NUMBER
MISADM_HYPO_YN - MISADM_HYPO4	MISADM_HYPO4	NUMBER
MISADM_CLASS	MISADM_CLASS_C	VARCHAR2
	MISADM_CLASS	VARCHAR2

	MISADM_CLASS_ND	VARCHAR2	
MISADM_C	_PROD	MISADM_PROD_C	VARCHAR2
		MISADM_PROD	VARCHAR2
MISADM_CLASS - MISADM_PRODOTH		MISADM_PRODOTH	VARCHAR2
MISADM_CLASS - MISADM_FREQ		MISADM_FREQ_C	VARCHAR2
		MISADM_FREQ	VARCHAR2
MISADM_CLASS - MISADM_FREQHIOOTH		MISADM_FREQHIOOTH	VARCHAR2
MISADM_CLASS - MISADM_DOSE		MISADM_DOSE_C	VARCHAR2
		MISADM_DOSE	VARCHAR2
MISADM_CLASS - MISADM_OVERDOSEOTH		MISADM_OVERDOSEOTH	VARCHAR2
MISADM_CLASS - MISADM_RUT		MISADM_RUT_C	VARCHAR2
		MISADM_RUT	VARCHAR2
MISADM_CLASS - MISADM_RUTOOTH		MISADM_RUTOOTH	VARCHAR2
MISADM_CLASS - MISADM_CLASSOTH		MISADM_CLASSOTH	VARCHAR2
MISADM_PRODLST		MISADM_PRODLST_C	VARCHAR2
		MISADM_PRODLST	VARCHAR2
		MISADM_PRODLST_ND	VARCHAR2
MISADM_FREQLOOTH		MISADM_FREQLOOTH	VARCHAR2
		MISADM_FREQLOOTH_ND	VARCHAR2
MISADM_UNDERDOSEOTH		MISADM_UNDERDOSEOTH	VARCHAR2
		MISADM_UNDERDOSEOTH_ND	VARCHAR2
MISADM_IMP2		MISADM_IMP2_ND	VARCHAR2
MISADM_IMP2 - Investigational Medicinal product 2	*MISADM_IMP2_CITMMISADMIMP2_C	VARCHAR2	
	*MISADM_IMP2_CITMMISADMIMP2	VARCHAR2	
MISADM_IMP3		MISADM_IMP3_ND	VARCHAR2
MISADM_IMP3 - Investigational Medicinal product 3	*MISADM_IMP3_CITMMISADMIMP3_C	VARCHAR2	
	*MISADM_IMP3_CITMMISADMIMP3	VARCHAR2	
<b>*RD_MISADMIN_SCTMISADMINCOMM</b>			
MISADM_COMM	MISADM_COMM	VARCHAR2	
	MISADM_COMM_ND	VARCHAR2	

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

CO=Comments FA=Findings About CE=Clinical Events														
FACAT=AE REQUIRING ADDITIONAL DATA CECAT=AE REQUIRING ADDITIONAL DATA														
COREF=MALIGNANT NEOPLASM FAOBJ=MALIGNANT NEOPLASM CTERM=MALIGNANT NEOPLASM														
[NEO_SEQ_NO] 0 < N3 CEREFD FAREFD RELREC: CE.FA														
[NEO_AE_NO] 0 < N3 CELNKID FALKID RELREC: CE.AE														
[NEO_EVENT_CODE] [A:1] [NEO_LOCATION] New primary neoplasm (with or without metastasis) Anatomical location of the primary neoplasm (not location of a metastasis): [A:191] Central nervous system [A:163] Upper respiratory system (nares, nasopharynx, oropharynx, larynx, vocal cords, glottis and trachea) [A:173] Lower respiratory system (lungs including bronchi and bronchioles) [A:55] Pleura [A:177] Breast [A:164] Upper gastrointestinal tract (oral cavity, oesophagus, stomach, duodenum) [A:167] Pancreas [A:48] Liver [A:157] Gallbladder (incl. extrahepatic bile ducts) [A:175] Kidney [A:162] Ureter [A:179] Bladder (urinary bladder, urethra) [A:176] Female reproductive system (uterus, cervix, endometrium, vagina, ovary) [A:171] Male reproductive system (testis, penis, prostate) [A:166] [NEO_LOCATION_SKIN] Skin [A:170] Melanoma [A:169] Non-melanoma [A:165] Thyroid gland [A:168] Other Endocrine glands (pituitary gland, parathyroid gland, adrenal gland, pineal gland) [A:49] Bone [A:192] Muscle [A:178] Blood [A:172] Lymph node [A:193] Spleen [A:999] [NEO_LOCATION_OTH] Other Specify: A200														
FAORRES when FATESTCD=PRYSTUOG [NEOPHTYP in SUPPFA]														
Note: FAORRES=Specify if available														
FAORRES when FATESTCD=PRYSTUOG														
[A:2] [NEO_LOCATION2] Recurrence of neoplasm Anatomical location of the previously diagnosed neoplasm: [A:191] Central nervous system [A:163] Upper respiratory system (nares, nasopharynx, oropharynx, larynx, vocal cords, glottis and trachea) [A:173] Lower respiratory system (lungs including bronchi and bronchioles) [A:55] Pleura [A:177] Breast [A:164] Upper gastrointestinal tract (oral cavity, oesophagus, stomach, duodenum) [A:174] Lower gastrointestinal tract (jejunum, ileum, colorectal) [A:167] Pancreas [A:48] Liver [A:157] Gallbladder (incl. extrahepatic bile ducts) [A:175] Kidney [A:162] Ureter [A:179] Bladder (urinary bladder, urethra) [A:176] Female reproductive system (uterus, cervix, endometrium, vagina, ovary) [A:171] Male reproductive system (testis, penis, prostate) [A:166] [grNEO_LOCATION_SKIN2] Skin [A:170] Melanoma [A:169] Non-melanoma [A:165] Thyroid gland [A:168] Other Endocrine glands (pituitary gland, parathyroid gland, adrenal gland, pineal gland) [A:49] Bone [A:192] Muscle [A:178] Blood [A:172] Lymph node [A:193] Spleen [A:999] [NEO_LOCATION_OTH2] Other Specify: A200														
FAORRES when FATESTCD=NEOSPEC [NEOPHTYP in SUPPFA]														
[A:3] [NEO_LOCATION3] Metastasis of previously diagnosed neoplasm Anatomical location of the previously diagnosed neoplasm (not the location of the metastasis): [A:191] Central nervous system [A:163] Upper respiratory system (nares, nasopharynx, oropharynx, larynx, vocal cords, glottis and trachea) [A:173] Lower respiratory system (lungs including bronchi and bronchioles) [A:55] Pleura [A:177] Breast [A:164] Upper gastrointestinal tract (oral cavity, oesophagus, stomach, duodenum) [A:174] Lower gastrointestinal tract (jejunum, ileum, colorectal) [A:167] Pancreas [A:48] Liver [A:157] Gallbladder (incl. extrahepatic bile ducts) [A:175] Kidney [A:162] Ureter [A:179] Bladder (urinary bladder, urethra) [A:176] Female reproductive system (uterus, cervix, endometrium, vagina, ovary) [A:171] Male reproductive system (testis, penis, prostate) [A:166] [grNEO_LOCATION_SKIN3] Skin [A:170] Melanoma [A:169] Non-melanoma [A:165] Thyroid gland [A:168] Other Endocrine glands (pituitary gland, parathyroid gland, adrenal gland, pineal gland) [A:49] Bone [A:192] Muscle [A:178] Blood [A:172] Lymph node [A:193] Spleen [A:999] [NEO_LOCATION_OTH3]														
FAORRES when FATESTCD=NEOSPEC [NEOPHTYP in SUPPFA]														

**FA=Findings About****FACAT=AE REQUIRING ADDITIONAL DATA****Note: FAORRES=Specify if available**

4.\* Were symptoms/signs (including test results) suggestive of this neoplasm present prior to administration of investigational medicinal product (IMP)?  
 Signs/signs includes results of study related procedures (physical examination, laboratory testing etc.) performed prior to first administration of IMP  
 [Symptoms/signs]

**FASCAT=NEOPLASM SIGNS AND SYMPTOMS**Other  
Specify  
A200[A:4]  Metastasis of unknown primary neoplasm[A:2]  No[A:1]  grpNEO\_DISEASE\_WORSE\_NYN 

Yes

[NEO\_SYM\_SUGGEST\_TEXT]

Specify:

A200

**FAORRES when FATESTCD=NEOSPEC****FAORRES when FATESTCD=NEOSYMP**

[NEO\_DISEASE\_WORSENING\_NYN]

Did condition progress (worsen) during the study?

[A:2]  No[A:1]  [NEO\_DISEASE\_WORSE\_TEXT]

Specify:

A200

**FAORRES when FATESTCD=NEOSYPR**

5.\* What led to investigation of the event?  
 [Investigation of event]

**FASCAT=NEOPLASM INVESTIGATION**

[NEO\_INVESTIGA\_EVENT\_CODE]

[A:1]  [NEO\_SIGN\_SYMPTOM\_TEXT]

Signs and symptoms

Specify:

A200

**FAORRES when FATESTCD=NEOREAIN**[A:2]  [NEO\_SCREEN\_DISEASE\_CODE]

Screening for specific disease

[A:3]  Screening programme[A:2]  Personal/family history of this type of neoplasm[A:3]  Incidental finding**NEOSCREE in SUPPFA**

6.\* Was diagnostic imaging performed?  
 [Diagnosis imaging performed]

**Note: FAORRES=Specify if available**

[NEO\_IMAGING\_DIAGNOS\_YN]

[A:2]  No[A:1]  grpNEO\_IMAGING\_DIAGNOSIS 

Yes

[NEO\_DIAGN\_DIAG\_ENDO]

[A:110]  [NEO\_DIAGN\_METHOD\_1\_TEXT]

Endoscopy

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOIMAPE**

[NEO\_DIAGN\_DIAG\_XRAY]

[A:102]  [NEO\_DIAGN\_METHOD\_2\_TEXT]

X-ray

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOXRAY**

[NEO\_DIAGN\_DIAG\_ULTRA]

[A:103]  [NEO\_DIAGN\_METHOD\_3\_TEXT]

Ultrasound

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOULTRA**

[NEO\_DIAGN\_DIAG\_CT]

[A:104]  [NEO\_DIAGN\_METHOD\_4\_TEXT]

CT Scan

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOCT**

[NEO\_DIAGN\_DIAG\_MRI]

[A:105]  [NEO\_DIAGN\_METHOD\_5\_TEXT]

MRI

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOMRI**

[NEO\_DIAGN\_DIAG\_PET]

[A:109]  [NEO\_DIAGN\_METHOD\_6\_TEXT]

PET scan

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOPET**

[NEO\_DIAGN\_DIAG\_PETCT]

[A:107]  [NEO\_DIAGN\_METHOD\_7\_TEXT]

PET/CT scan

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOPETCT**

[NEO\_DIAGN\_DIAG\_PETMRI]

[A:70]  [NEO\_DIAGN\_METHOD\_8\_TEXT]

PET/MRI scan

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOPETMR**

[NEO\_DIAGN\_DIAG\_PETSPEC]

[A:108]  [NEO\_DIAGN\_METHOD\_9\_TEXT]

PET/SPECT scan

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOSPECT**

[NEO\_DIAGN\_DIAG\_OTH]

[A:999]  [NEO\_DIAGN\_METHOD\_10\_TEXT]

Other

Specify imaging result(s) if applicable:

A200

**FAORRES when FATESTCD=NEOIMAOT**

**FA=Findings About****FACAT=AE REQUIRING ADDITIONAL DATA**

7.* Was i mination performed? ✓ If Yes, , y to specify details below [Pathologic examination performed?]	<b>FASCAT=NEOPLASM PATHOLOGIC EXAMINATION</b>		[A:996] Unknown	[NEO_PATHOLOGIC_EXAM_YN] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> Yes	<b>FAORRES when FATESTCD=NEOPATHO</b>	Specify result	Results of the pathologic examination
8.	Index No.	Date of examination	Pathologic examination				
<b>FASCAT=NEOPLASM PATHOLOGIC EXAMINATION</b>							
8.1 Assessment index number [read-only] [Index No.]	<b>NOT SUBMITTED</b>		[NEO_ASSESSMENT_INDEX] N3	[NEO_EXAM_DATE] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Rec <input type="checkbox"/> / Req <input type="checkbox"/> (2023-2030)	<b>FADTC</b>		
8.2* Date of examination ✓ [Date of examination]							
8.3* Pathologic examination based on ✓ [Pathologic examination]			[NEO_SAMPLE_TYPE] [A:142] <input type="radio"/> Biopsy specimen [A:143] <input type="radio"/> Surgical specimen [A:1] <input type="radio"/> Blood		<b>NEOSPEC in SUPPFA</b>		
8.4* Specify results ✓ [Specify result] (including immunostaining, receptor type (if applicable), pathological grading etc.)			[NEO_RESULT_TEXT] A400		<b>FAORRES when FATESTCD=NEOPATH1</b>		
					<b>NEOPATH2 in SUPPFA</b>		
8.5 Specify results of pathologic examination, part 1  Item for data into OC text question (1-200 chars) [hidden] [Pathologic examination, part 1]			[NEO_RESULT_TEXT1] A200				
8.6 Specify results of pathologic examination, part 2  Item for data into OC text question (201-400 chars) [hidden] [Pathologic examination, part 2]			[NEO_RESULT_TEXT2] A200				
8.7* Are results of the pathologic examination showing thyroid neoplasm deriving from the C-cells? ✓ For thyroid neoplasms deriving from the C-cells, specify classification according to the pathologic examination [Results of the pathologic examination]	<b>FASCAT=NEOPLASM PATHOLOGIC EXAMINATION</b>		[NEO_PATH_EXAM_YN] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> grpPATH_EXAM <input type="checkbox"/> Yes	<b>FAORRES when FATESTCD=NEOPATH</b>	[PATH_RESULTS] [A:61] <input type="radio"/> C-cell hyperplasia [A:75] <input type="radio"/> Medullary microcarcinoma (carcinoma in situ) [A:76] <input type="radio"/> Medullary carcinoma	<b>FAORRES when FATESTCD=NEOTYPTH</b>	
			[GEN_TEST_YN] Has any genetic testing for multiple endocrine neoplasia (MEN) been performed? [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> GEN_TEST_CON <input type="checkbox"/> Yes			<b>FAORRES when FATESTCD=NEOGENTE</b>	
			[GEN_TEST_CON] Describe the conclusions: A200			<b>FAORRES when FATESTCD=NEOGENCO</b>	
9.* Is a final pathologic diagnosis available? ✓ [Diagnosis available]			[NEO_FINAL_PATHO_DIAG_YN] [A:2] <input type="radio"/> [NEO_REASON_NOT_DONE_TEXT] No Specify reason: A200		<b>FAORRES when FATESTCD=NEOFIDIA</b>		
			[A:1] <input checked="" type="radio"/> [NEO_FINAL_PATHO_DIAG_TEXT] Yes Specify: A200				
10.* Are results of clinical staging available? ✓ Such as TNM classification or information about metastasis to lymph nodes or other organs [Results available]			[NEO_CLINICAL_STAGING_YN] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [NEO_CLINICAL_STAGING_TEXT] Yes Specify: A200		<b>FAORRES when FATESTCD=NEOCLSTA</b>		
11.* Was any treatment(s) given for this condition? ✓ Update concomitant medication as relevant [Treatment given]	<b>FASCAT=NEOPLASM TREATMENT</b>		[NEO_TREATMENT_YN] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> grpNEO_TREATMENT_Y <input type="checkbox"/> Yes	<b>FAORRES when FATESTCD=NEOTRT</b>	[NEO_TREATMENT_2] [A:2] <input type="checkbox"/> Surgery	<b>FAORRES when FATESTCD=NEOSURG</b>	
			[NEO_TREATMENT_76] [A:76] <input type="checkbox"/> Radiation		[NEO_TREATMENT_5] [A:5] <input type="checkbox"/> Chemotherapy	<b>FAORRES when FATESTCD=NEORADIA</b>	
			[NEO_TREATMENT_77] [A:77] <input type="checkbox"/> Hormonal therapy		[NEO_TREATMENT_78] [A:78] <input type="checkbox"/> Observation	<b>FAORRES when FATESTCD=NEOHORMO</b>	
			[NEO_TREATMENT_79] [A:79] <input type="checkbox"/> Palliative care		[NEO_TREATMENT_121] [A:121] <input type="checkbox"/> Immunotherapy	<b>FAORRES when FATESTCD=NEOPALLI</b>	
			[NEO_TREATMENT_999] [A:999] <input type="checkbox"/> [NEO_TREATMENT_OTH_TEXT] Other Specify: A200			<b>FAORRES when FATESTCD=NEOTRTOT</b>	
12.* Were there any relevant risk/confounding factors identified? ✓ [Any relevant risk/confounding factors identified]	<b>FASCAT=NEOPLASM RISK FACTORS</b>		[NEO_RISK_CON_FACTOR_YN] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> grpNEO_RISK_CON_FACT_YES <input type="checkbox"/> Yes	<b>FAORRES when FATESTCD=NEORISK</b>	[NEO_RISK_CON_FA_1] [A:30] <input type="checkbox"/> [NEO_RISK_CON_FA_1_TEXT] Occupational exposure Specify: A200	<b>FAORRES when FATESTCD=NEOCOEXP</b>	

<p>13.* Has the subject undergone screening procedures for this type of event prior to administration of investigational medicinal product?</p> <p><i>Screening refers to e.g. national screening programmes for breast cancer or colorectal cancer.</i></p> <p><i>Normal: no signs of disease</i>  <i>Abnormal: neoplasm observed</i>  <i>Indeterminate: possible indication of dysplasia/abnormal growth</i>  <i>[Undergone screening procedures]</i></p>	<p><b>FASCAT=NEOPLASM PRIOR SCREENING</b></p> <p><b>FAORRES when FATESTCD=NEOSMOKE</b></p> <p><b>FAORRES when FATESTCD=NEOSUNEX</b></p> <p><b>FAORRES when FATESTCD=NEOFAMHI</b></p> <p><b>FAORRES when FATESTCD=NEORISOT</b></p> <p><b>FAORRES when FATESTCD=NEOPRIOR</b></p> <p><b>FAORRES when FATESTCD=NEOPIMAG</b></p> <p><b>NEOPLAFU in SUPPFA</b></p> <p><b>FAORRES when FATESTCD=NEOPENDO</b></p> <p><b>NEOPLAFU in SUPPFA</b></p> <p><b>FAORRES when FATESTCD=NEOBIOP</b></p> <p><b>NEOPLAFU in SUPPFA</b></p> <p><b>FAORRES when FATESTCD=NEOLAB</b></p> <p><b>NEOPLAFU in SUPPFA</b></p> <p><b>FAORRES when FATESTCD=NEOPOT</b></p> <p><b>NEOPLAFU in SUPPFA</b></p> <p><b>FAORRES when FATESTCD=NEODEXP1</b></p> <p><b>NEOYEAR in SUPPFA</b></p>
<p>14.* Has the subject previously been exposed to GLP-1 (receptor agonist drugs prior to trial start)?</p> <p><i>If exposed less than 1 year, please enter 1 year</i>  <i>[Years of exposure]</i></p>	<p><b>FASCAT=NEOPLASM DRUG EXPOSURE</b></p> <p><b>NEODRUG in SUPPFA</b></p>

**CO=Comments FA=Findings About****COREF=MALIGNANT NEOPLASM FACAT=AE REQUIRING ADDITIONAL DATA**

15.	Has t <sup>h</sup> ~ If exposed less than 1 year, please enter 1 year [hidden] [Years of exposure]	<b>NEODRUG in SUPPFA</b>	0 < N2 [A:996] Unknown  [NEO_DRUG_CLASS_CODE_2] [A:2] No [A:1] <input checked="" type="radio"/> [grpNEO_DUR_YR_2] ☐ Yes [NEO_DURATION_YEAR_2] Number of years 0 < N2  [A:996] Unknown  [NEO_DRUG_CLASS_CODE_3] [A:2] No [A:1] <input checked="" type="radio"/> [grpNEO_DUR_YR_3] ☐ Yes [NEO_DURATION_YEAR_3] Number of years 0 < N2  [A:996] Unknown	<b>FAORRES when FATESTCD=NEODEXP2</b>
16.	Has the subject previously been exposed to [drug class]? If exposed less than 1 year, please enter 1 year [hidden] [Years of exposure]	<b>NEODRUG in SUPPFA</b>	[NEO_DRUG_CLASS_CODE_3] [A:2] No [A:1] <input checked="" type="radio"/> [grpNEO_DUR_YR_3] ☐ Yes [NEO_DURATION_YEAR_3] Number of years 0 < N2  [A:996] Unknown	<b>NEOYEARN in SUPPFA</b>
17.	<b>Sequence number</b>	<b>Information date</b>		<b>Additional information</b>
17.1	Other relevant information (that confirms this event and/or its outcome, e.g. relevant biomarker and genetic testing) Entry [sctNEO_LAB_REL_INFO]			<b>COREFID</b>
17.2*	Date of Information [Information date]		[NEO_INFO_DATE] (DD/MM/YYYY) Req ✓ / Req ✓ / Req ✓ (2023-2030)	<b>CODTC</b>
17.3*	Additional information on event [Additional information]		[NEO_INFO_OTH] A200	<b>COVAL when RDOMAIN=CE</b>

Key: [\*] = Item is required [✓] = Source verification required [☐] = Item is collapsible  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Malignant Neoplasm		
Type	RefName	Description
Form	MALIGNANT_NEOPLASM	Visit: AE This form is a Dynamic form which is to be triggered by the AE form to appear when AE category item #11 = Malignant Neoplasm
Item	NEO_SEQ_NO	Calculated in InForm via rule
Item	NEO_AE_NO	Integrations: A - please do not change the refname or format
Item	NEO_RESULT_TEXT1	Mapping of the characters 1-200 from item 10.3 'Specify results'. Read-only to DM only.
Item	NEO_RESULT_TEXT2	Mapping of the characters 201-400 from item 10.3 'Specify results'. Read-only to DM only.
Item	NEO_DRUG_CLASS_CODE_2	**Item DEACTIVATED**
Item	grpNEO_DUR_YR_2	**Item DEACTIVATED**
Item	NEO_DURATION_YEAR_2	**Item DEACTIVATED**
Item	NEO_DRUG_CLASS_CODE_3	**Item DEACTIVATED**
Item	grpNEO_DUR_YR_3	**Item DEACTIVATED**
Item	NEO_DURATION_YEAR_3	**Item DEACTIVATED**
Section	sctNEO_LAB_REL_INFO	Other relevant information (that confirms this event and/or its outcome, e.g. relevant biomarker and genetic testing)

Codelist Values Tables: Malignant Neoplasm						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cNEOPLASM_EVENT_CODE	String		New primary neoplasm (with or without metastasis)	1	ctmEVENT_CODE_1	NEO_EVENT_CODE
			Recurrence of neoplasm	2	ctmEVENT_CODE_2	
			Metastasis of previously diagnosed neoplasm	3	ctmEVENT_CODE_3	
			Metastasis of unknown primary neoplasm	4	ctmEVENT_CODE_4	
cNEO_LOC_CODE	String		Central nervous system	191	ctmNEO_LOC_CODE191	NEO_LOCATION, NEO_LOCATION2, NEO_LOCATION3
			Upper respiratory system (nares, nasopharynx, oropharynx, larynx, vocal cords, glottis and trachea)	163	ctmNEO_LOC_CODE163	
			Lower respiratory system (lungs including bronchi and bronchioles)	173	ctmNEO_LOC_CODE173	
			Pleura	55	ctmNEO_LOC_CODE55	
			Breast	177	ctmNEO_LOC_CODE177	
			Upper gastrointestinal tract (oral cavity, oesophagus, stomach, duodenum)	164	ctmNEO_LOC_CODE164	
			Lower gastrointestinal tract (jejunum, ileum, colorectal)	174	ctmNEO_LOC_CODE174	
			Pancreas	167	ctmNEO_LOC_CODE167	
			Liver	48	ctmNEO_LOC_CODE48	
			Gallbladder (incl. extrahepatic bile ducts)	157	ctmNEO_LOC_CODE157	
			Kidney	175	ctmNEO_LOC_CODE175	
			Ureter	162	ctmNEO_LOC_CODE162	
			Bladder (urinary bladder, urethra)	179	ctmNEO_LOC_CODE179	
			Female reproductive system (uterus, cervix, endometrium, vagina, ovary)	176	ctmNEO_LOC_CODE176	
			Male reproductive system (testis, penis, prostate)	171	ctmNEO_LOC_CODE171	
			Skin	166	ctmNEO_LOC_CODE166	
			Thyroid gland	165	ctmNEO_LOC_CODE165	
			Other Endocrine glands (pituitary gland, parathyroid gland, adrenal gland, pineal gland)	168	ctmNEO_LOC_CODE168	
			Bone	49	ctmNEO_LOC_CODE49	
			Muscle	192	ctmNEO_LOC_CODE192	
			Blood	178	ctmNEO_LOC_CODE178	
			Lymph node	172	ctmNEO_LOC_CODE172	
			Spleen	193	ctmNEO_LOC_CODE193	
			Other	999	ctmNEO_LOC_CODE999	
cNEO_LOC_SKIN_SPEC	String		Melanoma	170	ctmNEO_LOC_SKIN_SPEC170	NEO_LOCATION_SKIN_SPEC
			Non-melanoma	169	ctmNEO_LOC_SKIN_SPEC169	
cNEO_LOC_SKIN_SPEC2	String		Melanoma	170	ctmNEO_LOC_SKIN_SPEC170_1	NEO_LOCATION_SKIN_SPEC2, NEO_LOCATION_SKIN_SPEC3
			Non-melanoma	169	ctmNEO_LOC_SKIN_SPEC169_1	
cNEO_SYMP_SUGGEST_YN	String		No	2	ctmNEO_SYMP_SUGGEST_YN2	NEO_SYMP_SUGGEST_YN
			Yes	1	ctmNEO_SYMP_SUGGEST_YN1	
cNEO_DISEASE_WORSENING_YN	String		No	2	ctmNEO_DISEASE_WORSENING_YN2	NEO_DISEASE_WORSENING_YN
			Yes	1	ctmNEO_DISEASE_WORSENING_YN1	
cNEO_INVEST EVEN_CODE	String		Signs and symptoms	1	ctmNEO_INVE_EVENT_CODE1	NEO_INVESTIGA_EVENT_CODE
			Screening for specific disease	2	ctmNEO_INVE_EVENT_CODE2	
			Incidental finding	3	ctmNEO_INVE_EVENT_CODE3	
cNEO_SCREEN_DISEASE_CODE	String		Screening programme	3	ctmNEO_SCR_DISEASE_CODE3	NEO_SCREEN_DISEASE_CODE
			Personal/family history of this type of neoplasm	2	ctmNEO_SCR_DISEASE_CODE2	
cNOYESUNK	String		No	2	ctmNOYESUNK2	NEO_IMAGING_DIAGNOS_YN, GEN_TEST_YN

		Yes	1	ctmNOYESUNK1	
		Unknown	996	ctmNOYESUNK996	
cINEO_IMA <sup>G</sup>	ENDO	String	Endoscopy	110	ctmNEO_DIAG_ENDO NEO_DIAG_ENDO
cINEO_IMAG_DIAG_XRAY		String	X-ray	102	ctmNEO_DIAG_XRAY NEO_DIAG_XRAY
cINEO_IMAG_DIAG_ULTRA		String	Ultrasound	103	ctmNEO_DIAG_ULTRA NEO_DIAG_ULTRA
cINEO_IMAG_DIAG_CT		String	CT scan	104	ctmNEO_DIAG_CT NEO_DIAG_CT
cIMAG_IMAG_DIAG_MRI		String	MRI	105	ctmIMAG_DIAG_MRI NEO_DIAG_MRI
cINEO_IMAG_DIAG_PET		String	PET scan	109	ctmNEO_DIAG_PET NEO_DIAG_PET
cINEO_IMAG_DIAG_PETCT		String	PET/CT scan	107	ctmNEO_DIAG_PETCT NEO_DIAG_PETCT
cINEO_IMAG_DIAG_PETMRI		String	PET/MRI scan	70	ctmNEO_DIAG_PETMRI NEO_DIAG_PETMRI
cINEO_IMAG_DIAG_PETSPEC		String	PET/SPECT scan	108	ctmNEO_DIAG_PETSPEC NEO_DIAG_PETSPEC
cINEO_IMAG_DIAG_OTH		String	Other	999	ctmNEO_DIAG_OTH NEO_DIAG_OTH
cINOYES_1_1_1		String	No	2	ctmNOYES2_1_1_1 NEO_PATHOLOGIC_EXAM_YN, FOLLOW_UP_PLAN_YN_1
		Yes	1	ctmNOYES1_1_1	
cINEO_SAMPLE_TYPE		String	Biopsy specimen	142	ctmNEO_SAMPLE_TYPE_142 NEO_SAMPLE_TYPE
			Surgical specimen	143	ctmNEO_SAMPLE_TYPE_143
			Blood	1	ctmNEO_SAMPLE_TYPE_1
cINOYES_1		String	No	2	ctmNOYES2_1 NEO_PATH_EXAM_YN, NEO_RISK_CON_FACTOR_YN
		Yes	1	ctmNOYES1_1	
cI_PATH_RESULTS		String	C-cell hyperplasia	61	ctm_PATH_RESULTS_61 PATH_RESULTS
			Medullary microcarcinoma (carcinoma in situ)	75	ctm_PATH_RESULTS_75
			Medullary carcinoma	76	ctm_PATH_RESULTS_76
cINOYES_2		String	No	2	ctmNOYES2_2 NEO_FINAL_PATHO_DIAG_YN, NEO_CLINICAL_STAGING_YN, FOLLOW_UP_PLAN_YN_2, FOLLOW_UP_PLAN_YN_3, FOLLOW_UP_PLAN_YN_4, FOLLOW_UP_PLAN_YN_5
		Yes	1	ctmNOYES1_2	
cINOYES_3		String	No	2	ctmNOYES2_3 NEO_TREATMENT_YN
		Yes	1	ctmNOYES1_3	
cINEO_TRT_2		String	Surgery	2	ctmNEO_TRT_2 NEO_TREATMENT_2
cINEO_TRT_76		String	Radiation	76	ctmNEO_TRT_76 NEO_TREATMENT_76
cINEO_TRT_5		String	Chemotherapy	5	ctmNEO_TRT_5 NEO_TREATMENT_5
cINEO_TRT_75		String	Hormonal therapy	77	ctmNEO_TRT_75 NEO_TREATMENT_77
cINEO_TRT_78		String	Observation	78	ctmNEO_TRT_78 NEO_TREATMENT_78
cINEO_TRT_79		String	Palliative care	79	ctmNEO_TRT_79 NEO_TREATMENT_79
cINEO_TRT_121		String	Immunotherapy	121	ctmNEO_TRT_121 NEO_TREATMENT_121
cINEO_TRT_999		String	Other	999	ctmNEO_TRT_999 NEO_TREATMENT_999
cINEO_RISK_CON_FA_1		String	Occupational exposure	30	ctmNEO_RISK_CON_FA_1 NEO_RISK_CON_FA_1
cINEO_RISK_CON_FA_2		String	Smoking	31	ctmNEO_RISK_CON_FA_2 NEO_RISK_CON_FA_2
cINEO_RISK_CON_FA_3		String	Sun exposure	32	ctmNEO_RISK_CON_FA_3 NEO_RISK_CON_FA_3
cINEO_RISK_CON_FA_6		String	Family history of neoplasm	35	ctmNEO_RISK_CON_FA_6 NEO_RISK_CON_FA_6
cINEO_RISK_CON_FA_7		String	Other	999	ctmNEO_RISK_CON_FA_7 NEO_RISK_CON_FA_7
cINOYESUNK_3		String	No	2	ctmNOYESUNK_2 NEO_SCREENING_PROC_YN
		Yes	1	ctmNOYESUNK_1	
		Unknown	996	ctmNOYESUNK_996	
cINEO_METHOD_CODE_IMAG		String	Imaging	26	ctmNEO_METHOD_CODE_IMAG NEO_METHOD_CODE_IMAG
cINEO_NORMAL_ABN_CODE		String	Normal	1	ctmNEO_NORMAL_ABN_CODE_1 NEO_NORMAL_ABN_CODE_1
		Abnormal	2	ctmNEO_NORMAL_ABN_CODE_2 NEO_NORMAL_ABN_CODE_2	
		Indeterminate	80	ctmNEO_NORMAL_ABN_CODE_80 NEO_NORMAL_ABN_CODE_4, NEO_NORMAL_ABN_CODE_5	
cINEO_METHOD_CODE_ENDO		String	Endoscopy	110	ctmNEO_METHOD_CODE_ENDO NEO_METHOD_CODE_ENDO
cINEO_METHOD_CODE_BIOP		String	Biopsy	14	ctmNEO_METHOD_CODE_BIOP NEO_METHOD_CODE_BIOP
cINEO_METHOD_CODE_LAB		String	Laboratory tests	15	ctmNEO_METHOD_CODE_LAB NEO_METHOD_CODE_LAB
cINEO_METHOD_CODE_OTH		String	Other	999	ctmNEO_METHOD_CODE_OTH NEO_METHOD_CODE_OTH
cINEO_DRUG_CLASS_1		String	No	2	ctmDRUG_CLASS_1_N NEO_DRUG_CLASS_CODE_1
		Yes	1	ctmDRUG_CLASS_1_Y	
		Unknown	996	ctmDRUG_CLASS_1_UNK	
cINEO_DRUG_CLASS_2		String	No	2	ctmDRUG_CLASS_2_N NEO_DRUG_CLASS_CODE_2
		Yes	1	ctmDRUG_CLASS_2_Y	
		Unknown	996	ctmDRUG_CLASS_2_UNK	
cINEO_DRUG_CLASS_3		String	No	2	ctmDRUG_CLASS_3_N NEO_DRUG_CLASS_CODE_3
		Yes	1	ctmDRUG_CLASS_3_Y	
		Unknown	996	ctmDRUG_CLASS_3_UNK	

RDE Analytics: RD_MALIGNANT_NEOPLASM		
Data Variable RefName	RD Column Name	Column Data Type
NEO_SEQ_NO	NEO_SEQ_NO	NUMBER
	NEO_SEQ_NO_ND	VARCHAR2
NEO_AE_NO	NEO_AE_NO	NUMBER
	NEO_AE_NO_ND	VARCHAR2
NEO_EVENT_CODE	NEO_EVENT_CODE_C	VARCHAR2
	NEO_EVENT_CODE	VARCHAR2
	NEO_EVENT_CODE_ND	VARCHAR2
NEO_EVENT_CODE - NEO_LOCATION	NEO_LOCATION_C	VARCHAR2
	NEO_LOCATION	VARCHAR2
NEO_EVENT_CODE - NEO_LOCATION_SKIN_SPEC	NEO_LOCATION_SKIN_SPEC_C	VARCHAR2
	NEO_LOCATION_SKIN_SPEC	VARCHAR2
NEO_EVENT_CODE - NEO_LOCATION_OTH	NEO_LOCATION_OTH	VARCHAR2
NEO_EVENT_CODE - NEO_LOCATION2	NEO_LOCATION2_C	VARCHAR2
	NEO_LOCATION2	VARCHAR2
NEO_EVENT_CODE - NEO_LOCATION_SKIN_SPEC2	NEO_LOCATION_SKIN_SPEC2_C	VARCHAR2
	NEO_LOCATION_SKIN_SPEC2	VARCHAR2
NEO_EVENT_CODE - NEO_LOCATION_OTH2	NEO_LOCATION_OTH2	VARCHAR2
NEO_EVENT_CODE - NEO_LOCATION3	NEO_LOCATION3_C	VARCHAR2
	NEO_LOCATION3	VARCHAR2
NEO_EVENT_CODE - NEO_LOCATION_SKIN_SPEC3	NEO_LOCATION_SKIN_SPEC3_C	VARCHAR2
	NEO_LOCATION_SKIN_SPEC3	VARCHAR2
NEO_EVENT_CODE - NEO_LOCATION_OTH3	NEO_LOCATION_OTH3	VARCHAR2
NEO_SYMP_SUGGEST_YN	NEO_SYMP_SUGGEST_YN_C	VARCHAR2
	NEO_SYMP_SUGGEST_YN	VARCHAR2
	NEO_SYMP_SUGGEST_YN_ND	VARCHAR2

..	T_YN - NEO_SYM_SUGGEST_TEXT	NEO_SYM_SUGGEST_TEXT	VARCHAR2
NEO_SYM	N - NEO_DISEASE_WORSENING_YN	NEO_DISEASE_WORSENING_YN_C	VARCHAR2
		NEO_DISEASE_WORSENING_YN	VARCHAR2
NEO_SYM_SUGGEST_YN - NEO_DISEASE_WORSE_TEXT	NEO_DISEASE_WORSE_TEXT	VARCHAR2	
NEO_INVESTIGA_EVENT_CODE	NEO_INVESTIGA_EVENT_CODE_C	VARCHAR2	
	NEO_INVESTIGA_EVENT_CODE	VARCHAR2	
	NEO_INVESTIGA_EVENT_CODE_ND	VARCHAR2	
NEO_INVESTIGA_EVENT_CODE - NEO_SIGN_SYMPTOM_TEXT	NEO_SIGN_SYMPTOM_TEXT	VARCHAR2	
NEO_INVESTIGA_EVENT_CODE - NEO_SCREEN_DISEASE_CODE	NEO_SCREEN_DISEASE_CODE_C	VARCHAR2	
	NEO_SCREEN_DISEASE_CODE	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN	NEO_IMAGING_DIAGNOS_YN_C	VARCHAR2	
	NEO_IMAGING_DIAGNOS_YN	VARCHAR2	
	NEO_IMAGING_DIAGNOS_YN_ND	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - Endoscopy	*NEO_IMAG_DIAG_ENDO_NEO_DIAGNO_METHOD_1_TEXT_C	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_1_TEXT	*NEO_IMAG_DIAG_ENDO_NEO_DIAGNO_METHOD_1_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - X-ray	*NEO_IMAG_DIAG_XRAY_NEO_DIAGNO_METHOD_2_TEXT_C	VARCHAR2	
	*NEO_IMAG_DIAG_XRAY_NEO_DIAGNO_METHOD_2_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_2_TEXT	NEO_DIAGNO_METHOD_2_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - Ultrasound	*NEO_IMAG_DIAG_ULTRA_NEO_DIAGNO_METHOD_3_TEXT_C	VARCHAR2	
	*NEO_IMAG_DIAG_ULTRA_NEO_DIAGNO_METHOD_3_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_3_TEXT	NEO_DIAGNO_METHOD_3_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - CT scan	*NEO_IMAG_DIAG_CT_NEO_DIAGNO_METHOD_4_TEXT_C	VARCHAR2	
	*NEO_IMAG_DIAG_CT_NEO_DIAGNO_METHOD_4_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_4_TEXT	NEO_DIAGNO_METHOD_4_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - MRI	*NEO_IMAG_DIAG_MRI_NEO_DIAGNO_METHOD_5_TEXT_C	VARCHAR2	
	*NEO_IMAG_DIAG_MRI_NEO_DIAGNO_METHOD_5_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_5_TEXT	NEO_DIAGNO_METHOD_5_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - PET scan	*NEO_IMAG_DIAG_PET_NEO_DIAGNO_METHOD_6_TEXT_C	VARCHAR2	
	*NEO_IMAG_DIAG_PET_NEO_DIAGNO_METHOD_6_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_6_TEXT	NEO_DIAGNO_METHOD_6_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - PET/CT scan	*NEO_IMAG_DIAG_PETCT_NEO_DIAGNO_METHOD_7_TEXT_C	VARCHAR2	
	*NEO_IMAG_DIAG_PETCT_NEO_DIAGNO_METHOD_7_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_7_TEXT	NEO_DIAGNO_METHOD_7_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - PET/MRI scan	*NEO_IMAG_DIAG_PETMRI_NEO_DIAGNO_METHOD_8_TEXT_C	VARCHAR2	
	*NEO_IMAG_DIAG_PETMRI_NEO_DIAGNO_METHOD_8_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_8_TEXT	NEO_DIAGNO_METHOD_8_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - PET/SPECT scan	*NEO_IMAG_DIAG_PETSPEC_NEO_DIAGNO_METHOD_9_TEXT_C	VARCHAR2	
	*NEO_IMAG_DIAG_PETSPEC_NEO_DIAGNO_METHOD_9_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_9_TEXT	NEO_DIAGNO_METHOD_9_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - Other	*NEO_IMAG_DIAG_OTH_NEO_DIAGNO_METHOD_10_TEXT_C	VARCHAR2	
	*NEO_IMAG_DIAG_OTH_NEO_DIAGNO_METHOD_10_TEXT	VARCHAR2	
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_10_TEXT	NEO_DIAGNO_METHOD_10_TEXT	VARCHAR2	
NEO_PATHOLOGIC_EXAM_YN	NEO_PATHOLOGIC_EXAM_YN_C	VARCHAR2	
	NEO_PATHOLOGIC_EXAM_YN	VARCHAR2	
	NEO_PATHOLOGIC_EXAM_YN_ND	VARCHAR2	
NEO_FINAL_PATHO_DIAG_YN	NEO_FINAL_PATHO_DIAG_YN_C	VARCHAR2	
	NEO_FINAL_PATHO_DIAG_YN	VARCHAR2	
	NEO_FINAL_PATHO_DIAG_YN_ND	VARCHAR2	
NEO_FINAL_PATHO_DIAG_YN - NEO_REASON_NOT_DONE_TEXT	NEO_REASON_NOT_DONE_TEXT	VARCHAR2	
NEO_FINAL_PATHO_DIAG_YN - NEO_FINAL_PATHO_DIA_TEXT	NEO_FINAL_PATHO_DIA_TEXT	VARCHAR2	
NEO_CLINICAL_STAGING_YN	NEO_CLINICAL_STAGING_YN_C	VARCHAR2	
	NEO_CLINICAL_STAGING_YN	VARCHAR2	
	NEO_CLINICAL_STAGING_YN_ND	VARCHAR2	
NEO_CLINICAL_STAGING_YN - NEO_CLINICAL_STAGING_TEXT	NEO_CLINICAL_STAGING_TEXT	VARCHAR2	
NEO_TREATMENT_YN	NEO_TREATMENT_YN_C	VARCHAR2	
	NEO_TREATMENT_YN	VARCHAR2	
	NEO_TREATMENT_YN_ND	VARCHAR2	
NEO_TREATMENT_YN - Surgery	*NEO_TREATMENT_2_CITMNEOTRT2_C	VARCHAR2	
	*NEO_TREATMENT_2_CITMNEOTRT2	VARCHAR2	
NEO_TREATMENT_YN - Radiation	*NEO_TREATMENT_76_CITMNEOTRT76_C	VARCHAR2	
	*NEO_TREATMENT_76_CITMNEOTRT76	VARCHAR2	
NEO_TREATMENT_YN - Chemotherapy	*NEO_TREATMENT_5_CITMNEOTRT5_C	VARCHAR2	
	*NEO_TREATMENT_5_CITMNEOTRT5	VARCHAR2	
NEO_TREATMENT_YN - Hormonal therapy	*NEO_TREATMENT_77_CITMNEOTRT75_C	VARCHAR2	
	*NEO_TREATMENT_77_CITMNEOTRT75	VARCHAR2	
NEO_TREATMENT_YN - Observation	*NEO_TREATMENT_78_CITMNEOTRT78_C	VARCHAR2	
	*NEO_TREATMENT_78_CITMNEOTRT78	VARCHAR2	
NEO_TREATMENT_YN - Palliative care	*NEO_TREATMENT_79_CITMNEOTRT79_C	VARCHAR2	
	*NEO_TREATMENT_79_CITMNEOTRT79	VARCHAR2	
NEO_TREATMENT_YN - Immunotherapy	*NEO_TREATMENT_121_CITMNEOTRT121_C	VARCHAR2	
	*NEO_TREATMENT_121_CITMNEOTRT121	VARCHAR2	
NEO_TREATMENT_YN - Other	*NEO_TREATMENT_999_NEO_TREATMENT_OTH_TEXT_C	VARCHAR2	
	*NEO_TREATMENT_999_NEO_TREATMENT_OTH_TEXT	VARCHAR2	
NEO_TREATMENT_YN - NEO_TREATMENT_OTH_TEXT	NEO_TREATMENT_OTH_TEXT	VARCHAR2	
NEO_RISK_CON_FACTOR_YN	NEO_RISK_CON_FACTOR_YN_C	VARCHAR2	
	NEO_RISK_CON_FACTOR_YN	VARCHAR2	
	NEO_RISK_CON_FACTOR_YN_ND	VARCHAR2	
NEO_RISK_CON_FACTOR_YN - Occupational exposure	*NEO_RISK_CON_FA_1_NEO_RISK_CON_FA_1_TEXT_C	VARCHAR2	
	*NEO_RISK_CON_FA_1_NEO_RISK_CON_FA_1_TEXT	VARCHAR2	
NEO_RISK_CON_FACTOR_YN - NEO_RISK_CON_FA_1_TEXT	NEO_RISK_CON_FA_1_TEXT	VARCHAR2	
NEO_RISK_CON_FACTOR_YN - Smoking	*NEO_RISK_CON_FA_2_NEO_RISK_CON_FA_2_TEXT_C	VARCHAR2	
	*NEO_RISK_CON_FA_2_NEO_RISK_CON_FA_2_TEXT	VARCHAR2	
NEO_RISK_CON_FACTOR_YN - NEO_RISK_CON_FA_2_TEXT	NEO_RISK_CON_FA_2_TEXT	VARCHAR2	
NEO_RISK_CON_FACTOR_YN - Sun exposure	*NEO_RISK_CON_FA_3_NEO_RISK_CON_FA_3_TEXT_C	VARCHAR2	
	*NEO_RISK_CON_FA_3_NEO_RISK_CON_FA_3_TEXT	VARCHAR2	
NEO_RISK_CON_FACTOR_YN - NEO_RISK_CON_FA_3_TEXT	NEO_RISK_CON_FA_3_TEXT	VARCHAR2	
NEO_RISK_CON_FACTOR_YN - Family history of neoplasm	*NEO_RISK_CON_FA_6_NEO_RISK_CON_FA_6_TEXT_C	VARCHAR2	
	*NEO_RISK_CON_FA_6_NEO_RISK_CON_FA_6_TEXT	VARCHAR2	

