Annotated Study Book for Study Design:

Study Design Version: 1.0

Sponsor: Novo Nordisk

Study Design

Generated by Central Designer TM

May 26, 2023 10:29AM

Time and Events Schedule For Study Design:

#	Assessment	CRF	Screen (Screen) [S]	Enroll (Enroll) [S]	evtV1 (V1) [S]	evtELIG (Eligibility) [S]	evtV2 (V2) [S]	evtP3 (P3) [S]	evtV4 (V4) [S]	evtP5 (P5) [S]	evtV6 (V6) [S]	evtP7 (P7) [S]	evtV8 (V8) [S]	evtP9 (P9) [S]	evtV10 (V10) [S]	evtP11 (P11) [S]	evtV12 (V12) [S]
	Element		System														
	Visit Start Hours		0	0	0	168	336	672	1008	1344	1680	2016	2352	2688	3024	3360	3696
1	SCR	Scr	1														
2	ENR	Enr		1													
3	VISIT_DATE_DOV	DoV			1		1	1	1	1	1	1	1	1	1	1	1
4	SUBJECT_INFO_2	Inf Cons/Demog			2												
5	MEDHIST_MEDDRA1	MedHx/ConIll			3												
6	WEIGHT_HIST	Weight_Hx			4												
7	CHILDBEAR_POTENTIAL	ChBrPot			5-DF		3-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF
8	PREGVIS	Preg			6-DF		4-DF		3-DF		3-DF		3-DF		3-DF		3-DF
9	CONTRACEPTIVES_1	Contraceptive counselling			7-DF		5-DF		4-DF		4-DF		4-DF		4-DF		4-DF
10	VITAL_SIGN_SINGLE	VS			8		7				5				5		
11	LAB_SAMPLE_TAKEN_3	Lab			9						7				6		
12	TOBACCO_SU	Tobacco			10												
13	ECG_2	ECG			11												
14	OPHTHALMOSCOPY_1	Eye Exam			12-DF												
15	BODY_MEASUREMENT_1	Body Meas			13												
16	PHYSICAL_EXAM_4	PE			14												
17	TAN_STAG_MALE	Tanner Staging Male			15-DF												
18	TAN_STAG_FEMA	Tanner Staging Female			16-DF												
19	DXA_SCAN	DXA_SCAN			17-DF												
20	CSSRS_Parental_card	CSSRSparentalcard			18		15-DF		8-DF		10-DF		8-DF		10-DF		8-DF
21	CSSRSBASELINE	C-SSRS Baseline			19-DF												
22	PHQ9	PHQ9			20-DF												
23	COLLECTION_FUTURE_RESEARCH	Collection Future Research			21												
24	ELIG_CRIT_2	Elig				1											
25	RANDOMIS_CRIT	Rand					2										
26	MENSTRUAL_CYCLE	Menstrual cycle					6-DF										
27	LAB_SAMPLE_TAKEN_4	Lab					8										
28	BODY_MEASUREMENT_2	Body Meas					9						5				5
29	DOSAGE_1	First Dose					10										
30	DRUG_ADMIN_BASE	Drug Admin-Baseline					11										
31	EVAL_GLY_STAT	Eval Glycaemic Status					12-DF										
32	GLUCOSE_FASTING_3	Fasting Glucose					13-DF		6-DF		6-DF		6-DF		8-DF		6-DF
33	MENTAL_HEALTH	Mental Health Evaluation					14		7		9		7		9		7
34	X_RAY	X-ray bone age					16										
35	MISSD_ASSMNT	Missed Assessment					17-DF										
36	HEIGHT_REPEATED	HEIGHT_REPEATED					18-DF										
37	TREAT_DISCONT	Discontinuation						3	10	3	13	3	10	3	13	3	10
38	BODY_MEASUREMENT_3	Body Meas							5		8				7		
39	DOSECOLLECTION	Dose Collection Form							9-RF				9-RF				9-RF
40	DOSECOLLECTION_WITHPK	Dose Collection with PK data									11				11		
41	DRUG_ADMIN	Drug Admin									12				12		
42	EVAL_GLY_STAT_2	Eval glycaemic status															
43	CSSRSLAST	C-SSRS Since Last Visit															
44	AE_MEDDRA3	AE															
45	SIF	SIF															
46	MISADMIN	Misadministration															
47	MALIGNANT_NEOPLASM	Malignant Neoplasm															
48	HEPATIC_EVENT	Hepatic Event															
49	GALLBLADDER	Gallbladder															
50	DIABETIC_RETINO	Diab Retino															
51	PANCREATITIS	Pancrea															
52	ACUTE_KIDNEY_INJURY	AKI															
53	CONCOM_MED_MEDDRA_1	CM															
54	TECH_COMPL_FORM	Complaint															
55	PREGLOG	Preg Log															
56	WITHDRAWAL_FUTURE_RESEARCH	Withdrawal Future Research															
57	HYPO_5_PAED	Hypo															
58	PROCEDURES	Procedure															
59	RECONSENT	Reconsent															
60	PUBERTAL_STATUS_2	Menarche															
61	END_OF_TREATMENT	End of IMP Treatment															
62	END_OF_TRIAL_2	End of Study															
63	TERM	Sign Off															

#	Assessment	evtP13 (P13) [S]	evtV14 (V14) [S]	evtP15 (P15) [S]	evtV16 (V16) [S]	evtP17 (P17) [S]	evtV18 (V18) [S]	evtP19 (P19) [S]	evtV20 (V20) [S]	evtP21 (P21) [S]	evtV22 (V22) [S]	evtP23 (P23) [S]	evtV24 (V24) [S]	evtP25 (P25) [S]	evtV26 (V26) [S]	evtP27 (P27) [S]	evtV28 (V28) [S]	evtP29 (P29) [S]
	Visit Start Hours	4032	4368	4704	5040	5376	5712	6048	6384	6720	7056	7392	7728	8064	8400	8736	9072	9408
1	SCR																	
2	ENR																	
3	VISIT_DATE_DOV	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
4	SUBJECT_INFO_2																	
5	MEDHIST_MEDDRA1																	
6	WEIGHT_HIST																	
7	CHILDBEAR_POTENTIAL	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF
8	PREGVIS		3-DF		3-DF		3-DF		3-DF		3-DF		3-DF		3-DF		3-DF	
9	CONTRACEPTIVES_1		4-DF		4-DF		4-DF		4-DF		4-DF		4-DF		4-DF		4-DF	
10	VITAL_SIGN_SINGLE		6						5				6					
11	LAB_SAMPLE_TAKEN_3		7						7								7	
12	TOBACCO_SU																	
13	ECG_2												10					
14	OPHTHALMOSCOPY_1												11-DF					
15	BODY_MEASUREMENT_1				5				6						5		5	
16	PHYSICAL_EXAM_4		11										9					
17	TAN_STAG_MALE		12-DF										14-DF					
18	TAN_STAG_FEMA		13-DF										15-DF					
19	DXA_SCAN												17-DF					
20	CSSRS_Parental_card		15-DF		8-DF		8-DF		10-DF		8-DF		19-DF		8-DF		9-DF	
21	CSSRSBASELINE																	
22	PHQ9		17-DF										21-DF					
23	COLLECTION_FUTURE_RESEARCH																	
24	ELIG_CRIT_2																	
25	RANDOMIS_CRIT																	
26	MENSTRUAL_CYCLE		5-DF										5-DF					
27	LAB_SAMPLE_TAKEN_4												8					
28	BODY_MEASUREMENT_2												7					
29	DOSAGE_1																	
30	DRUG_ADMIN_BASE																	
31	EVAL_GLY_STAT																	
32	GLUCOSE_FASTING_3		9-DF		6-DF		6-DF		8-DF		6-DF		13-DF		6-DF		6-DF	
33	MENTAL_HEALTH		14		7		7		9		7		18		7		8	
34	X_RAY												16					
35	MISSD_ASSMNT												26-DF					
36	HEIGHT_REPEATED												24-DF					
37	TREAT_DISCONT	3	20	3	10	3	10	3	13	3	10	3	25	3	10	3	11	3
38	BODY_MEASUREMENT_3		10				5				5							
39	DOSECOLLECTION				9-RF		9-RF				9-RF				9-RF			
40	DOSECOLLECTION_WITHPK		18						11				22				10	
41	DRUG_ADMIN		19						12				23					
42	EVAL_GLY_STAT_2		8-DF										12-DF					
43	CSSRSLAST		16-DF										20-DF					
44	AE_MEDDRA3																	
45	SIF																	
46	MISADMIN																	
47	MALIGNANT_NEOPLASM																	
48	HEPATIC_EVENT																	
49	GALLBLADDER																	
50	DIABETIC_RETINO																	
51	PANCREATITIS																	
52	ACUTE_KIDNEY_INJURY																	
53	CONCOM_MED_MEDDRA_1																	
54	TECH_COMPL_FORM																	
55	PREGLOG																	
56	WITHDRAWAL_FUTURE_RESEARCH																	
57	HYPO_5_PAED																	
58	PROCEDURES																	
59	RECONSENT																	
60	PUBERTAL_STATUS_2																	
61	END_OF_TREATMENT																	
62	END_OF_TRIAL_2																	
63	TERM																	