..	*TOR_YN - NEO_RISK_CON_FA_6_TEXT	NEO_RISK_CON_FA_6_TEXT	VARCHAR2
NEO_RISK_CON_FA_6_YN	**TOR_YN - Other	*NEO_RISK_CON_FA_7_NEO_RISK_CON_FA_7_TEXT_C	VARCHAR2
		*NEO_RISK_CON_FA_7_NEO_RISK_CON_FA_7_TEXT	VARCHAR2
NEO_RISK_CON_FACTOR_YN - NEO_RISK_CON_FA_7_TEXT	NEO_RISK_CON_FA_7_TEXT	NEO_RISK_CON_FA_7_TEXT	VARCHAR2
NEO_SCREENING_PROC_YN	NEO_SCREENING_PROC_YN_C	NEO_SCREENING_PROC_YN	VARCHAR2
	NEO_SCREENING_PROC_YN	NEO_SCREENING_PROC_YN	VARCHAR2
	NEO_SCREENING_PROC_YN_ND	NEO_SCREENING_PROC_YN_ND	VARCHAR2
NEO_SCREENING_PROC_YN - Imaging	*NEO_METHOD_CODE_IMAG_GRP_NEO_METHOD_IMAG_C	*NEO_METHOD_CODE_IMAG_GRP_NEO_METHOD_IMAG	VARCHAR2
	*NEO_METHOD_CODE_IMAG_GRP_NEO_METHOD_IMAG	NEO_METHOD_CODE_IMAG_GRP_NEO_METHOD_IMAG	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_1_DATE	NEO_PROCEDURE_1_DATE	NEO_PROCEDURE_1_DATE	DATE
	NEO_PROCEDURE_1_DATE_DTS	NEO_PROCEDURE_1_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_1_DATE_DTR	NEO_PROCEDURE_1_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_1	NEO_NORMAL_ABN_CODE_1_C	NEO_NORMAL_ABN_CODE_1	VARCHAR2
	NEO_NORMAL_ABN_CODE_1	NEO_NORMAL_ABN_CODE_1	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_1	FOLLOW_UP_PLAN_YN_1_C	FOLLOW_UP_PLAN_YN_1	VARCHAR2
	FOLLOW_UP_PLAN_YN_1	FOLLOW_UP_PLAN_YN_1	VARCHAR2
NEO_SCREENING_PROC_YN - Endoscopy	*NEO_METHOD_CODE_ENDO_GRP_NEO_METHOD_ENDO_C	*NEO_METHOD_CODE_ENDO_GRP_NEO_METHOD_ENDO	VARCHAR2
	*NEO_METHOD_CODE_ENDO_GRP_NEO_METHOD_ENDO	NEO_METHOD_CODE_ENDO_GRP_NEO_METHOD_ENDO	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_2_DATE	NEO_PROCEDURE_2_DATE	NEO_PROCEDURE_2_DATE	DATE
	NEO_PROCEDURE_2_DATE_DTS	NEO_PROCEDURE_2_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_2_DATE_DTR	NEO_PROCEDURE_2_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_2	NEO_NORMAL_ABN_CODE_2_C	NEO_NORMAL_ABN_CODE_2	VARCHAR2
	NEO_NORMAL_ABN_CODE_2	NEO_NORMAL_ABN_CODE_2	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_2	FOLLOW_UP_PLAN_YN_2_C	FOLLOW_UP_PLAN_YN_2	VARCHAR2
	FOLLOW_UP_PLAN_YN_2	FOLLOW_UP_PLAN_YN_2	VARCHAR2
NEO_SCREENING_PROC_YN - Biopsy	*NEO_METHOD_CODE_BIOP_GRP_NEO_METHOD_BIOP_C	*NEO_METHOD_CODE_BIOP_GRP_NEO_METHOD_BIOP	VARCHAR2
	*NEO_METHOD_CODE_BIOP_GRP_NEO_METHOD_BIOP	NEO_METHOD_CODE_BIOP_GRP_NEO_METHOD_BIOP	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_3_DATE	NEO_PROCEDURE_3_DATE	NEO_PROCEDURE_3_DATE	DATE
	NEO_PROCEDURE_3_DATE_DTS	NEO_PROCEDURE_3_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_3_DATE_DTR	NEO_PROCEDURE_3_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_3	NEO_NORMAL_ABN_CODE_3_C	NEO_NORMAL_ABN_CODE_3	VARCHAR2
	NEO_NORMAL_ABN_CODE_3	NEO_NORMAL_ABN_CODE_3	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_3	FOLLOW_UP_PLAN_YN_3_C	FOLLOW_UP_PLAN_YN_3	VARCHAR2
	FOLLOW_UP_PLAN_YN_3	FOLLOW_UP_PLAN_YN_3	VARCHAR2
NEO_SCREENING_PROC_YN - Laboratory tests	*NEO_METHOD_CODE_LAB_GRP_NEO_METHOD_LAB_C	*NEO_METHOD_CODE_LAB_GRP_NEO_METHOD_LAB	VARCHAR2
	*NEO_METHOD_CODE_LAB_GRP_NEO_METHOD_LAB	NEO_METHOD_CODE_LAB_GRP_NEO_METHOD_LAB	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_4_DATE	NEO_PROCEDURE_4_DATE	NEO_PROCEDURE_4_DATE	DATE
	NEO_PROCEDURE_4_DATE_DTS	NEO_PROCEDURE_4_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_4_DATE_DTR	NEO_PROCEDURE_4_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_4	NEO_NORMAL_ABN_CODE_4_C	NEO_NORMAL_ABN_CODE_4	VARCHAR2
	NEO_NORMAL_ABN_CODE_4	NEO_NORMAL_ABN_CODE_4	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_4	FOLLOW_UP_PLAN_YN_4_C	FOLLOW_UP_PLAN_YN_4	VARCHAR2
	FOLLOW_UP_PLAN_YN_4	FOLLOW_UP_PLAN_YN_4	VARCHAR2
NEO_SCREENING_PROC_YN - Other	*NEO_METHOD_CODE_OTH_GRP_NEO_METHOD_OTH_C	*NEO_METHOD_CODE_OTH_GRP_NEO_METHOD_OTH	VARCHAR2
	*NEO_METHOD_CODE_OTH_GRP_NEO_METHOD_OTH	NEO_METHOD_CODE_OTH_GRP_NEO_METHOD_OTH	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_5_DATE	NEO_PROCEDURE_5_DATE	NEO_PROCEDURE_5_DATE	DATE
	NEO_PROCEDURE_5_DATE_DTS	NEO_PROCEDURE_5_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_5_DATE_DTR	NEO_PROCEDURE_5_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_5	NEO_NORMAL_ABN_CODE_5_C	NEO_NORMAL_ABN_CODE_5	VARCHAR2
	NEO_NORMAL_ABN_CODE_5	NEO_NORMAL_ABN_CODE_5	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_5	FOLLOW_UP_PLAN_YN_5_C	FOLLOW_UP_PLAN_YN_5	VARCHAR2
	FOLLOW_UP_PLAN_YN_5	FOLLOW_UP_PLAN_YN_5	VARCHAR2
NEO_DRUG_CLASS_CODE_1	NEO_DRUG_CLASS_CODE_1_C	NEO_DRUG_CLASS_CODE_1	VARCHAR2
	NEO_DRUG_CLASS_CODE_1	NEO_DRUG_CLASS_CODE_1	VARCHAR2
	NEO_DRUG_CLASS_CODE_1_ND	NEO_DRUG_CLASS_CODE_1_ND	VARCHAR2
NEO_DRUG_CLASS_CODE_1 - NEO_DURATION_YEAR_1	NEO_DURATION_YEAR_1	NEO_DURATION_YEAR_1	NUMBER
NEO_DRUG_CLASS_CODE_2	NEO_DRUG_CLASS_CODE_2_C	NEO_DRUG_CLASS_CODE_2	VARCHAR2
	NEO_DRUG_CLASS_CODE_2	NEO_DRUG_CLASS_CODE_2	VARCHAR2
	NEO_DRUG_CLASS_CODE_2_ND	NEO_DRUG_CLASS_CODE_2_ND	VARCHAR2
NEO_DRUG_CLASS_CODE_2 - NEO_DURATION_YEAR_2	NEO_DURATION_YEAR_2	NEO_DURATION_YEAR_2	NUMBER
NEO_DRUG_CLASS_CODE_3	NEO_DRUG_CLASS_CODE_3_C	NEO_DRUG_CLASS_CODE_3	VARCHAR2
	NEO_DRUG_CLASS_CODE_3	NEO_DRUG_CLASS_CODE_3	VARCHAR2
	NEO_DRUG_CLASS_CODE_3_ND	NEO_DRUG_CLASS_CODE_3_ND	VARCHAR2
NEO_DRUG_CLASS_CODE_3 - NEO_DURATION_YEAR_3	NEO_DURATION_YEAR_3	NEO_DURATION_YEAR_3	NUMBER
<b>*RD_MALIGNANT_NEOPLASM_SCTPATHOLOGIC_EXAMINATION</b>			
NEO_ASSESSMENT_INDEX	NEO_ASSESSMENT_INDEX	NEO_ASSESSMENT_INDEX	NUMBER
	NEO_ASSESSMENT_INDEX_ND	NEO_ASSESSMENT_INDEX_ND	VARCHAR2
NEO_EXAM_DATE	NEO_EXAM_DATE	NEO_EXAM_DATE	DATE
	NEO_EXAM_DATE_DTS	NEO_EXAM_DATE_DTS	VARCHAR2
NEO_SAMPLE_TYPE	NEO_SAMPLE_TYPE_C	NEO_SAMPLE_TYPE	VARCHAR2
	NEO_SAMPLE_TYPE	NEO_SAMPLE_TYPE	VARCHAR2
	NEO_SAMPLE_TYPE_ND	NEO_SAMPLE_TYPE_ND	VARCHAR2
NEO_RESULT_TEXT	NEO_RESULT_TEXT	NEO_RESULT_TEXT	VARCHAR2
	NEO_RESULT_TEXT_ND	NEO_RESULT_TEXT_ND	VARCHAR2
NEO_RESULT_TEXT1	NEO_RESULT_TEXT1	NEO_RESULT_TEXT1	VARCHAR2
	NEO_RESULT_TEXT1_ND	NEO_RESULT_TEXT1_ND	VARCHAR2
NEO_RESULT_TEXT2	NEO_RESULT_TEXT2	NEO_RESULT_TEXT2	VARCHAR2
	NEO_RESULT_TEXT2_ND	NEO_RESULT_TEXT2_ND	VARCHAR2
NEO_PATH_EXAM_YN	NEO_PATH_EXAM_YN_C	NEO_PATH_EXAM_YN	VARCHAR2
	NEO_PATH_EXAM_YN	NEO_PATH_EXAM_YN	VARCHAR2
	NEO_PATH_EXAM_YN_ND	NEO_PATH_EXAM_YN_ND	VARCHAR2
NEO_PATH_EXAM_YN - PATH_RESULTS	PATH_RESULTS_C	PATH_RESULTS	VARCHAR2
	PATH_RESULTS	PATH_RESULTS	VARCHAR2
NEO_PATH_EXAM_YN - GEN_TEST_YN	GEN_TEST_YN_C	GEN_TEST_YN	VARCHAR2
	GEN_TEST_YN	GEN_TEST_YN	VARCHAR2
NEO_PATH_EXAM_YN - GEN_TEST_CON	GEN_TEST_CON	GEN_TEST_CON	VARCHAR2
<b>*RD_MALIGNANT_NEOPLASM_SCTNEO_LAB_REL_INFO</b>			
NEO_REL_NO	NEO_REL_NO	NEO_REL_NO	NUMBER

NEO_NOD_TP	NEO_REL_NO_ND	VARCHAR2
	NEO_INFO_DATE	DATE
	NEO_INFO_DATE_DTS	VARCHAR2
	NEO_INFO_DATE_ND	VARCHAR2
NEO_INFO_OTH	NEO_INFO_OTH	VARCHAR2
	NEO_INFO_OTH_ND	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**LB=Laboratory Test Results FA=Findings About CE=Clinical Events**

: Hepatic Event (Hepatic Event) - Repeating Form [HEPATIC_EVENT]			FACAT=AE REQUIRING ADDITIONAL DATA		CECAT=AE REQUIRING ADDITIONAL DATA	
#	Related AE number	Signs and Symptoms	Laboratory Tests Provide available results from locally analysed laboratory tests at time of this event		Imaging performed?	Liver biopsy performed?
1			[SEQ_NO_HEPATIC] 0 < N3	<b>CEREFID</b> <b>FAREFID</b> <b>LBREFID</b> <b>RELREC: CE.FA</b> <b>RELREC: CE.LB</b>		<b>FAOBJ=HEPATIC EVENT</b>
2.	Related adverse event number [Related AE number]		[AE_NO_HEPATIC] 0 < N3	<b>CELNKID</b> <b>FALKID</b> <b>BLNKID</b> <b>RELREC: CE.AE</b>		<b>CETERM=HEPATIC EVENT</b>
3.*	Were there any signs/symptoms during the course of the event? [Signs and Symptoms]		[SYMPTOMS_A_YN] [A:2] No [A:1] [grpSYMPTOMS_Y] Yes [HEP_PRURITUS] [A:209] [ ] Pruritus [HEP_NAUSEA] [A:25] [ ] Nausea [HEP_VOMITING] [A:71] [ ] Vomiting [HEP_FATIGUE] [A:65] [ ] Fatigue [HEP_ABDOMINAL] [A:54] [ ] Abdominal pain [HEP_GASTRO] [A:210] [ ] Gastrointestinal bleeding [HEP_JAUNDICE] [A:73] [ ] Jaundice [HEP_ASCITES] [A:211] [ ] Ascites [HEP_ENSEPHALOPATHY] [A:212] [ ] Hepatic encephalopathy [HEP_OTH] [A:999] [ ] [grpSYMPTOMS_OTH] Other [HEP_CLIN_SYMP_OTH] Specify: A200	<b>FAORRES when FATESTCD=HEPSYMPT</b> <b>FAORRES when FATESTCD=HEPPRURI</b> <b>FAORRES when FATESTCD=HEPVOMIT</b> <b>FAORRES when FATESTCD=HEPFATIG</b> <b>FAORRES when FATESTCD=HEPGABLE</b> <b>FAORRES when FATESTCD=HEPENCEP</b>		
				<b>Note: FAORRES=Specify if available</b>		
4.	Test	Test done?		Sample collection date	Result	Reference range
	Laboratory Tests Provide available results from locally analysed laboratory tests at time of this event Entry [sctHEPATIC_2]			<b>LBCAT=AE REQUIRING ADDITIONAL DATA</b>		
4.1	Test [Test]			[HEP_LAB_TEST_EVENT] [cHEP_LPARM_CODE] <b>LBTEST/LBTESTCD</b>		
4.2*	Test done? [Test done?]			[HEP_LAB_TEST_YN] [A:1] Yes [A:2] No [A:996] Unknown	<b>NOT SUBMITTED</b>	
4.3	Sample collection date [Sample collection date]			[HEP_COLLECTION_DATE] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Reg <input type="checkbox"/> / Ret <input checked="" type="checkbox"/> (2023-2030)	<b>LBDTC</b>	
4.4	Result [Result]			[grp_HEP_RESULT] [HEP_LVALUE] Result: xxxx. [HEP_LPARM_UNIT] Unit: [cHEP_LPARM_UNIT] <b>LBORRES/LBORRESU</b>		
4.5	Reference range [Reference range]			[grp_HEP_REF_RANGE] [HEP_REF_RANGE_LOW] Lower normal limit: xxxx. [HEP_REF_RANGE_HIGH] Upper normal limit: xxxx.	<b>LORANCOL in SUPPLB</b> <b>HIRANCOL in SUPPLB</b>	
5.*	Was imaging performed? [Imaging performed?]			[IMAGING_A_YN] [A:2] No [A:1] [grpIMAGING_Y] Yes [grpIMAGING] [METHOD_CODE_103] [A:103] [ ] Ultrasound [METHOD_CODE_104] [A:104] [ ] CT Scan [METHOD_CODE_105] [A:105] [ ] MRI [METHOD_CODE_999] [A:999] [ ] [HEP_METHOD_TEXT] Other Specify: A200	<b>FAORRES when FATESTCD=HEPIMAGI</b> <b>FAORRES when FATESTCD=HEPULTRA</b> <b>FAORRES when FATESTCD=HEPCTSCA</b> <b>FAORRES when FATESTCD=HEPMRI</b> <b>FAORRES when FATESTCD=HEPIMAOT</b>	
				[IMAGING_FIND_A_YN] Were the imaging findings abnormal [A:2] No [A:1] [grpIMAGING_A_Y] Yes [ABN_GALL] [A:129] [ ] Gallstones [ABN_ASCITES] [A:130] [ ] Ascites [ABN_STEATOSIS] [A:131] [ ] Steatosis [ABN_LIV_TUMOUR] [A:132] [ ] Liver tumour [ABN_LIV_CYST] [A:133] [ ] Liver cyst [ABN_HP_VT] [A:134] [ ] Hepatic/Portal vein thrombosis [ABN_CIRRHOESIS] [A:135] [ ] Cirrhosis [ABN_OTH] [A:999] [ ] Other [ABNORMAL_TEXT] Specify: A200	<b>FAORRES when FATESTCD=HEPIMABN</b> <b>FAORRES when FATESTCD=HEPGALLS</b> <b>FAORRES when FATESTCD=HEPIMAS</b> <b>FAORRES when FATESTCD=HEPLIVTU</b> <b>FAORRES when FATESTCD=HEPOVET</b> <b>FAORRES when FATESTCD=HEPABIMO</b>	
					<b>Note: FAORRES=Specify if available</b>	

**FASCAT=HEPATIC EVENT SIGNS AND SYMPTOMS**

**FAORRES when FATESTCD=HEPNAUSE**

**FAORRES when FATESTCD=HEPABPAI**

**FAORRES when FATESTCD=HEPJAUND**

**FAORRES when FATESTCD=HEPASCIT**

**FAORRES when FATESTCD=HEPSYMOT**

**LBSCAT=HEPATIC EVENT LABORATORY TEST**

**FAORRES when FATESTCD=HEPSTEAI**

**FAORRES when FATESTCD=HEPLIVCY**

**FAORRES when FATESTCD=HEPCIRRHH**

**FA=Findings About****FACAT=AE REQUIRING ADDITIONAL DATA**

<p>7. Is there a known aetiology to the event? [Please consider non-prescription medications, e.g. herbal and dietary supplement products prior to the event and add to Concomitant Medication form as applicable] [Aetiology to the event?]</p> <p><b>FASCAT=HEPATIC EVENT LIVER BIOPSY</b></p> <p>[BIOPSY_YN] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpBIOPSY_Y] Yes Yes [BIOPSY_DIAGNOS_TEXT] Specify histological diagnosis: A200</p> <p>[A:996] <input type="radio"/> Unknown</p>	<p><b>FAORRES when FATESTCD=HEPLIVRF</b></p> <p><b>FAORRES when FATESTCD=HEPBIDIA</b></p> <p><b>Note: FAORRES=Specify if available</b></p>
<p>7. Is there a known aetiology to the event? [Please consider non-prescription medications, e.g. herbal and dietary supplement products prior to the event and add to Concomitant Medication form as applicable] [Aetiology to the event?]</p> <p><b>FASCAT=HEPATIC EVENT ETIOLOGY</b></p> <p><b>FAORRES when FATESTCD=HEPCV</b></p> <p><b>FAORRES when FATESTCD=HEPCVIHE</b></p> <p><b>FAORRES when FATESTCD=HEPALCLD</b></p> <p><b>FAORRES when FATESTCD=HEPAUIM</b></p> <p><b>FAORRES when FATESTCD=HEPPHYS</b></p>	<p><b>FAORRES when FATESTCD=HEPETIOL</b></p> <p><b>FAORRES when FATESTCD=HEPAVIHE</b></p> <p><b>FAORRES when FATESTCD=HEPNAFLD</b></p> <p><b>FAORRES when FATESTCD=HEPDECIR</b></p> <p><b>FAORRES when FATESTCD=HEPBINGE</b></p> <p><b>FAORRES when FATESTCD=HEPBILPA</b></p> <p><b>FAORRES when FATESTCD=HEPMALI</b></p> <p><b>FAORRES when FATESTCD=HEPAGENT</b></p>
<p>8. Drug-induced liver injury [hidden] [Drug-induced liver injury]</p> <p>9. Did the subject receive treatment(s) for this event? [Remember to update Concomitant Medication form (selecting primary indication 'Adverse event' and entering the same related AE number) if pharmaceutical treatment has been given. [Treatment(s)]]</p> <p><b>FASCAT=HEPATIC EVENT TREATMENT</b></p>	<p><b>DILI_AETIOLOGY_CODE</b> Potentially hepatotoxic agents within 30 days [A:1] <input type="radio"/> Potentially hepatotoxic agents within 30 days [A:99] Other</p> <p><b>TREATMENT_A_YN</b> [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpTREATMENT_TYPE] Yes Yes [TREATMENT_TYPE_131] [A:131] <input type="checkbox"/> Pharmaceutical treatment [TREATMENT_TYPE_999] [A:999] <input type="checkbox"/> [PPTRTMENT_OT] Other Other [TREATMENT_OTHER_1] Specify: A200</p>

Key: [\*] = Item is required    [v] = Source verification required    [ ] = Item is collapsible  
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
 Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Hepatic Event		
Type	RefName	Description
Form	HEPATIC_EVENT	Visit: AF
Item	AE_NO_HEPATIC	Integrations: A, R - please do not change the refname or format
Item	DILI_AETIOLOGY_CODE	**Item DEACTIVATED**

**Codelist Values Tables: Hepatic Event**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIHEP_NY	String		No	2	ctmHEP_NO	SYMPTOMS_A_YN
			Yes	1	ctmHEP_YES	
cIHEP_PRURITUS	String		Pruritus	209	ctmPRURITUS	HEP_PRURITUS
cIHEP_NAUSEA	String		Nausea	25	ctmNAUSEA	HEP_NAUSEA
cIHEP_VOMIT	String		Vomiting	71	ctmVOMIT	HEP_VOMITING
cIHEP_FATIGUE	String		Fatigue	65	ctmFATIGUE	HEP_FATIGUE
cIHEP_ABDOM	String		Abdominal pain	54	ctmABDOM	HEP_ABDOMINAL
cIHEP_GASTRO	String		Gastrointestinal bleeding	210	ctmGASTRO	HEP_GASTRO
cIHEP_JAUNDICE	String		Jaundice	73	ctmJAUNDICE	HEP_JAUNDICE
cIHEP_ASCITES	String		Ascites	211	ctmASCITES	HEP_ASCITES
cIHEP_ENSEPH	String		Hepatic encephalopathy	212	ctmENSEPH	HEP_ENSEPH
cIHEP_OTH	String		Other	999	ctmHEP_OTH	HEP_OTH
cIHEP_LPARM_CODE	String		Alanine Aminotransferase (ALT) Aspartate Aminotransferase (AST) Gamma Glutamyl Transpeptidase (GGT) Total Bilirubin Alkaline phosphatase (ALP) INR Prothrombin time (PT) Albumin Ammonia Sodium Potassium (K) Creatinine C Reactive Protein (CRP) WBC Eosinophils	603 604 91 605 606 41 134 42 135 133 136 627 619 618 138	ctmHEP_ALT ctmHEP_AST ctmHEP_GGT ctmHEP_BIL ctmHEP_ALP ctmHEP_INR ctmHEP_PT ctmHEP_ALB ctmHEP_AMM ctmHEP_SOD ctmHEP_K ctmHEP_CREAT ctmHEP_CRP ctmHEP_WBC ctmHEP_EOS	HEP_LAB_TEST_EVENT

		Platelets	139	ctmHEP_PLATE		
ciHEP_LA_YN	String	Yes	1	ctmHEP_LA_Y	HEP_LAB_TEST_YN	
		No	2	ctmHEP_LA_N		
		Unknown	996	ctmHEP_LA_UNK		
ciHEP_LPARM_UNIT	String	U/L	811	ctmHE_LAB_TESTU1	HEP_LPARM_UNIT	
		mg/dL	162	ctmLPARM_UNIT_162		
		umol/L	541	ctmLPARM_UNIT_541		
		ratio	852	ctmLPARM_UNIT_852		
		s	2	ctmLPARM_UNIT_2		
		g/dL	202	ctmLPARM_UNIT_202		
		g/L	203	ctmLPARM_UNIT_203		
		mg/L	163	ctmLPARM_UNIT_163		
		mmol/L	561	ctmLPARM_UNIT_561		
		10^-9/L	891	ctmLPARM_UNIT_891		
		10^3/uL	893	ctmLPARM_UNIT_893		
		cells/uL	154	ctmLPARM_UNIT_154		
		mEq/L	840	ctmLPARM_UNIT_840		
ciIMAGING_YN_1	String	No	2	ctmIMAGING_N	IMAGING_A_YN	
		Yes	1	ctmIMAGING_Y		
		Unknown	996	ctmIMAGING_UNK		
ciHEPA_IMAGE_ULTRA	String	Ultrasound	103	ctmHEPA_IMAGE_ULTRA	METHOD_CODE_103	
ciHEPA_IMAGE_CT	String	CT Scan	104	ctmHEPA_IMAGE_CT	METHOD_CODE_104	
ciHEPA_IMAGE_MRI	String	MRI	105	ctmHEPA_IMAGE_MRI	METHOD_CODE_105	
ciHEPA_IMAGE_OT	String	Other	999	ctmHEPA_IMAGE_OT	METHOD_CODE_999	
ciIMAGE_ABN_YN	String	No	2	ctmIMAGE_ABN_N	IMAGING_FIND_A_YN	
		Yes	1	ctmIMAGE_ABN_Y		
ciABN_GALL	String	Gallstones	129	ctmABN_GALL	ABN_GALL	
ciABN_ASCITES	String	Ascites	130	ctmABN_ASCITES	ABN_ASCITES	
ciABN_STEATOSIS	String	Steatosis	131	ctmABN_STEATOSIS	ABN_STEATOSIS	
ciABN_LTUMOUR	String	Liver tumour	132	ctmABN_LTUMOUR	ABN_LIV_TUMOUR	
ciABN_LCYST	String	Liver cyst	133	ctmABN_LCYST	ABN_LIV_CYST	
ciABN_HP_VT	String	Hepatic/Portal vein thrombosis	134	ctmABN_HP_VT	ABN_HP_VT	
ciABN_CIRRHOSIS	String	Cirrhosis	135	ctmABN_CIRRHOSIS	ABN_CIRRHOSIS	
ciABN_OTH	String	Other	999	ctmABN_OTH	ABN_OTH	
ciLIVER_BIOPSY	String	No	2	ctmBIOPSY_N	BIOPSY_YN	
		Yes	1	ctmBIOPSY_Y		
		Unknown	996	ctmBIOPSY_UNK		
ciAETIOLOGY_YN	String	No	2	ctmAETIOLOGY_N	AETIOLOGY_YN	
		Yes	1	ctmAETIOLOGY_Y		
ciHE_EVT_CAUSE1	String	Cardiovascular diseases or conditions (e.g. Hypoxic liver injury, Heart failure, Thromboembolic event, Severe hypotension, Right-sided heart failure).	136	ctmHE_EVT_CAUSE1	AETIOLOGY_CODE_136	
ciHE_EVT_CAUSE2	String	Acute viral hepatitis	137	ctmHE_EVT_CAUSE2	AETIOLOGY_CODE_137	
ciHE_EVT_CAUSE3	String	Chronic viral hepatitis	138	ctmHE_EVT_CAUSE3	AETIOLOGY_CODE_138	
ciHE_EVT_CAUSE4	String	Non-alcoholic fatty liver disease	105	ctmHE_EVT_CAUSE4	AETIOLOGY_CODE_105	
ciHE_EVT_CAUSE5	String	Decompenstation of cirrhosis	139	ctmHE_EVT_CAUSE5	AETIOLOGY_CODE_139	
ciHE_EVT_CAUSE6	String	Alcoholic liver disease	140	ctmHE_EVT_CAUSE6	AETIOLOGY_CODE_140	
ciHE_EVT_CAUSE11	String	Binge drinking	145	ctmHE_EVT_CAUSE11	AETIOLOGY_CODE_145	
ciHE_EVT_CAUSE7	String	Autoimmune hepatitis	141	ctmHE_EVT_CAUSE7	AETIOLOGY_CODE_141	
ciHE_EVT_CAUSE8	String	Biliary or pancreatic disorders	142	ctmHE_EVT_CAUSE8	AETIOLOGY_CODE_142	
ciHE_EVT_CAUSE9	String	Malignant disease	143	ctmHE_EVT_CAUSE9	AETIOLOGY_CODE_143	
ciHE_EVT_CAUSE12	String	Extensive physical activity	146	ctmHE_EVT_CAUSE12	AETIOLOGY_CODE_146	
ciHE_EVT_CAUSE10	String	Potentially hepatotoxic agents within 30 days	144	ctmHE_EVT_CAUSE10	AETIOLOGY_CODE_144	
ciDILI_AETIOLOGY_CODE	String	Potentially hepatotoxic agents within 30 days	1	ctmDILI_AETIOLOGY_CODE_1	DILI_AETIOLOGY_CODE	
		Other	999	ctmDILI_AETIOLOGY_CODE_999		
ciTREATMENT_YN	String	1 - TREATMENT_A_YN	No	2	ctmHEP_EVT_TRT_N	TREATMENT_A_YN
		Yes	1	ctmHEP_EVT_TRT_Y		
ciTRT_TYPE_131	String	Pharmaceutical treatment	131	ctmTRT_131	TREATMENT_TYPE_131	
ciTRT_TYPE_999	String	Other	999	ctmTRT_999	TREATMENT_TYPE_999	

RDE Analytics: RD_HEPATIC_EVENT		
Data Variable RefName	RD Column Name	Column Data Type
SEQ_NO_HEPATIC	SEQ_NO_HEPATIC	NUMBER
	SEQ_NO_HEPATIC_ND	VARCHAR2
AE_NO_HEPATIC	AE_NO_HEPATIC	NUMBER
	AE_NO_HEPATIC_ND	VARCHAR2
SYMPTOMS_A_YN	SYMPTOMS_A_YN_C	VARCHAR2
	SYMPTOMS_A_YN	VARCHAR2
	SYMPTOMS_A_YN_ND	VARCHAR2
SYMPTOMS_A_YN - Pruritus	HEP_PRURITUS_CITMPURITUS_C	VARCHAR2
	HEP_PRURITUS_CITMPURITUS	VARCHAR2
SYMPTOMS_A_YN - Nausea	HEP_NAUSEA_CITMNAUSEA_C	VARCHAR2
	HEP_NAUSEA_CITMNAUSEA	VARCHAR2
SYMPTOMS_A_YN - Vomiting	HEP_VOMITING_CITMVOMIT_C	VARCHAR2
	HEP_VOMITING_CITMVOMIT	VARCHAR2
SYMPTOMS_A_YN - Fatigue	HEP_FATIGUE_CITMFATIGUE_C	VARCHAR2
	HEP_FATIGUE_CITMFATIGUE	VARCHAR2
SYMPTOMS_A_YN - Abdominal pain	HEP_ABDOMINAL_CITMABDOM_C	VARCHAR2
	HEP_ABDOMINAL_CITMABDOM	VARCHAR2
SYMPTOMS_A_YN - Gastrointestinal bleeding	HEP_GASTRO_CITMGASTRO_C	VARCHAR2
	HEP_GASTRO_CITMGASTRO	VARCHAR2
SYMPTOMS_A_YN - Jaundice	HEP_JAUNDICE_CITMJAUNDICE_C	VARCHAR2
	HEP_JAUNDICE_CITMJAUNDICE	VARCHAR2
SYMPTOMS_A_YN - Ascites	HEP_ASCITES_CITMASCITES_C	VARCHAR2
	HEP_ASCITES_CITMASCITES	VARCHAR2
SYMPTOMS_A_YN - Hepatic encephalopathy	HEP_ENSEPH_CITMENSEPH_C	VARCHAR2
	HEP_ENSEPH_CITMENSEPH	VARCHAR2
SYMPTOMS_A_YN - Other	HEP_OTH_GRPSSYMPOTMS_OTH_C	VARCHAR2
	HEP_OTH_GRPSSYMPOTMS_OTH	VARCHAR2
SYMPTOMS_A_YN - HEP_CLIN_SYMP_OTH	HEP_CLIN_SYMP_OTH	VARCHAR2
IMAGING_A_YN	IMAGING_A_YN_C	VARCHAR2

	IMAGING_A_YN	IMAGING_A_YN	VARCHAR2
		IMAGING_A_YN_ND	VARCHAR2
		*METHOD_CODE_103_CITMHEPAIMAGEULTRA_C	VARCHAR2
		*METHOD_CODE_103_CITMHEPAIMAGEULTRA	VARCHAR2
	IMAGING_A_YN - CT Scan	*METHOD_CODE_104_CITMHEPAIMAGECT_C	VARCHAR2
		*METHOD_CODE_104_CITMHEPAIMAGECT	VARCHAR2
	IMAGING_A_YN - MRI	*METHOD_CODE_105_CITMHEPAIMAGEMRI_C	VARCHAR2
		*METHOD_CODE_105_CITMHEPAIMAGEMRI	VARCHAR2
	IMAGING_A_YN - Other	*METHOD_CODE_999_HEP_METHOD_TEXT_C	VARCHAR2
		*METHOD_CODE_999_HEP_METHOD_TEXT	VARCHAR2
	IMAGING_A_YN - HEP_METHOD_TEXT	HEP_METHOD_TEXT	VARCHAR2
	IMAGING_A_YN - IMAGING_FIND_A_YN	IMAGING_FIND_A_YN_C	VARCHAR2
		IMAGING_FIND_A_YN	VARCHAR2
	IMAGING_A_YN - Gallstones	ABN_GALL_CITMABNGALL_C	VARCHAR2
		ABN_GALL_CITMABNGALL	VARCHAR2
	IMAGING_A_YN - Ascites	*ABN_ASCITES_CITMABNASCITES_C	VARCHAR2
		*ABN_ASCITES_CITMABNASCITES	VARCHAR2
	IMAGING_A_YN - Steatosis	*ABN_STEATOSIS_CITMABNSTEATOSIS_C	VARCHAR2
		*ABN_STEATOSIS_CITMABNSTEATOSIS	VARCHAR2
	IMAGING_A_YN - Liver tumour	*ABN_LIV_TUMOUR_CITMABNLTUMOUR_C	VARCHAR2
		*ABN_LIV_TUMOUR_CITMABNLTUMOUR	VARCHAR2
	IMAGING_A_YN - Liver cyst	ABN_LIV_CYST_CITMABNLCYST_C	VARCHAR2
		ABN_LIV_CYST_CITMABNLCYST	VARCHAR2
	IMAGING_A_YN - Hepatic/Portal vein thrombosis	ABN_HP_VT_CITMABNHPVT_C	VARCHAR2
		ABN_HP_VT_CITMABNHPVT	VARCHAR2
	IMAGING_A_YN - Cirrhosis	*ABN_CIRRHOSIS_CITMABNCIRRHOSIS_C	VARCHAR2
		*ABN_CIRRHOSIS_CITMABNCIRRHOSIS	VARCHAR2
	IMAGING_A_YN - Other	ABN_OTH_CITMABNOOTH_C	VARCHAR2
		ABN_OTH_CITMABNOOTH	VARCHAR2
	IMAGING_A_YN - ABNORMAL_TEXT	ABNORMAL_TEXT	VARCHAR2
	BIOSPY_YN	BIOSPY_YN_C	VARCHAR2
		BIOSPY_YN	VARCHAR2
		BIOSPY_YN_ND	VARCHAR2
	BIOSPY_YN - BIOPSY_DIAGNOS_TEXT	BIOSPY_DIAGNOS_TEXT	VARCHAR2
	AETIOLOGY_YN	AETIOLOGY_YN_C	VARCHAR2
		AETIOLOGY_YN	VARCHAR2
		AETIOLOGY_YN_ND	VARCHAR2
	AETIOLOGY_YN - Cardiovascular diseases or conditions (e.g. Hypoxic liver injury, Heart failure, Thromboembolic event, Severe hypotension, Right-sided heart failure),	*AETIOLOGY_CODE_136_CITMHEEVTCAUSE1_C	VARCHAR2
		*AETIOLOGY_CODE_136_CITMHEEVTCAUSE1	VARCHAR2
	AETIOLOGY_YN - Acute viral hepatitis	*AETIOLOGY_CODE_137_CITMHEEVTCAUSE2_C	VARCHAR2
		*AETIOLOGY_CODE_137_CITMHEEVTCAUSE2	VARCHAR2
	AETIOLOGY_YN - Chronic viral hepatitis	*AETIOLOGY_CODE_138_CITMHEEVTCAUSE3_C	VARCHAR2
		*AETIOLOGY_CODE_138_CITMHEEVTCAUSE3	VARCHAR2
	AETIOLOGY_YN - Non-alcoholic fatty liver disease	*AETIOLOGY_CODE_105_CITMHEEVTCAUSE4_C	VARCHAR2
		*AETIOLOGY_CODE_105_CITMHEEVTCAUSE4	VARCHAR2
	AETIOLOGY_YN - Decompensation of cirrhosis	*AETIOLOGY_CODE_139_CITMHEEVTCAUSE5_C	VARCHAR2
		*AETIOLOGY_CODE_139_CITMHEEVTCAUSE5	VARCHAR2
	AETIOLOGY_YN - Alcoholic liver disease	*AETIOLOGY_CODE_140_CITMHEEVTCAUSE6_C	VARCHAR2
		*AETIOLOGY_CODE_140_CITMHEEVTCAUSE6	VARCHAR2
	AETIOLOGY_YN - Binge drinking	*AETIOLOGY_CODE_145_CITMHEEVTCAUSE11_C	VARCHAR2
		*AETIOLOGY_CODE_145_CITMHEEVTCAUSE11	VARCHAR2
	AETIOLOGY_YN - Autoimmune hepatitis	*AETIOLOGY_CODE_141_CITMHEEVTCAUSE7_C	VARCHAR2
		*AETIOLOGY_CODE_141_CITMHEEVTCAUSE7	VARCHAR2
	AETIOLOGY_YN - Biliary or pancreatic disorders	*AETIOLOGY_CODE_142_CITMHEEVTCAUSE8_C	VARCHAR2
		*AETIOLOGY_CODE_142_CITMHEEVTCAUSE8	VARCHAR2
	AETIOLOGY_YN - Malignant disease	*AETIOLOGY_CODE_143_CITMHEEVTCAUSE9_C	VARCHAR2
		*AETIOLOGY_CODE_143_CITMHEEVTCAUSE9	VARCHAR2
	AETIOLOGY_YN - Extensive physical activity	*AETIOLOGY_CODE_146_CITMHEEVTCAUSE12_C	VARCHAR2
		*AETIOLOGY_CODE_146_CITMHEEVTCAUSE12	VARCHAR2
	AETIOLOGY_YN - Potentially hepatotoxic agents within 30 days	*AETIOLOGY_CODE_144_DILI_AETIOLOGY_TEXT_C	VARCHAR2
		*AETIOLOGY_CODE_144_DILI_AETIOLOGY_TEXT	VARCHAR2
	AETIOLOGY_YN - DILI_AETIOLOGY_TEXT	DILI_AETIOLOGY_TEXT	VARCHAR2
	DILI_AETIOLOGY_CODE	DILI_AETIOLOGY_CODE_C	VARCHAR2
		DILI_AETIOLOGY_CODE	VARCHAR2
		DILI_AETIOLOGY_CODE_ND	VARCHAR2
	TREATMENT_A_YN	TREATMENT_A_YN_C	VARCHAR2
		TREATMENT_A_YN	VARCHAR2
		TREATMENT_A_YN_ND	VARCHAR2
	TREATMENT_A_YN - Pharmaceutical treatment	*TREATMENT_TYPE_131_CITMTRT131_C	VARCHAR2
		*TREATMENT_TYPE_131_CITMTRT131	VARCHAR2
	TREATMENT_A_YN - Other	*TREATMENT_TYPE_999_GRPTRTMENT_OT_C	VARCHAR2
		*TREATMENT_TYPE_999_GRPTRTMENT_OT	VARCHAR2
	TREATMENT_A_YN - TREATMENT_OTHER_1	TREATMENT_OTHER_1	VARCHAR2
	*RD_HEPATIC_EVENT_STHEPATIC_2		
	HEP_LAB_TEST_EVENT	HEP_LAB_TEST_EVENT_C	VARCHAR2
		HEP_LAB_TEST_EVENT	VARCHAR2
		HEP_LAB_TEST_EVENT_ND	VARCHAR2
	HEP_LAB_TEST_YN	HEP_LAB_TEST_YN_C	VARCHAR2
		HEP_LAB_TEST_YN	VARCHAR2
		HEP_LAB_TEST_YN_ND	VARCHAR2
	HEP_COLLECTION_DATE	HEP_COLLECTION_DATE	DATE
		HEP_COLLECTION_DATE_DTS	VARCHAR2
		HEP_COLLECTION_DATE_ND	VARCHAR2
	grp_HEP_RESULT	GRP_HEP_RESULT_ND	VARCHAR2
	grp_HEP_RESULT - HEP_LVALUE	HEP_LVALUE	FLOAT
	grp_HEP_RESULT - HEP_LPARAM_UNIT	HEP_LPARAM_UNIT_C	VARCHAR2
		HEP_LPARAM_UNIT	VARCHAR2
	grp_HEP_REF_RANGE	GRP_HEP_REF_RANGE_ND	VARCHAR2
	grp_HEP_REF_RANGE - HEP_REF_RANGE_LOW	HEP_REF_RANGE_LOW	FLOAT

	E - HEP_REF_RANGE_HIGH	HEP_REF_RANGE_HIGH	FLOAT
Key: [*] : *or table name in the actual RDE extract may be different.			