#	Assessment	evtV30 (V30) [S]	evtV31 (V31) [S]	evtP32 (P32) [S]	evtV33 (V33) [S]	evtP34 (P34) [S]	evtV35 (V35) [S]	evtAE (AE) [S]	evtCM (CM) [S]	evtTC (TC) [S]	evtPREG (Pregnancy) [S/D]	evtCONSENT (Consent) [S]	evtHypo (Hypo) [S]	evtPROCEDURE (Procedure) [S]	evtRECONSENT (RE-CONSENT) [S/D]	evtMENARCHE (MENARCHE) [S/D]	evtEND_TREAT (End Treat) [S]	evtEOS (End Study) [S]	evtSign (SIGN) [S]
	Visit Start Hours	9744	10080	10416	10752	11088	11424	11760	11761	11762	11763	11764	11765	11766	11767	11768	11769	11770	11771
1	SCR																		
2	ENR																		
3	VISIT_DATE_DOV	1	1	1	1	1	1												
4	SUBJECT_INFO_2																		
5	MEDHIST_MEDDRA1																		
6	WEIGHT_HIST																		
7	CHILDBEAR_POTENTIAL	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF												
8	PREGVIS	3-DF	3-DF		3-DF		3-DF												
9	CONTRACEPTIVES_1	4-DF	4-DF																
10	VITAL_SIGN_SINGLE	9	7				6												
11	LAB_SAMPLE_TAKEN_3		8				7												
12	TOBACCO_SU																		
13	ECG_2	12																	
14	OPHTHALMOSCOPY_1	11-DF																	
15	BODY_MEASUREMENT_1		5		4														
16	PHYSICAL_EXAM_4	10					8												
17	TAN_STAG_MALE	14-DF					10-DF												
18	TAN_STAG_FEMA	15-DF					11-DF												
19	DXA_SCAN	17-DF																	
20	CSSRS_Parental_card	19-DF			7-DF		13-DF												
21	CSSRSBASELINE																		
22	PHQ9	21-DF			9-DF		15-DF												
23	COLLECTION_FUTURE_RESEARCH																		
24	ELIG_CRIT_2																		
25	RANDOMIS_CRIT																		
26	MENSTRUAL_CYCLE	5-DF																	
27	LAB_SAMPLE_TAKEN_4	13																	
28	BODY_MEASUREMENT_2	6					9												
29	DOSAGE_1																		
30	DRUG_ADMIN_BASE																		
31	EVAL_GLY_STAT																		
32	GLUCOSE_FASTING_3	8-DF	6-DF		6-DF		5-DF												
33	MENTAL_HEALTH	18	9		5		12												
34	X_RAY	16																	
35	MISSD_ASSMNT	24-DF																	
36	HEIGHT_REPEATED						16-DF												
37	TREAT_DISCONT																		
38	BODY_MEASUREMENT_3																		
39	DOSECOLLECTION																		
40	DOSECOLLECTION_WITHPK	23	10																
41	DRUG_ADMIN	22																	
42	EVAL_GLY_STAT_2	7-DF					4-DF												
43	CSSRSLAST	20-DF			8-DF		14-DF												
44	AE_MEDDRA3							1-RF											
45	SIF							2-DF-RF											
46	MISADMIN							3-RF											
47	MALIGNANT_NEOPLASM							4-RF											
48	HEPATIC_EVENT							5-RF											
49	GALLBLADDER							6-RF											
50	DIABETIC_RETINO							7-DF-RF											
51	PANCREATITIS							8-RF											
52	ACUTE_KIDNEY_INJURY							9-RF											
53	CONCOM_MED_MEDDRA_1								1-RF										
54	TECH_COMPL_FORM									1-RF									
55	PREGLOG										1-RF								
56	WITHDRAWAL_FUTURE_RESEARCH											1							
57	HYPO_5_PAED												1-RF						
58	PROCEDURES													1-RF					
59	RECONSENT														1				
60	PUBERTAL_STATUS_2															1			
61	END_OF_TREATMENT																1		
62	END_OF_TRIAL_2																	1	
63	TERM																		1

Key: [S] = Scheduled Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit
C = Common Form DF = Dynamic Form RF = Repeating Form

: 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 / Req / Req (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

: InForm Enrollment (Enr) [ENR]		
InForm Enrollment [ENR]		
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.