LB=Laboratory Test Results

FA=Findings About

CE=Clinical Events

LBCAT=AE REQUIRING ADDITIONAL DATA

FACAT=AE REQUIRING ADDITIONAL DATA

CECAT=AE REQUIRING ADDITIONAL DATA

#	Gallbladder Disease event number	Related AE No.	Signs and Symptoms present	Laboratory tests Provide available results from locally analysed laboratory tests at time of this event	Imaging performed?	Was any treatment(s) given	Any relevant risk/confounding factors identified?
1				<p>[GALL_SEQ_NO] 0 &lt; N3</p> <p><b>CEREFID</b> <b>FAREFID</b> <b>LBREFID</b> <b>RELREC: CE,FA</b> <b>RELREC: CE,LB</b></p> <p>[GALL_AE_NO] 0 &lt; N3</p> <p><b>CELNKID</b> <b>FALNKID</b> <b>LBLNKID</b> <b>RELREC: CE,AE</b></p> <p>[GALL_CLIN_SYMPT_CODE_YN] [A:2] No [A:1] [grpGALL_CLININ_SYMPT_CODE] ☐ Yes</p> <p><b>FAORRES when FATESTCD=GDSYMP</b></p> <p>[GALL_CLINIC_SYMPT_ABPN] [A:54] ☐ [GALL_LOCATION_SUB_CODE] Abdominal pain [A:107] ☐ Right upper quadrant [A:156] ☐ Epigastric [A:999] ☐ Other</p> <p>[GALL_CLINIC_SYMPT_CODE] [A:25] ☐ Nausea [A:71] ☐ Vomiting [A:72] ☐ Fever [A:73] ☐ Jaundice/Icterus [A:74] ☐ Murphy's sign [A:999] ☐ Other</p> <p><b>FAORRES when FATESTCD=GDABPAIN</b></p> <p><b>LOCATION1-3 in SUPPFA</b></p> <p><b>FAORRES when FATESTCD=GDDINAUS</b></p> <p><b>FAORRES when FATESTCD=GDFEVER</b></p>			
				<p><b>FASCAT=GALLBLADDER DISEASE SIGNS AND SYMPTOMS</b></p> <p><b>FAORRES when FATESTCD=GDVOMIMI</b></p> <p><b>FAORRES when FATESTCD=GDJAUNDI</b></p> <p><b>FAORRES when FATESTCD=GDMUSIGN</b></p> <p><b>FAORRES when FATESTCD=GDOTSYMP</b></p>			
				<p><b>LBCAT=AE REQUIRING ADDITIONAL DATA</b></p> <p><b>LBSCAT=GALLBLADDER LABORATORY TEST</b></p>			
4.a	White blood count (WBC)	Test	Test done*	Sample collection date	Result	Reference range Use same units for reference range as the reported result	
4.b	C Reactive Protein (CRP)						
4.c	Total Bilirubin						
4.d	Indirect bilirubin (unconjugated)						
4.e	Direct bilirubin (conjugated)						
4.f	Alanine aminotransferase (ALT)						
4.g	Aspartate aminotransferase (AST)						
4.h	Alkaline phosphatase (ALP)						
4.i	Total Amylase						
4.j	Total Lipase						
4.k	Gamma Glutamyl Transferase (GGT)						
				<p><b>LBDTC</b></p> <p><b>LBORRES</b> <b>LBORRESU</b></p>			
4.1	Test	[Test]					
4.2*	Test done?	[Test done?]			<p><b>NOT SUBMITTED</b></p>		
4.3	Sample collection date	[Sample collection date]		<p>[GALL_COLLECTION_DATE] (DD/MM/YYYY) Req ☐ / Rec ☐ / Ret ☐ (2023-2030)</p>	<p><b>LBDTC</b></p>		
4.4	Result	[Result]					
4.5	Reference range Use same units for reference range as the reported result [Reference range Use same units for reference range as the reported result]			<p>[grpGALL_REF_RANGE] [GALL_REF_RANGE_LOW] Lower normal limit: xxxx [GALL_REF_RANGE_HIGH] Upper normal limit: xxxx</p>	<p><b>LORANCOL in SUPPLB</b></p> <p><b>HIRANCOL in SUPPLB</b></p>		
5.1	Was imaging performed? [Imaging performed?]			<p><b>FASCAT=GALLBLADDER DISEASE IMAGING</b></p> <p><b>FAORRES when FATESTCD=GDCTSCAN</b></p> <p><b>FAORRES when FATESTCD=GDIMAOT</b></p> <p><b>FAORRES when FATESTCD=GDDIMIN</b></p> <p><b>FAORRES when FATESTCD=GDIMFIAB</b></p> <p><b>FAORRES when FATESTCD=GDGALLST</b></p> <p><b>FAORRES when FATESTCD=GDDICOB</b></p> <p><b>FAORRES when FATESTCD=GDINCHCH</b></p>	<p><b>FAORRES when FATESTCD=GDIMPERF</b></p> <p><b>FAORRES when FATESTCD=GDULTSO</b></p> <p><b>FAORRES when FATESTCD=GDMRISCA</b></p> <p><b>FAORRES when FATESTCD=GDERCPER</b></p>		
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**LB=Laboratory Test Results****FA=Findings About****LBCAT=AE REQUIRING ADDITIONAL DATA****FACAT=AE REQUIRING ADDITIONAL DATA****FAORRES when FATESTCD=GDCHOPER****FAORRES when FATESTCD=GDSWLIPE****FAORRES when FATESTCD=GDRISFAC****FAORRES when FATESTCD=GDPREXPA****FAORRES when FATESTCD=GDRETEIL****FAORRES when FATESTCD=GDRIFAOT****TYPSURG in SUPPFA****FAORRES when FATESTCD=GDERCTRT****FAORRES when FATESTCD=GDMEDEV****FAORRES when FATESTCD=GDTREOTH****FAORRES when FATESTCD=GDFAMHIS****FAORRES when FATESTCD=GDGABYSU****FAORRES when FATESTCD=GDRAWELO**

7.\* Were there any relevant risk/confounding factors identified?

Medical events that the subject has experienced in the past should be recorded on the Medical History form  
[Any relevant risk/confounding factors identified?]**FASCAT=GALLBLADDER DISEASE RISK FACTORS**Key: [\*] = Item is required [ ✓ ] = Source verification required [ ☐ ] = Item is collapsible [ ☒ ] = Fixed item  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.**Study Object Descriptions: Gallbladder Disease**

Type	RefName	Description
Form	GALLBLADDER	Visit: AE
Item	GALL_SEQ_NO	Calculated in InForm via rule
Item	GALL_AE_NO	Integrations: A - please do not change the refname or format

**Codelist Values Tables: Gallbladder Disease**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIGALL_SYMP_CODE_YN	String		No	2	citmGALL_SYMP_2	GALL_CLIN_SYMP_CODE_YN
			Yes	1	citmGALL_SYMP_1	
cIGALL_CLINIC_SYMPTOM_PAIN	String		Abdominal pain	54	citmGALL_CLINIC_SYMPTOM_PAIN54	GALL_CLINIC_SYMPTOM_ABPN
cIGALL_LOCATION_SUB_CODE	String		Right upper quadrant	107	citmLOCATION_SUB1_CODE	
			Epigastric	156	citmLOCATION_SUB2_CODE	
cIGALL_CLINIC_SYMPTOM_CODE	String		Nausea	25	citmGALL_CLINIC_SYMPT_2_CODE	GALL_CLINIC_SYMPTOM_CODE
			Vomiting	71	citmGALL_CLINIC_SYMPT_3_CODE	
			Fever	72	citmGALL_CLINIC_SYMPT_4_CODE	
			Jaundice/Icterus	73	citmGALL_CLINIC_SYMPT_5_CODE	
			Murphy's sign	74	citmGALL_CLINIC_SYMPT_6_CODE	
			Other	999	citmGALL_CLINIC_SYMPT_7_CODE	
cIGALL_LPARM_CODE	String		White blood count (WBC)	618	citmGALL_LPARM_CODE_WBC	GALL_LAB_TEST
			C Reactive Protein (CRP)	619	citmGALL_LPARM_CODE_CRP	
			Total Bilirubin	605	citmGALL_LPARM_CODE_TB	
			Indirect bilirubin (unconjugated)	620	citmGALL_LPARM_CODE_IB	
			Direct bilirubin (conjugated)	621	citmGALL_LPARM_CODE_DB	
			Alanine aminotransferase (ALT)	603	citmGALL_LPARM_CODE_ALT	
			Aspartate aminotransferase (AST)	604	citmGALL_LPARM_CODE_AST	
			Alkaline phosphatase (ALP)	606	citmGALL_LPARM_CODE_ALP	
			Total Amylase	622	citmGALL_LPARM_CODE_AP	
			Total Lipase	92	citmGALL_LPARM_CODE_LIP	
			Gamma Glutamyl Transferase (GGT)	91	citmGALL_LPARM_CODE_GGT	
cIYESUNK	String		Yes	1	citmYESUNK1	GALL_LAB_TEST_YN
			No	2	citmYESUNK2	
			Unknown	996	citmYESUNK996	
cIGALL_LPARM_UNIT	String		10^3/UL	893	citmGALL_LPARM_893	GALL_LPARM_UNIT
			10^6/L	890	citmGALL_LPARM_890	
			10^9/L	891	citmGALL_LPARM_891	
			/mL	879	citmGALL_LPARM_879	
			/uL	773	citmGALL_LPARM_773	
			mg/dL	162	citmGALL_LPARM_162	
			mg/L	163	citmGALL_LPARM_163	
			ng/dL	122	citmGALL_LPARM_122	
			nmol/L	521	citmGALL_LPARM_521	
			umol/L	541	citmGALL_LPARM_541	
			U/L	811	citmGALL_LPARM_811	
cINOYESUNK	String		No	2	citmNOYESUNK2	GALL_IMAGING_YN, GALL_RISK_CON_FACTOR_YN
			Yes	1	citmNOYESUNK1	
			Unknown	996	citmNOYESUNK996	
cIGALL_METHOD_CODE	String		Ultrasound	103	citmGALL_METHOD_1_CODE	GALL_METHOD_CODE
			CT scan	104	citmGALL_METHOD_2_CODE	
			MRI	105	citmGALL_METHOD_3_CODE	
			Endoscopic retrograde cholangiopancreatogram (ERCP)	48	citmGALL_METHOD_4_CODE	
			Other	999	citmGALL_METHOD_5_CODE	
cIMAGING_INDICATION	String		Suspicion of pancreatitis	1	citmIMAGING_INDICATION1	IMAGING_INDICATION
			Suspicion of gallbladder disease (including gallstones and cholecystitis)	2	citmIMAGING_INDICATION2	
			Unspecific GI symptoms	3	citmIMAGING_INDICATION3	
			Other	999	citmIMAGING_INDICATION999	
cINOYES_1	String		No	2	citmNOYES2_1	GALLBLADDER_YN
			Yes	1	citmNOYES1_1	
cIGALLBLADDER_CODE	String		Gallstone(s) in the gallbladder	1	citmGALL_1_CODE	GALLBLADDER_CODE
			Gallstone(s) in the common bile duct	2	citmGALL_2_CODE	
			Obstructive gallstone	3	citmGALL_3_CODE	
			Indicating acute cholecystitis	7	citmGALL_7_CODE	
			Indicating chronic cholecystitis	8	citmGALL_8_CODE	
			Dilated common bile duct	4	citmGALL_4_CODE	
			Other	999	citmGALL_OTH999	GALL_OTH
cIGALL_OTH	String		No	2	citmNOYES2_1_1	GALL_TREATMENT_YN
cINOYES_1_1	String		Yes	1	citmNOYES1_1_1	

		Yes	1	citmNOYES1_1	
cIGALL_ΔTMH-N1 CONF	String	Antibiotics	70	citmGALL_TREATMENT_1_CODE	GALL_TREATMENT_CODE
		I.V. fluids	71	citmGALL_TREATMENT_2_CODE	
cIGALL_TREATMENT_CHOLECYST	String	Cholecystectomy	72	citmGALL_TREATMENT_CHOLECYST	GALL_TREATMENT_CHOLECYST
cIGALL_TREATMENT_SUB_CODE	String	Elective surgery	6	citmGALL_TREATMENT_SUB1_3_CODE	GALL_CHOLECYST
		Urgent surgery	8	citmGALL_TREATMENT_SUB2_3_CODE	
cIGALL_TREATMENT_ENDO	String	Endoscopic retrograde cholangiopancreatogram (ERCP)	73	citmGALL_TREATMENT_ENDO	GALL_TREATMENT_ENDO
cIGALL_TREATMENT_SHOCK	String	Shock wave lithotripsy	74	citmGALL_TREATMENT_SHOCK	GALL_TREATMENT_SHOCK
cIGALL_TREATMENT_MED	String	Medication to dissolve stones	75	citmGALL_TREATMENT_MED	GALL_TREATMENT_MED
cIGALL_TREATMENT_OTH	String	Other	999	citmGALL_TREATMENT_OTH	GALL_TREATMENT_OTH
cIGALL_RISK_CON_FA_CODE	String	Family history of gallstones	12	citmGALL_RISK_CON_FA_2_CODE	GALL_RISK_CON_FA_CODE
		Prior experience of similar pain	13	citmGALL_RISK_CON_FA_3_CODE	
		Gastric bypass surgery	14	citmGALL_RISK_CON_FA_4_CODE	
		Resection of the terminal ileum	16	citmGALL_RISK_CON_FA_6_CODE	
		Rapid weight loss	17	citmGALL_RISK_CON_FA_7_CODE	
		Other	999	citmGALL_RISK_CON_FA_8_CODE	

**RDE Analytics: RD\_GALLBLADDER**

Data Variable RefName	RD Column Name	Column Data Type
GALL_SEQ_NO	GALL_SEQ_NO	NUMBER
	GALL_SEQ_NO_ND	VARCHAR2
GALL_AE_NO	GALL_AE_NO	NUMBER
	GALL_AE_NO_ND	VARCHAR2
GALL_CLIN_SYMP_CODE_YN	GALL_CLIN_SYMP_CODE_YN_C	VARCHAR2
	GALL_CLIN_SYMP_CODE_YN	VARCHAR2
	GALL_CLIN_SYMP_CODE_YN_ND	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Abdominal pain	*GALL_CLINIC_SYMPTOM_ABPN_GALL_LOCATION_SUB_CODE_C	VARCHAR2
	*GALL_CLINIC_SYMPTOM_ABPN_GALL_LOCATION_SUB_CODE	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Right upper quadrant	*GALL_LOCATION_SUB_CODE_CITMLOCATIONSUB1CODE_C	VARCHAR2
	*GALL_LOCATION_SUB_CODE_CITMLOCATIONSUB1CODE	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Epigastric	*GALL_LOCATION_SUB_CODE_CITMLOCATIONSUB2CODE_C	VARCHAR2
	*GALL_LOCATION_SUB_CODE_CITMLOCATIONSUB2CODE	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Other	*GALL_LOCATION_SUB_CODE_CITMLOCATIONSUB3CODE_C	VARCHAR2
	*GALL_LOCATION_SUB_CODE_CITMLOCATIONSUB3CODE	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Nausea	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT2CODE_C	VARCHAR2
	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT2CODE	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Vomiting	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT3CODE_C	VARCHAR2
	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT3CODE	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Fever	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT4CODE_C	VARCHAR2
	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT4CODE	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Jaundice/Icterus	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT5CODE_C	VARCHAR2
	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT5CODE	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Murphy's sign	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT6CODE_C	VARCHAR2
	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT6CODE	VARCHAR2
GALL_CLIN_SYMP_CODE_YN - Other	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT7CODE_C	VARCHAR2
	*GALL_CLINIC_SYMPTOM_CODE_CITMGALLCLINICSYMPT7CODE	VARCHAR2
GALL_IMAGING_YN	GALL_IMAGING_YN_C	VARCHAR2
	GALL_IMAGING_YN	VARCHAR2
	GALL_IMAGING_YN_ND	VARCHAR2
GALL_IMAGING_YN - Ultrasound	*GALL_METHOD_CODE_CITMGALLMETHOD1CODE_C	VARCHAR2
	*GALL_METHOD_CODE_CITMGALLMETHOD1CODE	VARCHAR2
GALL_IMAGING_YN - CT scan	*GALL_METHOD_CODE_CITMGALLMETHOD2CODE_C	VARCHAR2
	*GALL_METHOD_CODE_CITMGALLMETHOD2CODE	VARCHAR2
GALL_IMAGING_YN - MRI	*GALL_METHOD_CODE_CITMGALLMETHOD3CODE_C	VARCHAR2
	*GALL_METHOD_CODE_CITMGALLMETHOD3CODE	VARCHAR2
GALL_IMAGING_YN - Endoscopic retrograde cholangiopancreatogram (ERCP)	*GALL_METHOD_CODE_CITMGALLMETHOD4CODE_C	VARCHAR2
	*GALL_METHOD_CODE_CITMGALLMETHOD4CODE	VARCHAR2
GALL_IMAGING_YN - Other	*GALL_METHOD_CODE_CITMGALLMETHOD5CODE_C	VARCHAR2
	*GALL_METHOD_CODE_CITMGALLMETHOD5CODE	VARCHAR2
GALL_IMAGING_YN - IMAGING_INDICATION	IMAGING_INDICATION_C	VARCHAR2
	IMAGING_INDICATION	VARCHAR2
GALL_IMAGING_YN - GALLBLADDER_YN	GALLBLADDER_YN_C	VARCHAR2
	GALLBLADDER_YN	VARCHAR2
GALL_IMAGING_YN - Gallstone(s) in the gallbladder	*GALLBLADDER_CODE_CITMGALL1CODE_C	VARCHAR2
	*GALLBLADDER_CODE_CITMGALL1CODE	VARCHAR2
GALL_IMAGING_YN - Gallstone(s) in the common bile duct	*GALLBLADDER_CODE_CITMGALL2CODE_C	VARCHAR2
	*GALLBLADDER_CODE_CITMGALL2CODE	VARCHAR2
GALL_IMAGING_YN - Obstructive gallstone	*GALLBLADDER_CODE_CITMGALL3CODE_C	VARCHAR2
	*GALLBLADDER_CODE_CITMGALL3CODE	VARCHAR2
GALL_IMAGING_YN - Indicating acute cholecystitis	*GALLBLADDER_CODE_CITMGALL7CODE_C	VARCHAR2
	*GALLBLADDER_CODE_CITMGALL7CODE	VARCHAR2
GALL_IMAGING_YN - Indicating chronic cholecystitis	*GALLBLADDER_CODE_CITMGALL8CODE_C	VARCHAR2
	*GALLBLADDER_CODE_CITMGALL8CODE	VARCHAR2
GALL_IMAGING_YN - Dilated common bile duct	*GALLBLADDER_CODE_CITMGALL4CODE_C	VARCHAR2
	*GALLBLADDER_CODE_CITMGALL4CODE	VARCHAR2
GALL_IMAGING_YN - Other	GALL_OTH_CITMGALLOTH999_C	VARCHAR2
	GALL_OTH_CITMGALLOTH999	VARCHAR2
GALL_IMAGING_YN - GALLBLADDER_OTHER	GALLBLADDER_OTHER	VARCHAR2
GALL_TREATMENT_YN	GALL_TREATMENT_YN_C	VARCHAR2
	GALL_TREATMENT_YN	VARCHAR2
	GALL_TREATMENT_YN_ND	VARCHAR2
GALL_TREATMENT_YN - Antibiotics	*GALL_TREATMENT_CODE_CITMGALLTREATMENT1CODE_C	VARCHAR2
	*GALL_TREATMENT_CODE_CITMGALLTREATMENT1CODE	VARCHAR2
GALL_TREATMENT_YN - I.V. fluids	*GALL_TREATMENT_CODE_CITMGALLTREATMENT2CODE_C	VARCHAR2
	*GALL_TREATMENT_CODE_CITMGALLTREATMENT2CODE	VARCHAR2
GALL_TREATMENT_YN - Cholecystectomy	*GALL_TREATMENT_CHOLECYST_GALL_CHOLECYST_C	VARCHAR2
	*GALL_TREATMENT_CHOLECYST_GALL_CHOLECYST	VARCHAR2
GALL_TREATMENT_YN - GALL_CHOLECYST	GALL_CHOLECYST_C	VARCHAR2
	GALL_CHOLECYST	VARCHAR2

-	N - Endoscopic retrograde cholangiopancreatogram (ERCP)	*GALL_TREATMENT_ENDO_CITMGALLTREATMENTEND03_C	VARCHAR2
GALL_TREATMENT_VN	- c <hock lithotripsy<="" td="" wave=""><td>*GALL_TREATMENT_SHOCK_CITMGALLTREATMENTSHOCK74_C</td><td>VARCHAR2</td></hock>	*GALL_TREATMENT_SHOCK_CITMGALLTREATMENTSHOCK74_C	VARCHAR2
GALL_TREATMENT_YN	- Medication to dissolve stones	*GALL_TREATMENT_MED_CITMGALLTREATMENTMED75_C	VARCHAR2
GALL_TREATMENT_YN	- Other	*GALL_TREATMENT_OTH_CITMGALLTREATMENTOTH999_C	VARCHAR2
GALL_RISK_CON_FACTOR_YN		*GALL_RISK_CON_FACTOR_YN_C	VARCHAR2
GALL_RISK_CON_FACTOR_YN		GALL_RISK_CON_FACTOR_YN	VARCHAR2
GALL_RISK_CON_FACTOR_YN		GALL_RISK_CON_FACTOR_YN_ND	VARCHAR2
GALL_RISK_CON_FACTOR_YN	- Family history of gallstones	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA2CODE_C	VARCHAR2
GALL_RISK_CON_FACTOR_YN	- Prior experience of similar pain	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA3CODE_C	VARCHAR2
GALL_RISK_CON_FACTOR_YN	- Gastric bypass surgery	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA4CODE_C	VARCHAR2
GALL_RISK_CON_FACTOR_YN	- Resection of the terminal ileum	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA6CODE_C	VARCHAR2
GALL_RISK_CON_FACTOR_YN	- Rapid weight loss	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA7CODE_C	VARCHAR2
GALL_RISK_CON_FACTOR_YN	- Other	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFABCODE_C	VARCHAR2
<b>*RD_GALLBLADDER_SCTGALL_LAB_TEST_EVENT</b>		*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFACODE	VARCHAR2
GALL_LAB_TEST		GALL_LAB_TEST_C	VARCHAR2
GALL_LAB_TEST		GALL_LAB_TEST	VARCHAR2
GALL_LAB_TEST		GALL_LAB_TEST_ND	VARCHAR2
GALL_LAB_TEST_YN		GALL_LAB_TEST_YN_C	VARCHAR2
GALL_LAB_TEST_YN		GALL_LAB_TEST_YN	VARCHAR2
GALL_COLLECTION_DATE		GALL_COLLECTION_DATE	DATE
GALL_COLLECTION_DATE		GALL_COLLECTION_DATE_DTS	VARCHAR2
GALL_COLLECTION_DATE		GALL_COLLECTION_DATE_ND	VARCHAR2
grpGALL_RESULT		GRPGALL_RESULT_ND	VARCHAR2
grpGALL_RESULT	- GALL_LVALUE	GALL_LVALUE	FLOAT
grpGALL_RESULT	- GALL_LPARAM_UNIT	GALL_LPARAM_UNIT_C	VARCHAR2
grpGALL_REF_RANGE		GALL_LPARAM_UNIT	VARCHAR2
grpGALL_REF_RANGE	- GALL_REF_RANGE_LOW	GRPGALL_REF_RANGE_ND	VARCHAR2
grpGALL_REF_RANGE	- GALL_REF_RANGE_HIGH	GALL_REF_RANGE_LOW	FLOAT
grpGALL_REF_RANGE	- GALL_REF_RANGE_HIGH	GALL_REF_RANGE_HIGH	FLOAT

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

FA=Findings About								CE=Clinical Events			
FACAT=AE REQUIRING ADDITIONAL DATA								CECAT=AE REQUIRING ADDITIONAL DATA			
<b>: Diabetic Retinopathy (Diab Retino) - Repeating Form [DIABETIC_RETINO]</b> # E Related adverse event number Diabetic retinopathy identified Current stage of diabetic retinopathy 1 Study ID: NN9838-4942 Note: T2D Participants only 1. Diabetic retinopathy event number [read-only] [Ev. No.] 2. Related adverse event number [Related adverse event number] 3. How was this event of diabetic retinopathy identified? [Diabetic retinopathy identified]								<b>FAOBJ=DIABETIC RETINOPATHY</b> <b>CEREFID</b> <b>FAREFID</b> <b>RELREC: CE.FA</b> <b>CELNKID</b> <b>FALNKID</b> <b>RELREC: CE,AE</b> <b>CETERM=DIABETIC RETINOPATHY</b> <b>FAORRES when FATESTCD=DMRIDENT</b> <b>Note: FAORRES=Specify if available</b>			
Current stage of diabetic retinopathy [sctDRET_EXAM] # Eye 4.a Right 4.b Left								<b>FASCAT=RETINOPATHY STAGE</b> <b>FAOC</b> <b>FALAT</b> <b>EYE_SIDE</b> [A:1] Right [A:2] Left <b>CURST_CODE</b> [A:125] Mild non-proliferative diabetic retinopathy [A:126] Moderate-severe non-proliferative diabetic retinopathy [A:123] Proliferative diabetic retinopathy <b>FAORRES when FATESTCD=DMRSTAGE</b>			
Conditions found on eye examination [sctDRET_COND] # Condition 5.a Diabetic macular oedema 5.b Vitreous haemorrhage 5.c Traction retinal detachment 5.d Neovascular glaucoma 5.e Cataract								<b>FASCAT=RETINOPATHY CONDITIONS</b> <b>FAORRES when FATESTCD=DMRTRD</b> <b>FAORRES when FATESTCD=DMRCAT</b> <b>FAOC=EYE</b> <b>FALAT=LEFT</b> <b>OTHFIND_CODE</b> [A:42] Diabetic macular oedema [A:30] Vitreous haemorrhage [A:39] Traction retinal detachment [A:40] Neovascular glaucoma [A:35] Cataract <b>FAORRES when FATESTCD=DMRMOD</b> <b>FAORRES when FATESTCD=DMRVHM</b> <b>FAORRES when FATESTCD=DMRNEOVS</b>			
Conditions found on eye examination Entry [sctDRET_COND] 5.1 Condition 5.2 Finding								<b>FASCAT=RETINOPATHY CONDITIONS</b> <b>FAORRES when FATESTCD=DMRTRD</b> <b>FAORRES when FATESTCD=DMRCAT</b> <b>FALOC=EYE</b> <b>FALAT=RIGHT</b> <b>FALAT=BILATERAL</b> <b>DRET_FIND_YN</b> [A:2] No [A:1] [grpOTH_FIND_Y] [checkbox] Yes [A:1] Right eye [A:2] Left eye [A:3] Both eyes (Bilateral)			
Other findings [sctDRET_OTH_FIND] # Eye 6.a Right 6.b Left								<b>FASCAT=RETINOPATHY OTHER FINDINGS</b> <b>FAOC</b> <b>FALAT</b> <b>EYE_SIDE_OTH</b> [A:1] Right [A:2] Left <b>DRET_OTH_FIND_YN</b> [A:2] No [A:1] [grpOTH_FIND_Y] [checkbox] Yes <b>FAORRES when FATESTCD=DMROTHFN</b> <b>Note: FAORRES=Specify if available</b>			
Worsening in visual acuity [sctDRET_VISACT] # Eye 7.a Right 7.b Left								<b>FASCAT=RETINOPATHY VISUAL ACUITY</b> <b>FAOC</b> <b>FALAT</b> <b>EYE_SIDE_VISACT</b> [A:1] Right [A:2] Left <b>DRET_VISACT_YN</b> [A:2] No [A:1] [grpVISACT_Y] [checkbox] Yes <b>FAORRES when FATESTCD=DMRWRACT</b> <b>DRET_VISACT_CODE</b> Specify current visual acuity (best corrected) [A:1] Mildly impaired visual acuity (e.g. Snellen >= 6/12 (20/40)) [A:2] Moderately impaired visual acuity (e.g. Snellen < 6/12 (20/40)) [A:3] Severely impaired visual acuity (e.g. Snellen < 6/60 (20/200)) [A:996] Unknown <b>FAORRES when FATESTCD=DMRCVIBC</b>			
8.* Were the diabetes retinopathy and related conditions verified by an ophthalmologist? [Ophthalmologist is a medical doctor specialised in eye diseases] [Disease verified]								<b>FAORRES when FATESTCD=DMROPTHA</b> <b>OPTHAL_VERIFY_YN</b> [A:2] No [A:1] Yes [A:996] Unknown			
Treatment information [sctDRET_TRT_CONF] 9.* Did the subject receive any treatment for this diabetic retinopathy? [Complete the below section and update concomitant medication as relevant] [Treatment received?]								<b>FASCAT=RETINOPATHY TREATMENT</b> <b>DRET_TREAT_CONFIRM</b> [A:2] No treatment, observation only [A:1] Yes <b>FAORRES when FATESTCD=DMRTREAT</b> <b>Treatment given?</b>			
10.a Focal/grid laser treatment/photocoagulation 10.b Scatter/pan-retinal laser treatment/photocoagulation 10.c Vitrectomy 10.d Anti-VEGF intravitreal agent											

		<b>FA=Findings About</b>	
		<b>FACAT=AE REQUIRING ADDITIONAL DATA</b>	
		<b>FAORRES when FATESTCD=DMRFLGP</b>	
		<b>FAORRES when FATESTCD=DMRSPLRP</b>	
		<b>FALOC</b>	
		<b>FALAT</b>	
10.2* Treatment given? [Treatment given?]		<b>[EYE_TREATMENT_CODE]</b> [A:1:29] <input type="radio"/> Focal/grid laser treatment/photocoagulation [A:1:30] <input type="radio"/> Scatter/pan-retinal laser treatment/photocoagulation [A:1:108] <input type="radio"/> Vitrectomy [A:1:107] <input type="radio"/> Anti-VEGF intravitreal agent	
		<b>FAORRES when FATESTCD=DMRVITRE</b>	
		<b>FAORRES when FATESTCD=DMRATVGF</b>	
		<b>FALAT=BILATERAL</b>	
Other treatment? [sctDRET_OTH_TREAT]		Any other treatment?*	
#	Eye		
11.a	Right		
11.b	Left		
Other treatment? Entry [sctDRET_OTH_TREAT]			
11.1	Eye [Eye]	<b>FALOC</b>	<b>FALAT</b>
11.2*	Any other treatment received? [Any other treatment?]	<b>[EYE_SIDE_OTH_TRT]</b> [A:1:1] <input type="radio"/> Right [A:2] <input type="radio"/> Left  <b>[DRET_OTH_TREAT_YN]</b> [A:2] <input type="radio"/> No [A:1] <input type="radio"/> <b>[grDRET_OTH_TREAT_Y]</b> <input checked="" type="checkbox"/> Yes [DRET_OTH_TREAT] Specify A200	
		<b>FAORRES when FATESTCD=DMRTRTOT</b>	
		<b>Note: FAORRES=Specify if available</b>	

Key: [\*] = Item is required [ ✓ ] = Source verification required [ ☐ ] = Item is collapsible [ █ ] = Fixed item  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Diabetic Retinopathy		
Type	RefName	Description
Form	DIABETIC_RETINO	Visit: AE
Item	DIA_SEQ_NO	Calculated in InForm via rule
Item	DIAB_RET_AE_NO	Integrations: A, R - please do not change the refname or format

Codelist Values Tables: Diabetic Retinopathy				
Codelist RefName	Codelist Data Type	Subset	Label	Code Codelist Item RefName Data Variable RefName
clEYE_ID_CODE	String		Routine eye examination (not related to study)	15 citmEYE_ID_15 EYE_IDENTIFY_CODE
			Protocol scheduled eye examination	8 citmEYE_ID_8
			Unscheduled eye examination	19 citmEYE_ID_19
			Other	999 citmEYE_ID_999
clEYE_SIDE	String		Right	1 citmEYE_SIDE_1 EYE_SIDE
			Left	2 citmEYE_SIDE_2 EYE_SIDE_OTH, EYE_SIDE_VISACT, EYE_SIDE_OTH_TRT
clCURST	String		Mild non-proliferative diabetic retinopathy	125 citmCURST_125 CURST_CODE
			Moderate-severe non-proliferative diabetic retinopathy	126 citmCURST_126
			Proliferative diabetic retinopathy	123 citmCURST_123
clOTHFIND	String		Diabetic macular oedema	42 citmOTHFIND_42 OTHFIND_CODE
			Vitreous haemorrhage	30 citmOTHFIND_30
			Traction retinal detachment	39 citmOTHFIND_39
			Neovascular glaucoma	40 citmOTHFIND_40
			Cataract	35 citmOTHFIND_35
clDRET_FIND_YN	String		No	2 citmDRET_FIND_N DRET_FIND_YN, DRET_OTH_FIND_YN
			Yes	1 citmDRET_FIND_Y
clDRET_FIND_Y	String		Right eye	1 citmDRET_FIND_1 DRET_FIND_Y
			Left eye	2 citmDRET_FIND_2
			Both eyes (Bilateral)	3 citmDRET_FIND_3
clVISACT_YN	String		No	2 citmVISACT_N DRET_VISACT_YN
			Yes	1 citmVISACT_Y
clVISACT	String		Mildly impaired visual acuity (e.g. Snellen >= 6/12 (20/40)	1 citmVISACT_1 DRET_VISACT_CODE
			Moderately impaired visual acuity (e.g. Snellen < 6/12 (20/40)	2 citmVISACT_2
			Severely impaired visual acuity (e.g. Snellen < 6/60 (20/200)	3 citmVISACT_3
			Unknown	996 citmVISACT_996
clOPTH_VER_YN	String		No	2 citmOPTH_VER_N OPTHAL_VERIFY_YN
			Yes	1 citmOPTH_VER_Y
			Unknown	996 citmOPTH_VER_UNK
clTREAT_YN	String		No treatment, observation only	2 citmTREAT_N DRET_TREAT_CONFIRM
			Yes	1 citmTREAT_Y
clEYE_TRTMNT	String		Focal/grid laser treatment/photocoagulation	129 citmEYE_TRT_129 EYE_TREATMENT_CODE
			Scatter/pan-retinal laser treatment/photocoagulation	130 citmEYE_TRT_130
			Vitrectomy	108 citmEYE_TRT_108
			Anti-VEGF intravitreal agent	107 citmEYE_TRT_107
clTRT_GIVEN_YN	String		No	2 citmTRT_GIVEN_N EYE_TRT_GIVEN_YN
			Yes	1 citmTRT_GIVEN_Y
clEYE_TRT_Y	String		Right eye	1 citmEYE_TRT_Y1 EYE_TRT_GIVEN_Y
			Left eye	2 citmEYE_TRT_Y2
			Both eyes (Bilateral)	3 citmEYE_TRT_Y3
clOTH_TRT_YN	String		No	2 citmOTH_TRT_N DRET_OTH_TREAT_YN
			Yes	1 citmOTH_TRT_Y

RDE Analytics: RD_DIABETIC_RETINO		
Data Variable RefName	RD Column Name	Column Data Type
DIA_SEQ_NO	DIA_SEQ_NO	NUMBER
	DIA_SEQ_NO_ND	VARCHAR2
DIAB_RET_AE_NO	DIAB_RET_AE_NO	NUMBER
	DIAB_RET_AE_NO_ND	VARCHAR2
EYE_IDENTIFY_CODE	EYE_IDENTIFY_CODE_C	VARCHAR2
	EYE_IDENTIFY_CODE	VARCHAR2
	EYE_IDENTIFY_CODE_ND	VARCHAR2
EYE_IDENTIFY_CODE - ID_OTHER	ID_OTHER	VARCHAR2
OPTHAL_VERIFY_YN	OPTHAL_VERIFY_YN_C	VARCHAR2