Study Object Descriptions: InForm Enrollment

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

RDE Analytics: RD_ENR

Data Variable RefName	RD Column Name	Column Data Type
PATIENT	PATIENT	NUMBER
	PATIENT_ND	VARCHAR2

	: Date of visit (DoV) [VISIT_DATE_DOV]	
Study ID:		
1.*	Date o [Date of visit]	**[VISIT_DATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
2.*	Contact type [Contact type]	**[CONTACT_TYPE_CODE]** *[A:21]* Site visit *[A:9]* Telephone contact *[A:23]* Visit entered in error *[A:28]* Remote video contact *[A:29]* Off-site visit *[A:30]* Visit missed
3.*	Was the visit impacted by COVID-19? *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]	**[VISIT_IMPACT]** *[A:1]* Yes *[A:2]* No

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,V31,P32,V33,P34,V35

Codelist Values Tables: Date of visit

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

: Informed Consent and Demography (Inf Cons/Demog) [SUBJECT_INFO_2]

Study ID:

Informed	**IFORM_CONSENT]**	
1.*	Date child assent obtained [Date child assent obtained]	**[INFORM_CONSENT_DATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
2.	Date and time informed consent obtained *[hidden]* [Date & Time]	**[INFORM_CONSENT_DATE_TIME] (DD/MM/YYYY hh:mm)** Req / Req / Req (2022-2035) Req : Req *24-hour clock*
3.	Date informed consent obtained by Parents/Legally Acceptable Representative (LAR) *[hidden]* [LAR Date]	**[LAR_CONSENT_DATE_1]** *[A:1]* **[LAR_CONSENT_DATE_V1] (DD/MM/YYYY)** Req / Req / Req (2022-2035) *[A:998]* N/A
4.	Date and time informed consent obtained by Parents/Legally Acceptable Representative (LAR) *[hidden]* [LAR Date and Time]	**[LAR_CONSENT_DATE_TIME_1]** *[A:1]* **[LAR_CONSENT_DATE_TIME_V1] (DD/MM/YYYY hh:mm)** Req / Req / Req (2022-2035) Req : Req *24-hour clock* *[A:998]* N/A
5.*	Date informed consent obtained by Parents/Legally Acceptable Representative (LAR) [Date of LAR]	**[LAR_CONSENT_DATE_2]** *[A:1]* **[LAR_CONSENT_DATE_V2] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
6.	Date informed consent obtained by Parents/Legally Acceptable Representative (LAR) *Only to be completed in countries where Informed Consent from both parents is required* [Date and Time of LAR]	**[LAR_CONSENT_DATE_TIME_2]** *[A:1]* **[LAR_CONSENT_DATE_TIME_V2] (DD/MM/YYYY)** Req / Req / Req (2023-2030) *[A:998]* N/A
Demography [sctDEMOGRAPHY]		
7.	Date of birth *[hidden]* [Date of birth]	**[BIRTH_DATE] (DD/MM/YYYY)** Req / Req / Req (1900-2030)
8.*	Date of birth [Date of birth]	**[BIRTH_DATE_ENTRY] (DD/MM/YYYY)** Req/Unk / Req/Unk / Req (1900-2030)
9.	Retired item - maintained on CRF due to legacy integration. Do not use *[hidden]* [Retired Item]	**[AGE_DERIVED]** 0 <= N3 Year(s)[b]
10.	Sex *[read-only]* [Sex]	**[SEX_CODE]** *[A:1]* Male *[A:2]* Female
11.	Sex single - Legacy Argus interfaced item. Do not change, use or transfer *[hidden]* [Retired Item]	**[SINGLE_SEX_CODE]** *[A:1]* To be selected
12.	Ethnicity *[hidden]* [Ethnicity]	**[ETHNIC_DETAIL_CODE]** *[A:8]* Hispanic or Latino *[A:9]* Not Hispanic or Latino
13.*	Subject self-reported ethnicity [Self-reported ethnicity]	**[ETHNIC1_IL]** *[A:HISPANIC OR LATINO]* Hispanic or Latino *[A:NOT HISPANIC OR LATINO]* Not Hispanic or Latino
14.	Ethnicity - Argus *[hidden]* [Ethnicity - Argus]	**[ARGUS_ETHNIC_X]** A200
15.	Race *[hidden]* [Race]	**[RACE_CODE]** *[A:27]* American Indian or Alaska Native *[A:4]* Asian *[A:18]* Black or African American *[A:24]* Native Hawaiian or Other Pacific Islander *[A:11]* White *[A:999]* **[CONSENT_SPECIFY_OTHER]** Other, specify: A200
16.*	Subject self-reported race *(Select all that apply, but at least one)* [Self-reported race]	**[RACE1_IK]** *[A:AMERICAN INDIAN OR ALASKA NATIVE]* American Indian or Alaska Native *[A:ASIAN]* Asian *[A:BLACK OR AFRICAN AMERICAN]* Black or African American *[A:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER]* Native Hawaiian or Other Pacific Islander *[A:WHITE]* White
17.	Race - Argus *[hidden]* [Race - Argus]	**[ARGUS_RACE_X]** A200
18.	Subject No. *[read-only]* [Subject No.]	**[PATIENT]** N6
19.	Hidden item – used for IMPACT interface for SCREEN visit (Visit 1) *[hidden]* [IMPACT - SCREEN Date]	**[IMPACT_SCREEN_DT] (DD/MM/YYYY)** Req / Req / Req (2022-2035)
Rescreening [sctRESCREEN]		
20.	Previous Subject No. *[hidden]* [Prev. Subject No.]	**[PREVSUBJ_IN]** N6

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_IL 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

: Medical History/Concomitant Illness (MedHx/ConIll) [MEDHIST_MEDDRA1]

Study ID:

1.*	Does t or has the subject previously had, any relevant conditions/illnesses? [Medical History]	**[MEDICAL_HISTORY_MEDDRA]** *[A:1]* ◯ Yes *[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
2.2*	Diagnosis (For subjects with Type 2 diabetes, please ensure to add the details on Diabetic retinopathy and neuropathy,if applicable) [Diagnosis]	**[DIAGCATEG_L]**

[A:WEIGHT DISORDER] ◯ **[MHTERM_WGT_L]**
Weight disorder
- *[A:OVERWEIGHT]* ◯ Overweight
- *[A:OBESITY]* ◯ Obesity
- *[A:OTHER WEIGHT DISORDER]* ◯ **[MHTERM_WGTOTH_X]**
  Other weight disorder, not listed above
  A200

[A:DIABETES] ◯ **[MHTERM_DIAB_L]**
Diabetes
- *[A:TYPE 2 DIABETES MELLITUS]* ◯ Type 2 diabetes mellitus
- *[A:OTHER TYPE OF DIABETES]* ◯ **[MHTERM_DIABOTH_X]**
  Other type of diabetes, not listed above
  A200

[A:EYE DISEASE] ◯ **[MHTERM_EYED_L]**
Eye disease
- *[A:DIABETIC RETINOPATHY]* ◯ Diabetic retinopathy
- *[A:OTHER EYE DISORDER]* ◯ **[MHTERM_EYEDOTH_X]**
  Other eye disorder, not listed above
  A200

[A:NEUROPATHY] ◯ **[MHTERM_NEURO_L]**
Neuropathy
- *[A:DIABETIC PERIPHERAL NEUROPATHY]* ◯ Diabetic peripheral neuropathy
- *[A:DIABETIC AUTONOMIC NEUROPATHY]* ◯ Diabetic autonomic neuropathy
- *[A:OTHER NEUROPATHY]* ◯ **[MHTERM_NEUROTH_X]**
  Other neuropathy, not listed above
  A200

[A:PSYCHIATRIC DISORDER] ◯ **[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]* ◯ **[MHTERM_PSYCHOTH_X]**
  Other psychiatric disorder, not listed above
  A200

[A:DYSLIPIDAEMIA] ◯ **[MHTERM_DYSLIP_L]**
Dyslipidaemia
- *[A:HYPERCHOLESTEROLAEMIA]* ◯ Hypercholesterolaemia
- *[A:HYPERTRIGLYCERIDEMIA]* ◯ Hypertriglyceridemia
- *[A:COMBINED HYPERLIPIDAEMIA]* ◯ Combined hyperlipidaemia
- *[A:OTHER LIPID METABOLISM DISORDER]* ◯ **[MHTERM_DYSLIPOTH_X]**
  Other lipid metabolism disorder, not listed above
  A200

[A:GLUCOSE METABOLISM DISORDER] ◯ **[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]* ◯ **[MHTERM_GLUCOTH_X]**
  Other glucose metabolism disorder, not listed above
  A200

[A:RESPIRATORY DISORDER] ◯ **[MHTERM_RESPIR_L]**
Respiratory disorder
- *[A:ASTHMA]* ◯ Asthma
- *[A:OBSTRUCTIVE SLEEP APNOEA SYNDROME]* ◯ Obstructive sleep apnoea syndrome
- *[A:OTHER RESPIRATORY DISORDER]* ◯ **[MHTERM_RESPIROTH_X]**
  Other respiratory disorder, not listed above
  A200

[A:CARDIOVASCULAR DISORDER AND PROCEDURE] ◯ **[MHTERM_CV1_L]**
Cardiovascular disorder and procedure
- *[A:HYPERTENSION]* ◯ Hypertension
- *[A:OTHER CARDIOVASCULAR DISORDER]* ◯ **[MHTERM_CVOTH_X]**
  Other cardiovascular disorder, not listed above
  A200

[A:LIVER DISEASE] ◯ **[MHTERM_LIVER_L]**
Liver disease
- *[A:NONALCOHOLIC FATTY LIVER DISEASE]* ◯ Nonalcoholic fatty liver disease
- *[A:OTHER LIVER DISEASE]* ◯ **[MHTERM_LIVEROTH_X]**
  Other liver disease, not listed above
  A200

[A:OTHER DISEASE] ◯ **[MHTERM_OT_X]**
Other disease, not listed above
A200

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

		[A:BINGE EATING] Binge eating *[A:OTHER EATING DISORDER]* **[MHTERM_EATDISOTH_X]** Other eating disorder, not listed above A200
2.24	Diabetic retinopathy *[hidden]* [Diabetic retinopathy]	**[MH_DIAGSUPL_RETINO_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.25	Diabetic macular oedema *[hidden]* [Diabetic macular oedema]	**[MH_DIAGSUPL_MACODM_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.26	Vitreous haemorrhage *[hidden]* [Vitreous haemorrhage]	**[MH_DIABSUPL_VITHAEM_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.27	Retinal tear *[hidden]* [Retinal tear]	**[MH_DIAGSUPL_RTEAR_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.28	Tractional retinal detachment *[hidden]* [Tractional retinal detachment]	**[MH_DIAGSUPL_RETDETCH_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.29	Retinal vein occlusion *[hidden]* [Retinal vein occlusion]	**[MH_DIAGSUPL_OCUL_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.30	Corneal opacity *[hidden]* [Corneal opacity]	**[MH_DIAGSUPL_OPAQ_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.31	Glaucoma *[hidden]* [Glaucoma]	**[MH_DIAGSUPL_GLAUC_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.32	Cataract *[hidden]* [Cataract]	**[MH_DIAGSUPL_CATR_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.33	Pseudophakia *[hidden]* [Pseudophakia]	**[MH_DIAGSUPL_PHAK_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.34	Eye injury *[hidden]* [Eye injury]	**[MH_DIAGSUPL_EYEINJ_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.35	Age-related macular degeneration *[hidden]* [Age-related macular degeneration]	**[MH_DIAGSUPL_MACDEG_L]** *[A:RIGHT EYE]* Right eye *[A:LEFT EYE]* Left eye
2.36	Gallbladder disease and procedure *[hidden]* [Gallbladder disease and procedure]	**[MHTERM_GALL1_L]** *[A:CHOLELITHIASIS]* Cholelithiasis *[A:CHOLECYSTITIS]* Cholecystitis *[A:BILIARY COLIC]* Biliary colic *[A:CHOLECYSTECTOMY]* Cholecystectomy *[A:OTHER GALLBLADDER DISORDER]* **[MHTERM_GALLOTH_X]** Other gallbladder disorder, not listed above A200
2.37	Gallbladder disease *[hidden]* [Gallbladder disease]	**[MHTERM_GALL2_L]** *[A:CHOLELITHIASIS]* Cholelithiasis *[A:CHOLECYSTITIS]* Cholecystitis *[A:BILIARY COLIC]* Biliary colic *[A:CHOLECYSTECTOMY]* Cholecystectomy *[A:OTHER GALLBLADDER DISORDER]* **[MHTERM_GALL2OTH_X]** Other gallbladder disorder, not listed above A200
2.38	Gastrointestinal disorder and neoplasm *[hidden]* [Gastrointestinal disorder and neoplasm]	**[MHTERM_GASTRO_L]** *[A:GASTROOESOPHAGEAL REFLUX DISEASE]* Gastrooesophageal 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:CROHNS 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
2.39	Genitourinary tract disorder *[hidden]* [Genitourinary tract disorder]	**[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]* **[MH_DIAGSUPL_MENSDIS_L]** Menstrual disorder *[A:OLIGOMENORRHOEA]* Oligomenorrhoea *[A:POLYMENORRHOEA]* Polymenorrhoea *[A:AMENORRHOEA]* Amenorrhoea *[A:POLYCYSTIC OVARIAN SYNDROME]* Polycystic ovarian syndrome *[A:OTHER GENITOURINARY TRACT DISORDER]* **[MHTERM_GENURNOTH_X]** Other genitourinary tract disorder, not listed above A200
2.40	Heart failure *[hidden]* [Heart failure]	**[MHTERM_HRTFAIL_L]** *[A:HEART FAILURE WITH PRESERVED EJECTION FRACTION]* **[MH_DIAGSUPL_HFPEF_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_HFREF_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_HFUNK_L]** Heart failure (with unknown ejection fraction)