	OPHAL_VERIFY_YN	VARCHAR2
	OPHAL_VERIFY_YN_ND	VARCHAR2
DRET_TREAT_CONFIRM_DM	DRET_TREAT_CONFIRM_C	VARCHAR2
	DRET_TREAT_CONFIRM	VARCHAR2
	DRET_TREAT_CONFIRM_ND	VARCHAR2
<b>*RD_DIABETIC_RETINO_SCTDRET_EXAM</b>		
EYE_SIDE	EYE_SIDE_C	VARCHAR2
	EYE_SIDE	VARCHAR2
	EYE_SIDE_ND	VARCHAR2
CURST_CODE	CURST_CODE_C	VARCHAR2
	CURST_CODE	VARCHAR2
	CURST_CODE_ND	VARCHAR2
<b>*RD_DIABETIC_RETINO_SCTDRET_COND</b>		
OTHFIND_CODE	OTHFIND_CODE_C	VARCHAR2
	OTHFIND_CODE	VARCHAR2
	OTHFIND_CODE_ND	VARCHAR2
DRET_FIND_YN	DRET_FIND_YN_C	VARCHAR2
	DRET_FIND_YN	VARCHAR2
	DRET_FIND_YN_ND	VARCHAR2
DRET_FIND_YN - DRET_FIND_Y	DRET_FIND_Y_C	VARCHAR2
	DRET_FIND_Y	VARCHAR2
<b>*RD_DIABETIC_RETINO_SCTDRET_OTH_FIND</b>		
EYE_SIDE_OTH	EYE_SIDE_OTH_C	VARCHAR2
	EYE_SIDE_OTH	VARCHAR2
	EYE_SIDE_OTH_ND	VARCHAR2
DRET_OTH_FIND_YN	DRET_OTH_FIND_YN_C	VARCHAR2
	DRET_OTH_FIND_YN	VARCHAR2
	DRET_OTH_FIND_YN_ND	VARCHAR2
DRET_OTH_FIND_YN - DRET_OTH_FIND	DRET_OTH_FIND	VARCHAR2
<b>*RD_DIABETIC_RETINO_SCTDRET_VISACT</b>		
EYE_SIDE_VISACT	EYE_SIDE_VISACT_C	VARCHAR2
	EYE_SIDE_VISACT	VARCHAR2
	EYE_SIDE_VISACT_ND	VARCHAR2
DRET_VISACT_YN	DRET_VISACT_YN_C	VARCHAR2
	DRET_VISACT_YN	VARCHAR2
	DRET_VISACT_YN_ND	VARCHAR2
DRET_VISACT_YN - DRET_VISACT_CODE	DRET_VISACT_CODE_C	VARCHAR2
	DRET_VISACT_CODE	VARCHAR2
<b>*RD_DIABETIC_RETINO_SCTDRET_TRT_GIVEN</b>		
EYE_TREATMENT_CODE	EYE_TREATMENT_CODE_C	VARCHAR2
	EYE_TREATMENT_CODE	VARCHAR2
	EYE_TREATMENT_CODE_ND	VARCHAR2
EYE_TRT_GIVEN_YN	EYE_TRT_GIVEN_YN_C	VARCHAR2
	EYE_TRT_GIVEN_YN	VARCHAR2
	EYE_TRT_GIVEN_YN_ND	VARCHAR2
EYE_TRT_GIVEN_YN - EYE_TRT_GIVEN_Y	EYE_TRT_GIVEN_Y_C	VARCHAR2
	EYE_TRT_GIVEN_Y	VARCHAR2
<b>*RD_DIABETIC_RETINO_SCTDRET_OTH_TREAT</b>		
EYE_SIDE_OTH_TRT	EYE_SIDE_OTH_TRT_C	VARCHAR2
	EYE_SIDE_OTH_TRT	VARCHAR2
	EYE_SIDE_OTH_TRT_ND	VARCHAR2
DRET_OTH_TREAT_YN	DRET_OTH_TREAT_YN_C	VARCHAR2
	DRET_OTH_TREAT_YN	VARCHAR2
	DRET_OTH_TREAT_YN_ND	VARCHAR2
DRET_OTH_TREAT_YN - DRET_OTH_TREAT	DRET_OTH_TREAT	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

LB=Laboratory Test Results				FA=Findings About Events or Interventions				CE=Clinical Events		
LBCAT=AE REQUIRING ADDITIONAL DATA				FACAT=AE REQUIRING ADDITIONAL DATA				CECAT=AE REQUIRING ADDITIONAL DATA		
: Pancreatitis (Pancrea) - Repeating Form [PANCREATITIS]										
#	is No.	Related AE No.	Upper abdominal pain	Signs/symptoms	Laboratory Tests Provide available results from locally analysed laboratory tests at time of this event		Was imaging performed?	Acute complications	Treatment	Risk/confounding factors
1					[PANC_SEQ_NO] 0 < N3	<b>CEREFID</b> <b>FAREFID</b> <b>LBREFID</b> <b>RELREC: CE,FA</b> <b>RELREC: CE,LB</b>				<b>CETERM=PANCREATITIS</b>
1.	Pancreatic event number [read-only] [Pancreatitis No.]				[PANC_AE_NO] 0 < N3	<b>CELNKID</b> <b>FALNKID</b> <b>LBLNKID</b> <b>RELREC: CE,AE</b>				
2.*	Related adverse event number [Related AE No.]				[ABDOMINAL_PAIN_YN] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> Yes	<b>FAORRES when FATESTCD=PANABPN</b>				
3.*	Did the subject have significant upper abdominal pain? [Upper abdominal pain]				[PANC_SYMPTOMS_YN] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> Yes	<b>FAORRES when FATESTCD=PANSYMP</b>				
4.*	Were other signs/symptoms present during the course of the event? [Signs/symptoms]				[PANC_CLINIC_SYMP_CODE] [A:25] <input type="checkbox"/> Nausea [A:71] <input type="checkbox"/> Vomiting [A:72] <input type="checkbox"/> Fever [A:999] <input type="checkbox"/> Other [A:996] <input type="checkbox"/> Unknown	<b>FAORRES when FATESTCD=PANVOMIT</b>				
<b>FASCAT=PANCREATITIS SIGNS AND SYMPTOMS</b>						<b>FAORRES when FATESTCD=PANNASEA</b>				
						<b>FAORRES when FATESTCD=PANFEVER</b>				
Laboratory Tests Provide available results from locally analysed laboratory tests at time of this event [sctPANC_LAB_TEST_EVENT]										
#	Test	Test done*	Sample collection date	Result	Reference range Use same units for reference range as the reported result					
5.a	Total Amylase	<b>LBORRES/LBORRESU when LBTESTCD=AMYLASE</b>			<b>LBSCAT=PANCREATITIS LABORATORY TEST</b>					
5.b	Total Lipase	<b>LBORRES/LBORRESU when LBTESTCD=LIPASET</b>			<b>LBORRES/LBORRESU when LBTESTCD=ALP</b>					
5.c	Alanine Aminotransferase (ALT)	<b>LBORRES/LBORRESU when LBTESTCD=ALT</b>			<b>LBORRES/LBORRESU when LBTESTCD=CRP</b>					
5.d	Aspartate Aminotransferase (AST)	<b>LBORRES/LBORRESU when LBTESTCD=AST</b>			<b>LBORRES/LBORRESU when LBTESTCD=BILI</b>					
5.e	Total Bilirubin	<b>LBORRES/LBORRESU when LBTESTCD=GLUC</b>			<b>LBORRES/LBORRESU when LBTESTCD=WBC</b>					
Laboratory Tests Provide available results from locally analysed laboratory tests at time of this event Entry [sctPANC_LAB_TEST_EVENT]										
5.1	Test [Test]			<b>LBTESTCD</b>						
5.2*	Test done? [Test done?]			<b>NOT SUBMITTED</b>						
5.3	Sample collection date [Sample collection date]			<b>LBDTC</b>						
5.4	Result [Result]			<b>LBORRES</b> <b>LBORRESU</b>						
5.5	Reference range Use same units for reference range as the reported result [Reference range] Use same units for reference range as the reported result			<b>LORANCOL in SUPPLB</b> <b>HIRANCOL in SUPPLB</b>						
6.*	Was imaging performed? [Was imaging performed?]	<b>FASCAT=PANCREATITIS IMAGING</b>  <b>FAORRES when FATESTCD=PANCT</b> <b>FAORRES when FATESTCD=PANMRI</b>  <b>FAORRES when FATESTCD=PANIGCON</b>		<b>FAORRES when FATESTCD=PANIMAPE</b>  <b>FAORRES when FATESTCD=PANULTRA</b> <b>FAORRES when FATESTCD=PANIMAOT</b>						
		<b>FASCAT=PANCREATITIS IMAGING ACUTE</b>		<b>FAORRES when FATESTCD=PANIACON</b>  <b>FAORRES when FATESTCD=PANOBLSTR</b> <b>FAORRES when FATESTCD=PANPERPF</b> <b>FAORRES when FATESTCD=PANOEDIP</b> <b>FAORRES when FATESTCD=PANNECRP</b>						
		<b>FASCAT=PANCREATITIS IMAGING CHRONIC</b>		<b>FAORRES when FATESTCD=PANCALCI</b>  <b>FAORRES when FATESTCD=PANDILPD</b> <b>FAORRES when FATESTCD=PANCHROT</b>						
7.*	Were any acute complications present during the course of the event? [Acute complications]	<b>FAORRES when FATESTCD=PANACOMP</b>  <b>FAORRES when FATESTCD=PANRESFV</b>		<b>FAORRES when FATESTCD=PANSEPSI</b>  <b>FAORRES when FATESTCD=PANGIHEM</b> <b>FAORRES when FATESTCD=PANRENFD</b> <b>FAORRES when FATESTCD=PANACOOT</b>						
8.	What treatment(s) did the subject receive for this condition? Standard treatment: e.g. pain killers, antibiotics, hospitalisation [Treatment]	<b>FASCAT=PANCREATITIS COMPLICATIONS</b>		<b>FAORRES when FATESTCD=PANTRT</b>						
9.*	Were there any relevant risk/confounding factors identified? [Risk/confounding factors]	<b>FASCAT=PANCREATITIS RISK FACTORS</b>		<b>FAORRES when FATESTCD=PANRRFAC</b>						

**FA=Findings About****FACAT=AE REQUIRING ADDITIONAL DATA**

**FAORRES when FATESTCD=PANALCON**  
**FAORRES when FATESTCD=PANTRUMA**  
**FAORRES when FATESTCD=PANHYCAL**

[A:1] [grpRISK\_CON\_FA\_CODE] ☐  
 Yes  
 [RISK\_CON\_FA\_CODE]  
 [A:4]  Gallstones  
 [A:5]  Alcohol consumption  
 [A:6]  Family history of pancreatitis  
 [A:7]  Hypertriglyceridemia  
 [A:9]  Trauma to the pancreas (incl. endoscopic retrograde cholangiopancreatography (ERCP))  
 [A:11]  Hypercalcemia  
 [A:99]  Other  
 [A:996] [Unknown]

**FAORRES when FATESTCD=PANHGALS**  
**FAORRES when FATESTCD=PANFHISP**  
**FAORRES when FATESTCD=PANHTGLY**  
**FAORRES when FATESTCD=PANRISOT**

Key: [\*] = Item is required [✓] = Source verification required [□] = Item is collapsible [■] = Fixed item  
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
 Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Pancreatitis		
Type	RefName	Description
Form	PANCREATITIS	
Visit	AE	This form is a Dynamic form which is to be triggered by the AE form to appear when AE category item 11= Pancreatitis
Item	PANC_SEQ_NO	Calculated in InForm via rule
Item	PANC_AE_NO	Integrations: A, R - please do not change the refname or format

Codelist Values Tables: Pancreatitis			
Codelist RefName	Codelist Data Type	Subset	Label
cIABDOMINAL_PAIN_YN	String	No	2 citmABDOMINAL_PAIN_YN1
		Yes	1 citmABDOMINAL_PAIN_YN2
cIPANC_SYMPTOMS_YN	String	No	2 citmPANC_SYMPTOMS_YN1
		Yes	1 citmPANC_SYMPTOMS_YN2
cIPANC_CLINIC_SYMPT_CODE	String	Unknown	996 citmPANC_SYMPTOMS_YN3
		Nausea	25 citmPANCCLINIC_SYMPT_1_CODE
cIPANC_LPARM_CODE	String	Vomiting	71 citmPANCCLINIC_SYMPT_2_CODE
		Fever	72 citmPANCCLINIC_SYMPT_3_CODE
cIPANC_LPARM_CODE	String	Other	999 citmPANCCLINIC_SYMPT_4_CODE
		Total Amylase	622 citmPANC_LPARM_CODE_AMY
cYESNOUNK	String	Total Lipase	92 citmPANC_LPARM_CODE_LIP
		Alanine Aminotransferase (ALT)	603 citmPANC_LPARM_CODE_ALT
cIPANC_LPARM_CODE	String	Aspartate Aminotransferase (AST)	604 citmPANC_LPARM_CODE_AST
		Total Bilirubin	605 citmPANC_LPARM_CODE_TBIL
cIPANC_LPARM_CODE	String	Alkaline Phosphatase (ALP)	606 citmPANC_LPARM_CODE_ALP
		C Reactive Protein (CRP)	619 citmPANC_LPARM_CODE_CRP
cIPANC_LPARM_CODE	String	White blood count (WBC)	618 citmPANC_LPARM_CODE_WBC
		Blood glucose	316 citmPANC_LPARM_CODE_GLU
cIPANC_LPARM_UNIT	String	U/L	811 citmPANC_LPARM_UNIT_811
		mg/dL	162 citmPANC_LPARM_UNIT_162
cIPANC_LPARM_UNIT	String	umol/L	541 citmPANC_LPARM_UNIT_541
		mg/L	163 citmPANC_LPARM_UNIT_163
cIPANC_LPARM_UNIT	String	ng/dL	122 citmPANC_LPARM_UNIT_122
		nmol/L	521 citmPANC_LPARM_UNIT_521
cIPANC_LPARM_UNIT	String	10^3/uL	893 citmPANC_LPARM_UNIT_893
		10^6/L	890 citmPANC_LPARM_UNIT_890
cIPANC_LPARM_UNIT	String	10^9/L	891 citmPANC_LPARM_UNIT_891
		/mL	879 citmPANC_LPARM_UNIT_879
cIPANC_LPARM_UNIT	String	/uL	773 citmPANC_LPARM_UNIT_773
		mmol/L	561 citmPANC_LPARM_UNIT_561
cIPANC_IMAGING_YN	String	No	2 citmPANC_IMAGING_YN1
		Yes	1 citmPANC_IMAGING_YN2
cIPANC_METHOD_CODE	String	Unknown	996 citmPANC_IMAGING_YN3
		Ultrasound	103 citmPANC_METHOD_1_CODE
cIPANC_METHOD_CODE	String	CT scan	104 citmPANC_METHOD_2_CODE
		MRI	105 citmPANC_METHOD_3_CODE
cIPANC_METHOD_CODE	String	Other	999 citmPANC_METHOD_4_CODE
		Obstructive gallstone	97 citmACUTE_PANCR_1_CODE
cIPANC_GALLSTONE_YN	String	Dilated common bile duct	98 citmACUTE_PANCR_2_CODE
		Peri-pancreatic fluid	99 citmACUTE_PANCR_3_CODE
cIPANC_GALLSTONE_YN	String	Oedematous or interstitial pancreatitis	100 citmACUTE_PANCR_4_CODE
		Necrotising pancreatitis	101 citmACUTE_PANCR_5_CODE
cIPANC_GALLSTONE_YN	String	Other	999 citmACUTE_PANCR_6_CODE
		No	2 citmCHRONIC_PANCR_YN1
cIPANC_CHRONIC_YN	String	Yes	1 citmCHRONIC_PANCR_YN2
		Calification of pancreas	102 citmCHRONIC_PANCR_1_CODE
cIPANC_CHRONIC_CODE	String	Atrophy of the pancreas	103 citmCHRONIC_PANCR_2_CODE
		Dilatation of pancreatic ducts	104 citmCHRONIC_PANCR_3_CODE
cIPANC_CHRONIC_CODE	String	Pseudocysts	105 citmCHRONIC_PANCR_4_CODE
		Other	999 citmCHRONIC_PANCR_5_CODE
cIPANC_COMPLICATION_YN	String	No	2 citmCOMPLICATION_YN1
		Yes	1 citmCOMPLICATION_YN2
cIPANC_COMPLICATION_CODE	String	Unknown	996 citmCOMPLICATION_YN3
		Sepsis	141 citmPANC_COMPLICATION_1_CODE
cIPANC_COMPLICATION_CODE	String	Gastrointestinal haemorrhage	142 citmPANC_COMPLICATION_2_CODE
		Respiratory failure requiring ventilation	143 citmPANC_COMPLICATION_3_CODE
cIPANC_COMPLICATION_CODE	String	Renal failure requiring dialysis	144 citmPANC_COMPLICATION_4_CODE
		Other	999 citmPANC_COMPLICATION_5_CODE
cITREATMENT_TYPE_CODE	String	None	30 citmTREATMENT_TYPE_CODE1
		Standard treatment	61 citmTREATMENT_TYPE_CODE2
		Intensive care treatment	62 citmTREATMENT_TYPE_CODE3

		Other	999	citmTREATMENT_TYPE_CODE4	
		Unknown	996	citmTREATMENT_TYPE_CODE5	
c RISK_CON	String	No	2	citmRISK_CON_FACTOR_YN2	RISK_CON_FACTOR_YN
		Yes	1	citmRISK_CON_FACTOR_YN1	
		Unknown	996	citmRISK_CON_FACTOR_YN3	
c RISK_CON_FA_CODE	String	Gallstones	4	citmRISK_CON_FA_1_CODE	RISK_CON_FA_CODE
		Alcohol consumption	5	citmRISK_CON_FA_2_CODE	
		Family history of pancreatitis	6	citmRISK_CON_FA_4_CODE	
		Hypertriglyceridaemia	7	citmRISK_CON_FA_5_CODE	
		Trauma to the pancreas (incl. endoscopic retrograde cholangiopancreatography (ERCP))	9	citmRISK_CON_FA_7_CODE	
		Hypercalcaemia	11	citmRISK_CON_FA_9_CODE	
		Other	999	citmRISK_CON_FA_10_CODE	

**RDE Analytics: RD\_PANCREATITIS**

Data Variable RefName	RD Column Name	Column Data Type
PANC_SEQ_NO	PANC_SEQ_NO	NUMBER
	PANC_SEQ_NO_ND	VARCHAR2
PANC_AE_NO	PANC_AE_NO	NUMBER
	PANC_AE_NO_ND	VARCHAR2
ABDOMINAL_PAIN_YN	ABDOMINAL_PAIN_YN_C	VARCHAR2
	ABDOMINAL_PAIN_YN	VARCHAR2
	ABDOMINAL_PAIN_YN_ND	VARCHAR2
PANC_SYMPTOMS_YN	PANC_SYMPTOMS_YN_C	VARCHAR2
	PANC_SYMPTOMS_YN	VARCHAR2
	PANC_SYMPTOMS_YN_ND	VARCHAR2
PANC_SYMPTOMS_YN - Nausea	*PANC_CLINIC_SYMPT_CODE_CITMPANCLINICSYMP1CODE_C	VARCHAR2
	*PANC_CLINIC_SYMPT_CODE_CITMPANCLINICSYMP1CODE	VARCHAR2
PANC_SYMPTOMS_YN - Vomiting	*PANC_CLINIC_SYMPT_CODE_CITMPANCLINICSYMP2CODE_C	VARCHAR2
	*PANC_CLINIC_SYMPT_CODE_CITMPANCLINICSYMP2CODE	VARCHAR2
PANC_SYMPTOMS_YN - Fever	*PANC_CLINIC_SYMPT_CODE_CITMPANCLINICSYMP3CODE_C	VARCHAR2
	*PANC_CLINIC_SYMPT_CODE_CITMPANCLINICSYMP3CODE	VARCHAR2
PANC_SYMPTOMS_YN - Other	*PANC_CLINIC_SYMPT_CODE_CITMPANCLINICSYMP4CODE_C	VARCHAR2
	*PANC_CLINIC_SYMPT_CODE_CITMPANCLINICSYMP4CODE	VARCHAR2
PANC_IMAGING_YN	PANC_IMAGING_YN_C	VARCHAR2
	PANC_IMAGING_YN	VARCHAR2
	PANC_IMAGING_YN_ND	VARCHAR2
PANC_IMAGING_YN - Ultrasound	*PANC_METHOD_CODE_CITMPANCMETHOD1CODE_C	VARCHAR2
	*PANC_METHOD_CODE_CITMPANCMETHOD1CODE	VARCHAR2
PANC_IMAGING_YN - CT scan	*PANC_METHOD_CODE_CITMPANCMETHOD2CODE_C	VARCHAR2
	*PANC_METHOD_CODE_CITMPANCMETHOD2CODE	VARCHAR2
PANC_IMAGING_YN - MRI	*PANC_METHOD_CODE_CITMPANCMETHOD3CODE_C	VARCHAR2
	*PANC_METHOD_CODE_CITMPANCMETHOD3CODE	VARCHAR2
PANC_IMAGING_YN - Other	*PANC_METHOD_CODE_CITMPANCMETHOD4CODE_C	VARCHAR2
	*PANC_METHOD_CODE_CITMPANCMETHOD4CODE	VARCHAR2
PANC_IMAGING_YN - PANC_GALLSTONE_YN	PANC_GALLSTONE_YN_C	VARCHAR2
	PANC_GALLSTONE_YN	VARCHAR2
PANC_IMAGING_YN - ACUTE_PANCR_YN	ACUTE_PANCR_YN_C	VARCHAR2
	ACUTE_PANCR_YN	VARCHAR2
PANC_IMAGING_YN - Obstructive gallstone	*ACUTE_PANCR_CODE_CITMACUTEPANCR1CODE_C	VARCHAR2
	*ACUTE_PANCR_CODE_CITMACUTEPANCR1CODE	VARCHAR2
PANC_IMAGING_YN - Dilated common bile duct	*ACUTE_PANCR_CODE_CITMACUTEPANCR2CODE_C	VARCHAR2
	*ACUTE_PANCR_CODE_CITMACUTEPANCR2CODE	VARCHAR2
PANC_IMAGING_YN - Peri-pancreatic fluid	*ACUTE_PANCR_CODE_CITMACUTEPANCR3CODE_C	VARCHAR2
	*ACUTE_PANCR_CODE_CITMACUTEPANCR3CODE	VARCHAR2
PANC_IMAGING_YN - Oedematous or interstitial pancreatitis	*ACUTE_PANCR_CODE_CITMACUTEPANCR4CODE_C	VARCHAR2
	*ACUTE_PANCR_CODE_CITMACUTEPANCR4CODE	VARCHAR2
PANC_IMAGING_YN - Necrotising pancreatitis	*ACUTE_PANCR_CODE_CITMACUTEPANCR5CODE_C	VARCHAR2
	*ACUTE_PANCR_CODE_CITMACUTEPANCR5CODE	VARCHAR2
PANC_IMAGING_YN - Other	*ACUTE_PANCR_CODE_CITMACUTEPANCR6CODE_C	VARCHAR2
	*ACUTE_PANCR_CODE_CITMACUTEPANCR6CODE	VARCHAR2
PANC_IMAGING_YN - CHRONIC_PANCR_YN	CHRONIC_PANCR_YN_C	VARCHAR2
	CHRONIC_PANCR_YN	VARCHAR2
PANC_IMAGING_YN - Calcification of pancreas	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR1CODE_C	VARCHAR2
	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR1CODE	VARCHAR2
PANC_IMAGING_YN - Atrophy of the pancreas	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR2CODE_C	VARCHAR2
	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR2CODE	VARCHAR2
PANC_IMAGING_YN - Dilatation of pancreatic ducts	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR3CODE_C	VARCHAR2
	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR3CODE	VARCHAR2
PANC_IMAGING_YN - Pseudocysts	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR4CODE_C	VARCHAR2
	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR4CODE	VARCHAR2
PANC_IMAGING_YN - Other	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR5CODE_C	VARCHAR2
	*CHRONIC_PANCR_CODE_CITMCHRONICPANCR5CODE	VARCHAR2
COMPLICATION_YN	COMPLICATION_YN_C	VARCHAR2
	COMPLICATION_YN	VARCHAR2
	COMPLICATION_YN_ND	VARCHAR2
COMPLICATION_YN - Sepsis	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION1CODE_C	VARCHAR2
	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION1CODE	VARCHAR2
COMPLICATION_YN - Gastrointestinal haemorrhage	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION2CODE_C	VARCHAR2
	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION2CODE	VARCHAR2
COMPLICATION_YN - Respiratory failure requiring ventilation	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION3CODE_C	VARCHAR2
	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION3CODE	VARCHAR2
COMPLICATION_YN - Renal failure requiring dialysis	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION4CODE_C	VARCHAR2
	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION4CODE	VARCHAR2
COMPLICATION_YN - Other	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION5CODE_C	VARCHAR2
	*PANC_COMPLICATION_CODE_CITMPANCCOMPLICATION5CODE	VARCHAR2
TREATMENT_TYPE_CODE	TREATMENT_TYPE_CODE_C	VARCHAR2
	TREATMENT_TYPE_CODE	VARCHAR2
	TREATMENT_TYPE_CODE_ND	VARCHAR2
RISK_CON_FACTOR_YN	RISK_CON_FACTOR_YN_C	VARCHAR2

	RISK_CON_FACTOR_YN	VARCHAR2
RISK_CON_FACTOR_YN - Gallstones	RISK_CON_FACTOR_YN_ND	VARCHAR2
	*RISK_CON_FA_CODE_CITMRISKCONFA1CODE_C	VARCHAR2
	*RISK_CON_FA_CODE_CITMRISKCONFA1CODE	VARCHAR2
RISK_CON_FACTOR_YN - Alcohol consumption	*RISK_CON_FA_CODE_CITMRISKCONFA2CODE_C	VARCHAR2
	*RISK_CON_FA_CODE_CITMRISKCONFA2CODE	VARCHAR2
RISK_CON_FACTOR_YN - Family history of pancreatitis	*RISK_CON_FA_CODE_CITMRISKCONFA4CODE_C	VARCHAR2
	*RISK_CON_FA_CODE_CITMRISKCONFA4CODE	VARCHAR2
RISK_CON_FACTOR_YN - Hypertriglyceridemia	*RISK_CON_FA_CODE_CITMRISKCONFA5CODE_C	VARCHAR2
	*RISK_CON_FA_CODE_CITMRISKCONFA5CODE	VARCHAR2
RISK_CON_FACTOR_YN - Trauma to the pancreas (incl. endoscopic retrograde cholangiopancreatography (ERCP))	*RISK_CON_FA_CODE_CITMRISKCONFA7CODE_C	VARCHAR2
	*RISK_CON_FA_CODE_CITMRISKCONFA7CODE	VARCHAR2
RISK_CON_FACTOR_YN - Hypercalcaemia	*RISK_CON_FA_CODE_CITMRISKCONFA9CODE_C	VARCHAR2
	*RISK_CON_FA_CODE_CITMRISKCONFA9CODE	VARCHAR2
RISK_CON_FACTOR_YN - Other	*RISK_CON_FA_CODE_CITMRISKCONFA10CODE_C	VARCHAR2
	*RISK_CON_FA_CODE_CITMRISKCONFA10CODE	VARCHAR2
<b>*RD_PANCREATITIS_SCTPANC_LAB_TEST_EVENT</b>		
PANC_LAB_TEST	PANC_LAB_TEST_C	VARCHAR2
	PANC_LAB_TEST	VARCHAR2
	PANC_LAB_TEST_ND	VARCHAR2
PANC_LAB_TEST_YN	PANC_LAB_TEST_YN_C	VARCHAR2
	PANC_LAB_TEST_YN	VARCHAR2
PANC_COLLECTION_DATE	PANC_COLLECTION_DATE	DATE
	PANC_COLLECTION_DATE_DTS	VARCHAR2
	PANC_COLLECTION_DATE_ND	VARCHAR2
grpPANC_RESULT	GRPPANC_RESULT_ND	VARCHAR2
grpPANC_RESULT - PANC_LVALUE_1	PANC_LVALUE_1	FLOAT
grpPANC_RESULT - PANC_LPARAM_UNIT	PANC_LPARAM_UNIT_C	VARCHAR2
	PANC_LPARAM_UNIT	VARCHAR2
grpPANC_REF_RANGE	GRPPANC_REF_RANGE_ND	VARCHAR2
grpPANC_REF_RANGE - PANC_REF_RANGE_LOW	PANC_REF_RANGE_LOW	FLOAT
grpPANC_REF_RANGE - PANC_REF_RANGE_HIGH	PANC_REF_RANGE_HIGH	FLOAT

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**LB=Laboratory Test Results****LBCAT=AE REQUIRING ADDITIONAL DATA****FA=Findings About Events or Interventions****FACAT=AE REQUIRING ADDITIONAL DATA****CE=Clinical Events****CECAT=AE REQUIRING ADDITIONAL DATA**

: Acute Kidney Injury (AKI) - Repeating Form [ACUTE_KIDNEY_INJURY]			Provide available results from locally analysed laboratory tests at time of this event			Nephrotoxic agents?	Evidence or suspicion of conditions to event?	Was imaging performed in relation to the event?	Kidney biopsy diagnosis?	Family history of kidney disease?		
#	Injury No.	Related AE No.	Event present itself?	Laboratory Tests								
1				Provide available results from locally analysed laboratory tests at time of this event								
Study ID: NN9536-4512												
1.	Acute Kidney Injury number [read-only] [Acute Kidney Injury No.]			[RENAL_SEQ_NO] 0 < N3	CEREFID	FAREFID	LBREFID	RELREC: CE,FA	RELREC: CE,LB			
2.*	Related adverse event number [Related AE No.]			[RENAL_AE_NO] 0 < N3	CELNKID	FALNKID	LBLNKID	RELREC: CE,AE				
3.*	How did this event present itself? [Event present itself?]			[EVENT_PRESENT_CODE] [A:15] Increase in serum creatinine ≥ 0.3 mg/dL within 48 hours [A:16] Increase in serum creatinine to ≥ 1.5 times baseline within 7 days [A:17] Urine volume < 0.5 mL/kg/h for 6 hours [A:999] [EVENT_PRESENT_OTHER] Other Specify: A200		FAORRES when FATESTCD=AKISC48	FAORRES when FATESTCD=AKISCI7D	FAORRES when FATESTCD=AKIUV6H				
	FASCAT=ACUTE KIDNEY INJURY PRESENT							Note: FAORRES=Specify if available				
	FAORRES when FATESTCD=AKIPROTH											
Laboratory Tests Provide available results from locally analysed laboratory tests at time of this event [sctRENAL_LAB_TESTS]												
#	Test	Test done?*	Procedure	Sample collection date	Result	Reference range Use same units for reference range as the reported result			Test Medium			
4.a	Blood urea nitrogen (BUN)								BLOOD			
4.b	Serum creatinine								BLOOD			
4.c	Serum cystatin C								BLOOD			
4.d	Urinary albumin/creatinine ratio (ACR)								URINE			
4.e	Urine albumin								URINE			
4.f	Urine protein								URINE			
4.g	24-hour urine creatinine clearance								URINE			
Laboratory Tests Provide available results from locally analysed laboratory tests at time of this event Entry [sctRENAL_LAB_TESTS]												
4.1	Test [Test]	LBORRES/LBORRESU when LBTESTCD=CREAT LBORRES/LBORRESU when LBTESTCD=ALBCREAT LBORRES/LBORRESU when LBTESTCD=CREATCLR			[REN_DESC_TEST] [A:93] Blood urea nitrogen (BUN) [A:627] Serum creatinine [A:159] Serum cystatin C [A:155] Urinary albumin/creatinine ratio (ACR) [A:42] Urine albumin [A:95] Urine protein [A:631] 24-hour urine creatinine clearance	LBORRES/LBORRESU when LBTESTCD=UREAN LBORRES/LBORRESU when LBTESTCD=CYSTATC LBORRES/LBORRESU when LBTESTCD=ALB LBORRES/LBORRESU when LBTESTCD=PROT						
4.2*	Test done? [Test done?]	NOT SUBMITTED			[REN_EVT_YN] [A:1] Yes [A:2] No [A:996] Unknown							
4.3	Procedure [Procedure]				[REN_DESC_TEST_PROC] [A:115] Random spot urine sample [A:116] First morning urine sample [A:117] [DURATION_SAMPLE_HOUR] Timed urine collection: 0 < N2 hours[b]	AKILABI in SUPPLB	AKIDURU in SUPPLB					
4.4	Sample collection date [Sample collection date]				[REN_SAMPLE_DATE] (DD/MM/YYYY) Req ✓ / Req ✓ / Req ✓ (2023-2030)	LBDTC						
4.5	Result [Result]				[grpREN_RESULT] [REN_LVALUE] xxxx.	LBORRES						
4.6	Reference range [Reference range] [Use same units for reference range as the reported result]				[REN_EV_REF_RANGE] [REN_RES_LOW_RANGE] Lower normal limit: xxxx. [REN_RES_HIGH_RANGE] Upper normal limit: xxxx.	LORANCOL in SUPPLB	HIRANCOL in SUPPLB					
4.7	Test Medium [hidden] [Test Medium]				[TEST_MEDIUM_CODE] [A:2] BLOOD [A:4] URINE							
#	Test	Test done?*	Sample collection date	Result	Reference range Use same units for reference range as the reported result			Test Medium				
5.a	Measured glomerular filtration rate (mGFR)				LBSCAT=ACUTE KIDNEY INJURY LABORATORY TEST			URINE				
5.b	Estimated glomerular filtration rate (eGFR)							URINE				
5.1	Test [Test]	NOT SUBMITTED			[REN_DESC_TEST_1] [A:48] Measured glomerular filtration rate (mGFR) [A:49] Estimated glomerular filtration rate (eGFR)	LBORRES/LBORRESU when LBTESTCD=GFR						
5.2*	Test done? [Test done?]	NOT SUBMITTED			[REN_EVT_YN_1] [A:1] Yes [A:2] No [A:996] Unknown	LBORRES/LBORRESU when LBTESTCD=GFRE						
5.3	Sample collection date [Sample collection date]				[REN_SAMPLE_DATE_1] (DD/MM/YYYY) Req ✓ / Req ✓ / Req ✓ (2023-2030)	LBDTC						
5.4	Result [Result]				[grpREN_RESULT_1] [REN_LVALUE_1] xxxx.	LBORRES						
5.5	Reference range [Reference range] [Use same units for reference range as the reported result]				[REN_EV_REF_RANGE_1] [REN_RES_LOW_RANGE_1] Lower normal limit: xxxx. [REN_RES_HIGH_RANGE_1] Upper normal limit: xxxx.	LORANCOL in SUPPLB	HIRANCOL in SUPPLB					
5.6	Test Medium [hidden] [Test Medium]				[TEST_MEDIUM_CODE_1] [A:4] URINE							
#	Test	Test done?*	Sample collection date	Result	Test Method			Test Medium				
6.a	Erythrocytes (urine dipstick)				DIPSTICK			URINE				
6.b	Leukocytes (urine dipstick)				DIPSTICK			URINE				
6.c	Albumin (urine dipstick)				DIPSTICK			URINE				
6.d	Nitrite (urine dipstick)				DIPSTICK			URINE				
6.e	Urine Culture				MICROBIAL CULTURE			URINE				
6.f	Urine microscopy				MICROSCOPY			URINE				
6.1	Test [Test]	LBSCAT=ACUTE KIDNEY INJURY LABORATORY TEST			[REN_DESC_TEST_2] [A:628] Erythrocytes (urine dipstick) [A:632] Leukocytes (urine dipstick) [A:629] Albumin (urine dipstick)	LBORRES when LBTESTCD=RBC and LBSPEC=URINE						
	LBMETHOD=DIPSTICK MEASUREMENT METHOD					LBORRES when LBTESTCD=WBC and LBSPEC=URINE						
						LBORRES when LBTESTCD=ALB and LBSPEC=URINE						

		<b>FA=Findings About</b>	<b>LBCAT=AE REQUIRING ADDITIONAL DATA</b>	<b>LB=Laboratory Test Results</b>
		<b>FACAT=AE REQUIRING ADDITIONAL DATA</b>	<b>LBORRES when LBTESTCD=NITRITE and LBSPEC=URINE</b>	
		<b>LBMETHOD=MICROBIAL CULTURE</b>	<b>LBORRES when LBTESTCD=URNCULTR and LBSPEC=URINE</b>	
		<b>LBMETHOD=MICROSCOPY</b>	<b>LBORRES when LBTESTCD=URNMICRO and LBSPEC=URINE</b>	
		<b>NOT SUBMITTED</b>		
6.2*	Test uu [Test done?]	[A:47] <input type="radio"/> Nitrite (urine dipstick) [A:620] <input type="radio"/> Urine Culture [A:160] <input type="radio"/> Urine microscopy [A:996] <input type="radio"/> Unknown  [REN_EVT_YN_2] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No [A:996] <input type="radio"/> Unknown  [REN_SAMPLE_DATE_2] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2023-2030)	<b>LBDTC</b>	
6.3	Sample collection date [Sample collection date]			
6.4	Result	A200	<b>LBORRES</b>	
6.5	Test Method [hidden] [Test Method]	[TEST_METHOD] [A:69] <input type="radio"/> DIPSTICK [A:129] <input type="radio"/> MICROBIAL CULTURE [A:130] <input type="radio"/> MICROSCOPY		
6.6	Test Medium [hidden] [Test Medium]	[TEST_MEDIUM_CODE_2] [A:4] <input type="radio"/> URINE		
7.*	Has the subject received any nephrotoxic agents within the last 3 months?  Update concomitant medication as relevant [Nephrotoxic agents?]	<b>FASCAT=ACUTE KIDNEY INJURY NEPHROTOXIC TREATMENTS</b>	  [NEPHROTOX_AGENT_YN] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> [grpNEPHROTOX_AG_CD] <input type="checkbox"/> Yes [NEPHROTOX_AGENT_CODE] [A:1] <input type="checkbox"/> [NEPHROTOX_AGENT_TEXT] Aminoglycoside(s) Specify: A80  [NEPHROTOX_AG_CODE1] [A:2] <input type="checkbox"/> [NEPHROTOX_AGENT_TEXT_1] Nonsteroidal anti-inflammatory drug(s) (NSAIDs) Specify: A80  [NEPHROTOX_AG_CODE1_1] [A:3] <input type="checkbox"/> [NEPHROTOX_AGENT_TEXT_2] IV contrast Specify: A80  [NEPHROTOX_AG_CODE1_2] [A:4] <input type="checkbox"/> [NEPHROTOX_AGENT_TEXT_3] Initiation of a renin-angiotensin-aldosterone system inhibitor(s) Specify: A80  [NEPHROTOX_AG_CODE1_3] [A:999] <input type="checkbox"/> [NEPHROTOX_AGENT_TEXT_4] Other Specify: A200	<b>FAORRES when FATESTCD=AKINDA3M</b> <b>FAORRES when FATESTCD=AKIAMINO</b> <b>FAORRES when FATESTCD=AKINSAID</b> <b>FAORRES when FATESTCD=AKIIVCON</b> <b>FAORRES when FATESTCD=AKIRASBL</b> <b>FAORRES when FATESTCD=AKINDAO</b>
8.*	Was there evidence or suspicion of conditions which could explain or have contributed to the event?  [Evidence or suspicion of conditions to event?]	<b>FASCAT=ACUTE KIDNEY INJURY CONDITIONS</b>	  [CONDITION_YN] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> [grpCONDITION_CODE1] <input type="checkbox"/> Yes [CONDITION_CODE] [A:4] <input type="checkbox"/> Acute urinary tract infection [CONDITION_CODE_1] [A:5] <input type="checkbox"/> Chronic urinary tract infection [CONDITION_CODE_1_1] [A:6] <input type="checkbox"/> Post-renal obstructive disease [CONDITION_CODE_1_2] [A:1] <input type="checkbox"/> Hypertension [CONDITION_CODE_1_4] [A:16] <input type="checkbox"/> Recent volume depletion secondary to GI symptoms [CONDITION_CODE_1_5] [A:15] <input type="checkbox"/> Recent volume depletion due to other/unknown cause [CONDITION_CODE_1_3] [A:14] <input type="checkbox"/> Recent decrease in cardiac output or hypotension [CONDITION_CODE_1_3] [A:7] <input type="checkbox"/> Recent decrease in renal perfusion due to volume depletion, decreased cardiac output or hypotension [CONDITION_CODE_1_4] [A:57] <input type="checkbox"/> Progression of chronic kidney disease [CONDITION_CODE_1_5] [A:9] <input type="checkbox"/> Primary glomerulonephritis [CONDITION_CODE_1_6] [A:10] <input type="checkbox"/> Systemic autoimmune disease [CONDITION_CODE_1_7] [A:11] <input type="checkbox"/> Recent streptococcal infection [CONDITION_CODE_1_8] [A:12] <input type="checkbox"/> Renal artery stenosis [CONDITION_CODE_1_9] [A:13] <input type="checkbox"/> Renal vein thrombosis [CONDITION_CODE_1_11] [A:29] <input type="checkbox"/> Volume depletion for other reasons than gastrointestinal symptoms [CONDITION_CODE_1_12] [A:56] <input type="checkbox"/> Connective tissue disease or vasculitis [CONDITION_CODE_1_10] [A:999] <input type="checkbox"/> [grp_CONDITION_OTHER] <input type="checkbox"/> Other [CONDITION_OTHER] Specify: A200	<b>FAORRES when FATESTCD=AKICONDI</b> <b>FAORRES when FATESTCD=AKIAURIN</b> <b>FAORRES when FATESTCD=AKICURIN</b> <b>FAORRES when FATESTCD=AKIPROBS</b> <b>FAORRES when FATESTCD=AKIHYPER</b> <b>FAORRES when FATESTCD=AKIRDCOH</b> <b>FAORRES when FATESTCD=AKIDRP</b> <b>FAORRES when FATESTCD=AKIPRGLO</b> <b>FAORRES when FATESTCD=AKISYAUD</b> <b>FAORRES when FATESTCD=AKIREAST</b> <b>FAORRES when FATESTCD=AKIREVET</b>
9.*	Was imaging performed in relation to the event?  [Was imaging performed in relation to the event?]	<b>FASCAT=ACUTE KIDNEY INJURY IMAGING</b>	  [IMAGING_DIAGNOSIS_YN] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> [grpIMAGING_DIAG_MET] <input type="checkbox"/> Yes [IMAGING_DIAGNOSIS_METHOD] [A:103] <input type="checkbox"/> Ultrasound [IMAGING_DIAG_MET_1] [A:104] <input type="checkbox"/> CT scan [IMAGING_DIAG_MET_1_1] [A:111] <input type="checkbox"/> Renal angi-imaging (e.g. angiography, angio-CT, angio-MRI) [IMAGING_DIAG_MET_2] [A:999]	<b>FAORRES when FATESTCD=AKIIMAGE</b> <b>FAORRES when FATESTCD=AKIULTRA</b> <b>FAORRES when FATESTCD=AKICTSCA</b> <b>FAORRES when FATESTCD=AKIRANIM</b>

**FA=Findings About****FACAT=AE REQUIRING ADDITIONAL DATA**

		[grpMETHOD_TEXT] <input type="checkbox"/> Other [METHOD_TEXT] Specify: A200	<b>FAORRES when FATESTCD=AKIIMOTH</b>
		[SUM_IMAGE_RES] Summary of imaging results: A200	<b>FAORRES when FATESTCD=AKIHISTO</b>
10.* Was a kidney biopsy performed in relation to the event? [Kidney biopsy diagnosis?]	<b>FASCAT=ACUTE KIDNEY INJURY BIOPSY</b>	[A:996] <input type="radio"/> Unknown  [BIOPSY_DIAGNOSIS_YN] [A:2] <input type="radio"/> No [A:1] <input checked="" type="radio"/> [grpBIOPSY_DIAGNOSIS_TEXT] <input type="checkbox"/> Yes [BIOPSY_DIAGNOSIS_TEXT] Summary of histology results A200  [A:996] <input type="radio"/> Unknown	<b>FAORRES when FATESTCD=AKIBIOPS</b>  <b>FAORRES when FATESTCD=AKIBIHIS</b>
11.* Is there any family history of kidney disease? [Family history of kidney disease?]		[RELATIVE_HIST_YN1] [A:2] <input type="radio"/> No [A:1] <input type="radio"/> Yes [A:996] <input type="radio"/> Unknown	<b>FAORRES when FATESTCD=AKIFAMHI</b>
12. Specify: [hidden] [Specify:]		[grpRELATIVE_HIST_TEXT] Yes [RELATIVE_HIST_TEXT] Specify: A200	

Key: [\*] = Item is required   [✓] = Source verification required   [B] = Base Unit   [□] = Item is collapsible   [■] = Fixed item   [■] = Blank cell  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.

**Study Object Descriptions: Acute Kidney Injury**

Type	RefName	Description
Form	ACUTE_KIDNEY_INJURY	Visit: AE This form is a dynamic form which is to be triggered by the AE form to appear when AE category item AE_CATEGORY_MATCH_YN = Acute kidney injury
Item	RENAL_SEQ_NO	Calculated in InForm via rule
Item	RENAL_AE_NO	Integrations: A - please do not change the refname or format
Item	TEST_MEDIUM_CODE	Item required for OC
Item	TEST_MEDIUM_CODE_1	Item required for OC
Item	TEST_METHOD	Item required for OC
Item	TEST_MEDIUM_CODE_2	Item required for OC
Item	grpRELATIVE_HIST_TEXT	**Item DEACTIVATED**
Item	RELATIVE_HIST_TEXT	**Item DEACTIVATED**

**Codelist Values Tables: Acute Kidney Injury**

Codelist RefName	Codelist Data Type	Subset Label	Code	Codelist Item RefName	Data Variable RefName
cEVENT_PRESENT_CODE	String	Increase in serum creatinine $\geq$ 0.3 mg/dL within 48 hours Increase in serum creatinine to $\geq$ 1.5 times baseline within 7 days Urine volume < 0.5 mL/kg/h for 6 hours Other	15	ctmEVENT_PRESENT_CODE6	EVENT_PRESENT_CODE
			16	ctmEVENT_PRESENT_CODE7	
			17	ctmEVENT_PRESENT_CODE3	
			999	ctmEVENT_PRESENT_CODE999	
cREN_DESC_TEST	String	Blood urea nitrogen (BUN) Serum creatinine Serum cystatin C Urinary albumin/creatinine ratio (ACR) Urine albumin Urine protein 24-hour urine creatinine clearance	93	ctmREN_DESC_TEST93_1	REN_DESC_TEST
			627	ctmREN_DESC_TEST627	
			159	ctmREN_DESC_TEST159	
			155	ctmREN_DESC_TEST155	
			42	ctmREN_DESC_TEST42	
			95	ctmREN_DESC_TEST95	
			631	ctmREN_DESC_TEST631	
cREN_EVT_YN	String	Yes No Unknown	1	ctmREN_EVT_YN1	REN_EVT_YN,
			2	ctmREN_EVT_YN2	REN_EVT_YN_1
			996	ctmREN_EVT_YN996	
cREN_DESC_TEST_URINE	String	Random spot urine sample First morning urine sample Timed urine collection	115	ctmREN_DESC_TEST_URALB115	REN_DESC_TEST_PROC
			116	ctmREN_DESC_TEST_URALB116	
			117	ctmREN_DESC_TEST_URALB117	
cREN_LPARM_UNIT	String	mg/dL mmol/L umol/L mg/mmol mg/g g/L mL/min ug/L	162	ctmREN_LPARM_UNIT_OTH_162	REN_LPARM_UNIT
			144	ctmREN_LPARM_UNIT_OTH_144	
			541	ctmREN_LPARM_UNIT_OTH_541	
			170	ctmREN_LPARM_UNIT_OTH_170	
			169	ctmREN_LPARM_UNIT_OTH_169	
			203	ctmREN_LPARM_UNIT_OTH_203	
			145	ctmREN_LPARM_UNIT_OTH_145	
			143	ctmREN_LPARM_UNIT_OTH_143	
cITEST_MED	String	BLOOD URINE	3	ctmTEST_MEDIUM_3	TEST_MEDIUM_CODE
			4	ctmTEST_MEDIUM_4	
cREN_DESC_TEST_1	String	Measured glomerular filtration rate (mGFR) Estimated glomerular filtration rate (eGFR)	48	ctmREN_DESC_TEST44	REN_DESC_TEST_1
			49	ctmREN_DESC_TEST49	
cREN_LPARM_UNIT_1	String	mg/dL mmol/L umol/L mg/mmol mg/g g/L mL/min ug/L	162	ctmREN_LPARM_UNIT_OTH_162_1	REN_LPARM_UNIT_1
			144	ctmREN_LPARM_UNIT_OTH_144_1	
			541	ctmREN_LPARM_UNIT_OTH_541_1	
			170	ctmREN_LPARM_UNIT_OTH_170_1	
			169	ctmREN_LPARM_UNIT_OTH_169_1	
			203	ctmREN_LPARM_UNIT_OTH_203_1	
			145	ctmREN_LPARM_UNIT_OTH_145_1	
			143	ctmREN_LPARM_UNIT_OTH_143_1	
cITEST_MED_1	String	URINE	4	ctmTEST_MEDIUM_4	TEST_MEDIUM_CODE_1
cREN_DESC_TEST_2	String	Erythrocytes (urine dipstick) Leukocytes (urine dipstick) Albumin (urine dipstick)	628	ctmREN_DESC_TEST628	REN_DESC_TEST_2
			632	ctmREN_DESC_TEST632	
			629	ctmREN_DESC_TEST629	

		Nitrite (urine dipstick)	47	ctmREN_DESC_TEST47	
		Urine Culture	630	ctmREN_DESC_TEST630	
		Urine microscopy	160	ctmREN_DESC_TEST630_1	
cIREN_EVT_YN_1	String	Yes	1	ctmREN_EVT_YN1_1	REN_EVT_YN_2
		No	2	ctmREN_EVT_YN2_1	
		Unknown	996	ctmREN_EVT_YN996_1	
cTEST_METHOD	String	DIPSTICK	69	ctmTEST_METHOD_69	TEST_METHOD
		MICROBIAL CULTURE	129	ctmTEST_METHOD_129	
		MICROSCOPY	130	ctmTEST_METHOD_13	
cTEST_MED_2	String	URINE	4	ctmTEST_MEDIUM_4	TEST_MEDIUM_CODE_2
cINOYESUNK_4	String	No	2	ctmINOYESUNK2_3_1	
		Yes	1	ctmINOYESUNK1_3_1	
		Unknown	996	ctmINOYESUNK996_3_1	
cNEPHROTOX_AGENT_CODE	String	Aminoglycoside(s)	1	ctmNEPHROTOX_AGENT_CODE1	NEPHROTOX_AGENT_CODE
cNEPHROTOX_AG_CODE1	String	Nonsteroidal anti-inflammatory drug(s) (NSAIDs)	2	ctmNEPHROTOX_AGENT_CODE2	NEPHROTOX_AG_CODE1
cNEPH_AG_CODE1_1	String	IV contrast	3	ctmNEPHROTOX_AGENT_CODE3	NEPHROTOX_AG_CODE1_1
cNEPH_AG_CODE1_2	String	Initiation of a RAS blockade	4	ctmNEPHROTOX_AGENT_CODE4	NEPHROTOX_AG_CODE1_2
cNEPH_AG_CODE1_3	String	Other potentially nephrotoxic drugs	999	ctmNEPHROTOX_AGENT_CODE999	NEPHROTOX_AG_CODE1_3
cCONDITION_YN	String	Acute urinary tract infection	4	ctmCONDITION_YN4	CONDITION_CODE
cCONDITION_YN1	String	Chronic urinary tract infection	5	ctmCONDITION_YN5	CONDITION_CODE1
cCONDITION_YN1_1	String	Post-renal obstructive disease	6	ctmCONDITION_YN6	CONDITION_CODE1_1
cCONDITION_YN1_2	String	Hypertension	1	ctmCONDITION_YN1	CONDITION_CODE1_2
cCONDITION_YN1_4	String	Recent volume depletion secondary to GI symptoms	16	ctmCONDITION_YN14	CONDITION_CODE1_4
cCONDITION_YN1_5	String	Recent volume depletion due to other/unknown cause	15	ctmCONDITION_YN15	CONDITION_CODE1_5
cCONDITION_YN1_11	String	Recent decrease in cardiac output or hypotension	14	ctmCONDITION_YN1_1	CONDITION_CODE1_13
cCONDITION_YN1_3	String	Recent decrease in renal perfusion due to volume depletion, decreased cardiac output or hypotension	7	ctmCONDITION_YN7	CONDITION_CODE1_3
cCONDITION_YN1_4	String	Progression of chronic kidney disease	57	ctmCONDITION_YN57	CONDITION_CODE1_4
cCONDITION_YN1_5	String	Primary glomerulonephritis	9	ctmCONDITION_YN9	CONDITION_CODE1_5
cCONDITION_YN1_6	String	Systemic autoimmune disease	10	ctmCONDITION_YN10	CONDITION_CODE1_6
cCONDITION_YN1_7	String	Recent streptococcal infection	11	ctmCONDITION_YN11	CONDITION_CODE1_7
cCONDITION_YN1_8	String	Renal artery stenosis	12	ctmCONDITION_YN12	CONDITION_CODE1_8
cCONDITION_YN1_9	String	Renal vein thrombosis	13	ctmCONDITION_YN13	CONDITION_CODE1_9
cCONDITION_CODE1_11	String	Volume depletion for other reasons than gastrointestinal symptoms	29	ctmCONDITION_YN29	CONDITION_CODE1_11
cCONDITION_CODE1_12	String	Connective tissue disease or vasculitis	56	ctmCONDITION_YN56	CONDITION_CODE1_12
cCONDITION_YN1_10	String	Other, specify:	999	ctmCONDITION_YN999	CONDITION_CODE1_10
cIMAG_DIAG_METH	String	Ultrasound	103	ctmIMAG_DIAG METH103	IMAGING_DIAGNOSIS_METHOD
cIMAGING_DIAG_MET1	String	CT scan	104	ctmIMAG_DIAG METH104	IMAGING_DIAG_MET1
cIMAGING_DIAG_MET1_1	String	Renal angi-imaging (e.g. angiography, angio-CT, angio-MRI)	111	ctmIMAG_DIAG METH111	IMAGING_DIAG_MET1_1
cIMAGING_DIAG_MET1_2	String	Other	999	ctmIMAG_DIAG METH999	IMAGING_DIAG_MET1_2

**RDE Analytics: RD\_ACUTE\_KIDNEY\_INJURY**

Data Variable RefName	RD Column Name	Column Data Type
RENAL_SEQ_NO	RENAL_SEQ_NO	NUMBER
	RENAL_SEQ_NO_ND	VARCHAR2
RENAL_AE_NO	RENAL_AE_NO	NUMBER
	RENAL_AE_NO_ND	VARCHAR2
EVENT_PRESENT_CODE	EVENT_PRESENT_CODE_ND	VARCHAR2
EVENT_PRESENT_CODE - Increase in serum creatinine ≥ 0.3 mg/dL within 48 hours	*EVENT_PRESENT_CODE_CITMEVENTPRESENTCODE6_C	VARCHAR2
	*EVENT_PRESENT_CODE_CITMEVENTPRESENTCODE6	VARCHAR2
EVENT_PRESENT_CODE - Increase in serum creatinine to ≥ 1.5 times baseline within 7 days	*EVENT_PRESENT_CODE_CITMEVENTPRESENTCODE7_C	VARCHAR2
	*EVENT_PRESENT_CODE_CITMEVENTPRESENTCODE7	VARCHAR2
EVENT_PRESENT_CODE - Urine volume < 0.5 mL/kg/h for 6 hours	*EVENT_PRESENT_CODE_CITMEVENTPRESENTCODE3_C	VARCHAR2
	*EVENT_PRESENT_CODE_CITMEVENTPRESENTCODE3	VARCHAR2
EVENT_PRESENT_CODE - Other	*EVENT_PRESENT_CODE_EVENT_PRESENT_OTHER_C	VARCHAR2
	*EVENT_PRESENT_CODE_EVENT_PRESENT_OTHER	VARCHAR2
EVENT_PRESENT_CODE - EVENT_PRESENT_OTHER	EVENT_PRESENT_OTHER	VARCHAR2
NEPHROTOXIC_AGENT_YN	NEPHROTOXIC_AGENT_YN_C	VARCHAR2
	NEPHROTOXIC_AGENT_YN	VARCHAR2
	NEPHROTOXIC_AGENT_YN_ND	VARCHAR2
NEPHROTOXIC_AGENT_YN - Aminoglycoside(s)	*NEPHROTOX_AGENT_CODE_NEPHROTOX_AGENT_TEXT_C	VARCHAR2
	*NEPHROTOX_AGENT_CODE_NEPHROTOX_AGENT_TEXT	VARCHAR2
NEPHROTOXIC_AGENT_YN - NEPHROTOX_AGENT_TEXT	NEPHROTOX_AGENT_TEXT	VARCHAR2
NEPHROTOXIC_AGENT_YN - Nonsteroidal anti-inflammatory drug(s) (NSAIDs)	*NEPHROTOX_AG_CODE1_NEPHROTOX_AGENT_TEXT_1_C	VARCHAR2
	*NEPHROTOX_AG_CODE1_NEPHROTOX_AGENT_TEXT_1	VARCHAR2
NEPHROTOXIC_AGENT_YN - NEPHROTOX_AGENT_TEXT_1	NEPHROTOX_AGENT_TEXT_1	VARCHAR2
NEPHROTOXIC_AGENT_YN - IV contrast	*NEPHROTOX_AG_CODE1_1_NEPHROTOX_AGENT_TEXT_2_C	VARCHAR2
	*NEPHROTOX_AG_CODE1_1_NEPHROTOX_AGENT_TEXT_2	VARCHAR2
NEPHROTOXIC_AGENT_YN - NEPHROTOX_AGENT_TEXT_2	NEPHROTOX_AGENT_TEXT_2	VARCHAR2
NEPHROTOXIC_AGENT_YN - Initiation of a RAS blockade	*NEPHROTOX_AG_CODE1_2_NEPHROTOX_AGENT_TEXT_3_C	VARCHAR2
	*NEPHROTOX_AG_CODE1_2_NEPHROTOX_AGENT_TEXT_3	VARCHAR2
NEPHROTOXIC_AGENT_YN - NEPHROTOX_AGENT_TEXT_3	NEPHROTOX_AGENT_TEXT_3	VARCHAR2
NEPHROTOXIC_AGENT_YN - Other potentially nephrotoxic drugs	*NEPHROTOX_AG_CODE1_3_NEPHROTOX_AGENT_TEXT_4_C	VARCHAR2
	*NEPHROTOX_AG_CODE1_3_NEPHROTOX_AGENT_TEXT_4	VARCHAR2
NEPHROTOXIC_AGENT_YN - NEPHROTOX_AGENT_TEXT_4	NEPHROTOX_AGENT_TEXT_4	VARCHAR2
CONDITION_YN	CONDITION_YN_C	VARCHAR2
	CONDITION_YN	VARCHAR2
	CONDITION_YN_ND	VARCHAR2
CONDITION_YN - Acute urinary tract infection	*CONDITION_CODE_CITMCONDITIONYN4_C	VARCHAR2
	*CONDITION_CODE_CITMCONDITIONYN4	VARCHAR2
CONDITION_YN - Chronic urinary tract infection	*CONDITION_CODE1_CITMCONDITIONYN5_C	VARCHAR2
	*CONDITION_CODE1_CITMCONDITIONYN5	VARCHAR2
CONDITION_YN - Post-renal obstructive disease	*CONDITION_CODE1_1_CITMCONDITIONYN6_C	VARCHAR2
	*CONDITION_CODE1_1_CITMCONDITIONYN6	VARCHAR2
CONDITION_YN - Hypertension	*CONDITION_CODE1_2_CITMCONDITIONYN1_C	VARCHAR2
	*CONDITION_CODE1_2_CITMCONDITIONYN1	VARCHAR2
CONDITION_YN - Recent volume depletion secondary to GI symptoms	*CONDITION_CODE1_4_CITMCONDITIONYN14_C	VARCHAR2
	*CONDITION_CODE1_4_CITMCONDITIONYN14	VARCHAR2
CONDITION_YN - Recent volume depletion due to other/unknown cause	*CONDITION_CODE1_5_CITMCONDITIONYN15_C	VARCHAR2
	*CONDITION_CODE1_5_CITMCONDITIONYN15	VARCHAR2

-	:ent decrease in cardiac output or hypotension	*CONDITION_CODE1_13_CITMCONDITIONYN51_C	VARCHAR2
CONDITION_YN	+crease in renal perfusion due to volume depletion, decreased cardiac output or hypotension	*CONDITION_CODE1_13_CITMCONDITIONYN51	VARCHAR2
		*CONDITION_CODE1_3_CITMCONDITIONYN7_C	VARCHAR2
		*CONDITION_CODE1_3_CITMCONDITIONYN7	VARCHAR2
CONDITION_YN - Progression of chronic kidney disease		*CONDITION_CODE1_4_CITMCONDITIONYN57_C	VARCHAR2
		*CONDITION_CODE1_4_CITMCONDITIONYN57	VARCHAR2
CONDITION_YN - Primary glomerulonephritis		*CONDITION_CODE1_5_CITMCONDITIONYN9_C	VARCHAR2
		*CONDITION_CODE1_5_CITMCONDITIONYN9	VARCHAR2
CONDITION_YN - Systemic autoimmune disease		*CONDITION_CODE1_6_CITMCONDITIONYN10_C	VARCHAR2
		*CONDITION_CODE1_6_CITMCONDITIONYN10	VARCHAR2
CONDITION_YN - Recent streptococcal infection		*CONDITION_CODE1_7_CITMCONDITIONYN11_C	VARCHAR2
		*CONDITION_CODE1_7_CITMCONDITIONYN11	VARCHAR2
CONDITION_YN - Renal artery stenosis		*CONDITION_CODE1_8_CITMCONDITIONYN12_C	VARCHAR2
		*CONDITION_CODE1_8_CITMCONDITIONYN12	VARCHAR2
CONDITION_YN - Renal vein thrombosis		*CONDITION_CODE1_9_CITMCONDITIONYN13_C	VARCHAR2
		*CONDITION_CODE1_9_CITMCONDITIONYN13	VARCHAR2
CONDITION_YN - Volume depletion for other reasons than gastrointestinal symptoms		*CONDITION_CODE1_11_CITMCONDITIONYN29_C	VARCHAR2
		*CONDITION_CODE1_11_CITMCONDITIONYN29	VARCHAR2
CONDITION_YN - Connective tissue disease or vasculitis		*CONDITION_CODE1_12_CITMCONDITIONYN56_C	VARCHAR2
		*CONDITION_CODE1_12_CITMCONDITIONYN56	VARCHAR2
CONDITION_YN - Other, specify:		*CONDITION_CODE1_10_GRP_CONDITION_OTHER_C	VARCHAR2
		*CONDITION_CODE1_10_GRP_CONDITION_OTHER	VARCHAR2
CONDITION_YN - CONDITION_OTHER	CONDITION_OTHER		VARCHAR2
IMAGING_DIAGNOSIS_YN	IMAGING_DIAGNOSIS_YN_C		VARCHAR2
	IMAGING_DIAGNOSIS_YN		VARCHAR2
	IMAGING_DIAGNOSIS_YN_ND		VARCHAR2
IMAGING_DIAGNOSIS_YN - Ultrasound	*IMAGING_DIAGNOSIS_METHOD_CITMIMAGDIAGMETH103_C		VARCHAR2
	*IMAGING_DIAGNOSIS_METHOD_CITMIMAGDIAGMETH103		VARCHAR2
IMAGING_DIAGNOSIS_YN - CT scan	*IMAGING_DIAG_MET1_CITMIMAGDIAGMETH104_C		VARCHAR2
	*IMAGING_DIAG_MET1_CITMIMAGDIAGMETH104		VARCHAR2
IMAGING_DIAGNOSIS_YN - Renal angio-imaging (e.g. angiography, angio-CT, angio-MRI)	*IMAGING_DIAG_MET1_1_CITMIMAGDIAGMETH111_C		VARCHAR2
	*IMAGING_DIAG_MET1_1_CITMIMAGDIAGMETH111		VARCHAR2
IMAGING_DIAGNOSIS_YN - Other	*IMAGING_DIAG_MET1_2_GRPMETHOD_TEXT_C		VARCHAR2
	*IMAGING_DIAG_MET1_2_GRPMETHOD_TEXT		VARCHAR2
IMAGING_DIAGNOSIS_YN - METHOD_TEXT	METHOD_TEXT		VARCHAR2
IMAGING_DIAGNOSIS_YN - SUM_IMAGE_RES	SUM_IMAGE_RES		VARCHAR2
BIOPSY_DIAGNOSIS_YN	BIOPSY_DIAGNOSIS_YN_C		VARCHAR2
	BIOPSY_DIAGNOSIS_YN		VARCHAR2
	BIOPSY_DIAGNOSIS_YN_ND		VARCHAR2
BIOPSY_DIAGNOSIS_YN - BIOPSY_DIAGNOSIS_TEXT	BIOPSY_DIAGNOSIS_TEXT		VARCHAR2
RELATIVE_HIST_YN1	RELATIVE_HIST_YN1_C		VARCHAR2
	RELATIVE_HIST_YN1		VARCHAR2
	RELATIVE_HIST_YN1_ND		VARCHAR2
grpRELATIVE_HIST_TEXT	GRPRELATIVE_HIST_TEXT_ND		VARCHAR2
grpRELATIVE_HIST_TEXT - RELATIVE_HIST_TEXT	RELATIVE_HIST_TEXT		VARCHAR2
<b>*RD_ACUTE_KIDNEY_INJURY_SCTRENAL_LAB_TESTS</b>			
REN_DESC_TEST	REN_DESC_TEST_C		VARCHAR2
	REN_DESC_TEST		VARCHAR2
	REN_DESC_TEST_ND		VARCHAR2
REN_EVT_YN	REN_EVT_YN_C		VARCHAR2
	REN_EVT_YN		VARCHAR2
	REN_EVT_YN_ND		VARCHAR2
REN_DESC_TEST_PROC	REN_DESC_TEST_PROC_C		VARCHAR2
	REN_DESC_TEST_PROC		VARCHAR2
	REN_DESC_TEST_PROC_ND		VARCHAR2
	REN_DESC_TEST_PROC_IB		VARCHAR2
REN_DESC_TEST_PROC - DURATION_SAMPLE_HOUR	DURATION_SAMPLE_HOUR		NUMBER
	DURATION_SAMPLE_HOUR_U		VARCHAR2
REN_SAMPLE_DATE	REN_SAMPLE_DATE		DATE
	REN_SAMPLE_DATE_DTS		VARCHAR2
	REN_SAMPLE_DATE_ND		VARCHAR2
grpREN_RESULT	GRPREN_RESULT_ND		VARCHAR2
grpREN_RESULT - REN_LVALUE	REN_LVALUE		FLOAT
grpREN_RESULT - REN_LPARAM_UNIT	REN_LPARAM_UNIT_C		VARCHAR2
	REN_LPARAM_UNIT		VARCHAR2
grpREN_EVT_REF_RANGE	GRPREN_EVT_REF_RANGE_ND		VARCHAR2
grpREN_EVT_REF_RANGE - REN_RES_LOW_RANGE	REN_RES_LOW_RANGE		FLOAT
grpREN_EVT_REF_RANGE - REN_RES_HIGH_RANGE	REN_RES_HIGH_RANGE		FLOAT
TEST_MEDIUM_CODE	TEST_MEDIUM_CODE_C		VARCHAR2
	TEST_MEDIUM_CODE		VARCHAR2
	TEST_MEDIUM_CODE_ND		VARCHAR2
<b>*RD_ACUTE_KIDNEY_INJURY_SCTRENAL_LAB_TESTS_1</b>			
REN_DESC_TEST_1	REN_DESC_TEST_1_C		VARCHAR2
	REN_DESC_TEST_1		VARCHAR2
	REN_DESC_TEST_1_ND		VARCHAR2
REN_EVT_YN_1	REN_EVT_YN_1_C		VARCHAR2
	REN_EVT_YN_1		VARCHAR2
	REN_EVT_YN_1_ND		VARCHAR2
REN_SAMPLE_DATE_1	REN_SAMPLE_DATE_1		DATE
	REN_SAMPLE_DATE_1_DTS		VARCHAR2
	REN_SAMPLE_DATE_1_ND		VARCHAR2
grpREN_RESULT_1	GRPREN_RESULT_1_ND		VARCHAR2
grpREN_RESULT_1 - REN_LVALUE1	REN_LVALUE1		FLOAT
grpREN_RESULT_1 - REN_LPARAM_UNIT_1	REN_LPARAM_UNIT_1_C		VARCHAR2
	REN_LPARAM_UNIT_1		VARCHAR2
grpREN_EVT_REF_RANGE_1	GRPREN_EVT_REF_RANGE_1_ND		VARCHAR2
grpREN_EVT_REF_RANGE_1 - REN_RES_LOW_RANGE_1	REN_RES_LOW_RANGE_1		FLOAT
grpREN_EVT_REF_RANGE_1 - REN_RES_HIGH_RANGE_1	REN_RES_HIGH_RANGE_1		FLOAT
TEST_MEDIUM_CODE_1	TEST_MEDIUM_CODE_1_C		VARCHAR2

	TEST_MEDIUM_CODE_1	VARCHAR2
	TEST_MEDIUM_CODE_1_ND	VARCHAR2
<b>*RD_ACUTE</b> <b>EV_TNINJURY_SCTRENAL_LAB_TESTS_2</b>		
REN_DESC_TEST_2	REN_DESC_TEST_2_C	VARCHAR2
	REN_DESC_TEST_2	VARCHAR2
	REN_DESC_TEST_2_ND	VARCHAR2
REN_EVT_YN_2	REN_EVT_YN_2_C	VARCHAR2
	REN_EVT_YN_2	VARCHAR2
	REN_EVT_YN_2_ND	VARCHAR2
REN_SAMPLE_DATE_2	REN_SAMPLE_DATE_2	DATE
	REN_SAMPLE_DATE_2_DTS	VARCHAR2
	REN_SAMPLE_DATE_2_ND	VARCHAR2
REN_LVALUE_2	REN_LVALUE_2	VARCHAR2
	REN_LVALUE_2_ND	VARCHAR2
TEST_METHOD	TEST_METHOD_C	VARCHAR2
	TEST_METHOD	VARCHAR2
	TEST_METHOD_ND	VARCHAR2
TEST_MEDIUM_CODE_2	TEST_MEDIUM_CODE_2_C	VARCHAR2
	TEST_MEDIUM_CODE_2	VARCHAR2
	TEST_MEDIUM_CODE_2_ND	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**CM=Concomitant Medications**

Concomitant Medication (CM) - Repeating Form [CONCOM_MED_MEDDRA_1]						Rescue medication (Only applicable for T2D subjects with a central HbA1c value above 8.5% (69 mmol/mol))	Frequency	Route	Primary Indication	
#	Medication	Start date	Continuing?	Dose					<b>CMCAT=GENERAL</b>	
1										
Concomitant Medication [CONCOM_MED_MEDDRA_1]										
Study ID: NN9536-4512										
During the study from week 0 to week 111, participants should not initiate any weight-lowering medication which is not the IMP. If such treatment is initiated, the participant should be instructed to stop the weight-lowering medication. (Refer section 6.8 in protocol)										
1.	Seq. No. [read-only] [Seq. No.]	[CONCOM_SEQ_NO] N4	<b>CMREFID</b>							
2.*	Medication [Medication]	[SCAT1] [A:1] <input checked="" type="radio"/> [SCAT1_L2] Antihypertensive therapy and diuretics [A:1] <input type="radio"/> Atenolol [A:11] <input type="radio"/> Amlodipine [A:58] <input type="radio"/> Aliskiren [A:56] <input type="radio"/> Azilsartan medoxomil [A:38] <input type="radio"/> Benazepril [A:2] <input type="radio"/> Bisoprolol [A:23] <input type="radio"/> Bumetanide [A:18] <input type="radio"/> Bendrofumethiazide [A:27] <input type="radio"/> Canrenone [A:5] <input type="radio"/> Carvediol [A:37] <input type="radio"/> Captopril [A:30] <input type="radio"/> Clonidine [A:43] <input type="radio"/> Clazapril [A:50] <input type="radio"/> Candesartan [A:46] <input type="radio"/> Delapril [A:15] <input type="radio"/> Diltiazem [A:54] <input type="radio"/> Eprosartan [A:26] <input type="radio"/> Eplerenone [A:33] <input type="radio"/> Enalapril [A:22] <input type="radio"/> Furosemide [A:13] <input type="radio"/> Felodipine [A:57] <input type="radio"/> Filmsartan [A:39] <input type="radio"/> Fosinopril [A:32] <input type="radio"/> Hydralazine [A:17] <input type="radio"/> Hydrochlorothiazide [A:51] <input type="radio"/> Irbesartan [A:44] <input type="radio"/> Imidapril [A:20] <input type="radio"/> Indapamide [A:6] <input type="radio"/> Labetalol [A:14] <input type="radio"/> Lercanidipine [A:49] <input type="radio"/> Losartan [A:35] <input type="radio"/> Lisinopril [A:3] <input type="radio"/> Metoprolol [A:21] <input type="radio"/> Metolazone [A:29] <input type="radio"/> Moxonidine [A:28] <input type="radio"/> Methyldopa [A:47] <input type="radio"/> Moexipril [A:10] <input type="radio"/> Nadolol [A:4] <input type="radio"/> Nebivolol [A:12] <input type="radio"/> Nifdipine [A:53] <input type="radio"/> Olmesartan [A:36] <input type="radio"/> Perindopril [A:8] <input type="radio"/> Propanolol [A:40] <input type="radio"/> Quinapril [A:34] <input type="radio"/> Ramipril [A:9] <input type="radio"/> Sotalol [A:25] <input type="radio"/> Spironolactone [A:45] <input type="radio"/> Spirapril [A:7] <input type="radio"/> Timolol [A:31] <input type="radio"/> Terazosin [A:48] <input type="radio"/> Temocapril [A:55] <input type="radio"/> Telmisartan [A:19] <input type="radio"/> Trichlormethiazide [A:24] <input type="radio"/> Torasemide [A:42] <input type="radio"/> Trandolapril [A:52] <input type="radio"/> Valsartan [A:16] <input type="radio"/> Verapamil [A:41] <input type="radio"/> Zofenopril [A:2] <input checked="" type="radio"/> [SCAT2_L2] Antidiabetes Preparations, Excl. Diet Products [A:3] <input type="radio"/> Amiflpramone [A:13] <input type="radio"/> Bupropion, Naltrexone [A:7] <input type="radio"/> Cathine [A:8] <input type="radio"/> Clobenzorex [A:4] <input type="radio"/> Dexfenfluramine [A:6] <input type="radio"/> Etiaminofetamine [A:12] <input type="radio"/> Ephedrine, Combinations [A:2] <input type="radio"/> Fenfuramine [A:11] <input type="radio"/> Lorcaserin [A:5] <input type="radio"/> Mazindol [A:9] <input type="radio"/> Mefenorex [A:14] <input type="radio"/> Orlistat [A:1] <input type="radio"/> Phentermine [A:15] <input type="radio"/> Rimonabant [A:10] <input type="radio"/> Sibutramine [A:16] <input type="radio"/> Liraglutide [A:3] <input checked="" type="radio"/> [SCAT3_L2] Lipid modifying agents [A:9] <input type="radio"/> Aflacumab [A:2] <input type="radio"/> Atorvastatin [A:14] <input type="radio"/> Bezafibrate [A:10] <input type="radio"/> Colesevelam [A:11] <input type="radio"/> Colestyramine [A:12] <input type="radio"/> Colestipol [A:16] <input type="radio"/> Ciprofibrate [A:8] <input type="radio"/> Evolocumab [A:17] <input type="radio"/> Ezetimibe [A:6] <input type="radio"/> Fluvastatin [A:13] <input type="radio"/> Fenofibrate [A:15] <input type="radio"/> Gemfibrozil [A:5] <input type="radio"/> Lovastatin [A:19] <input type="radio"/> Lovaza (Omega-3-triglycerides) [A:20] <input type="radio"/> OMEGA-3 TRIGLYCERIDES [A:3] <input type="radio"/> Pravastatin [A:7] <input type="radio"/> Pitavastatin [A:4] <input type="radio"/> Rosuvastatin [A:1] <input type="radio"/> Simvastatin [A:21] <input type="radio"/> Vascepa (Icosapent Ethyl)	<b>CMSCAT</b>	<b>CMTRT</b>	<b>CMSCAT</b>	<b>CMTRT</b>	<b>CMSCAT</b>	<b>CMTRT</b>		

**CM=Concomitant Medications****CMCAT=GENERAL**

<p>[A:4] <input type="checkbox"/> [SCAT4_L2] Sodium-Glucose Co-Transporter 2(SGLT2 Inhibitors)</p> <p>[A:1] <input type="checkbox"/> Dapagliflozin  [A:2] <input type="checkbox"/> Canagliflozin  [A:3] <input type="checkbox"/> Empagliflozin  [A:4] <input type="checkbox"/> Erzuligliflozin  [A:5] <input type="checkbox"/> Ipragliflozin  [A:6] <input type="checkbox"/> Sotagliflozin  [A:7] <input type="checkbox"/> Luseogliflozin</p> <p>[A:5] <input type="checkbox"/> [SCATS_L2] Biguanides</p> <p>[A:1] <input type="checkbox"/> Metformin</p> <p>[A:6] <input type="checkbox"/> Glinide</p> <p>[A:7] <input type="checkbox"/> Thiazolidinedione</p> <p>[A:8] <input type="checkbox"/> <math>\alpha</math>-glucosidase inhibitors [AGI]</p> <p>[A:9] <input type="checkbox"/> Sulfonylureas</p> <p>[A:999] <input type="checkbox"/> [SCAT_OTH] Other medications, not listed above</p> <p>A200</p>	
<b>CMSCAT</b>	
<b>CMTRT</b>	
<p>[A:5] <input type="checkbox"/> [SCATS_L2] Biguanides</p> <p>[A:1] <input type="checkbox"/> Metformin</p> <p>[A:6] <input type="checkbox"/> Glinide</p> <p>[A:7] <input type="checkbox"/> Thiazolidinedione</p> <p>[A:8] <input type="checkbox"/> <math>\alpha</math>-glucosidase inhibitors [AGI]</p> <p>[A:9] <input type="checkbox"/> Sulfonylureas</p> <p>[A:999] <input type="checkbox"/> [SCAT_OTH] Other medications, not listed above</p> <p>A200</p>	
<b>CMSCAT</b>	
<b>CMSCAT</b>	
<b>CMSCAT</b>	
<b>CMSCAT</b>	
<p>3. Generic or Trade name [hidden] [Drug Name]</p> <p>[INV_DRUG1_TEXT]</p> <p>A200</p>	
<p>4. Country Code [hidden] [Country Code]</p> <p>[COUNTRY_ISO_CODE]</p> <p>[cCOUNTRY_ISO_CODE]</p>	
<p>5.* Start date [Start date]</p> <p>[CONCOM_START_DATE] (DD/MM/YYYY) Req/Unk <input checked="" type="checkbox"/> / Req <input type="checkbox"/> (1925-2030) <b>CMSTDTC</b></p>	
<p>6. Start date and time [hidden] [Start date and time]</p> <p>[CONCOM_START_DATE_TIME] (DD/MM/YYYY hh:mm) Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1900-2035)</p> <p>Req/Unk <input type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock</p>	
<p>7.* Continuing? [Continuing?]</p> <p>[CONCOM_STOP_DATE]</p> <p>[A:1] <input type="checkbox"/> Yes  [A:2] <input type="checkbox"/> [STOP_DATE_CM] (DD/MM/YYYY) No, Stop date Req/Unk <input type="checkbox"/> / Req/Unk <input checked="" type="checkbox"/> (2023-2030) <b>CΜENDTC</b></p> <p><b>CMENRF=ONGOING</b></p>	
<p>8. Continuing? [Continuing?]</p> <p>[CONCOM_STOP_DATE_TIME]</p> <p>[A:1] <input type="checkbox"/> Yes  [A:2] <input type="checkbox"/> [STOP_DATE_NCM_1] (DD/MM/YYYY hh:mm) No, Stop date and time Req/Unk <input type="checkbox"/> / Req/Unk <input checked="" type="checkbox"/> / Req <input type="checkbox"/> (2022-2035)</p> <p>Req/Unk <input type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock</p>	
<p>9. Dose (Only for the weight-related co-morbidities like diabetes, hypertension, and dyslipidaemia) [Dose]</p> <p>[grpDOSE] [DOSE] Dose &lt; xxxxxx.</p> <p>[CONCOM_UNIT2] Unit: [A:160] <input type="checkbox"/> mg  [A:420] <input type="checkbox"/> mL  [A:140] <input type="checkbox"/> ug  [A:200] <input type="checkbox"/> g  [A:830] <input type="checkbox"/> IU  [A:999] <input type="checkbox"/> [CONCOM_UNIT2_999] Other unit, specify: A10</p> <p><b>CMDOSE</b></p> <p><b>CMDOSU UNITCOLL in SUPPCM</b></p>	
<p>10. Rescue medication (Only applicable for T2D subjects with a central HbA1c value above 8.5% (69 mmol/mol)) [Rescue medication] (Only applicable for T2D subjects with a central HbA1c value above 8.5% (69 mmol/mol))</p> <p>[RESCUE_MED]</p> <p>[A:1] <input type="checkbox"/> Yes  [A:2] <input type="checkbox"/> No</p> <p><b>CMCAT=RESCUE MEDICATION</b></p>	
<p>11. Frequency [Frequency]</p> <p>[grpFREQUENCY_CODE] [FREQUENCY_CODE]</p> <p>[A:1] <input type="checkbox"/> Daily  [A:2] <input type="checkbox"/> Weekly  [A:999] <input type="checkbox"/> [FREQUENCY_OTHER_TEXT] Other frequency, specify: A50</p> <p><b>CMDOSFRO FREQCOLL in SUPPCM</b></p> <p><b>FREQOTH in SUPPCM</b></p>	
<p>12. Total Daily Dose [hidden] [Total Daily Dose]</p> <p>[grpTOTAL_DAILY_DOSE] [TOTAL_DAILY_DOSE]</p> <p>0 &lt; xxxxxx.</p> <p>[CONCOM_UNIT] Unit: [A:160] <input type="checkbox"/> mg  [A:420] <input type="checkbox"/> mL  [A:140] <input type="checkbox"/> ug  [A:200] <input type="checkbox"/> g  [A:830] <input type="checkbox"/> IU  [A:999] <input type="checkbox"/> [CONCOM_UNIT999] Other unit, specify: A10</p>	
<p>13. Route (Only for the weight-related co-morbidities like diabetes, hypertension, and dyslipidaemia) [Route]</p> <p>[grpCONCOM_ROUTE_CODE] [CONCOM_ROUTE_CODE]</p> <p>[cCONCOM_ROUTE_CODE]</p> <p><b>CMROUTE ROUTCOLL in SUPPCM</b></p>	
<p>14. Administered during surgery [hidden] [Administered during surgery]</p> <p>[ADMSURG_YN]</p> <p>[A:1] <input type="checkbox"/> Yes [A:2] <input type="checkbox"/> No</p>	
<p>15.* Primary Indication</p> <p>Remember to fill in/update in the Medical History/Concomitant Illness form, if applicable, or to fill in an Adverse Event form for which the concomitant medication is administered [Primary Indication]</p> <p>[PRIM_INDICATION]</p> <p>[PRIM_INDICATION_1] [A:1] <input type="checkbox"/> [PRIM_INDICATION_AE_NO] Adverse Event, enter Adverse Event no. 0 &lt; N3 <b>RELREC: CM.AE</b></p> <p>[A:2] <input type="checkbox"/> [PRIM_INDICATION_MED_HIST_1] Medical History/Concomitant Illness, enter seq. no. 0 &lt; N3 <b>RELREC: CM.MH</b></p> <p>[A:13] <input type="checkbox"/> [PRIM_INDICATION_COVID_AEI] COVID-19 treatment, enter Adverse Event no. 0 &lt; N3</p> <p>[A:14] <input type="checkbox"/> COVID-19 vaccine</p> <p>[A:15] <input type="checkbox"/> COVID-19 prophylactic</p> <p>[A:6] <input type="checkbox"/> Prophylactic</p> <p>[A:999] <input type="checkbox"/> [PRIM_INDICATION_OTHER_1] Other, specify: A200</p> <p><b>CMINDC</b></p>	
<p>16. Primary Indication [hidden] [Primary Indication]</p> <p>[PRIM_INDICATION]</p> <p>[A:1] <input type="checkbox"/> [PRIM_INDICATION_AE_NO] Adverse Event, enter Adverse Event no. 0 &lt; N3</p> <p>[A:2] <input type="checkbox"/> [PRIM_INDICATION_MED_HIST] Medical History/Concomitant Illness, enter seq. no. 0 &lt; N3</p> <p>[A:7] <input type="checkbox"/> Prophylactic</p> <p>[A:999] <input type="checkbox"/> [PRIM_INDICATION_OTHER] Other, specify: A200</p>	