		[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:OTHER HEART FAILURE DISEASE] **[MHTERM_HRTFLOTH_X]** Other heart failure disease, not listed above A200
2.41	Kidney disease *[hidden]* [Kidney disease]	**[MHTERM_KIDNEY_L]** [A:DIABETIC NEPHROPATHY] Diabetic nephropathy (diabetic kidney disease) [A:CHRONIC KIDNEY DISEASE] Chronic kidney disease (other than diabetic kidney disease and defined as estimated or measured GFR <60 ml/min per 1.73 m2 or markers of kidney damage for > 3 months) [A:OTHER KIDNEY DISORDER] **[MHTERM_KIDNYOTH_X]** Other kidney disorder, not listed above A200
2.42	Musculoskeletal system disorder *[hidden]* [Musculoskeletal system disorder]	**[MHTERM_MUSSKL_L]** [A:KNEE OSTEOARTHRITIS] Knee osteoarthritis [A:HIPS OSTEOARTHRITIS] Hips osteoarthritis [A:HYPERURICAEMIA] Hyperuricaemia (Gout) [A:MUSCULOSKELETAL PAIN] Musculoskeletal pain [A:OTHER MUSCULOSKELETAL SYSTEM DISORDER] **[MHTERM_MUSSKLOTH_X]** Other musculoskeletal system disorder, not listed above A200
2.43	Pancreatic disease *[hidden]* [Pancreatic disease]	**[MHTERM_PANCREA_L]** [A:ACUTE PANCREATITIS] Acute pancreatitis [A:CHRONIC PANCREATITIS] Chronic pancreatitis [A:OTHER PANCREATIC DISEASE] **[MHTERM_PANCROTH_X]** Other pancreatic disease, not listed above A200
2.44	Skin cancer and skin disorder *[hidden]* [Skin cancer and skin disorder]	**[MHTERM_SKIN_L]** [A:BASAL CELL CARCINOMA] Basal cell carcinoma [A:SQUAMOUS CELL CARCINOMA] Squamous cell carcinoma [A:MALIGNANT MELANOMA] Malignant melanoma [A:PSORIASIS] Psoriasis [A:ATOPIC DERMATITIS] Atopic dermatitis [A:ECZEMA] Eczema [A:OTHER SKIN CANCER OR SKIN DISORDER] **[MHTERM_SKINOTH_X]** Other skin cancer or skin disorder, not listed above A200
2.45	Thyroid disorder *[hidden]* [Thyroid disorder]	**[MHTERM_THYR_L]** [A:HYPERTHYROIDISM] Hyperthyroidism [A:HYPOTHYROIDISM] Hypothyroidism [A:OTHER THYROID DISORDER] **[MHTERM_THYROTH_X]** Other thyroid disorder, not listed above A200

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: Medical History/Concomitant Illness

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_HYPTRYG_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_DIABSUPL_VITHAEM_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_RTEAR_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_RETDETCH_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_OCUL_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_OPAQ_L	**Item DEACTIVATED**
Item	MH_DIAGSUPL_GLAUC_L	**Item DEACTIVATED**