	'e name concatenated with country code [hidden] Name]	[DRUG1_TEXT] A200
18.	Hidden Item - Legacy item used for Argus Interface [hidden] [Hidden Legacy Item]	[PRIM_INDICATION_CODE] Indication 1 text (e.g. 'Diabetes Mellitus' or 'Diabetes Complications' having the following sub-categories: [A:4] <input type="checkbox"/> Diabetic retinopathy [A:6] <input type="checkbox"/> Diabetic neuropathy [A:5] <input type="checkbox"/> Diabetic nephropathy [A:7] <input type="checkbox"/> Macroangiopathy (including peripheral vascular disease)
19.	Hidden Item - Legacy item used for Argus Interface [hidden] [Hidden Legacy Item]	[COMPLICATION_CODE] Indication 2 text (e.g. 'Crohn's Disease' or 'Bleeding complications' having the following sub-categories: [A:1] <input type="checkbox"/> Complication 1 text [A:2] <input type="checkbox"/> Complication 2 text [A:3] <input type="checkbox"/> Complication 3 text [A:4] <input type="checkbox"/> Complication 4 text [A:5] <input type="checkbox"/> Complication 5 text [A:6] <input type="checkbox"/> Complication 6 text
20.	Other, specify: [hidden] [Other, specify:]	[CONCOM_ROUTE_TEXT] A25
21.	Is the medication an investigational medicinal product for a COVID-19 study? [hidden]	[MED_COVID_19] [A:2] <input type="checkbox"/> No [A:1] <input checked="" type="checkbox"/> [grpMED_COVID_19] Yes [TRIAL_ID] COVID-19 Study ID: A85  [SPONSOR_NAME] Sponsor name: A85

Key: [\*] = Item is required [✓] = Source verification required [□] = Item is collapsible [⊖] = Key item  
Note: Associated form = Adverse Events / Safety Information Form.  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Concomitant Medication		
Type	RefName	Description
Form	CONCOM_MED_MEDDRA_1	Item 2 is a key item  Visit: CM
Item	CONCOM_SEQ_NO	Calculated in InForm via rule Integrations: A, R - please do not change the refname or format
Item	INV_DRUG1_TEXT	Integrations: A, R - please do not change the refname or format
Item	COUNTRY_ISO_CODE	Item used for coding purposes. Edit rights given to DM only.
Item	CONCOM_START_DATE	Integrations: A, R - please do not change the refname or format
Item	CONCOM_START_DATE_TIME	* *Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	CONCOM_STOP_DATE	Integrations: A, R - please do not change the refname or format
Item	CONCOM_STOP_DATE_TIME	* *Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	grpDOSE	Integrations: A, R - please do not change the refname or format
Item	grpFREQUENCY_CODE	Integrations: A - please do not change the refname or format
Item	grpTOTAL_DAILY_DOSE	* *Item DEACTIVATED** Integrations: A, R - please do not change the refname or format
Item	grpCONCOM_ROUTE_CODE	Integrations: A - please do not change the refname or format
Item	ADM_SURG_YN	* *Item DEACTIVATED** Integrations: A - please do not change the refname or format
Item	PRIM_INDICATION	Integrations: A - please do not change the refname or format Mapped from PRIM_INDICATION_1
Item	DRUG1_TEXT	Item used for coding purposes
Item	PRIM_INDICATION_CODE	* *Item DEACTIVATED** This is an ARGUS integration item and should not be deleted
Item	COMPLICATION_CODE	* *Item DEACTIVATED** This is an ARGUS integration item and should not be deleted
Item	CONCOM_ROUTE_TEXT	* *Item DEACTIVATED** This is an ARGUS integration item and should not be deleted
Item	MED_COVID_19	* *Item DEACTIVATED**

Keys (navigation)/Uniqueness: Concomitant Medication		
Item	Unique	Order #
CONCOM_MED_MEDDRA_1 (Repeating form)		
sctCONCOM_MED_MEDDRA_1		
CONCOM_START_DATE	None	1

Codelist Values Tables: Concomitant Medication						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clSCAT	String		Antihypertensive therapy and diuretics	1	ctmsCAT1_L1	SCAT
			Antibesity Preparations, Excl. Diet Products	2	ctmsCAT2_L1	
			Lipid modifying agents	3	ctmsCAT3_L1	
			Sodium-Glucose Co-Transporter 2(SGLT2 Inhibitors)	4	ctmsCAT4_L1	
			Biguanides	5	ctmsCAT12_L1	
			Glinide	6	ctmsCAT14_L1	
			Thiazolidinedione	7	ctmsCAT15_L1	
			α-glucosidase inhibitors [AGI]	8	ctmsCAT16_L1	
			Sulfonylureas	9	ctmsCAT17_L1	
			Other medications	999	ctmsCAT999	
clSCAT1_L2	String		Atenolol	1	ctmsCAT1_L2_1	SCAT1_L2
			Amlodipine	11	ctmsCAT1_L2_2	
			Afiskiren	58	ctmsCAT1_L2_3	
			Azilsartan medoxomil	56	ctmsCAT1_L2_4	
			Benzopril	38	ctmsCAT1_L2_5	
			Bisoprolol	2	ctmsCAT1_L2_6	
			Bumetanide	23	ctmsCAT1_L2_7	
			Bendroflumethiazide	18	ctmsCAT1_L2_8	
			Cannrenoate	27	ctmsCAT1_L2_9	
			Carvedilol	5	ctmsCAT1_L2_10	
			Captopril	37	ctmsCAT1_L2_11	
			Clonidine	30	ctmsCAT1_L2_12	
			Cilazapril	43	ctmsCAT1_L2_13	

		Candesartan	50	ctmsCAT1_L2_14
		Delapril	46	ctmsCAT1_L2_15
		Diltiazem	15	ctmsCAT1_L2_16
		Eprosartan	54	ctmsCAT1_L2_17
		Eplerenone	26	ctmsCAT1_L2_18
		Enalapril	33	ctmsCAT1_L2_19
		Furosemide	22	ctmsCAT1_L2_20
		Felodipine	13	ctmsCAT1_L2_21
		Filmasartan	57	ctmsCAT1_L2_22
		Fosinopril	39	ctmsCAT1_L2_23
		Hydralazine	32	ctmsCAT1_L2_24
		Hydrochlorothiazide	17	ctmsCAT1_L2_25
		Ibesartan	51	ctmsCAT1_L2_26
		Imidapril	44	ctmsCAT1_L2_27
		Indapamide	20	ctmsCAT1_L2_28
		Labetalol	6	ctmsCAT1_L2_29
		Lercanidipine	14	ctmsCAT1_L2_30
		Losartan	49	ctmsCAT1_L2_31
		Lisinopril	35	ctmsCAT1_L2_32
		Metoprolol	3	ctmsCAT1_L2_33
		Metolazone	21	ctmsCAT1_L2_34
		Moxonidine	29	ctmsCAT1_L2_35
		Methyldopa	28	ctmsCAT1_L2_36
		Moexipril	47	ctmsCAT1_L2_37
		Nadolol	10	ctmsCAT1_L2_38
		Nebivolol	4	ctmsCAT1_L2_39
		Nifedipine	12	ctmsCAT1_L2_40
		Olmesartan	53	ctmsCAT1_L2_41
		Perindopril	36	ctmsCAT1_L2_42
		Propanolol	8	ctmsCAT1_L2_43
		Quinapril	40	ctmsCAT1_L2_44
		Ramipril	34	ctmsCAT1_L2_45
		Sotalol	9	ctmsCAT1_L2_46
		Spiroperolactone	25	ctmsCAT1_L2_47
		Spirapril	45	ctmsCAT1_L2_48
		Timolol	7	ctmsCAT1_L2_49
		Terazosin	31	ctmsCAT1_L2_50
		Temocapril	48	ctmsCAT1_L2_51
		Telmisartan	55	ctmsCAT1_L2_52
		Trichlormethiazide	19	ctmsCAT1_L2_53
		Torasemide	24	ctmsCAT1_L2_54
		Trandolapril	42	ctmsCAT1_L2_55
		Valsartan	52	ctmsCAT1_L2_56
		Verapamil	16	ctmsCAT1_L2_57
		Zofenopril	41	ctmsCAT1_L2_58
cISCAT2_L2	String	Amfepramone	3	ctmsCAT2_L2_1
		Bupropion, Naltrexone	13	ctmsCAT2_L2_2
		Cathine	7	ctmsCAT2_L2_3
		Clobenzorex	8	ctmsCAT2_L2_4
		Dexfenfluramine	4	ctmsCAT2_L2_5
		Etilamfetamine	6	ctmsCAT2_L2_6
		Ephedrine, Combinations	12	ctmsCAT2_L2_7
		Fenfuramine	2	ctmsCAT2_L2_8
		Lorcaserin	11	ctmsCAT2_L2_9
		Mazindol	5	ctmsCAT2_L2_10
		Mefenorex	9	ctmsCAT2_L2_11
		Orlistat	14	ctmsCAT2_L2_12
		Pheptermine	1	ctmsCAT2_L2_13
		Rimonabant	15	ctmsCAT2_L2_14
		Sibutramine	10	ctmsCAT2_L2_15
		Liraglutide	16	ctmsCAT2_L2_16
cISCAT3_L2	String	Airocumab	9	ctmsCAT3_L2_1
		Atorvastatin	2	ctmsCAT3_L2_2
		Bezafibrate	14	ctmsCAT3_L2_3
		Colesevelam	10	ctmsCAT3_L2_4
		Colestyramine	11	ctmsCAT3_L2_5
		Colestipol	12	ctmsCAT3_L2_6
		Ciprofibrate	16	ctmsCAT3_L2_7
		Evolocumab	8	ctmsCAT3_L2_8
		Ezetimibe	17	ctmsCAT3_L2_9
		Fluvastatin	6	ctmsCAT3_L2_10
		Fenofibrate	13	ctmsCAT3_L2_11
		Gemfibrozil	15	ctmsCAT3_L2_12
		Lovastatin	5	ctmsCAT3_L2_13
		Lovaza (Omega-3-triglycerides)	19	ctmsCAT3_L2_14
		OMEGA-3 TRIGLYCERIDES	20	ctmsCAT3_L2_15
		Pravastatin	3	ctmsCAT3_L2_16
		Pitavastatin	7	ctmsCAT3_L2_17
		Rosuvastatin	4	ctmsCAT3_L2_18
		Simvastatin	1	ctmsCAT3_L2_19
		Vascepa (icosapent Ethyl)	21	ctmsCAT3_L2_20
cISCAT4_L2	String	Dapagliflozin	1	ctmsCAT4_L2_1
		Canagliflozin	2	ctmsCAT4_L2_2
		Empagliflozin	3	ctmsCAT4_L2_3
		Ertugliflozin	4	ctmsCAT4_L2_4
		Ipragliflozin	5	ctmsCAT4_L2_5
		Sotagliflozin	6	ctmsCAT4_L2_6
		Luseogliflozin	7	ctmsCAT4_L2_7
cISCAT5_L2	String	Metformin	1	ctmsCAT5_L2_1

DE	String			COUNTRY_ISO_CODE
	Afghanistan, AF	AF	AfghanistanAF	
	Albania, AL	AL	AlbaniaAL	
	Algeria, DZ	DZ	AlgeriaDZ	
	American Samoa, AS	AS	AmericanSamoaAS	
	Andorra, AD	AD	AndorraAD	
	Angola, AO	AO	NewCodeListItem	
	Anguilla, AI	AI	AnguillaAI	
	Antarctica, AQ	AQ	AntarcticaAQ	
	Antigua and Barbuda, AG	AG	AntiguaandBarbudaAG	
	Argentina, AR	AR	ArgentinaAR	
	Armenia, AM	AM	ArmeniaAM	
	Aruba, AW	AW	ArubaAW	
	Australia, AU	AU	AustraliaAU	
	Austria, AT	AT	AustriaAT	
	Azerbaijan, AZ	AZ	AzerbaijanAZ	
	Bahamas, BS	BS	BahamasBS	
	Bahrain, BH	BH	BahrainBH	
	Bangladesh, BD	BD	BangladeshBD	
	Barbados, BB	BB	BarbadosBB	
	Belarus, BY	BY	BelarusBY	
	Belgium, BE	BE	BelgiumBE	
	Belize, BZ	BZ	BelizeBZ	
	Benin, BJ	BJ	BeninBJ	
	Bermuda, BM	BM	BermudaBM	
	Bhutan, BT	BT	BhutanBT	
	Bolivia, BO	BO	BoliviaBO	
	Bosnia and Herzegovina, BA	BA	BosniaandHerzegovinaBA	
	Botswana, BW	BW	BotswanaBW	
	Bouvet Island, BV	BV	BouvetIslandBV	
	Brazil, BR	BR	BrazilBR	
	British Indian Ocean Territory, IO	IO	BritishIndianOceanTerritoryIO	
	Brunei Darussalam, BN	BN	BruneiDarussalamBN	
	Bulgaria, BG	BG	BulgariaBG	
	Burkina Faso, BF	BF	BurkinaFasoBF	
	Burundi, BI	BI	BurundiBI	
	Cambodia, KH	KH	CambodiaKH	
	Cameron, CM	CM	CamerounCM	
	Canada, CA	CA	CanadaCA	
	Cape Verde, CV	CV	CapeVerdeCV	
	Cayman Islands, KY	KY	CaymanIslandsKY	
	Central African Republic, CF	CF	CentralAfricanRepublicCF	
	Chad, TD	TD	ChadTD	
	Chile, CL	CL	ChileCL	
	China, CN	CN	ChinaCN	
	Christmas Island, CX	CX	ChristmasIslandCX	
	Cocos (Keeling) Islands, CC	CC	CocosKeelingIslandsCC	
	Colombia, CO	CO	ColombiaCO	
	Comoros, KM	KM	ComorosKM	
	Congo, CG	CG	CongoCG	
	Congo, The Democratic Republic of the, CD	CD	CongoTheDemocraticRepublicoftheCD	
	Cook Islands, CK	CK	CookIslandsCK	
	Costa Rica, CR	CR	CostaRicaCR	
	Côte D'Ivoire, CI	CI	CocirteDivoireCI	
	Croatia, HR	HR	CroatiaHR	
	Cuba, CU	CU	CubaCU	
	Cyprus, CY	CY	CyprusCY	
	Czech Republic, CZ	CZ	CzechRepublicCZ	
	Denmark, DK	DK	DenmarkDK	
	Djibouti, DJ	DJ	DjiboutiDJ	
	Dominica, DM	DM	DominicaDM	
	Dominican Republic, DO	DO	DominicanRepublicDO	
	Ecuador, EC	EC	EcuadorEC	
	Egypt, EG	EG	EgyptEG	
	El Salvador, SV	SV	ElSalvadorSV	
	Equatorial Guinea, GQ	GQ	EquatorialGuineaGQ	
	Eritrea, ER	ER	EritreaER	
	Estonia, EE	EE	EstoniaEE	
	Ethiopia, ET	ET	EthiopiaET	
	Falkland Islands (Malvinas), FK	FK	FalklandIslandsMalvinasFK	
	Faroe Islands, FO	FO	FaroeIslandsFO	
	Fiji, FJ	FJ	FijiFJ	
	Finland, FI	FI	FinlandFI	
	France, FR	FR	FranceFR	
	French Guiana, GF	GF	FrenchGuianaGF	
	French Polynesia, PF	PF	FrenchPolynesiaPF	
	French Southern Territories, TF	TF	FrenchSouthernTerritoriesTF	
	Gabon, GA	GA	GabonGA	
	Gambia, GM	GM	GambiaGM	
	Georgia, GE	GE	GeorgiaGE	
	Germany, DE	DE	GermanyDE	
	Ghana, GH	GH	GhanaGH	
	Gibraltar, GI	GI	GibraltarGI	
	Greece, GR	GR	GreeceGR	
	Greenland, GL	GL	GreenlandGL	
	Grenada, GD	GD	GrenadaGD	
	Guadeloupe, GP	GP	GuadeloupeGP	
	Guam, GU	GU	GuamGU	
	Guatemala, GT	GT	GuatemalaGT	
	Guernsey, GG	GG	GuernseyGG	

Guinea, GN	GN	GuineaGN
Guinea-bissau, GW	GW	GuineabissauGW
Guyana, GY	GY	GuyanaGY
Haiti, HT	HT	HaitiHT
Heard Island and McDonald Islands, HM	HM	HeardIslandandMcDonaldIslandsHM
Holy see (Vatican City State), VA	VA	HolyseeVaticanCityStateVA
Honduras, HN	HN	HondurasHN
Hong Kong, HK	HK	HongKongHK
Hungary, HU	HU	HungaryHU
Iceland, IS	IS	IcelandIS
India, IN	IN	IndiaIN
Indonesia, ID	ID	IndonesiaID
Iran, Islamic Republic of, IR	IR	IranIslamicRepublicofIR
Iraq, IQ	IQ	IraqIQ
Ireland, IE	IE	IrelandIE
Isle of Man, IM	IM	IsleofManIM
Israel, IL	IL	IsraelIL
Italy, IT	IT	ItalyIT
Jamaica, JM	JM	JamaicaJM
Japan, JP	JP	JapanJP
Jersey, JE	JE	JerseyJE
Jordan, JO	JO	JordanJO
Kazakhstan, KZ	KZ	KazakhstanKZ
Kenya, KE	KE	KenyaKE
Kiribati, KI	KI	KiribatiKI
Korea, Democratic People's Republic of, KP	KP	KoreaDemocraticPeoplesRepublicofKP
Korea, Republic of, KR	KR	KoreaRepublicofKR
Kuwait, KW	KW	KuwaitKW
Kyrgyzstan, KG	KG	KyrgyzstanKG
Lao People's Democratic Republic, LA	LA	LaoPeoplesDemocraticRepublicLA
Latvia, LV	LV	LatviaLV
Lebanon, LB	LB	LebanonLB
Lesotho, LS	LS	LesothoLS
Liberia, LR	LR	LiberiaLR
Libyan Arab Jamahiriya, LY	LY	LibyanArabJamahiriyaLY
Liechtenstein, LI	LI	LiechtensteinLI
Lithuania, LT	LT	LithuaniaLT
Luxembourg, LU	LU	LuxembourgLU
Macao, MO	MO	MacaoMO
Macedonia, The Former Yugoslav Republic of, MK	MK	MacedoniaTheFormerYugoslavRepublicofMK
Madagascar, MG	MG	MadagascarMG
Malawi, MW	MW	MalawiMW
Malaysia, MY	MY	MalaysiaMY
Maldives, MV	MV	MaldivesMV
Mali, ML	ML	MaliML
Malta, MT	MT	MaltaMT
Marshall Islands, MH	MH	MarshallIslandsMH
Martinique, MQ	MQ	MartiniqueMQ
Mauritania, MR	MR	MauritaniaMR
Mauritius, MU	MU	MauritiusMU
Mayotte, YT	YT	MayotteYT
Mexico, MX	MX	MexicoMX
Micronesia, Federated States of, FM	FM	MicronesiaFederatedStatesofFM
Moldova, MD	MD	MoldovaMD
Monaco, MC	MC	MonacoMC
Mongolia, MN	MN	MongoliaMN
Montenegro, ME	ME	MontenegroME
Montserrat, MS	MS	MontserratMS
Morocco, MA	MA	MoroccoMA
Mozambique, MZ	MZ	MozambiqueMZ
Myanmar, MM	MM	MyanmarMM
Namibia, NA	NA	NamibiaNA
Nauru, NR	NR	NauruNR
Nepal, NP	NP	NepalNP
Netherlands, NL	NL	NetherlandsNL
Netherlands Antilles, AN	AN	NetherlandsAntillesAN
New Caledonia, NC	NC	NewCaledoniaNC
New Zealand, NZ	NZ	NewZealandNZ
Nicaragua, NI	NI	NicaraguaNI
Niger, NE	NE	NigerNE
Nigeria, NG	NG	NigeriaNG
Niue, NU	NU	NiueNU
Norfolk Island, NF	NF	NorfolkIslandNF
Northern Mariana Islands, MP	MP	NorthernMarianaIslandsMP
Norway, NO	NO	NorwayNO
Oman, OM	OM	OmanOM
Pakistan, PK	PK	PakistanPK
Palau, PW	PW	PalauPW
Palestinian Territory, Occupied, PS	PS	PalestinianTerritoryOccupiedPS
Panama, PA	PA	PanamaPA
Papua New Guinea, PG	PG	PapuaNewGuineaPG
Paraguay, PY	PY	ParaguayPY
Peru, PE	PE	PeruPE
Philippines, PH	PH	PhilippinesPH
Pitcairn, PN	PN	PitcairnPN
Poland, PL	PL	PolandPL
Portugal, PT	PT	PortugalPT
Puerto Rico, PR	PR	PuertoRicoPR
Qatar, QA	QA	QatarQA
Réunion, RE		

		RE	ReacuteunionRE
Romania, RO		RO	RomaniaRO
Russian Federation, RU		RU	RussianFederationRU
Rwanda, RW		RW	RwandaRW
Saint Barthélemy, BL		BL	SaintBartheacutelemyBL
Saint Helena, SH		SH	SaintHelenaSH
Saint Kitts and Nevis, KN		KN	SaintKittsandNevisKN
Saint Lucia, LC		LC	SaintLuciaLC
Saint Martin, MF		MF	SaintMartinMF
Saint Pierre and Miquelon, PM		PM	SaintPierreadMiquelonPM
Saint Vincent and the Grenadines, VC		VC	SaintVincentandtheGrenadinesVC
Samoa, WS		WS	SamoaWS
San Marino, SM		SM	SanMarinoSM
Sao Tome and Principe, ST		ST	SaoTomeandPrincipeST
Saudi Arabia, SA		SA	SaudiArabiaSA
Senegal, SN		SN	SenegalSN
Serbia, RS		RS	SerbiaRS
Seychelles, SC		SC	SeychellesSC
Sierra Leone, SL		SL	SierraLeoneSL
Singapore, SG		SG	SingaporeSG
Slovakia, SK		SK	SlovakiaSK
Slovenia, SI		SI	SloveniaSI
Solomon Islands, SB		SB	SolomonIslandsSB
Somalia, SO		SO	SomaliaSO
South Africa, ZA		ZA	SouthAfricaZA
South Georgia and the South Sandwich Islands, GS		GS	SouthGeorgiaandtheSouthSandwichIslandsGS
Spain, ES		ES	SpainES
Sri Lanka, LK		LK	SriLankaLK
Sudan, SD		SD	SudanSD
Suriname, SR		SR	SurinameSR
Svalbard and Jan Mayen, SJ		SJ	SvalbardandJanMayenSJ
Swaziland, SZ		SZ	SwazilandSZ
Sweden, SE		SE	SwedenSE
Switzerland, CH		CH	SwitzerlandCH
Syrian Arab Republic, SY		SY	SyrianArabRepublicSY
Taiwan, Province of China, TW		TW	TaiwanProvinceofChinaTW
Tajikistan, TJ		TJ	TajikistanTJ
Tanzania, United Republic of, TZ		TZ	TanzaniaUnitedRepublicofTZ
Thailand, TH		TH	ThailandTH
Timor-Leste, TL		TL	TimorLesteTL
Togo, TG		TG	TogoTG
Tokelau, TK		TK	TokelauTK
Tonga, TO		TO	TongaTO
Trinidad and Tobago, TT		TT	TrinidadandTobagoTT
Tunisia, TN		TN	TunisiaTN
Turkey, TR		TR	TurkeyTR
Turkmenistan, TM		TM	TurkmenistanTM
Turks and Caicos Islands, TC		TC	TurksandCaicosIslandsTC
Tuvalu, TV		TV	TuvaluTV
Uganda, UG		UG	UgandaUG
Ukraine, UA		UA	UkraineUA
United Arab Emirates, AE		AE	UnitedArabEmiratesAE
United Kingdom, GB		GB	UnitedKingdomGB
United States, US		US	UnitedStatesUS
United States Minor Outlying Islands, UM		UM	UnitedStatesMinorOutlyingIslandsUM
Uruguay, UY		UY	UruguayUY
Uzbekistan, UZ		UZ	UzbekistanUZ
Vanuatu, VU		VU	VanuatuVU
Venezuela, VE		VE	VenezuelaVE
Viet Nam, VN		VN	VietNamVN
Virgin Islands, British, VG		VG	VirginIslandsBritishVG
Virgin Islands, U.S., VI		VI	VirginIslandsUSVI
Wallis and Futuna, WF		WF	WallisandFutunaWF
Western Sahara, EH		EH	WesternSaharaEH
Yemen, YE		YE	YemenYE
Zambia, ZM		ZM	ZambiaZM
Zimbabwe, ZW		ZW	ZimbabweZW
Aland Islands, AX		AX	AringlandIslandsAX
clCONTINUING_YN	String	Yes	1 citmCONTINUING_Y
		No	2 citmCONTINUING_N
clCONCOM_UNIT	String	mg	160 citmCONCOM_UNIT160
		mL	420 citmCONCOM_UNIT420
		ug	140 citmCONCOM_UNIT140
		g	200 citmCONCOM_UNIT200
		IU	830 citmCONCOM_UNIT830
		Other	999 citmCONCOM_UNIT999
clRESCUE_MED	String	Yes	1 citmRESCUE_MED1
		No	2 citmRESCUE_MED2
clFREQUENCY_CODE	String	Daily	1 citmFREQUENCY_CODE1
		Weekly	2 citmFREQUENCY_CODE2
		Other, specify	999 citmFREQUENCY_CODE999
clCONCOM_ROUTE_CODE	String	Subcutaneous	304 citmCONCOM_ROUTE_CODE304
		Oral	288 citmCONCOM_ROUTE_CODE048
		Other	999 citmCONCOM_ROUTE_CODE999
clADM_SURG_YN	String	Yes	1 clADM_SURG_Y
		No	2 clADM_SURG_N
clPRIM_IND	String	Adverse Event	1 citmPRIM_IND_1
		Medical History/Concomitant Illness	2 citmPRIM_IND_2
		COVID-19 treatment	13 citmPRIM_IND_13

		COVID-19 vaccine	14	ctmPRIM_IND_14	
		COVID-19 prophylactic	15	ctmPRIM_IND_15	
		Prophylactic	6	ctmPRIM_IND_6	
		Other	999	ctmPRIM_IND_OTH	
ctPRIM_INDICATION	String	Adverse Event, enter Adverse Event no.	1	ctmPRIM_INDICATION_AE_NO	PRIM_INDICATION
		Medical History/Concomitant Illness, enter seq. no	2	ctmPRIM_INDICATION_MED_HIST	
		Prophylactic	6	ctmPRIM_INDICATION_PRO	
		Other, specify	999	ctmPRIM_INDICATION_SPECIFY_OTHER	
ctPRIM_INDICATION_CODE	String	Diabetic retinopathy	4	ctmPRIM_INDICATION_CODE4	PRIM_INDICATION_CODE
		Diabetic neuropathy	6	ctmPRIM_INDICATION_CODE6	
		Diabetic nephropathy	5	ctmPRIM_INDICATION_CODE5	
		Macroangiopathy (including peripheral vascular disease)	7	ctmPRIM_INDICATION_CODE7	
ctCOMPLICATION_CODE	String	Complication 1 text	1	ctmCOMPLICATION_CODE1	COMPLICATION_CODE
		Complication 2 text	2	ctmCOMPLICATION_CODE2	
		Complication 3 text	3	ctmCOMPLICATION_CODE3	
		Complication 4 text	4	ctmCOMPLICATION_CODE4	
		Complication 5 text	5	ctmCOMPLICATION_CODE5	
		Complication 6 text	6	ctmCOMPLICATION_CODE6	
ctMED_COVID_19	String	No	2	ctmMED_COVID_19_N	MED_COVID_19
		Yes	1	ctmMED_COVID_19_Y	

RDE Analytics: RD_CONCOM_MED_MEDDRA_1		
Data Variable RefName	RD Column Name	Column Data Type
CONCOM_SEQ_NO	CONCOM_SEQ_NO	NUMBER
	CONCOM_SEQ_NO_ND	VARCHAR2
SCAT	SCAT_C	VARCHAR2
	SCAT	VARCHAR2
	SCAT_ND	VARCHAR2
SCAT - SCAT1_L2	SCAT1_L2_C	VARCHAR2
	SCAT1_L2	VARCHAR2
SCAT - SCAT2_L2	SCAT2_L2_C	VARCHAR2
	SCAT2_L2	VARCHAR2
SCAT - SCAT3_L2	SCAT3_L2_C	VARCHAR2
	SCAT3_L2	VARCHAR2
SCAT - SCAT4_L2	SCAT4_L2_C	VARCHAR2
	SCAT4_L2	VARCHAR2
SCAT - SCATS_L2	SCATS_L2_C	VARCHAR2
	SCATS_L2	VARCHAR2
SCAT - SCAT_OTH	SCAT_OTH	VARCHAR2
INV_DRUG1_TEXT	INV_DRUG1_TEXT	VARCHAR2
	INV_DRUG1_TEXT_ND	VARCHAR2
COUNTRY_ISO_CODE	COUNTRY_ISO_CODE_C	VARCHAR2
	COUNTRY_ISO_CODE	VARCHAR2
	COUNTRY_ISO_CODE_ND	VARCHAR2
CONCOM_START_DATE	CONCOM_START_DATE	DATE
	CONCOM_START_DATE_DTS	VARCHAR2
	CONCOM_START_DATE_DTR	VARCHAR2
	CONCOM_START_DATE_ND	VARCHAR2
CONCOM_START_DATE_TIME	CONCOM_START_DATE_TIME	DATE
	CONCOM_START_DATE_TIME_DTS	VARCHAR2
	CONCOM_START_DATE_TIME_DTR	VARCHAR2
	CONCOM_START_DATE_TIME_ND	VARCHAR2
CONCOM_STOP_DATE	CONCOM_STOP_DATE_C	VARCHAR2
	CONCOM_STOP_DATE	VARCHAR2
	CONCOM_STOP_DATE_ND	VARCHAR2
CONCOM_STOP_DATE - STOP_DATE_CM	STOP_DATE_CM	DATE
	STOP_DATE_CM_DTS	VARCHAR2
	STOP_DATE_CM_DTR	VARCHAR2
CONCOM_STOP_DATE_TIME	CONCOM_STOP_DATE_TIME_C	VARCHAR2
	CONCOM_STOP_DATE_TIME	VARCHAR2
	CONCOM_STOP_DATE_TIME_ND	VARCHAR2
CONCOM_STOP_DATE_TIME - STOP_DATE_NCM_1	STOP_DATE_NCM_1	DATE
	STOP_DATE_NCM_1_DTS	VARCHAR2
	STOP_DATE_NCM_1_DTR	VARCHAR2
grpDOSE	GRPDOSE_ND	VARCHAR2
grpDOSE - DOSE	DOSE	FLOAT
grpDOSE - CONCOM_UNIT2	CONCOM_UNIT2_C	VARCHAR2
	CONCOM_UNIT2	VARCHAR2
grpDOSE - CONCOM_UNIT2_999	CONCOM_UNIT2_999	VARCHAR2
RESCUE_MED	RESCUE_MED_C	VARCHAR2
	RESCUE_MED	VARCHAR2
	RESCUE_MED_ND	VARCHAR2
grpFREQUENCY_CODE	GRPFREQUENCY_CODE_ND	VARCHAR2
grpFREQUENCY_CODE - FREQUENCY_CODE	FREQUENCY_CODE_C	VARCHAR2
	FREQUENCY_CODE	VARCHAR2
grpFREQUENCY_CODE - FREQUENCY_OTHER_TEXT	FREQUENCY_OTHER_TEXT	VARCHAR2
grpTOTAL_DAILY_DOSE	GRPTOTAL_DAILY_DOSE_ND	VARCHAR2
grpTOTAL_DAILY_DOSE - TOTAL_DAILY_DOSE	TOTAL_DAILY_DOSE	FLOAT
grpTOTAL_DAILY_DOSE - CONCOM_UNIT	CONCOM_UNIT_C	VARCHAR2
	CONCOM_UNIT	VARCHAR2
grpTOTAL_DAILY_DOSE - CONCOM_UNIT999	CONCOM_UNIT999	VARCHAR2
grpCONCOM_ROUTE_CODE	GRPCONCOM_ROUTE_CODE_ND	VARCHAR2
grpCONCOM_ROUTE_CODE - CONCOM_ROUTE_CODE	CONCOM_ROUTE_CODE_C	VARCHAR2
	CONCOM_ROUTE_CODE	VARCHAR2
ADM_SURG_YN	ADM_SURG_YN_C	VARCHAR2
	ADM_SURG_YN	VARCHAR2
	ADM_SURG_YN_ND	VARCHAR2
grpPRIM_INDICATION	GRPPRIM_INDICATION_ND	VARCHAR2
grpPRIM_INDICATION - PRIM_INDICATION_1	PRIM_INDICATION_1_C	VARCHAR2

	PRIM_INDICATION_1	VARCHAR2
grpPRIM_INDICATION - PRIM_INDICATION_AE_NO_1	PRIM_INDICATION_AE_NO_1	NUMBER
grpPRIM_INDICATION - PRIM_INDICATION_MED_HIST_1	*PRIM_INDICATION_MED_HIST_1	NUMBER
grpPRIM_INDICATION - PRIM_INDICATION_COVID_AE	PRIM_INDICATION_COVID_AE	NUMBER
grpPRIM_INDICATION - PRIM_INDICATION_OTHER_1	PRIM_INDICATION_OTHER_1	VARCHAR2
PRIM_INDICATION	PRIM_INDICATION_C	VARCHAR2
	PRIM_INDICATION	VARCHAR2
	PRIM_INDICATION_ND	VARCHAR2
PRIM_INDICATION - PRIM_INDICATION_AE_NO	PRIM_INDICATION_AE_NO	NUMBER
PRIM_INDICATION - PRIM_INDICATION_MED_HIST	PRIM_INDICATION_MED_HIST	NUMBER
PRIM_INDICATION - PRIM_INDICATION_OTHER	PRIM_INDICATION_OTHER	VARCHAR2
DRUG1_TEXT	DRUG1_TEXT	VARCHAR2
	DRUG1_TEXT_ND	VARCHAR2
PRIM_INDICATION_CODE	PRIM_INDICATION_CODE_C	VARCHAR2
	PRIM_INDICATION_CODE	VARCHAR2
	PRIM_INDICATION_CODE_ND	VARCHAR2
COMPLICATION_CODE	COMPLICATION_CODE_C	VARCHAR2
	COMPLICATION_CODE	VARCHAR2
	COMPLICATION_CODE_ND	VARCHAR2
CONCOM_ROUTE_TEXT	CONCOM_ROUTE_TEXT	VARCHAR2
	CONCOM_ROUTE_TEXT_ND	VARCHAR2
MED_COVID_19	MED_COVID_19_C	VARCHAR2
	MED_COVID_19	VARCHAR2
	MED_COVID_19_ND	VARCHAR2
MED_COVID_19 - TRIAL_ID	TRIAL_ID	VARCHAR2
MED_COVID_19 - SPONSOR_NAME	SPONSOR_NAME	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**FA=Findings About Events or Interventions** **CE=Clinical Events**
**FACAT=COMPLAINT****CECAT=COMPLAINT**

: Technical Complaints (Complaint) - Repeating Form [TECH_COMPL_FORM]									
#	No.	Product	Batch No.	DUN	Onset date	Description	Sample sent	AE related	Related Adverse Event number(s)
1									<b>FAOBJ=TECHNICAL COMPLAINT</b> <b>CETERM=TECHNICAL COMPLAINT</b>
Study ID: NN9536-4512									
1.	Technical complaint number [read-only] [Seq. No.]		[COMPLAINT_NO] N3				<b>CEREFID</b>	<b>FAREFID</b>	<b>RELREC: CE,FA</b>
2.*	Product [Product]						<b>FAORRES when FATESTCD=COMPSAMP</b>		
3.*	Batch No. / Code No. / Lot No. Can be found on the label. Include batch, code or lot no., even if the technical complaint sample cannot be obtained. [Batch No.]		[BATCH_ID2] [A:1] <input type="radio"/> [BATCH_ID] A20 [A:998] <input type="radio"/> N/A			<b>FAORRES when FATESTCD=BATCH_ID</b>			
4.*	Kit ID/DUN Fill out one form per Kit ID/DUN. [DUN]		[DUN_ID2] [A:1] <input type="radio"/> [DUN_ID_2] N7 [A:998] <input type="radio"/> N/A			<b>FAORRES when FATESTCD=KITIDDUN</b>			
5.*	Onset date of technical complaint [Onset date]		[TC_START_DATE] (DD/MM/YYYY) Req/Unk <input checked="" type="radio"/> / Req/Unk <input type="radio"/> / Req <input type="radio"/> (2023-2030)			<b>FADTC</b>	<b>CESTDTC</b>		
6.*	Description of the technical complaint  Describe the affected product part and affected product function. Describe in detail how the fault has occurred. [Description]		[grpCOMPLAINT_TEXT] [COMPLAINT_TEXT] A400			<b>FAORRES when FATESTCD=EVTDESC1</b>			
						<b>EVTDESC2 in SUPPFA</b>			
Send the sample to Novo Nordisk for investigation [sctCOMPLAINT_SAMPLE_RETURNED]									
7.*	Will the technical complaint sample be sent to Novo Nordisk for investigation?  If Yes, remember to include a print/copy of this form in the shipment of the sample(s). [Sample sent]		[COMP_SAMPLE_RETURN_YN] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> [COM_SAMP_RETURN_TEXT] No, specify why: A200			<b>FAORRES when FATESTCD=CSAMPRET</b>			
						<b>Note: If No, then FAORRES=Specify</b>			
8.*	Is the technical complaint related to adverse events (AEs)? If Yes, Add Entry to specify details below. Also fill in an Adverse Event Form (AE) [AE related]		[AE_RELATION_YN] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No			<b>NOT SUBMITTED</b>			
9.						<b>SAE related</b>			
Related Adverse Event number(s) Entry [sctAE_NO_SAE_MESE_REL_REL_INFO]									
9.1*	Adverse Event number [AE number]		[AE_NO_2] 0 < N3			<b>CELNKID</b>	<b>FALNKID</b>	<b>RELREC: CE.FA</b>	
9.2*	Is the technical complaint related to SAE? If Yes, fill in a Safety Information Form (SIF) [SAE related]		[TC_RELAT_SAE_AESL_YN] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No			<b>NOT SUBMITTED</b>			
Reporting of TC for <Name(s) of device(s) for which this information must be collected according to protocol> according to the protocol.									
Please complete the following question if the complaint is concerning a device for which the protocol states that it must be evaluated if the TC could have led to an SAE [sctPOTENTIAL_NDESAE]									
10.	Could the technical complaint have led to an SAE if:  If Yes, fill in a Device Deficiency that could have led to an SAE Form [hidden] [Could have led to SAE]		[grpPOTENTIAL_NDESAE_YN] [TC_SUITABLE_ACTION] Suitable action had not been taken? [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No						
			[TC_INTERVENTION] Intervention had not been made? [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No						
			[TC_CIRCUMSTANCES] The circumstances had been less fortunate? [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No						
11.	Is the technical complaint considered a pen-injector use error?  If Yes, fill in Pen-Injector Use Error form accordingly [hidden] [Pen-injector use error]		[PEN_USE_ERR] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> No						
12.	Office use only Item is used for rule logic [hidden] [Office use]		[OFFICE_USE] N5						
13.	Follow up Email sent date(office use only) [hidden] [Office use]		[OFFICE_USE1] (DD/MM/YYYY) Req <input checked="" type="radio"/> / Req <input type="radio"/> / Req <input type="radio"/> (2022-2035)						
14.	Office use only Item is used for rule logic [hidden] [Office use]		[OFFICE_USE2] N5						
15.	Office use only Item used for email notification [hidden] [Office use]		[OFFICE_USE3] N3						
16.	Description of the technical complaint, part 1 Item for data into OC text question (1-200 chars) [hidden] [Description P1]		[COMPLAINT_TEXT1] A200						
17.	Description of the technical complaint, part 2 Item for data into OC text question (201-400 chars) [hidden] [Description P2]		[COMPLAINT_TEXT2] A200						
18.	Phase [hidden] [Phase]		[TRIAL_PHASE_CODE] A1						
Key: [*] = Item is required [ ✓ ] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.									