-	[illegible]_CATR_L	**Item DEACTIVATED**
Item	MH_D_GS_[illegible]HAK_L	**Item DEACTIVATED**
Item	MH_D_GS_[illegible]VEINJ_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
clYESNO	String		Yes	1	citmYESNO1	MEDICAL_HISTORY_MEDDRA
			No	2	citmYESNO2	
clDIAGCATEG_L	String	1 - clDIAGCATEG_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	
clMHTERM_WGT_L	String	1 - clMHTERM_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	
clMHTERM_EYED_L	String	1 - clMHTERM_EYED_L	Diabetic retinopathy	DIABETIC RETINOPATHY	citmMHTERM_EYED_L_1	MHTERM_EYED_L
			Other eye disorder, not listed above	OTHER EYE DISORDER	citmMHTERM_EYED_L_13	
clMHTERM_NEURO_L	String		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	
clMHTERM_PSYCH_L	String	1 - clMHTERM_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	
clMHTERM_DYSLIP_L	String		Hypercholesterolaemia	HYPERCHOLESTEROLAEMIA	citmclMHTERM_DYSLIP_L_1	MHTERM_DYSLIP_L
			Hypertriglyceridemia	HYPERTRIGLYCERIDEMIA	citmclMHTERM_DYSLIP_L_2	
			Combined hyperlipidaemia	COMBINED HYPERLIPIDAEMIA	citmclMHTERM_DYSLIP_L_3	
			Other lipid metabolism disorder, not listed above	OTHER LIPID METABOLISM DISORDER	citmclMHTERM_DYSLIP_L_4	
clMHTERM_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	
clMHTERM_RESPIR_L	String	1 - clMHTERM_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	
clMHTERM_CV1_L	String	1 - clMHTERM_CV1_L	Hypertension	HYPERTENSION	citmMHTERM_CV1_L_2	MHTERM_CV1_L
			Other cardiovascular disorder, not listed above	OTHER CARDIOVASCULAR DISORDER	citmMHTERM_CV1_L_18	
clMHTERM_LIVER_L	String	1 - clMHTERM_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	
clCOMPLICATIONS_YN	String		Yes	1	citmclCOMPLICATIONS_Y	COMPLICATIONS_YN
			No	2	citmclCOMPLICATIONS_N	
clCONTINUING_YN	String		Yes	1	citmCONTINUING_Y	STOP_DATE
			No	2	citmCONTINUING_N	
clCONTINUING_YN_2	String		Yes	1	CONTINUING_Y_2	CONTINUING_YN
			No	2	CONTINUING_N_2	
clCTCAE_SEVERITY_CODE	String		1 Mild AE	1	citmCTCAE_SEVERITY_1	CTCAE_SEVERITY_CODE
			2 Moderate AE	2	citmCTCAE_SEVERITY_2	
			3 Severe AE	3	citmCTCAE_SEVERITY_3	
			4 Life-threatening or disabling AE	4	citmCTCAE_SEVERITY_4	
			5 Death related to AE	5	citmCTCAE_SEVERITY_5	
clMHTERM_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	
clMH_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	
clMH_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	
clMH_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	
clMH_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	
clMH_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	citmMH_DIAGSUPL_PAD_L_2	
			Stage IIB - claudication after <200 m of walking	STAGE IIB – CLAUDICATION AFTER <200 M OF WALKING	citmMH_DIAGSUPL_PAD_L_3	
			Stage III - rest pain	STAGE III – REST PAIN	citmMH_DIAGSUPL_PAD_L_4	
			Stage IV - necrosis and/or gangrene of the limb	STAGE IV – NECROSIS AND/OR GANGRENE OF THE LIMB	citmMH_DIAGSUPL_PAD_L_5	
clMH_DIAGSUPL_REVAS_L	String		Peripheral artery angioplasty including stent	PERIPHERAL ARTERY ANGIOPLASTY INCLUDING STENT	citmMH_DIAGSUPL_REVAS_L_1	MH_DIAGSUPL_REVAS_L
			Peripheral artery surgery including reconstruction	PERIPHERAL ARTERY SURGERY INCLUDING RECONSTRUCTION	citmMH_DIAGSUPL_REVAS_L_2	
			Unknown revascularisation	UNKNOWN REVASCULARISATION	citmMH_DIAGSUPL_REVAS_L_3	
clMH_DIAGSUPL_AMPUT_L	String		Amputation above knee	AMPUTATION ABOVE KNEE	citmMH_DIAGSUPL_AMPUT_L_1	MH_DIAGSUPL_AMPUT_L
			Amputation below knee	AMPUTATION BELOW KNEE	citmMH_DIAGSUPL_AMPUT_L_2	
			Amputation at or above ankle	AMPUTATION AT OR ABOVE ANKLE	citmMH_DIAGSUPL_AMPUT_L_3	
			Amputation below ankle	AMPUTATION BELOW ANKLE	citmMH_DIAGSUPL_AMPUT_L_4	
clMH_DIAGSUPL_FIBR_L	String		Paroxysmal atrial fibrillation	PAROXYSMAL ATRIAL FIBRILLATION	citmMH_DIAGSUPL_FIBR_L_1	MH_DIAGSUPL_FIBR_L
			Persistent atrial fibrillation	PERSISTENT ATRIAL FIBRILLATION	citmMH_DIAGSUPL_FIBR_L_2	
			Permanent atrial fibrillation	PERMANENT ATRIAL FIBRILLATION	citmMH_DIAGSUPL_FIBR_L_3	
clMHTERM_CV2_L	String		Coronary heart disease	CORONARY HEART DISEASE	citmMHTERM_CV2_L_1	MHTERM_CV2_L
			Hypertension	HYPERTENSION	citmMHTERM_CV2_L_2	
			Stable angina pectoris	STABLE ANGINA PECTORIS	citmMHTERM_CV2_L_3	
			Angina pectoris unstable	ANGINA PECTORIS UNSTABLE	citmMHTERM_CV2_L_4	
			Coronary artery stenosis	CORONARY ARTERY STENOSIS	citmMHTERM_CV2_L_5	
			Myocardial infarction	MYOCARDIAL INFARCTION	citmMHTERM_CV2_L_6	
			Percutaneous coronary intervention	PERCUTANEOUS CORONARY INTERVENTION	citmMHTERM_CV2_L_7	
			Coronary artery bypass graft	CORONARY ARTERY BYPASS GRAFT	citmMHTERM_CV2_L_8	
			Stroke	STROKE	citmMHTERM_CV2_L_9	
			Transient ischemic attack	TRANSIENT ISCHEMIC ATTACK	citmMHTERM_CV2_L_10	
			Carotid artery stenosis (≥50% stenosis)	CAROTID ARTERY STENOSIS (>=50% STENOSIS)	citmMHTERM_CV2_L_11	
			Carotid revascularisation	CAROTID REVASCULARISATION	citmMHTERM_CV2_L_12	
			Peripheral arterial disease (atherosclerotic disease)	PERIPHERAL ARTERIAL DISEASE (ATHEROSCLEROTIC DISEASE)	citmMHTERM_CV2_L_13	
			Peripheral artery stenosis (≥50% stenosis)	PERIPHERAL ARTERY STENOSIS (>=50% STENOSIS)	citmMHTERM_CV2_L_14	
			Peripheral revascularisation	PERIPHERAL REVASCULARISATION	citmMHTERM_CV2_L_15	
			Leg amputation (only due to atherosclerosis)	LEG AMPUTATION (ONLY DUE TO ATHEROSCLEROSIS)	citmMHTERM_CV2_L_16	
			Atrial fibrillation	ATRIAL FIBRILLATION	citmMHTERM_CV2_L_17	
			Other cardiovascular disorder, not listed above	OTHER CARDIOVASCULAR DISORDER	citmMHTERM_CV2_L_18	
clMH_DIAGSUPL_HYPCOL_L	String		Primary (genetic)	PRIMARY (GENETIC)	citmMH_DIAGSUPL_HYPCOL_L_1	MH_DIAGSUPL_HYPCOL_L
			Secondary (acquired)	SECONDARY (ACQUIRED)	citmMH_DIAGSUPL_HYPCOL_L_2	
			Unknown type	UNKNOWN TYPE	citmMH_DIAGSUPL_HYPCOL_L_3	
clMH_DIAGSUPL_HYPTRYG_L	String		Primary (genetic)	PRIMARY (GENETIC)	citmMH_DIAGSUPL_HYPTRYG_L_1	MH_DIAGSUPL_HYPTRYG_L
			Secondary (acquired)	SECONDARY (ACQUIRED)	citmMH_DIAGSUPL_HYPTRYG_L_2	
			Unknown type	UNKNOWN TYPE	citmMH_DIAGSUPL_HYPTRYG_L_3	
clMH_DIAGSUPL_HYPLIP_L	String		Primary (genetic)	PRIMARY (GENETIC)	citmMH_DIAGSUPL_HYPLIP_L_1	MH_DIAGSUPL_HYPLIP_L
			Secondary (acquired)	SECONDARY (ACQUIRED)	citmMH_DIAGSUPL_HYPLIP_L_2	
			Unknown type	UNKNOWN TYPE	citmMH_DIAGSUPL_HYPLIP_L_3	
clMHTERM_EATDIS_L	String		Bulimia nervosa	BULIMIA NERVOSA	citmMHTERM_EATDIS_L_1	MHTERM_EATDIS_L
			Anorexia nervosa	ANOREXIA NERVOSA	citmMHTERM_EATDIS_L_2	
			Binge eating	BINGE EATING	citmMHTERM_EATDIS_L_3	
			Other eating disorder, not listed above	OTHER EATING DISORDER	citmMHTERM_EATDIS_L_4	
clMH_DIAGSUPL_RETINO_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_RETINO_L_1	MH_DIAGSUPL_RETINO_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_RETINO_L_2	
clMH_DIAGSUPL_MACODM_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_MACODM_L_1	MH_DIAGSUPL_MACODM_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_MACODM_L_2	
clMH_DIABSUPL_VITHAEM_L	String		Right eye	RIGHT EYE	citmMH_DIABSUPL_VITHAEM_L_1	MH_DIABSUPL_VITHAEM_L
			Left eye	LEFT EYE	citmMH_DIABSUPL_VITHAEM_L_2	
clMH_DIAGSUPL_RTEAR_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_RTEAR_L_1	MH_DIAGSUPL_RTEAR_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_RTEAR_L_2	
clMH_DIAGSUPL_RETDETCH_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_RETDETCH_L_1	MH_DIAGSUPL_RETDETCH_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_RETDETCH_L_2	
clMH_DIAGSUPL_OCUL_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_OCUL_L_1	MH_DIAGSUPL_OCUL_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_OCUL_L_2	
clMH_DIAGSUPL_OPAQ_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_OPAQ_L_1	MH_DIAGSUPL_OPAQ_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_OPAQ_L_2	
clMH_DIAGSUPL_GLAUC_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_GLAUC_L_1	MH_DIAGSUPL_GLAUC_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_GLAUC_L_2	
clMH_DIAGSUPL_CATR_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_CATR_L_1	MH_DIAGSUPL_CATR_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_CATR_L_2	
clMH_DIAGSUPL_PHAK_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_PHAK_L_1	MH_DIAGSUPL_PHAK_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_PHAK_L_2	
clMH_DIAGSUPL_EYEINJ_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_EYEINJ_L_1	MH_DIAGSUPL_EYEINJ_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_EYEINJ_L_2	
clMH_DIAGSUPL_MACDEG_L	String		Right eye	RIGHT EYE	citmMH_DIAGSUPL_MACDEG_L_1	MH_DIAGSUPL_MACDEG_L
			Left eye	LEFT EYE	citmMH_DIAGSUPL_MACDEG_L_2	
clMHTERM_GALL1_L	String		Cholelithiasis	CHOLELITHIASIS	citmMHTERM_GALL1_L_1	MHTERM_GALL1_L
			Cholecystitis	CHOLECYSTITIS	citmMHTERM_GALL1_L_2	
			Biliary colic	BILIARY COLIC	citmMHTERM_GALL1_L_3	
			Cholecystectomy	CHOLECYSTECTOMY	citmMHTERM_GALL1_L_4	
			Other gallbladder disorder, not listed above	OTHER GALLBLADDER DISORDER	citmMHTERM_GALL1_L_5	
clMHTERM_GALL2_L	String		Cholelithiasis	CHOLELITHIASIS	citmMHTERM_GALL2_L_1	MHTERM_GALL2_L
			Cholecystitis	CHOLECYSTITIS	citmMHTERM_GALL2_L_2	
			Biliary colic	BILIARY COLIC	citmMHTERM_GALL2_L_3	
			Cholecystectomy	CHOLECYSTECTOMY	citmMHTERM_GALL2_L_4	
			Other gallbladder disorder, not listed above	OTHER GALLBLADDER DISORDER	citmMHTERM_GALL2_L_5	
clMHTERM_GASTRO_L	String		Gastrooesophageal reflux disease	GASTROOESOPHAGEAL REFLUX DISEASE	citmMHTERM_GASTRO_L_1	MHTERM_GASTRO_L
			Benign neoplasm of colon	BENIGN NEOPLASM OF COLON	citmMHTERM_GASTRO_L_2	
			Carcinoma in situ of colon	CARCINOMA IN SITU OF COLON	citmMHTERM_GASTRO_L_3	
			Malignant neoplasm of colon	MALIGNANT NEOPLASM OF COLON	citmMHTERM_GASTRO_L_4	
			Crohn's disease	CROHNS DISEASE	citmMHTERM_GASTRO_L_5	
			Ulcerative colitis	ULCERATIVE COLITIS	citmMHTERM_GASTRO_L_6	
			Gastric ulcer	GASTRIC ULCER	citmMHTERM_GASTRO_L_7	
			Other gastrointestinal disorder or neoplasm, not listed above	OTHER GASTROINTESTINAL DISORDER OR NEOPLASM	citmMHTERM_GASTRO_L_8	
clMHTERM_GENURN_L	String		Involuntary impaired fertility (both male and female)	INVOLUNTARY IMPAIRED FERTILITY	citmMHTERM_GENURN_L_1	MHTERM_GENURN_L
			Infertility (both male and female)	INFERTILITY	citmMHTERM_GENURN_L_2	