Study Object Descriptions: Technical Complaints		
Type	RefName	Description
Form	TECH_COMPL_FORM	Visit: Complaint Note to CTDM: Evaluate for SDV requirement in device studies
Item	COMPLAINT_NO	Calculated in InForm via rule
Item	grpPOTENTIAL_NDESAE_YN	**Item DEACTIVATED**
Item	PEN_USE_ERR	**Item DEACTIVATED**
Item	OFFICE_USE3	Item used for email notification
Item	COMPLAINT_TEXT1	Characters 1-200 mapped from 'Description of the technical complaint'

-	EXT2	Characters 201-400 mapped from 'Description of the technical complaint'
Item   TR	PHA	Populated by a rule in Inform

Codelist Values Tables: Technical Complaints						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clCOMPLAINT_SAMPL_CODE	String		Semaglutide/Semaglutide placebo, 0.5 ml single dose pen-injector (For US Sites)	1	ctmCOMPLAINT_SAMPL_1	COMPLAINT_SAMPL_CODE
			Semaglutide/Semaglutide placebo, 0.75 ml single dose pen-injector (For US Sites)	2	ctmCOMPLAINT_SAMPL_2	
			Semaglutide/Semaglutide placebo, 1.5 ml PDS290 pen injector (EU and International Sites)	3	ctmCOMPLAINT_SAMPL_3	
			Semaglutide/Semaglutide placebo, 3 ml PDS290 pen injector (EU and International Sites)	4	ctmCOMPLAINT_SAMPL_4	
clBATCH_ID	String		N/A	1	ctmbATCH_ID	BATCH_ID2
				998	ctmbATCH_NA	
clDUN_ID	String		N/A	1	ctmdUN_ID	DUN_ID2
				998	ctmdUN_NA	
clCOMP_SAMPL_RETURN_YN	String		Yes	1	ctmCOMP_SAMPL_RETURN_Y	COMP_SAMPL_RETURN_YN
			No	2	ctmCOMP_SAMPL_RETURN_N	
clAE_RELATION_YN	String		Yes	1	ctmaE_RELATION_Y	AE_RELATION_YN
			No	2	ctmaE_RELATION_N	
clTC_RELAT_SAE_MESE_YN	String		Yes	1	ctmTC_RELAT_SAE_MESE_Y	TC_RELAT_SAE_AESI_YN
			No	2	ctmTC_RELAT_SAE_MESE_N	
clTC_SUITABLE_ACTION	String		Yes	1	ctmTC_SUITABLE_ACTION1	TC_SUITABLE_ACTION
			No	2	ctmTC_SUITABLE_ACTION2	
clTC_INTERVENTION	String		Yes	1	ctmTC_INTERVENTION1	TC_INTERVENTION
			No	2	ctmTC_INTERVENTION2	
clTC_CIRCUMSTANCES	String		Yes	1	ctmTC_CIRCUMSTANCES1	TC_CIRCUMSTANCES
			No	2	ctmTC_CIRCUMSTANCES2	
clPEN_ERR	String		yes	1	ctmPEN_ERR_Y	PEN_USE_ERR
			No	2	ctmPEN_ERR_N	

RDE Analytics: RD_TECH_COMPL_FORM		
Data Variable RefName	RD Column Name	Column Data Type
COMPLAINT_NO	COMPLAINT_NO	NUMBER
	COMPLAINT_NO_ND	VARCHAR2
COMPLAINT_SAMPL_CODE	COMPLAINT_SAMPL_CODE_C	VARCHAR2
	COMPLAINT_SAMPL_CODE	VARCHAR2
	COMPLAINT_SAMPL_CODE_ND	VARCHAR2
BATCH_ID2	BATCH_ID2_C	VARCHAR2
	BATCH_ID2	VARCHAR2
	BATCH_ID2_ND	VARCHAR2
BATCH_ID2 - BATCH_ID	BATCH_ID	VARCHAR2
DUN_ID2	DUN_ID2_C	VARCHAR2
	DUN_ID2	VARCHAR2
	DUN_ID2_ND	VARCHAR2
DUN_ID2 - DUN_ID_2	DUN_ID_2	NUMBER
TC_START_DATE	TC_START_DATE	DATE
	TC_START_DATE_DTS	VARCHAR2
	TC_START_DATE_DTR	VARCHAR2
	TC_START_DATE_ND	VARCHAR2
grpCOMPLAINT_TEXT	GRPCOMPLAINT_TEXT_ND	VARCHAR2
grpCOMPLAINT_TEXT - COMPLAINT_TEXT	COMPLAINT_TEXT	VARCHAR2
COMP_SAMPL_RETURN_YN	COMP_SAMPL_RETURN_YN_C	VARCHAR2
	COMP_SAMPL_RETURN_YN	VARCHAR2
	COMP_SAMPL_RETURN_YN_ND	VARCHAR2
COMP_SAMPL_RETURN_YN - COM_SAMP_RETURN_TEXT	COM_SAMP_RETURN_TEXT	VARCHAR2
AE_RELATION_YN	AE_RELATION_YN_C	VARCHAR2
	AE_RELATION_YN	VARCHAR2
	AE_RELATION_YN_ND	VARCHAR2
grpPOTENTIAL_NDESAE_YN	GRPPOTENTIAL_NDESAE_YN_ND	VARCHAR2
grpPOTENTIAL_NDESAE_YN - TC_SUITABLE_ACTION	TC_SUITABLE_ACTION_C	VARCHAR2
	TC_SUITABLE_ACTION	VARCHAR2
grpPOTENTIAL_NDESAE_YN - TC_INTERVENTION	TC_INTERVENTION_C	VARCHAR2
	TC_INTERVENTION	VARCHAR2
grpPOTENTIAL_NDESAE_YN - TC_CIRCUMSTANCES	TC_CIRCUMSTANCES_C	VARCHAR2
	TC_CIRCUMSTANCES	VARCHAR2
PEN_USE_ERR	PEN_USE_ERR_C	VARCHAR2
	PEN_USE_ERR	VARCHAR2
	PEN_USE_ERR_ND	VARCHAR2
OFFICE_USE	OFFICE_USE	NUMBER
	OFFICE_USE_ND	VARCHAR2
OFFICE_USE1	OFFICE_USE1	DATE
	OFFICE_USE1_DTS	VARCHAR2
	OFFICE_USE1_ND	VARCHAR2
OFFICE_USE2	OFFICE_USE2	NUMBER
	OFFICE_USE2_ND	VARCHAR2
OFFICE_USE3	OFFICE_USE3	NUMBER
	OFFICE_USE3_ND	VARCHAR2
COMPLAINT_TEXT1	COMPLAINT_TEXT1	VARCHAR2
	COMPLAINT_TEXT1_ND	VARCHAR2
COMPLAINT_TEXT2	COMPLAINT_TEXT2	VARCHAR2
	COMPLAINT_TEXT2_ND	VARCHAR2
TRIAL_PHASE_CODE	TRIAL_PHASE_CODE	VARCHAR2
	TRIAL_PHASE_CODE_ND	VARCHAR2
*RD_TECH_COMPL_FORM_SCTAE_NO_SAE_MESE_REL_REL_INFO		
AE_NO_2	AE_NO_2	NUMBER
	AE_NO_2_ND	VARCHAR2
TC_RELAT_SAE_AESI_YN	TC_RELAT_SAE_AESI_YN_C	VARCHAR2
	TC_RELAT_SAE_AESI_YN	VARCHAR2
	TC_RELAT_SAE_AESI_YN_ND	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**LB=Laboratory Test Results****LBCAT=PREGNANCY TEST**

Pregnancy Test Log (Preg Log) - Repeating Form [PREGLOG]			
#	Pregnancy Test		
1			
Study ID: NN9536-4512 If Positive, the subject must be discontinued from investigational medicinal product. The paper Pregnancy forms must also be completed.			
Pregnancy Test [sctPREGLOG]			
#	Test	Medium	Date of test
1.a	PREGNANCY_TEST_RESULT	Urine	
Pregnancy Test Entry [sctPREGLOG]			
1.1	Test [hidden] [Test]	[PREGLOG_LBTPCD_L] [A:1] <input type="radio"/> PREGNANCY_TEST_RESULT	
1.2	Medium (read-only) [Medium]	[PREGLOG_LBSPEC_L] [A:4] <input type="radio"/> Urine	<b>LBSPEC</b>
1.3	Result [Result]	[PREGLOG_LBORRES_L] [A:1] <input type="radio"/> Positive [A:2] <input type="radio"/> Negative	<b>LBORRES when LBTESTCD=HCG</b>
1.4	Date of test [Date of test]	[PREGLOG_LBDTC_D] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030)	<b>LBDTC</b>
Key: <input checked="" type="checkbox"/> = Fixed item Note: Source verification critical settings made in InForm will override any settings made in Central Designer.			

## Study Object Descriptions: Pregnancy Test Log

Type	RefName	Description
Form	PREGLOG	Visit: Preg The Visit is dynamically triggered from the Childbearing Potential form if the response is Yes

Codelist Values Tables: Pregnancy Test Log						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIPREGLOG_LBTMPCD	String		PREGNANCY_TEST_RESULT	1	ctmPREGLOG_TEST	PREGLOG_LBTPCD_L
cIPREGLOG_LBSPEC	String			4	ctmPREGLOG_U	PREGLOG_LBSPEC_L
cIPREGLOG_LBORRES	String		Positive	1	ctmPREGLOG_POS	PREGLOG_LBORRES_L
			Negative	2	ctmPREGLOG_NEG	

RDE Analytics: RD_PREGLOG		
Data Variable RefName	RD Column Name	Column Data Type
<b>RD_PREGLOG_SCTPREGLOG</b>		
PREGLOG_LBTPCD_L	PREGLOG_LBTPCD_L_C	VARCHAR2
	PREGLOG_LBTPCD_L	VARCHAR2
	PREGLOG_LBTPCD_L_ND	VARCHAR2
PREGLOG_LBSPEC_L	PREGLOG_LBSPEC_L_C	VARCHAR2
	PREGLOG_LBSPEC_L	VARCHAR2
	PREGLOG_LBSPEC_L_ND	VARCHAR2
PREGLOG_LBORRES_L	PREGLOG_LBORRES_L_C	VARCHAR2
	PREGLOG_LBORRES_L	VARCHAR2
	PREGLOG_LBORRES_L_ND	VARCHAR2
PREGLOG_LBDTC_D	PREGLOG_LBDTC_D	DATE
	PREGLOG_LBDTC_D_DTS	VARCHAR2
	PREGLOG_LBDTC_D_ND	VARCHAR2

**DS=Disposition****DSCAT=OTHER EVENT**

: Withdrawal of Consent to Biosamples for Future Research (Withdrawal Future Research) [WITHDRAWAL_FUTURE_RESEARCH]		DSDECOD=FUTURE RESEARCH BIOSAMPLE CONSENT WITHDRAWN	
Study ID:			
1.* Biosan withdrawn [Biosamples Consent withdrawn]	<b>DTERM=BIOSAMPLE CONSENT WITHDRAWN</b> <input type="radio"/> No <input checked="" type="radio"/> [grpWITH_DTERM_1] Yes <small>[DSSTDTC_4] (DD/MM/YYYY) Req ✓ / Req ✎ / Req ✎ (2023-2030)</small> <span style="border: 1px solid black; padding: 2px;">DSSTDTC</span>		
2. xxxx Consent withdrawn [hidden] [xxxx Consent withdrawn]	<input type="radio"/> No <input checked="" type="radio"/> [grpWITH_DTERM_2] Yes <small>[DSSTDTC_5] (DD/MM/YYYY) Req ✓ / Req ✎ / Req ✎ (2022-2035)</small>		
3. xxxx Consent withdrawn [hidden] [xxxx Consent withdrawn]	<input type="radio"/> No <input checked="" type="radio"/> [grpWITH_DTERM_3] Yes <small>[DSSTDTC_6] (DD/MM/YYYY) Req ✓ / Req ✎ / Req ✎ (2022-2035)</small>		

Key: [\*] = Item is required   [ ] = Item is collapsible  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.  
Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Withdrawal of Consent to Biosamples for Future Research		
Type	RefName	Description
Form	WITHDRAWAL_FUTURE_RESEARCH	Visit: ReConsent
Item	WITH_DTERM_2	**Item DEACTIVATED**
Item	WITH_DTERM_3	**Item DEACTIVATED**

Codelist Values Tables: Withdrawal of Consent to Biosamples for Future Research						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIDTERM_YN_4	String	No	2	citmDTERM_4N	WITH_DTERM_1	
		Yes	1	citmDTERM_4Y		
cIDTERM_YN_5	String	No	2	citmDTERM_5N	WITH_DTERM_2	
		Yes	1	citmDTERM_5Y		
cIDTERM_YN_6	String	No	2	citmDTERM_6N	WITH_DTERM_3	
		Yes	1	citmDTERM_6Y		

RDE Analytics: *RD_WITHDRAWAL_FUTURE_RESEARCH		
Data Variable RefName	RD Column Name	Column Data Type
WITH_DTERM_1	WITH_DTERM_1_C	VARCHAR2
	WITH_DTERM_1	VARCHAR2
	WITH_DTERM_1_ND	VARCHAR2
WITH_DTERM_1 - DSSTDTC_4	DSSTDTC_4	DATE
	DSSTDTC_4_DTS	VARCHAR2
	WITH_DTERM_2_C	VARCHAR2
WITH_DTERM_2	WITH_DTERM_2	VARCHAR2
	WITH_DTERM_2_ND	VARCHAR2
	WITH_DTERM_2_ND	VARCHAR2
WITH_DTERM_2 - DSSTDTC_5	DSSTDTC_5	DATE
	DSSTDTC_5_DTS	VARCHAR2
	WITH_DTERM_3_C	VARCHAR2
WITH_DTERM_3	WITH_DTERM_3	VARCHAR2
	WITH_DTERM_3_ND	VARCHAR2
	WITH_DTERM_3_ND	VARCHAR2
WITH_DTERM_3 - DSSTDTC_6	DSSTDTC_6	DATE
	DSSTDTC_6_DTS	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**CM=Concomitant/Prior Medications** **ZE=Event Related Treatments** **XH=Hypoglycaemic Events**

**CMCAT=DOSE AS REPORTED AS PART OF HYPO** **ZECAT=ADMINISTRATION OF TRIAL PRODUCT**

**XTERM=HYPOGLYCAEMIC EPISODE**

Hypoglycaemic Episode (Hypo) - Repeating Form [HYPO_5_PAED]																								
#	Seq.	ite & time of hypo episode	Lowest glucose value	Related to physical activity	Was the subject asleep	Severe Hypo	IMP Details	Drug of interest Details	Date and time of last main meal	SAE	Symptoms experienced	Medical person helping	Where was the subject treated	Convulsions or fits (seizure)	Did the subject pass out (loss of conscious/in a coma)	Type of treatment	Did the subject feel better after the treatment	Contributing factors						
1																								
Study ID: NN9536-4512 Note: For T2D participants only																								
<b>Part 1 [sctHYPO_5]</b>																								
1.	Hypoglycaemic episode number [read-only] [Seq. No.]											[HYPOS_SEQ_NO] 0 < N3	XHREFID ZEREFID CMREFID RELREC: XH,ZE RELREC: XH,CM											
2.*	Start date and time of the hypoglycaemic episode Report time as Unk/Unk if diary response is 'Unknown' for time of episode. [Start date & time of hypo episode]											[HYPOS_STDTIM] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock	XHSTDTC											
3.*	Lowest glucose value recorded during the hypoglycaemic episode Report 'Not done' if diary response is 'Unknown'. [Lowest glucose value]											[HYPOS_LOWEST] [A:1] <input checked="" type="checkbox"/> grpHPOS_LOWEST [HYPOS_GLUC_LEVEL] [HYPOS_GLUC_UNIT] 0 <= xxxx. [A:561] mmol/L [A:162] mg/dL [A:997] Not done	GLUCLOW/GLUCLOWU in SUPPXH											
4.	Stop date and time of the hypoglycaemic episode Report time as Unk/Unk if diary response is 'Unknown' for time of episode. [hidden] [Stop date & time of hypo episode]											[HYPOS_STOP_DTTM] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock	XHENDT											
5.*	Did the hypoglycaemic episode occur in relation to physical activity? [Related to physical activity]											[HYPOS_PHYS_ACT] [A:1] <input checked="" type="checkbox"/> Yes [A:2] <input type="checkbox"/> No [A:996] <input type="checkbox"/> Unknown	EXERREL in SUPPXH											
6.*	Was the subject asleep when the hypoglycaemic episode occurred? [Was the subject asleep]											[HYPOS_ASLEEP_YN] [A:1] <input checked="" type="checkbox"/> HPOS_SYNWAKE_YN Yes Did the symptoms of the hypoglycaemic episode wake up the subject? [A:1] <input checked="" type="checkbox"/> Yes [A:2] <input type="checkbox"/> No [A:2] <input type="checkbox"/> No	ASHYOC in SUPPXH HYPSYWKU in SUPPXH											
7.	Were there any symptoms? [hidden] [Symptomatic]											[SYMPTOM_EPISODE_YN] [A:1] <input type="checkbox"/> Yes [A:2] <input type="checkbox"/> No												
8.*	Was the hypoglycaemic episode severe enough to result in: • unconsciousness • or a seizure • or were carbohydrates, glucagon or IV glucose needed for the subject to recover? [Severe Hypo]											[HYPOS_SEVERE_YN] [A:1] <input type="checkbox"/> Yes [A:2] <input type="checkbox"/> No	COGIMTRT in SUPPXH											
<b>IMP Details [sctHYPO_5_TRT]</b>																								
#	Investigational medicinal product											Date and time of last dose*						Dose and unit*						
9.a	Semaglutide/ Semaglutide placebo																							
<b>IMP Detail Entry [sctHYPO_5_TRT]</b>																								
9.1	Investigational medicinal product [Investigational medicinal product]											ZEMOOD=PERFORMED						ZETRT=Semaglutide/Semaglutide placebo						
9.2.*	Date and time of last dose [Date and time of last dose]											[HYPOS_ECTRT] [A:1] <input checked="" type="checkbox"/> Semaglutide/ Semaglutide placebo [HYPOS_ECTSTDAT] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock	ZESTDTC											
9.3*	Dose and unit [Dose and unit]											[grpHPOS_ECODE] [HYPOS_ECODE] [HYPOS_ECODOSU] XXXXX.X [A:1] <input type="checkbox"/> mg	ZEDOSE ZEDOSU											
<b>Drug of interest Details [sctHYPO_5_TRT2]</b>																								
#	Medication											Date and time of last dose*						Dose and unit*						
10.a	Metformin																							
10.b	Basal Insulin																							
<b>Drug of interest Details Entry [sctHYPO_5_TRT2]</b>																								
10.1	Medication [Medication]											[HYPOS_CMTRT] [A:113] <input checked="" type="checkbox"/> Metformin [A:4] <input type="checkbox"/> Basal Insulin	CMTRT=Metformin CMTRT=Basal Insulin											
10.2*	Date and time of last dose [Date and time of last dose]											[HYPOS_CMSTDAT] (DD/MM/YYYY hh:mm) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock	CMSTDTC											
10.3*	Dose and unit [Dose and unit]											[grpHPOS_CMDOSE] [HYPOS_CMDOSE] [HYPOS_CMDOSU] XXXXX.X [A:1] <input type="checkbox"/> mg [A:2] <input type="checkbox"/> U	CMDOSE CMDOSU											
11.*	Date and time of last main meal (not including snacks) before the hypoglycaemic episode Report date and time as Unk/Unk Unk/Unk if diary response is 'Unknown' [Date and time of last main meal]											[HYPOS_MLDAT] (DD/MM/YYYY hh:mm) Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input checked="" type="checkbox"/> (2023-2030) Req/Unk <input checked="" type="checkbox"/> : Req/Unk <input checked="" type="checkbox"/> 24-hour clock	LMEALDTC in SUPPXH											
12.*	Is the hypoglycaemic episode a Serious Adverse Event (SAE)? [SAE]											[HYPOS_SAE_YN] [A:2] <input type="checkbox"/> No [A:1] <input checked="" type="checkbox"/> HPOS_RELAE Yes Enter primary AE no:   0 < N3	XHSER											
<b>Part 2 [sctHYPO_5_2]</b>																								
The questions below are ONLY to be completed if the hypoglycaemic episode was severe enough to result in unconsciousness or seizure or if carbohydrates, glucagon or IV glucose were needed for the subject to recover.																								
13.	Symptoms experienced by the subject during the hypoglycaemic episode [Symptoms experienced]											[grpHPOS_SYM] [HYPOS_SYM_NAUS] [A:1] <input type="checkbox"/> Feeling sick (nausea) [HYPOS_SYM_SHAK] [A:2] <input type="checkbox"/> Feeling shaky (shakiness) [HYPOS_SYM_SWIT] [A:3] <input type="checkbox"/> Feeling sweaty (sweatiness) [HYPOS_SYM_AGIT] [A:4] <input type="checkbox"/> Feeling anxious (agitation) [HYPOS_SYM_TRED] [A:5] <input type="checkbox"/> Feeling tired (tiredness) [HYPOS_SYM_IRR] [A:6] <input type="checkbox"/> Feeling short-tempered (irritability) [HYPOS_SYM_HUN] [A:7] <input type="checkbox"/> Feeling hungry (hunger) [HYPOS_SYM_CONC] [A:8] <input type="checkbox"/> Finding it hard to think (poor concentration) [HYPOS_SYM_DEC] [A:9] <input type="checkbox"/> Not able to make a decision (poor judgement and confusion) [HYPOS_SYM_MEM] [A:10] <input type="checkbox"/> Cannot remember things that happened recently (problems with short-term memory) [HYPOS_SYM_DIZ] [A:11] <input type="checkbox"/> Feeling your head spin and unsteady walking (dizziness and unsteady gait) [HYPOS_SYM_ERR] [A:12] <input type="checkbox"/> Behaviour which is not normal (erratic behaviour) [HYPOS_SYM_PALP] [A:13] <input type="checkbox"/> Rapid or irregular heartbeat (palpitations) [HYPOS_SYM_HDACH] [A:14] <input type="checkbox"/> Headache [HYPOS_SYM_NMARE] [A:15] <input type="checkbox"/> Nightmares [HYPOS_SYM_TRMB]	HYCLIN01-HYCLIN15 in SUPPXH											

**XH=Hypoglycaemic Events****XTERM=HYPOGLYCAEMIC EPISODE**14. Was a medical person helping the subject to handle the hypoglycaemic episode?  
[Medical person helping][A:16]  Trembling

[HYPOS\_SYM\_HEAR]

[A:17]  Hearing problems (difficulty hearing)

[HYPOS\_SYM\_SIGHT]

[A:18]  Sight problems (blurred or double vision, disturbed colour vision)

[HYPOS\_SYM\_CRY]

[A:19]  Non-stop crying (inconsolable crying)

[HYPOS\_SYM\_SPECH]

[A:20]  Slurred speech

[HYPOS\_SYM\_PALE]

[A:21]  Extreme pale skin (pallor)

[HYPOS\_SYM\_OTH]

[A:999]  Other15. Where was the subject treated for the hypoglycaemic episode?  
[Where was the subject treated]

[HYPOS\_MEDHELP\_YN]

[A:1]  Yes[A:2]  No[A:996]  Unknown**MEDIPERS in SUPPXH**16. Did the subject have convulsions or fits (seizure) during the hypoglycaemic episode?  
[Convulsions or fits (seizure)]

[HYPOS\_SEIZUR\_YN]

[A:1]  Yes[A:2]  No**SEIZURYN in SUPPXH**17. Did the subject pass out (loss of conscious/in a coma) during the hypoglycaemic episode?  
[Did the subject pass out (loss of conscious/in a coma)]

[HYPOS\_UNCONCOMA\_YN]

[A:1]  Yes[A:2]  No**SUBUNCON in SUPPXH**18. What type of treatment was given to the subject during the hypoglycaemic episode?  
[Type of treatment]

[HYPOS\_TRT]

[HYPOS\_TRTCARB8]

[A:1]  Something to eat or drink (carbohydrates)

[HYPOS\_TRTGGON]

[A:2]  Glucagon injection

[HYPOS\_TRTGLUC]

[A:4]  IV glucose

[HYPOS\_TRTOOTH]

[A:999]  Other**HYTRECD1-HYTRECD4 in SUPPXH**19. Did the subject feel better after the treatment?  
[Did the subject feel better after the treatment]

[HYPOS\_BETRAFFTTRT\_YN]

[A:1]  Yes[A:2]  No**HYALLEVI in SUPPXH**20. Which of the following factors does the subject think may have contributed to the hypoglycaemic episode?  
[Contributing factors]

[HYPOS\_FACTORS]

[HYPOS\_DIETCNG]

[A:1]  Change of diet

[HYPOS\_MISOMEAL]

[A:2]  Missed meal

[HYPOS\_PHYACT]

[A:5]  Physical activity

[HYPOS\_ALCH]

[A:8]  Drinking alcohol

[HYPOS\_DOSCLERR]

[A:8]  Made a mistake in calculating the dose of diabetes medication

[HYPOS\_ACCHIDOS]

[A:9]  Accidentally took too high dose of diabetes medication

[HYPOS\_MEDMIXUP]

[A:10]  Mixed up the diabetes medications

[HYPOS\_DEVUSEERK]

[A:20]  Made a mistake when using the device

[HYPOS\_OTHFACT]

[A:999]  Other

[HYPOS\_UNKFAC]

[A:996]  Unknown**HYPOREC1-HYPORE10 in SUPPXH**21. Office use only [hidden]  
[HypoOfficeOnly]

[Hypo\_OFFICES]

N3

Key: [\*] = Item is required [✓] = Source verification required [?] = Key item [■] = Fixed item

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

**Study Object Descriptions: Hypoglycaemic Episode**

Type	RefName	Description
Form	HYPO_5_PAED	Item 2 is a key item  Visit: Hype
Item	HYPO5_SEQ_NO	Calculated in InForm via rule
Item	HYPOS_STOP_DTTM	**Item DEACTIVATED**
Item	SYMPTOM_EPISODE_YN	**Item DEACTIVATED**
Item	HYPOS_RELAE	Integrations: A, R - please do not change the refname or format
Item	Hypo_OFFICES	Item used for email

**Keys (navigation)/Uniqueness: Hypoglycaemic Episode**

Item	Unique	Order #
<b>HYPO_5_PAED (Repeating form)</b>		
<b>sctHYPO_5</b>		
HYPOS_STDTTM	None	1

**Codelist Values Tables: Hypoglycaemic Episode**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cIHYPO5_LOWEST	String		Done	1	ctmGLUC_LOW_1	HYPOS_LOWEST
			Not done	997	ctmGLUC_LOW_997	
cIHYPOS_GLUCLOW_U	String		mmol/L	561	ctmGLUC_UNIT_MMOLL	HYPOS_GLUC_UNIT
			mg/dL	162	ctmGLUC_UNIT_MGDL	
cIPHYACT_YN	String		Yes	1	ctmPHYACT_Y	HYPOS_PHYS_ACT
			No	2	ctmPHYACT_N	
			Unknown	996	ctmPHYACT_UNK	
cIASLEEP_YN	String		Yes	1	ctmASLEEP_Y	HYPOS_ASLEEP_YN
			No	2	ctmASLEEP_N	
cISYMWAKE_YN	String		Yes	1	ctmSYMWAKE_Y	HYPOS_SYMWAKE_YN
			No	2	ctmSYMWAKE_N	
cISYMPTOM_EPISODE_YN	String		Yes	1	ctmSYMPTOM_EPISODE_Y	SYMPTOM_EPISODE_YN

		No	2	ctmSYMPTOM_EPISODE_N
c1SEV_H_yn	String	Yes	1	ctmSEV_HYPO_Y HYPOS_SEVERE_YN
		No	2	ctmSEV_HYPO_N
c1HPOS_ECTRTRT	String	Semaglutide/ Semaglutide placebo	1	ctmHPOS_ECTRTRT_1 HYPOS_ECTRTRT
c1HPOS_ECDOSU	String	mg	1	ctmHPOS_UNIT1 HYPOS_ECDOSU
c1HPOS_CMTRT	String	Metformin	113	ctmHPOS_CMTRT_1 HYPOS_CMTRT
		Basal Insulin	4	ctmHPOS_CMTRT_2
c1HPOS_CMDOSU	String	mg	1	ctmHPOS_CMUNIT1 HYPOS_CMDOSU
		U	2	ctmHPOS_CMUNIT2
c1HPOS_SAE_YN	String	No	2	ctmHPOS_SAE_N HYPOS_SAE_YN
		Yes	1	ctmHPOS_SAE_Y
c1HPOS_SYM_NAUS	String	Feeling sick (nausea)	1	ctmHPOS_SYM_NAUS HYPOS_SYM_NAUS
c1HPOS_SYM_SHAK	String	Feeling shaky (shakiness)	2	ctmHPOS_SYM_SHAK HYPOS_SYM_SHAK
c1HPOS_SYM_SWT	String	Feeling sweaty (sweatiness)	3	ctmHPOS_SYM_SWT HYPOS_SYM_SWT
c1HPOS_SYM_AGIT	String	Feeling anxious (agitation)	4	ctmHPOS_SYM_AGIT HYPOS_SYM_AGIT
c1HPOS_SYM_TIRED	String	Feeling tired (tiredness)	5	ctmHPOS_SYM_TIRED HYPOS_SYM_TIRED
c1HPOS_SYMIRR	String	Feeling short-tempered (irritability)	6	ctmHPOS_SYMIRR HYPOS_SYMIRR
c1HPOS_SYM_HUN	String	Feeling hungry (hunger)	7	ctmHPOS_SYM_HUN HYPOS_SYM_HUN
c1HPOS_SYM_CONC	String	Finding it hard to think (poor concentration)	8	ctmHPOS_SYM_CONC HYPOS_SYM_CONC
c1HPOS_SYM_DEC	String	Not able to make a decision (poor judgement and confusion)	9	ctmHPOS_SYM_DEC HYPOS_SYM_DEC
c1HPOS_SYM_MEM	String	Cannot remember things that happened recently (problems with short-term memory)	10	ctmHPOS_SYM_MEM HYPOS_SYM_MEM
c1HPOS_SYM_DIZ	String	Feeling your head spin and unsteady walking (dizziness and unsteady gait)	11	ctmHPOS_SYM_DIZ HYPOS_SYM_DIZ
c1HPOS_SYM_ERR	String	Behaviour which is not normal (erratic behaviour)	12	ctmHPOS_SYM_ERR HYPOS_SYM_ERR
c1HPOS_SYM_PALP	String	Rapid or irregular heartbeat (palpitations)	13	ctmHPOS_SYM_PALP HYPOS_SYM_PALP
c1HPOS_SYM_HDACH	String	Headache	14	ctmHPOS_SYM_HDACH HYPOS_SYM_HDACH
c1HPOS_SYM_NMARE	String	Nightmares	15	ctmHPOS_SYM_NMARE HYPOS_SYM_NMARE
c1HPOS_SYM_TRMB	String	Trembling	16	ctmHPOS_SYM_TRMB HYPOS_SYM_TRMB
c1HPOS_SYM_HEAR	String	Hearing problems (difficulty hearing)	17	ctmHPOS_SYM_HEAR HYPOS_SYM_HEAR
c1HPOS_SYM_SIGT	String	Sight problems (blurred or double vision, disturbed colour vision)	18	ctmHPOS_SYM_SIGT HYPOS_SYM_SIGT
c1HPOS_SYM_CRY	String	Non-stop crying (inconsolable crying)	19	ctmHPOS_SYM_CRY HYPOS_SYM_CRY
c1HPOS_SYM_SPCH	String	Slurred speech	20	ctmHPOS_SYM_SPCH HYPOS_SYM_SPCH
c1HPOS_SYM_PALE	String	Extreme pale skin (pallor)	21	ctmHPOS_SYM_PALE HYPOS_SYM_PALE
c1HPOS_SYM_OTH	String	Other	999	ctmHPOS_SYM_OTH HYPOS_SYM_OTH
c1HPOS_MEDHELP_YN	String	Yes	1	ctmHPOS_MEDHELP_1 HYPOS_MEDHELP_YN
		No	2	ctmHPOS_MEDHELP_2
		Unknown	996	ctmHPOS_MEDHELP_996
c1HPOS_TRTINCLIN	String	In clinic, emergency room or hospital	11	ctmHPOS_TRTINCLIN HYPOS_TRTINCLIN
c1HPOS_AMBUL_YN	String	Yes	1	ctmHPOS_AMBUL_Y HYPOS_AMBUL_YN
		No	2	ctmHPOS_AMBUL_N
c1HPOS_TRTOTLLOC	String	Other	999	ctmHPOS_TRTOTLLOC HYPOS_TRTOTLLOC
c1HPOS_SEIZUR_YN	String	Yes	1	ctmHPOS_SEIZUR_Y HYPOS_SEIZUR_YN
		No	2	ctmHPOS_SEIZUR_N
c1HPOS_UNCONCOMA_YN	String	Yes	1	ctmHPOS_UNCONCOMA_Y HYPOS_UNCONCOMA_YN
		No	2	ctmHPOS_UNCONCOMA_N
c1HPOS_TRTCARB	String	Something to eat or drink (carbohydrates)	1	ctmHPOS_TRTCARB HYPOS_TRTCARB
c1HPOS_TRTGON	String	Glucagon injection	2	ctmHPOS_TRTGON HYPOS_TRTGON
c1HPOS_TRTGLUC	String	IV glucose	4	ctmHPOS_TRTGLUC HYPOS_TRTGLUC
c1HPOS_TRTOTLTH	String	Other	999	ctmHPOS_TRTOTLTH HYPOS_TRTOTLTH
c1HPOS_BETRAFFTTRT_YN	String	Yes	1	ctmHPOS_BETRAFFTTRT_Y HYPOS_BETRAFFTTRT_YN
		No	2	ctmHPOS_BETRAFFTTRT_N
c1HPOS_DIETCNG	String	Change of diet	1	ctmHPOS_DIETCNG HYPOS_DIETCNG
c1HPOS_MISDMEAL	String	Missed meal	2	ctmHPOS_MISDMEAL HYPOS_MISDMEAL
c1HPOS_PHYACT	String	Physical activity	5	ctmHPOS_PHYACT HYPOS_PHYACT
c1HPOS_ALCH	String	Drinking alcohol	18	ctmHPOS_ALCH HYPOS_ALCH
c1HPOS_DOSCLCERR	String	Made a mistake in calculating the dose of diabetes medication	8	ctmHPOS_DOSCLCERR HYPOS_DOSCLCERR
c1HPOS_ACCHIDOS	String	Accidentally took too high dose of diabetes medication	9	ctmHPOS_ACCHIDOS HYPOS_ACCHIDOS
c1HPOS_MEDMIXUP	String	Mixed up the diabetes medications	10	ctmHPOS_MEDMIXUP HYPOS_MEDMIXUP
c1HPOS_DEVUSEERR	String	Made a mistake when using the device	20	ctmHPOS_DEVUSEERR HYPOS_DEVUSEERR
c1HPOS_OTHFACT	String	Other	999	ctmHPOS_OTHFACT HYPOS_OTHFACT
c1HPOS_UNKFACT	String	Unknown	996	ctmHPOS_UNKFACT HYPOS_UNKFACT

RDE Analytics: RD_HYPO_5_PAED		
Data Variable RefName	RD Column Name	Column Data Type
HYPOS_SEQ_NO	HYPOS_SEQ_NO	NUMBER
	HYPOS_SEQ_NO_ND	VARCHAR2
HYP05_STDTTM	HYPOS_STDTTM	DATE
	HYPOS_STDTTM_DTS	VARCHAR2
	HYPOS_STDTTM_DTR	VARCHAR2
	HYPOS_STDTTM_ND	VARCHAR2
HYP05_LOWEST	HYPOS_LOWEST_C	VARCHAR2
	HYPOS_LOWEST	VARCHAR2
	HYPOS_LOWEST_ND	VARCHAR2
HYP05_LOWEST - HYPOS_GLUC_LEVEL	HYPOS_GLUC_LEVEL	FLOAT
HYP05_LOWEST - HYPOS_GLUC_UNIT	HYPOS_GLUC_UNIT_C	VARCHAR2
	HYPOS_GLUC_UNIT	VARCHAR2
HYP05_STOP_DTTM	HYPOS_STOP_DTTM	DATE
	HYPOS_STOP_DTTM_DTS	VARCHAR2
	HYPOS_STOP_DTTM_DTR	VARCHAR2
	HYPOS_STOP_DTTM_ND	VARCHAR2
HYP05_PHYS_ACT	HYPOS_PHYS_ACT_C	VARCHAR2
	HYPOS_PHYS_ACT	VARCHAR2
	HYPOS_PHYS_ACT_ND	VARCHAR2
HYP05_ASLEEP_YN	HYPOS_ASLEEP_YN_C	VARCHAR2
	HYPOS_ASLEEP_YN	VARCHAR2
	HYPOS_ASLEEP_YN_ND	VARCHAR2
HYP05_ASLEEP_YN - HYPOS_SYMWAKE_YN	HYPOS_SYMWAKE_YN_C	VARCHAR2
	HYPOS_SYMWAKE_YN	VARCHAR2
SYMPTOM_EPISODE_YN	SYMPTOM_EPISODE_YN_C	VARCHAR2
	SYMPTOM_EPISODE_YN	VARCHAR2

HYP05_S_FRF	SYMPOTM_EPISODE_YN_ND	VARCHAR2
	HYP05_SEVERE_YN_C	VARCHAR2
	HYP05_SEVERE_YN	VARCHAR2
	HYP05_SEVERE_YN_ND	VARCHAR2
HYP05_MLDAT	HYP05_MLDAT	DATE
	HYP05_MLDAT_DTS	VARCHAR2
	HYP05_MLDAT_DTR	VARCHAR2
	HYP05_MLDAT_ND	VARCHAR2
HYP05_SAE_YN	HYP05_SAE_YN_C	VARCHAR2
	HYP05_SAE_YN	VARCHAR2
	HYP05_SAE_YN_ND	VARCHAR2
HYP05_SAE_YN - HYPOS_RELAE	HYP05_RELAE	NUMBER
grpHYPOS_SYM	GRPHYPOS_SYM_ND	VARCHAR2
grpHYPOS_SYM - Feeling sick (nausea)	*HYP05_SYM_NAUS_CITMHPOSSYMSNAUS_C	VARCHAR2
grpHYPOS_SYM - Feeling shaky (shakiness)	*HYP05_SYM_NAUS_CITMHPOSSYMSNAUS	VARCHAR2
grpHYPOS_SYM - Feeling tired (tiredness)	*HYP05_SYM_SHAK_CITMHPOSSYMSHAK	VARCHAR2
grpHYPOS_SYM - Feeling sweaty (sweatiness)	*HYP05_SYM_SWT_CITMHPOSSYMSWT_C	VARCHAR2
grpHYPOS_SYM - Feeling anxious (agitation)	*HYP05_SYM_SWT_CITMHPOSSYMSWT	VARCHAR2
grpHYPOS_SYM - Feeling short-tempered (irritability)	*HYP05_SYM_AGIT_CITMHPOSSYMSAGIT_C	VARCHAR2
grpHYPOS_SYM - Feeling hungry (hunger)	*HYP05_SYM_AGIT_CITMHPOSSYMSAGIT	VARCHAR2
grpHYPOS_SYM - Finding it hard to think (poor concentration)	*HYP05_SYM_TIRED_CITMHPOSSYMTIRED_C	VARCHAR2
grpHYPOS_SYM - Not able to make a decision (poor judgement and confusion)	*HYP05_SYM_TIRED_CITMHPOSSYMTIRED	VARCHAR2
grpHYPOS_SYM - Cannot remember things that happened recently (problems with short-term memory)	*HYP05_SYM_IRR_CITMHPOSSYMMIRR_C	VARCHAR2
grpHYPOS_SYM - Feeling your head spin and unsteady walking (dizziness and unsteady gait)	*HYP05_SYM_IRR_CITMHPOSSYMMIRR	VARCHAR2
grpHYPOS_SYM - Behaviour which is not normal (erratic behaviour)	*HYP05_SYM_MEM_CITMHPOSSYMMEM_C	VARCHAR2
grpHYPOS_SYM - Rapid or irregular heartbeat (palpitations)	*HYP05_SYM_MEM_CITMHPOSSYMMEM	VARCHAR2
grpHYPOS_SYM - Headache	*HYP05_SYM_DIZ_CITMHPOSSYMDIZ_C	VARCHAR2
grpHYPOS_SYM - Nightmares	*HYP05_SYM_DIZ_CITMHPOSSYMDIZ	VARCHAR2
grpHYPOS_SYM - Trembling	*HYP05_SYM_ERR_CITMHPOSSYMMERR_C	VARCHAR2
grpHYPOS_SYM - Hearing problems (difficulty hearing)	*HYP05_SYM_ERR_CITMHPOSSYMMERR	VARCHAR2
grpHYPOS_SYM - Sight problems (blurred or double vision, disturbed colour vision)	*HYP05_SYM_PALP_CITMHPOSSYMPALP_C	VARCHAR2
grpHYPOS_SYM - Non-stop crying (inconsolable crying)	*HYP05_SYM_PALP_CITMHPOSSYMPALP	VARCHAR2
grpHYPOS_SYM - Slurred speech	*HYP05_SYM_HDACH_CITMHPOSSYMHDACH_C	VARCHAR2
grpHYPOS_SYM - Extreme pale skin (pallor)	*HYP05_SYM_HDACH_CITMHPOSSYMHDACH	VARCHAR2
grpHYPOS_SYM - Other	*HYP05_SYM_TRMB_CITMHPOSSYMTMB_C	VARCHAR2
HYP05_MEDHELP_YN	HYP05_MEDHELP_YN_C	VARCHAR2
	HYP05_MEDHELP_YN	VARCHAR2
	HYP05_MEDHELP_YN_ND	VARCHAR2
grpHYPOS_TRTINCLIN	GRPHYPOS_TRTINCLIN_ND	VARCHAR2
grpHYPOS_TRTINCLIN - In clinic, emergency room or hospital	*HYP05_TRTINCLIN_HYPOS_AMBUL_YN_C	VARCHAR2
	*HYP05_TRTINCLIN_HYPOS_AMBUL_YN	VARCHAR2
grpHYPOS_TRTINCLIN - HYPOS_AMBUL_YN	HYP05_AMBUL_YN_C	VARCHAR2
	HYP05_AMBUL_YN	VARCHAR2
grpHYPOS_TRTINCLIN - Other	*HYP05_TRTOOTHLOC_CITMHPO5TRTOOTHLOC_C	VARCHAR2
	*HYP05_TRTOOTHLOC_CITMHPO5TRTOOTHLOC	VARCHAR2
HYP05_SEIZUR_YN	HYP05_SEIZUR_YN_C	VARCHAR2
	HYP05_SEIZUR_YN	VARCHAR2
	HYP05_SEIZUR_YN_ND	VARCHAR2
HYP05_UNCONCOMA_YN	HYP05_UNCONCOMA_YN_C	VARCHAR2
	HYP05_UNCONCOMA_YN	VARCHAR2
	HYP05_UNCONCOMA_YN_ND	VARCHAR2
grpHYPOS_TRT	GRPHYPOS_TRT_ND	VARCHAR2
grpHYPOS_TRT - Something to eat or drink (carbohydrates)	*HYP05_TRTCARB_CITMHPO5RTCARB_C	VARCHAR2
	*HYP05_TRTCARB_CITMHPO5RTCARB	VARCHAR2
grpHYPOS_TRT - Glucagon injection	*HYP05_TRTGGON_CITMHPO5RTTGGON_C	VARCHAR2
	*HYP05_TRTGGON_CITMHPO5RTTGGON	VARCHAR2
grpHYPOS_TRT - IV glucose	*HYP05_TRTGLUC_CITMHPO5RTGLUC_C	VARCHAR2
	*HYP05_TRTGLUC_CITMHPO5RTGLUC	VARCHAR2
grpHYPOS_TRT - Other	*HYP05_TRTOOTH_CITMHPO5RTTOOTH_C	VARCHAR2
	*HYP05_TRTOOTH_CITMHPO5RTTOOTH	VARCHAR2
HYP05_BETRAFFTRT_YN	HYP05_BETRAFFTRT_YN_C	VARCHAR2
	HYP05_BETRAFFTRT_YN	VARCHAR2
	HYP05_BETRAFFTRT_YN_ND	VARCHAR2
grpHYPOS_FACTORS	GRPHYPOS_FACTORS_ND	VARCHAR2
grpHYPOS_FACTORS - Change of diet	*HYP05_DIETCNG_CITMHPO5DIETCNG_C	VARCHAR2
	*HYP05_DIETCNG_CITMHPO5DIETCNG	VARCHAR2
grpHYPOS_FACTORS - Missed meal	*HYP05_MISDEAL_CITMHPO5MISDEAL_C	VARCHAR2

grpHYPO	*HYPOS_MISDMEAL_CITMHYPOS MISDMEAL	VARCHAR2
	*HYPOS_PHYACT_CITMHYPOS PHYACT_C	VARCHAR2
	*HYPOS_PHYACT_CITMHYPOS PHYACT	VARCHAR2
grpHYPOS_FACTORS - Drinking alcohol	HYP05_ALCH_CITMHYPOSALCH_C	VARCHAR2
	HYP05_ALCH_CITMHYPOSALCH	VARCHAR2
grpHYPOS_FACTORS - Made a mistake in calculating the dose of diabetes medication	*HYPOS_DOSCLCERR_CITMHYPOS05DOSCLCERR_C	VARCHAR2
	*HYPOS_DOSCLCERR_CITMHYPOS05DOSCLCERR	VARCHAR2
grpHYPOS_FACTORS - Accidentally took too high dose of diabetes medication	*HYPOS_ACHIDOS_CITMHYPOSACCHIDOS_C	VARCHAR2
	*HYPOS_ACHIDOS_CITMHYPOSACCHIDOS	VARCHAR2
grpHYPOS_FACTORS - Mixed up the diabetes medications	*HYPOS_MEDMIXUP_CITMHYPOSMEDMIXUP_C	VARCHAR2
	*HYPOS_MEDMIXUP_CITMHYPOSMEDMIXUP	VARCHAR2
grpHYPOS_FACTORS - Made a mistake when using the device	*HYPOS_DEVUSEERR_CITMHYPOSDEVUSEERR_C	VARCHAR2
	*HYPOS_DEVUSEERR_CITMHYPOSDEVUSEERR	VARCHAR2
grpHYPOS_FACTORS - Other	*HYPOS_OTHFACT_CITMHYPOS05OTHFACT_C	VARCHAR2
	*HYPOS_OTHFACT_CITMHYPOS05OTHFACT	VARCHAR2
grpHYPOS_FACTORS - Unknown	*HYPOS_UNKFACT_CITMHYPOSUNKFACT_C	VARCHAR2
	*HYPOS_UNKFACT_CITMHYPOSUNKFACT	VARCHAR2
Hypo_OFFICE5	HYPO_OFFICES	NUMBER
	HYPO_OFFICES_ND	VARCHAR2
<b>*RD_HYPO_5_PAED_SCTHYPO_5_TRT</b>		
HYPOS_ECTR	HYP05_ECTR_C	VARCHAR2
	HYP05_ECTR	VARCHAR2
	HYP05_ECTR_ND	VARCHAR2
HYPOS_ECSTDAT	HYP05_ECSTDAT	DATE
	HYP05_ECSTDAT_DTS	VARCHAR2
	HYP05_ECSTDAT_DTR	VARCHAR2
	HYP05_ECSTDAT_ND	VARCHAR2
grpHYPOS_ECDOSE	GPHYPOS_ECDOSE_ND	VARCHAR2
grpHYPOS_ECDOSE - HYPOS_ECDOSE	HYP05_ECDOSE	FLOAT
grpHYPOS_ECDOSE - HYPOS_ECDOSU	HYP05_ECDOSU_C	VARCHAR2
	HYP05_ECDOSU	VARCHAR2
<b>*RD_HYPO_5_PAED_SCTHYPO_5_TRT2</b>		
HYPOS_CMTRT	HYP05_CMTRT_C	VARCHAR2
	HYP05_CMTRT	VARCHAR2
	HYP05_CMTRT_ND	VARCHAR2
HYPOS_CMSTDAT	HYP05_CMSTDAT	DATE
	HYP05_CMSTDAT_DTS	VARCHAR2
	HYP05_CMSTDAT_DTR	VARCHAR2
	HYP05_CMSTDAT_ND	VARCHAR2
grpHYPOS_CMDOSE	GPHYPOS_CMDOSE_ND	VARCHAR2
grpHYPOS_CMDOSE - HYPOS_CMDOSE	HYP05_CMDOSE	FLOAT
grpHYPOS_CMDOSE - HYPOS_CMDOSU	HYP05_CMDOSU_C	VARCHAR2
	HYP05_CMDOSU	VARCHAR2

Key: [\*] = The column and/or table name in the actual RDE extract may be different.