			Urinary incontinence (both male and female)	URINARY INCONTINENCE	citmMHTERM_GENURN_L_3	
			Menstrual disorder	MENSTRUAL DISORDER	citmMHTERM_GENURN_L_4	
			Polycystic ovarian syndrome	POLYCYSTIC OVARIAN SYNDROME	citmMHTERM_GENURN_L_5	
			Other genitourinary tract disorder, not listed above	OTHER GENITOURINARY TRACT DISORDER	citmMHTERM_GENURN_L_6	
clMH_DIAGSUPL_MENSDIS_L	String		Oligomenorrhoea	OLIGOMENORRHOEA	citmMH_DIAGSUPL_MENSDIS_L_1	MH_DIAGSUPL_MENSDIS_L
			Polymenorrhoea	POLYMENORRHOEA	citmMH_DIAGSUPL_MENSDIS_L_2	
			Amenorrhoea	AMENORRHOEA	citmMH_DIAGSUPL_MENSDIS_L_3	
clMHTERM_HRTFAIL_L	String		Heart failure with preserved ejection fraction (HFpEF)	HEART FAILURE WITH PRESERVED EJECTION FRACTION	citmMHTERM_HRTFAIL_L_1	MHTERM_HRTFAIL_L
			Heart failure with reduced ejection fraction (HFrEF)	HEART FAILURE WITH REDUCED EJECTION FRACTION	citmMHTERM_HRTFAIL_L_2	
			Heart failure (with unknown ejection fraction)	HEART FAILURE (WITH UNKNOWN EJECTION FRACTION)	citmMHTERM_HRTFAIL_L_3	
			Other heart failure disease, not listed above	OTHER HEART FAILURE DISEASE	citmMHTERM_HRTFAIL_L_4	
clMH_DIAGSUPL_HFPEF_L	String		NYHA class I	NYHA CLASS I	citmMH_DIAGSUPL_HFPEF_L_1	MH_DIAGSUPL_HFPEF_L
			NYHA class II	NYHA CLASS II	citmMH_DIAGSUPL_HFPEF_L_2	
			NYHA class III	NYHA CLASS III	citmMH_DIAGSUPL_HFPEF_L_3	
			NYHA class IV	NYHA CLASS IV	citmMH_DIAGSUPL_HFPEF_L_4	
clMH_DIAGSUPL_HFREF_L	String		NYHA class I	NYHA CLASS I	citmMH_DIAGSUPL_HFREF_L_1	MH_DIAGSUPL_HFREF_L
			NYHA class II	NYHA CLASS II	citmMH_DIAGSUPL_HFREF_L_2	
			NYHA class III	NYHA CLASS III	citmMH_DIAGSUPL_HFREF_L_3	
			NYHA class IV	NYHA CLASS IV	citmMH_DIAGSUPL_HFREF_L_4	
clMH_DIAGSUPL_HFUNK_L	String		NYHA class I	NYHA CLASS I	citmMH_DIAGSUPL_HFUNK_L_1	MH_DIAGSUPL_HFUNK_L
			NYHA class II	NYHA CLASS II	citmMH_DIAGSUPL_HFUNK_L_2	
			NYHA class III	NYHA CLASS III	citmMH_DIAGSUPL_HFUNK_L_3	
			NYHA class IV	NYHA CLASS IV	citmMH_DIAGSUPL_HFPEF_L_4_2	
clMHTERM_KIDNEY_L	String		Diabetic nephropathy (diabetic kidney disease)	DIABETIC NEPHROPATHY	citmMHTERM_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 m2 or markers of kidney damage for > 3 months)	CHRONIC KIDNEY DISEASE	citmMHTERM_KIDNEY_L_2	
			Other kidney disorder, not listed above	OTHER KIDNEY DISORDER	citmMHTERM_KIDNEY_L_3	
clMHTERM_MUSSKL_L	String		Knee osteoarthritis	KNEE OSTEOARTHRITIS	citmMHTERM_MUSSKL_L_1	MHTERM_MUSSKL_L
			Hips osteoarthritis	HIPS OSTEOARTHRITIS	citmMHTERM_MUSSKL_L_2	
			Hyperuricaemia (Gout)	HYPERURICAEMIA	citmMHTERM_MUSSKL_L_3	
			Musculoskeletal pain	MUSCULOSKELETAL PAIN	citmMHTERM_MUSSKL_L_4	
			Other musculoskeletal system disorder, not listed above	OTHER MUSCULOSKELETAL SYSTEM DISORDER	citmMHTERM_MUSSKL_L_5	
clMHTERM_PANCREA_L	String		Acute pancreatitis	ACUTE PANCREATITIS	citmMHTERM_PANCREA_L_1	MHTERM_PANCREA_L
			Chronic pancreatitis	CHRONIC PANCREATITIS	citmMHTERM_PANCREA_L_2	
			Other pancreatic disease, not listed above	OTHER PANCREATIC DISEASE	citmMHTERM_PANCREA_L_3	
clMHTERM_SKIN_L	String		Basal cell carcinoma	BASAL CELL CARCINOMA	citmMHTERM_SKIN_L_1	MHTERM_SKIN_L
			Squamous cell carcinoma	SQUAMOUS CELL CARCINOMA	citmMHTERM_SKIN_L_2	
			Malignant melanoma	MALIGNANT MELANOMA	citmMHTERM_SKIN_L_3	
			Psoriasis	PSORIASIS	citmMHTERM_SKIN_L_4	
			Atopic dermatitis	ATOPIC DERMATITIS	citmMHTERM_SKIN_L_5	
			Eczema	ECZEMA	citmMHTERM_SKIN_L_6	
			Other skin cancer or skin disorder, not listed above	OTHER SKIN CANCER OR SKIN DISORDER	citmMHTERM_SKIN_L_7	
clMHTERM_THYR_L	String		Hyperthyroidism	HYPERTHYROIDISM	citmMHTERM_THYR_L_1	MHTERM_THYR_L
			Hypothyroidism	HYPOTHYROIDISM	citmMHTERM_THYR_L_2	
			Other thyroid disorder, not listed above	OTHER THYROID DISORDER	citmMHTERM_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_WGTOTH_X	MHTERM_WGTOTH_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_DIABSUPL_VITHAEM_L	MH_DIABSUPL_VITHAEM_L_C	VARCHAR2
	MH_DIABSUPL_VITHAEM_L	VARCHAR2
	MH_DIABSUPL_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

: Weight History (Weight_Hx) [WEIGHT_HIST]

Study ID:

This form is [illegible]llect 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.