**PR=Procedures****PRCAT=SURGERY**

: SURGICAL PROCEDURES (Procedure) - Repeating Form [PROCEDURES]					
#	Seq no	Date	Name	Reason for procedure	
1					
Study ID: NN9536-4512					
SURGICAL PROCEDURES [sctPROCEDURES]					
1.	SEQ NO [read-only] [Seq no]		[PRO_NO_SEQ_NO] N4	<b>PRREFID</b>	
2.*	Date of procedure [Date]		[PRO_DATE] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2023-2030)	<b>PRSTDTC</b>	
3.	Procedure Name [Name]		[DIAG1_CATEG] [A:2] <input checked="" type="checkbox"/> [DIAG_TERM10] Bariatric surgery [A:1] <input type="checkbox"/> Bariatric gastric balloon insertion [A:2] <input type="checkbox"/> Bariatric gastric balloon removal [A:3] <input type="checkbox"/> Duodenal-Jejunal bypass sleeve therapy [A:4] <input type="checkbox"/> Endoscopic sleeve gastropathy [A:5] <input type="checkbox"/> Gastric banding (includes laparoscopic adjustable gastric band) [A:6] <input type="checkbox"/> Gastric band repositioning [A:7] <input type="checkbox"/> Gastric banding reversal [A:8] <input type="checkbox"/> Gastric bypass (roux-en-y) [A:9] <input type="checkbox"/> Gastric bypass reversal [A:10] <input type="checkbox"/> Duodenal switch [A:99] <input type="checkbox"/> [DIAG_TERM100TH] Other, specify: A200	<b>PRSCAT=BARIATRIC SURGERY</b>	
				<b>Note: PRTRT=Specify if available</b>	
			[A:1] <input checked="" type="checkbox"/> [DIAG_TERM9] Knee surgery [A:4] <input checked="" type="checkbox"/> [DIAGTERM94] Partial knee replacement [A:1] <input type="checkbox"/> Right [A:2] <input type="checkbox"/> Left [A:3] <input type="checkbox"/> Bilateral [A:5] <input checked="" type="checkbox"/> [DIAGTERM95] Total knee replacement [A:1] <input type="checkbox"/> Right [A:2] <input type="checkbox"/> Left [A:3] <input type="checkbox"/> Bilateral [A:99] <input type="checkbox"/> [DIAGTERM90TH] Other, specify: A200	<b>PRSCAT=KNEE SURGERY</b>	
				<b>PRLAT</b>	<b>PRTRT</b>
			[A:3] <input checked="" type="checkbox"/> [DIAG_TERM11_L] Hip Surgery [A:1] <input type="checkbox"/> Partial hip replacement [A:2] <input type="checkbox"/> Total hip replacement [A:3] <input type="checkbox"/> [DIAG_TERM110TH_X] Other, specify: A200	<b>PRSCAT=HIP SURGERY</b>	
				<b>Note: PRTRT=Specify if available</b>	
4.	Baker's cyst excision [hidden] [Baker's cyst excision]		[DIAGTERM91] [A:1] <input type="checkbox"/> Right [A:2] <input type="checkbox"/> Left [A:3] <input type="checkbox"/> Bilateral		
5.	Joint debridement [hidden] [Joint debridement]		[DIAGTERM92] [A:1] <input type="checkbox"/> Right [A:2] <input type="checkbox"/> Left [A:3] <input type="checkbox"/> Bilateral		
6.	Revision arthroplasty [hidden] [Revision arthroplasty]		[DIAGTERM93] [A:1] <input type="checkbox"/> Right [A:2] <input type="checkbox"/> Left [A:3] <input type="checkbox"/> Bilateral		
7.*	Reason for procedure [Reason for procedure ]		[REAS_PROC] [A:86] <input type="checkbox"/> [AE_NO] Adverse Event, enter Adverse Event no. N3 [A:2] <input checked="" type="checkbox"/> [grp_MM_NO1] Medical History/Concomitant Illness, enter seq. no. [MH1_NO1] [SUB_GRP_MM_NO1] Was the subject previously ineligible for procedure, now eligible due to weight loss? [A:1] <input type="checkbox"/> Yes [A:2] <input type="checkbox"/> No [A:99] <input type="checkbox"/> [REAS_OTH] Other, specify A200	<b>RELREC: PR,AE</b>	
				<b>RELREC: PR,MH</b>	
				<b>Note: PRTRT=Specify if available</b>	

Key: [\*] = Item is required [✓] = Source verification required  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

**Study Object Descriptions: SURGICAL PROCEDURES**

Type	RefName	Description
Form	PROCEDURES	Visit: Procedure
Item	DIAGTERM91	**Item DEACTIVATED**
Item	DIAGTERM92	**Item DEACTIVATED**
Item	DIAGTERM93	**Item DEACTIVATED**

**Codelist Values Tables: SURGICAL PROCEDURES**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cPROCEDURE_NAME	String		Bariatric surgery	2	citmPROC_NAME2	DIAG1_CATEG
			Knee Surgery	1	citmPROC_NAME1	
			Hip Surgery	3	citmPROC_NAME3	
cDIAGTERM10	String		Bariatric gastric balloon insertion	1	citmDIAGTERM101	DIAG_TERM10
			Bariatric gastric balloon removal	2	citmDIAGTERM102	
			Duodenal-Jejunal bypass sleeve therapy	3	citmDIAGTERM103	
			Endoscopic sleeve gastropathy	4	citmDIAGTERM104	
			Gastric banding (includes laparoscopic adjustable gastric band)	5	citmDIAGTERM105	
			Gastric band repositioning	6	citmDIAGTERM106	
			Gastric banding reversal	7	citmDIAGTERM107	
			Gastric bypass (roux-en-y)	8	citmDIAGTERM108	
			Gastric bypass reversal	9	citmDIAGTERM109	
			Duodenal switch	10	citmDIAGTERM110	

cDIAGTE_M4	ring	Other, specify	99	ctmDIAGTERM111	
		Partial knee replacement	4	ctmDIAGTERM94	DIAG_TERM9
		Total knee replacement	5	ctmDIAGTERM95	
		Other, specify	99	ctmDIAGTERM90TH	
cSUB_DIAG_TERM91	String	Right	1	ctmSUB_DIAG_TERM911	DIAGTERM94, DIAGTERM95,
		Left	2	ctmSUB_DIAG_TERM912	DIAGTERM91, DIAGTERM92, DIAGTERM93
		Bilateral	3	ctmSUB_DIAG_TERM913	
cDIAGTERM11_L	String	Partial hip replacement	1	ctmDIAGTERM11_L_1	DIAG_TERM11_L
		Total hip replacement	2	ctmDIAGTERM11_L_2	
		Other	3	ctmDIAGTERM11_L_3	
cIAE_MH_OTH	String	Adverse event	86	ctmAENO_1	REAS_PROC
		Medical History/Concomitant Illness	2	ctmMHNO_1	
		Other, specify	99	ctmOTH_99	
cYESNO_4	String	Yes	1	ctmYESNO1_4	SUB_GRP_MH_NO1
		No	2	ctmYESNO2_4	

**RDE Analytics: RD\_PROCEDURES**

Data Variable RefName	RD Column Name	Column Data Type
PRO_NO_SEQ_NO	PRO_NO_SEQ_NO	NUMBER
	PRO_NO_SEQ_NO_ND	VARCHAR2
PRO_DATE	PRO_DATE	DATE
	PRO_DATE_DTS	VARCHAR2
	PRO_DATE_ND	VARCHAR2
DIAG1_CATEG	DIAG1_CATEG_C	VARCHAR2
	DIAG1_CATEG	VARCHAR2
	DIAG1_CATEG_ND	VARCHAR2
DIAG1_CATEG - DIAG_TERM10	DIAG_TERM10_C	VARCHAR2
	DIAG_TERM10	VARCHAR2
DIAG1_CATEG - DIAG_TERM10OTH	DIAG_TERM10OTH	VARCHAR2
DIAG1_CATEG - DIAG_TERM9	DIAG_TERM9_C	VARCHAR2
	DIAG_TERM9	VARCHAR2
DIAG1_CATEG - DIAGTERM94	DIAGTERM94_C	VARCHAR2
	DIAGTERM94	VARCHAR2
DIAG1_CATEG - DIAGTERM95	DIAGTERM95_C	VARCHAR2
	DIAGTERM95	VARCHAR2
DIAG1_CATEG - DIAGTERM90TH	DIAGTERM90TH	VARCHAR2
DIAG1_CATEG - DIAG_TERM11_L	DIAG_TERM11_L_C	VARCHAR2
	DIAG_TERM11_L	VARCHAR2
DIAG1_CATEG - DIAG_TERM11OTH_X	DIAG_TERM11OTH_X	VARCHAR2
DIAGTERM91	DIAGTERM91_C	VARCHAR2
	DIAGTERM91	VARCHAR2
	DIAGTERM91_ND	VARCHAR2
DIAGTERM92	DIAGTERM92_C	VARCHAR2
	DIAGTERM92	VARCHAR2
	DIAGTERM92_ND	VARCHAR2
DIAGTERM93	DIAGTERM93_C	VARCHAR2
	DIAGTERM93	VARCHAR2
	DIAGTERM93_ND	VARCHAR2
REAS_PROC	REAS_PROC_C	VARCHAR2
	REAS_PROC	VARCHAR2
	REAS_PROC_ND	VARCHAR2
REAS_PROC - AE_NO	AE_NO	NUMBER
REAS_PROC - MH1_NO1	MH1_NO1	NUMBER
REAS_PROC - SUB_GRP_MH_NO1	SUB_GRP_MH_NO1_C	VARCHAR2
	SUB_GRP_MH_NO1	VARCHAR2
REAS_PROC - REAS_OTH	REAS_OTH	VARCHAR2

DS=Disposition		
<b>: Consent for Legal age (Reconsent) [RECONSENT]</b>		
<b>Study ID:</b> Complete the minor reaches legal age while participating in the trial and has only signed an age specific informed consent form. If the re-consent is obtained then please complete date of consent for Biosamples for future research, if applicable.		
1.* Date of re-consent [Date of consent]	<input style="width: 100%;" type="text"/> [CONSENT_DATE_LEGAL] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2023-2030)	
2. Date of re-consent obtained for Biosamples for future research [Biosample consent]	<input style="width: 100%;" type="text"/> [BIOSAMPLE_CONSENT1] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2023-2030)	
<b>DSSTDTC DS TERM=LEGAL AGE CONSENT DSDECOD=BIOSAMPLE CONSENT</b>		
<b>DSSTDTC DS TERM=FUTURE BIOSAMPLE CONSENT</b>		
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		
<b>Study Object Descriptions: Consent for Legal age</b>		
<b>Type</b>	<b>RefName</b>	<b>Description</b>
Form	RECONSENT	Non-visit (This form will be collected for administrative purpose and mapped to OC but not in SDTM)
<b>RDE Analytics: RD_RECONSENT</b>		
<b>Data Variable</b>	<b>RefName</b>	<b>RD Column Name</b>
CONSENT_DATE_LEGAL		CONSENT_DATE_LEGAL DATE
		CONSENT_DATE_LEGAL_DTS VARCHAR2
		CONSENT_DATE_LEGAL_ND VARCHAR2
BIOSAMPLE_CONSENT1		BIOSAMPLE_CONSENT1 DATE
		BIOSAMPLE_CONSENT1_DTS VARCHAR2
		BIOSAMPLE_CONSENT1_ND VARCHAR2

**RP=Reproductive System Findings****RPCAT=PUBERTAL STATUS**

<b>Date of Menarche (Menarche) [PUBERTAL_STATUS_2]</b>	
<p><b>Study ID:</b> Note: Females only, who reaches childbearing potential during the course of study.</p> <p>1.* <input type="text" value="Date of Menarche"/> [Date of Menarche]</p> <p>Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</p>	
<b>[MENARCHE_DT] (DD/MM/YYYY)</b> Req/Unk <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2023-2030)	

**RPORRES when RPTESTCD=FMPSTDTC****Study Object Descriptions: Date of Menarche**

Type	RefName	Description
Form	PUBERTAL_STATUS_2	Visit: Menarche

**RDE Analytics: RD\_PUBERTAL\_STATUS\_2**

Data Variable RefName	RD Column Name	Column Data Type
MENARCHE_DT	MENARCHE_DT	DATE
	MENARCHE_DT_TS	VARCHAR2
	MENARCHE_DT_TDR	VARCHAR2
	MENARCHE_DT_ND	VARCHAR2

**Note: If two trial products are administered then the latest Date of last dose of investigational product should be considered**

: End of IMP Treatment (End of IMP Treatment) [END_OF_TREATMENT]	
<p>Study ID: This form is completed once the subject has permanently stopped taking investigational medicinal product (IMP).</p> <p>Please remember to register the discontinuation of IMP in RTSM, if applicable.</p> <p>1. Date of last dose of investigational medicinal product (Semaglutide/Semaglutide placebo) [Last date on IMP]</p> <p>2. Date of last dose of investigational medicinal product (IMP 2) [hidden] [Last date on IMP]</p> <p>3. Date and time of last dose of investigational medicinal product [hidden] [Last date and time on IMP]</p> <p>4.* Has the subject completed the planned study intervention? Select 'Yes' if the subject has received the required intervention as defined by protocol and attended the last planned visit in the intervention period. Select 'No' if the subject has permanently discontinued IMP before the end of planned intervention and/or if the subject has not attended the last planned visit in the intervention period. [Study intervention completion]</p>	
<p>[LAST_TRIAL_PROD_DATE_1] [A:1] <input type="radio"/> [LAST_TRIAL_PROD_DATE_P1] (DD/MM/YYYY) Req ✓ / Req ✓ / Req ✓ (2023-2030) [A:998] N/A</p> <p>[LAST_TRIAL_PROD_DATE_2] [A:1] <input type="radio"/> [LAST_TRIAL_PROD_DATE_P2] (DD/MM/YYYY) Req ✓ / Req ✓ / Req ✓ (2022-2035) [A:998] N/A</p> <p>[LAST_TRIAL_PROD_TIME_1] [A:1] <input type="radio"/> [LAST_TRIAL_PROD_TIME_2] (DD/MM/YYYY hh:mm) Req ✓ / Req ✓ / Req ✓ (2022-2035) Req ✓ : Req ✓ 24-hour clock [A:998] N/A</p> <p>[TREAT_COMPLETION_YN] [A:1] <input type="radio"/> Yes [A:2] <input type="radio"/> [DISCONT_REASON_1] No</p>	
<p><b>DSSTDTC</b> <b>DSDECOD=LAST DATE ON TRIAL PRODUCT</b> <b>DTERM=LAST DATE ON TRIAL PRODUCT</b></p> <p><b>DSDECOD=COMPLETED TREATMENT</b> <b>DSCAT=OTHER EVENT</b></p> <p><b>DSDECOD=ADVERSE EVENT</b></p> <p><b>DSDECOD=PROTOCOL DEVIATION</b></p> <p><b>DSDECOD=LOST TO FOLLOW-UP</b></p> <p><b>DTERM=PREGNANCY</b> <b>DSDECOD=PREGNANCY</b></p> <p><b>DSDECOD=EPI/PANDEMIC</b></p> <p><b>DSDECOD=LACK OF EFFICACY</b></p> <p><b>DTERM</b> <b>DSDECOD=PHYSICIAN DECISION</b></p> <p><b>DSDECOD=SITE CLOSURE</b></p> <p><b>DTERM</b> <b>DSDECOD=OTHER</b></p> <p><b>DTERM</b></p>	
<p>Primary reason for discontinuation of investigational medicinal product(s):</p> <p>[A:11] <input type="radio"/> [AE_HYPO_1] Adverse Event [A:11] <input type="radio"/> [grpAE_NO_2] Adverse event no.: [AE_NO_1] 0 &lt; N3 [A:71] <input type="radio"/> [grpHYPO_NO_1] Hypoglycaemic episode no. (only if not reported on AE form): [HYPO_NO_1] 0 &lt; N3</p> <p>[A:29] <input type="radio"/> [PD_SUB_REASON_CODE] Protocol deviation [A:20] <input type="radio"/> Included in the study in violation of the inclusion and/or exclusion criteria [A:203] <input type="radio"/> Intention of becoming pregnant [A:227] <input type="radio"/> Simultaneous use of an approved or non-approved investigational medicinal product in another clinical trial [A:71] <input type="radio"/> Calcitonin ≥50 ng/L [A:72] <input type="radio"/> Suspicion of acute pancreatitis [A:73] <input type="radio"/> Diagnosis of type 1 diabetes [A:999] <input type="radio"/> [PD_SUB_REASON_OTHER] Other, specify A200</p> <p>[A:39] <input type="radio"/> Lack of efficacy [A:12] <input type="radio"/> Lost to follow-up [A:41] <input type="radio"/> Pregnancy [A:38] <input type="radio"/> [INV_DIS_OTH] At the discretion of the Investigator Specify A200</p> <p>[A:152] <input type="radio"/> Site closure [A:153] <input type="radio"/> [DISCONT_REASON_EPI] Epi/Pandemic Specify A200</p> <p>[A:999] <input type="radio"/> [DISCONT_REA_SUB_OT] Other (only to be selected if none of the above options are applicable) [A:46] <input type="radio"/> Withdrawal of consent [A:999] <input type="radio"/> [DISCONT_REASON_OTHER_1] Other, specify A200</p>	
<p>5. Lack of efficacy [hidden] [Lack of efficacy]</p> <p>6. Other, specify [hidden]</p> <p>7. Technical problems Specify [hidden]</p> <p>8. Hidden item – used for IMPACT interface for Withdrawal from treatment [hidden] [IMPACT - Withdrawal from treatment]</p>	
<p>[LE_SUB_REASON_CODE_1] [A:T1] <input type="radio"/> Trial specific criterion [A:T2] <input type="radio"/> Trial specific criterion [A:999] <input type="radio"/> Other</p> <p>[LE_SUB_REASON_OTHER_1] A200</p> <p>[TP_SUB_REASON_SPEC_1] A200</p> <p>[grpIMPACT_EOTREAT] [IMPACT_TREAT_DT] (DD/MM/YYYY) IMPACT Withdrawal date Req ✓ / Req ✓ / Req ✓ (2023-2030) [IMPACT_TREAT_REASON] IMPACT With. Reas. Code A50</p>	

Key: [\*] = Item is required    [✓] = Source verification required  
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

**Study Object Descriptions: End of IMP Treatment**

Type	RefName	Description
Form	END_OF_TREATMENT	Visit: End Treat
Item	LAST_TRIAL_PROD_DATE_2	**Item DEACTIVATED**
Item	LAST_TRIAL_PROD_TIME_1	**Item DEACTIVATED**
Item	LE_SUB_REASON_CODE_1	**Item DEACTIVATED**
Item	LE_SUB_REASON_OTHER_1	**Item DEACTIVATED**
Item	TP_SUB_REASON_SPEC_1	**Item DEACTIVATED**
Item	grpIMPACT_EOTREAT	**Item DEACTIVATED**

**Codelist Values Tables: End of IMP Treatment**

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName

	String	Date	1 citmLAST_PROD_DT_P1	LAST_TRIAL_PROD_DATE_1
		N/A	998 citmLAST_PROD_NA_P1	
cLAST_PROD_DATE	String	Date	1 citmLAST_PROD_DT_P2	LAST_TRIAL_PROD_DATE_2
		N/A	998 citmLAST_PROD_NA_P2	
cLAST_PROD_DT	String	Date and time	1 citmLAST_PROD_DTTM	LAST_TRIAL_PROD_TIME_1
		N/A	998 citmLAST_PROD_NA	
cTREAT_COMPLETION_YN	String	Yes	1 citmTREAT_COMPLETION_Y	TREAT_COMPLETION_YN
		No	2 citmTREAT_COMPLETION_N	
cDISCONT_REASON_1	String	1 - cDISCONT_REASON_1	11 citmDISCONT_REASON11_1	DISCONT_REASON_1
		Adverse Event	29 citmDISCONT_REASON13_1	
		Protocol deviation	39 citmDISCONT_REASON39_1	
		Lack of efficacy	12 citmDISCONT_REASON12_1	
		Lost to follow-up	4 citmDISCONT_REASON4_1	
		Pregnancy	38 citmDISCONT_REASON38	
		At the discretion of the Investigator	152 citmDISCONT_REASON152	
		Site closure	153 citmDISCONT_REASON153	
		Epi/Pandemic	999 citmDISCONT_REASON999_1	
		Other		
cAE_HYPO_1	String	Adverse event no.	11 citmAE_1	AE_HYPO_1
		Hypoglycaemic episode no.	71 citmHYPO_1	
cPD_SUB_REASON	String	Included in the study in violation of the inclusion and/or exclusion criteria	201 citmPD_SUB_REASON201	PD_SUB_REASON_CODE
		Intention of becoming pregnant	203 citmPD_SUB_REASON203	
		Simultaneous use of an approved or non-approved investigational medicinal product in another clinical trial	727 citmPD_SUB_REASON727	
		Calcitonin ≥ 50 ng/L	T1 citmPD_SUB_REASONT1	
		Suspicion of acute pancreatitis	T2 citmPD_SUB_REASONT2	
		Diagnosis of type 1 diabetes	T3 citmPD_SUB_REASONT3	
		Other	999 citmPD_SUB_REASON999	
cSUB_REAS_OT	String	1 - cSUB_REAS_OT	46 citmSUB_REASON_0T4	DISCONT_REASON_SUB_OT
		Withdrawal of consent	999 citmSUB_REASON_0T999	
		Other, specify		
cLE_SUB_REASON_1	String	Trial specific criterion	T1 citmLE_SUB_REASON1_1	LE_SUB_REASON_CODE_1
		Trial specific criterion	T2 citmLE_SUB_REASON2_1	
		Other	999 citmLE_SUB_REASON999_1	

RDE Analytics: RD-END_OF_TREATMENT		
Data Variable RefName	RD Column Name	Column Data Type
LAST_TRIAL_PROD_DATE_1	LAST_TRIAL_PROD_DATE_1_C	VARCHAR2
	LAST_TRIAL_PROD_DATE_1	VARCHAR2
	LAST_TRIAL_PROD_DATE_1_ND	VARCHAR2
LAST_TRIAL_PROD_DATE_1 - LAST_TRIAL_PROD_DATE_P1	LAST_TRIAL_PROD_DATE_P1	DATE
	LAST_TRIAL_PROD_DATE_P1_DTS	VARCHAR2
LAST_TRIAL_PROD_DATE_2	LAST_TRIAL_PROD_DATE_2_C	VARCHAR2
	LAST_TRIAL_PROD_DATE_2	VARCHAR2
	LAST_TRIAL_PROD_DATE_2_ND	VARCHAR2
LAST_TRIAL_PROD_DATE_2 - LAST_TRIAL_PROD_DATE_P2	LAST_TRIAL_PROD_DATE_P2	DATE
	LAST_TRIAL_PROD_DATE_P2_DTS	VARCHAR2
LAST_TRIAL_PROD_TIME_1	LAST_TRIAL_PROD_TIME_1_C	VARCHAR2
	LAST_TRIAL_PROD_TIME_1	VARCHAR2
	LAST_TRIAL_PROD_TIME_1_ND	VARCHAR2
LAST_TRIAL_PROD_TIME_1 - LAST_TRIAL_PROD_TIME_2	LAST_TRIAL_PROD_TIME_2	DATE
	LAST_TRIAL_PROD_TIME_2_DTS	VARCHAR2
TREAT_COMPLETION_YN	TREAT_COMPLETION_YN_C	VARCHAR2
	TREAT_COMPLETION_YN	VARCHAR2
	TREAT_COMPLETION_YN_ND	VARCHAR2
TREAT_COMPLETION_YN - DISCONT_REASON_1	DISCONT_REASON_1_C	VARCHAR2
	DISCONT_REASON_1	VARCHAR2
TREAT_COMPLETION_YN - AE_HYPO_1	AE_HYPO_1_C	VARCHAR2
	AE_HYPO_1	VARCHAR2
TREAT_COMPLETION_YN - AE_NO1_1	AE_NO1_1	NUMBER
TREAT_COMPLETION_YN - HYPO_NO1_1	HYPO_NO1_1	NUMBER
TREAT_COMPLETION_YN - PD_SUB_REASON_CODE	PD_SUB_REASON_CODE_C	VARCHAR2
	PD_SUB_REASON_CODE	VARCHAR2
TREAT_COMPLETION_YN - PD_SUB_REASON_OTHER	PD_SUB_REASON_OTHER	VARCHAR2
TREAT_COMPLETION_YN - INV_DIS_OTH	INV_DIS_OTH	VARCHAR2
TREAT_COMPLETION_YN - DISCONT_REASON_EPI	DISCONT_REASON_EPI	VARCHAR2
TREAT_COMPLETION_YN - DISCONT_REASON_EA_SUB_OT	DISCONT_REASON_EA_SUB_OT_C	VARCHAR2
	DISCONT_REASON_EA_SUB_OT	VARCHAR2
TREAT_COMPLETION_YN - DISCONT_REASON_OTHER_1	DISCONT_REASON_OTHER_1	VARCHAR2
LE_SUB_REASON_CODE_1	LE_SUB_REASON_CODE_1_C	VARCHAR2
	LE_SUB_REASON_CODE_1	VARCHAR2
	LE_SUB_REASON_CODE_1_ND	VARCHAR2
LE_SUB_REASON_OTHER_1	LE_SUB_REASON_OTHER_1	VARCHAR2
	LE_SUB_REASON_OTHER_1_ND	VARCHAR2
TP_SUB_REASON_SPEC_1	TP_SUB_REASON_SPEC_1	VARCHAR2
	TP_SUB_REASON_SPEC_1_ND	VARCHAR2
grpIMPACT_EOTREAT	GRPIMPACT_EOTREAT_ND	VARCHAR2
grpIMPACT_EOTREAT - IMPACT_TREAT_DT	IMPACT_TREAT_DT	DATE
	IMPACT_TREAT_DT_DTS	VARCHAR2
grpIMPACT_EOTREAT - IMPACT_TREAT_REAS	IMPACT_TREAT_REAS	VARCHAR2

**DS=Disposition****DSCAT=DISPOSITION EVENT**

: End of Study (End of Study) [END_OF_TRIAL_2]	
<p><b>Study ID:</b> This form is used at the end of subject participation in the clinical study (e.g. study completion, screening failure, Withdrawal from study)</p> <p>1. Date subject's participation ended in the study  <input checked="" type="checkbox"/> [Date subject's participation ended in the study]</p> <p>2. Specify primary reason participation ended  <input checked="" type="checkbox"/> If the subject participation ended prior to randomisation, complete the RTSM Screening Failure session.  [Specify primary reason participation ended]</p>	
<b>DTERM=COMPLETED</b> <b>DSDECOD=COMPLETED</b> <b>DSDECOD=WITHDRAWAL OF CONSENT</b>	
<b>DSDECOD=WITHDRAWAL BY PARENT/GUARDIAN</b>	
<b>DSDECOD=LOST TO FOLLOW-UP</b>	
<b>DSDECOD=PHYSICIAN DECISION</b>	
<b>DSDECOD=SITE CLOSURE</b> <b>DTERM=SITE CLOSURE</b> <b>DSDECOD=EPI/PANDEMIC</b>	
<b>DSDECOD=DEATH</b> <b>DTERM=DEATH</b>	
<p>3. Failing to meet randomisation requirements [hidden]  [Failing to meet randomisation requirements]</p> <p>4. Hidden item – used for IMPACT interface [hidden]  [Hidden item – used for IMPACT interface]</p> <p>5. Hidden item – used for InForm subject status flags [hidden]  [Hidden item – used for InForm subject status flags]</p> <p>6. Hidden item – used for InForm subject discontinuation flags [hidden]  [Hidden item – used for InForm subject discontinuation flags]</p>	
<p>Key: [*] = Item is required    [ ] = Source verification required  Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</p>	

[TRIAL_COMPL_DT_YN_2] (DD/MM/YYYY) Req / / Req (2023-2030)	
<p><b>DSSTDTC</b></p> <p>[A:2] Subject completed the study  <input type="radio"/> Screen failure (defined as subject not eligible for participation according to in/exclusion criteria)  <input type="radio"/> [WITHDR_CONS_REAS] Withdrawal of consent by subject  Specify reason, if available  A200</p>	
<p><b>DTERM</b></p> <p>[A:13] [WITHDR_CONS_LAR] Withdrawal of consent by subject's parent or subject's legally acceptable representative (LAR)  Specify reason, if available  A200</p>	
<p><b>DTERM</b></p> <p>[A:6] [LOST_FU_REASON] Lost to follow-up  Specify reason, if available  A200</p>	
<p><b>DTERM</b></p> <p>[A:8] [INVEST_DECIS_REAS] Investigator decision  Specify reason, if available  A200</p>	
<p><b>DTERM</b></p> <p>[A:152] Site closure  <input type="radio"/> [EPI_PAN_SPECIFY] Epi/Pandemic  Specify  A200</p>	
<p><b>DTERM</b></p> <p>[A:3] Death</p>	
<p>[FAIL_RAND_REQ]  [A:122] Run-in criteria failure  [A:126] Randomisation criteria failure</p>	
<p>[grpIMPACT_INTERFACE]  [IMPACT_A_NUL] (DD/MM/YYYY)  Null field  Req / / Req / / Req (2023-2030)</p>	
<p>[IMPACT_B_DATE] (DD/MM/YYYY)  Discontinuation Date  Req / / Req / / Req (2023-2030)</p>	
<p>[IMPACT_C_REAS]  Discontinuation code A15</p>	
<p>[STATUS_FLG]  [cSTATUS_FLG] ✓</p>	
<p>[STATUS_DISC_REAS]  [cSTATUS_DISC_REAS] ✓</p>	

Study Object Descriptions: End of Study		
Type	RefName	Description
Form	END_OF_TRIAL_2	Visit: End Study
Item	FAIL_RAND_REQ	**Item DEACTIVATED**
Item	grpIMPACT_INTERFACE	Integrations: Impact - please do not change the refname or format

Codelist Values Tables: End of Study						
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
cITRIAL_COMPLETION_YN_2	String	1 - cITRIAL_COMPLETION_YN_3	Subject completed the study Screen failure (defined as subject not eligible for participation according to in/exclusion criteria) Withdrawal of consent by subject Withdrawal of consent by subject's parent or subject's legally acceptable representative (LAR) Lost to follow-up Investigator decision Site closure Epi/Pandemic Death	2	citmTRIAL_COMPL_2	TRIAL_COMPLETION_YN_2
cFAIL_RAND_REQ	String		Run-in criteria failure Randomisation criteria failure	122	citmFAIL_RAND_REQ_122	FAIL_RAND_REQ
cSTATUS_FLG	String		Completed Did not complete	C	citmSTATUS_FLG_C	STATUS_FLG
cSTATUS_DISC_REAS	String		Screening Failure Discontinuation from trial	SF	citmSTATUS_DISC_REAS_SF	STATUS_DISC_REAS
				DC	citmSTATUS_DISC_REAS_DC	

RDE Analytics: RD_END_OF_TRIAL_2		
Data Variable RefName	RD Column Name	Column Data Type
TRIAL_COMPL_DT_YN_2	TRIAL_COMPL_DT_YN_2	DATE
	TRIAL_COMPL_DT_YN_2_DTS	VARCHAR2
	TRIAL_COMPL_DT_YN_2_ND	VARCHAR2
TRIAL_COMPLETION_YN_2	TRIAL_COMPLETION_YN_2_C	VARCHAR2
	TRIAL_COMPLETION_YN_2	VARCHAR2
	TRIAL_COMPLETION_YN_2_ND	VARCHAR2
TRIAL_COMPLETION_YN_2 - WITHDR_CONS_REAS	WITHDR_CONS_REAS	VARCHAR2
TRIAL_COMPLETION_YN_2 - WITHDR_CONS_LAR	WITHDR_CONS_LAR	VARCHAR2
TRIAL_COMPLETION_YN_2 - LOST_FU_REASON	LOST_FU_REASON	VARCHAR2
TRIAL_COMPLETION_YN_2 - INVEST_DECIS_REAS	INVEST_DECIS_REAS	VARCHAR2
TRIAL_COMPLETION_YN_2 - EPI_PAN_SPECIFY	EPI_PAN_SPECIFY	VARCHAR2
FAIL_RAND_REQ	FAIL_RAND_REQ_C	VARCHAR2
	FAIL_RAND_REQ	VARCHAR2
	FAIL_RAND_REQ_ND	VARCHAR2

CE	GRPIMPACT_INTERFACE_IND	VARCHAR2
grpIMPAC_NTRPF_CE - IMPACT_A_NUL	IMPACT_A_NUL	DATE
	IMPACT_A_NUL_DTS	VARCHAR2
grpIMPACT_INTERFACE - IMPACT_B_DATE	IMPACT_B_DATE	DATE
	IMPACT_B_DATE_DTS	VARCHAR2
grpIMPACT_INTERFACE - IMPACT_C_REAS	IMPACT_C_REAS	VARCHAR2
STATUS_FLG	STATUS_FLG_C	VARCHAR2
	STATUS_FLG	VARCHAR2
	STATUS_FLG_ND	VARCHAR2
STATUS_DISC_REAS	STATUS_DISC_REAS_C	VARCHAR2
	STATUS_DISC_REAS	VARCHAR2
	STATUS_DISC_REAS_ND	VARCHAR2

**NOT SUBMITTED**

<b>: Case Book Sign Off (Sign Off) [TERM]</b>	
Study ID:	
1.* Prepar [Sign off]	for sign off
[itmCBSign] [A:1] <input type="checkbox"/>	
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

Study Object Descriptions: Case Book Sign Off		
Type	RefName	Description
Form	TERM	Visit: Sign

Codelist Values Tables: Case Book Sign Off					
Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName
clmCBSign_1	String		1	clmCBSign_1	itmCBSign

RDE Analytics: RD_TERM		
Data Variable RefName	RD Column Name	Column Data Type
itmCBSign	ITMCBSIGN_ND	VARCHAR2
itmCBSign -	ITMCBSIGN_CITMCBSIGN1_C	VARCHAR2
	ITMCBSIGN_CITMCBSIGN1	VARCHAR2

Properties For Study Design:			
InForm Sf	Property Type	Data Object RefName	Data Object Path RefName
Screening	Visit	Screen	Screen
Enrollment	Visit	Enroll	Enroll
Screening	Form	SCR	Screen.SCR
Enrollment	Form	ENR	Enroll.ENR
Patient Identification	Form	SUBJECT_INFO_2	evtV1.SUBJECT_INFO_2
Study Completion	Form	END_OF_TRIAL_2	evtEOS.END_OF_TRIAL_2
Reg Docs	Form	Unassigned	Unassigned
Visit Report	Form	Unassigned	Unassigned
Visit Approval	Form	Unassigned	Unassigned
Initials (Screening)	Item	INITIALS	Screen.SCR.INITIALS
DOB (Screening)	Item	BIRTH_DATE_SCR	Screen.SCR.BIRTH_DATE_SCR
Screening date (Screening)	Item	Unassigned	Unassigned
Patient No. (Enrollment)	Item	PATIENT	Enroll.ENR.PATIENT evtV1.SUBJECT_INFO_2.sctDEMOGRAPHY.PATIENT
Initials (Patient Identification)	Item	Unassigned	Unassigned
Completion status (Study Completion)	Item	STATUS_FLG	evtEOS.END_OF_TRIAL_2.sctEND_OF_TRIAL_2.STATUS_FLG
Drop out reason (Study Completion)	Item	STATUS_DISC_REAS	evtEOS.END_OF_TRIAL_2.sctEND_OF_TRIAL_2.STATUS_DISC_REAS
DOV (Date of Visit)	Item	VISIT_DATE	evtv14.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evtp17.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evtp11.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evtv31.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv24.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv23.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv1.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp19.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evtp22.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evtp23.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp21.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv35.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp35.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv2.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv26.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv33.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv28.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv16.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv32.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp8.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv4.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv20.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv2.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv26.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp15.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp29.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv12.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv30.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp13.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp27.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp19.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv10.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evv12.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp25.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE evp3.VISIT_DATE.DOV.sctVISIT_DATE.VISIT_DATE
Randomization field (Randomization)	Item	Unassigned	Unassigned

ected Health Information Table		
Item RefN	Section RefName	Form RefName
No items h as "Personal/Protected Health Information".		
<b>Please note:</b> emails sent from the trial server by the InForm application are not encrypted. If you are subject to HIPAA requirements, you should identify and block all Personal/Protected Health Information items that may be included in email notifications.		

<b>Ins For Study Design:</b>
No unit con

for Study:	
No Review	n defined.

<b>Annotations Summary Table:</b>	
No in-place	been defined.

<b>\$ for Study Design:</b>
No custom in defined.