1.*	What was subject's weight a year ago? [What was your weight a year ago]	**[grpWGTHX_YEAR]** **[WGTHX_YEAR] [WGTHX_UNIT]** xxx.x *[A:220]* ◯ kg *[A:700]* ◯ lb
2.*	What has been the subject's weight at birth? [What has been the subject's weight at birth?]	**[WGTHX_BIRTH1]** *[A:1]* ◯ **[grpWGTHX_BIRTH]** **[WGTHX_BIRTH] [WGTHX_BIRTH_UNIT]** xxx.x *[A:220]* ◯ kg *[A:700]* ◯ lb *[A:2]* ◯ Unknown
3.*	What has been the subject's maximum weight? [What has been your maximum weight?]	**[grpWGTHX_MAX]** **[WGTHX_MAX] [WGTHX_UNIT1]** xxx.x *[A:220]* ◯ kg *[A:700]* ◯ lb
4.*	How old was the subject at that time when he/she gained maximum weight? [How old were you at that time?]	**[WGTHX_YEARS]** N2 years
5.	In the subject's own opinion, was the subject overweight or obese when *[hidden]* [Subject overweight or obese]	**[grpWGTHX_OPN_OBAS]** **[WGTHX_OPN_OBAS1]** 5 years old *[A:2]* ◯ No *[A:1]* ◯ Yes **[WGTHX_OPN_OBAS2]** 11 years old *[A:2]* ◯ No *[A:1]* ◯ Yes
6.	What is the least the subject has ever weighed as an adult? *[hidden]* [What is the least you have ever weighed as an adult?]	**[grpWGTHX_LEAST]** **[WGTHX_LEAST] [WGTHX_LEAST_UNIT]** xxxxx. *[A:220]* ◯ kg *[A:700]* ◯ lb
7.*	How many times has the subject intentionally lost ≥ 11 lb/5 kg? [How many times have you intentionally lost ≥ 10 pounds/5 kg?]	**[WGTHX_LOSTLBS]** *[A:59]* ◯ Never *[A:414]* ◯ 1-2 *[A:415]* ◯ 3-5 *[A:416]* ◯ 6-10 *[A:417]* ◯ >10
8.*	Which of the following methods has the subject tried for weight loss (regardless of how much weight they lost)? (Tick all that apply) [Which of the following methods has the subject tried for weight loss (regardless of how much weight they lost)?]	**[grpWGTHX_WEIGHTLOSS]** **[WEIGHTLOSS1]** *[A:1]* ☐ self-directed (i.e., "on my own," using only books, websites, mobile apps, activity trackers or fitness monitors) **[WEIGHTLOSS2]** *[A:1]* ☐ weight loss program (e.g., Weight Watchers, insurance-offered program, dietary counselling, personal training, very-low-calorie diet, full meal replacement) **[WEIGHTLOSS3]** *[A:1]* ☐ over-the-counter weight loss aids **[WEIGHTLOSS4]** *[A:1]* ☐ Off-label prescription medications for obesity **[WEIGHTLOSS5]** *[A:1]* ☐ Prescription Anti-Obesity medications **[WEIGHTLOSS6]** *[A:1]* ☐ none of the above
9.*	Regarding bariatric surgery, has the subject ever [Regarding bariatric surgery, has the subject ever]	**[grpWGTHX_BARIATRIC]** **[BARIATRIC1]** *[A:1]* ☐ considered pursuing bariatric surgery **[BARIATRIC2]** *[A:1]* ☐ discussed bariatric surgery with a healthcare provider **[BARIATRIC3]** *[A:1]* ☐ begun preparations for bariatric surgery **[BARIATRIC4]** *[A:1]* ☐ been offered bariatric surgery, but declined **[BARIATRIC5]** *[A:1]* ☐ none of the above
10.*	Did any of the subject's first degree relatives ever have overweight or obesity? (First degree relative is defined as biological parent or sibling, if unknown select 'No') [Obesity in first degree relatives?]	**[WGTHX_OBESITY_YN]** *[A:2]* ◯ No *[A:1]* ◯ Yes
11.	What has the subject's weight gain pattern been from age 18 to present: *[hidden]* [What has your weight gain pattern been from age 18 to present:]	**[WGTHX_GAIN]** *[A:409]* ◯ No pattern *[A:410]* ◯ Gradual increase of weight *[A:411]* ◯ Sudden weight gain in relation to pregnancy *[A:412]* ◯ Sudden weight gain in relation to pharmacological treatment *[A:413]* ◯ Yo-yo pattern/weight cycling due to intermittent weight loss treatment (diet and exercise or pharmacological)
12.	Number of pregnancies If male just specify 0 (zero) *[hidden]* [Number of pregnancies:]	**[WGTHX_PREG]** N2
13.	Yes *[hidden]* [Yes]	**[grpWGTHX_OBESITY]** **[WGTHX_OBESITY]** If yes, whom: **[WGTHX_OBESYES]** *[A:8]* ☐ Mother *[A:9]* ☐ Father **[WGTHX_OBESYES2]** *[A:2]* ☐ **[WGTHX_OBESITY_NUM1]** Any sibling(s) If yes, please specify number: N2 **[WGTHX_OBESYES3]** *[A:3]* ☐ **[WGTHX_OBESITY_NUM2]** Any children If yes, please specify number: N2
14.	18 years old *[hidden]* [18 years old]	**[WGTHX_OPN_OBAS3]** *[A:2]* ◯ No *[A:1]* ◯ Yes

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: 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

	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clWGTH	String		kg	220	citmWGTHX_UNIT1	WGTHX_UNIT, WGTHX_UNIT1, WGTHX_LEAST_UNIT
			lb	700	citmWGTHX_UNIT2	
clWGTHX_BIRTH1	String		Known	1	citmWGTHX_BIRTH1	WGTHX_BIRTH1
			Unknown	2	citmWGTHX_BIRTH2	
clWGTHX_BIRTH_UNIT	String		kg	220	citmWGTHX_BIRTH_UNIT1	WGTHX_BIRTH_UNIT
			lb	700	citmWGTHX_BIRTH_UNIT2	
clWGTHX_OPN_OBAS1	String		No	2	citmWGTHX_OPN_OBAS2	WGTHX_OPN_OBAS1, WGTHX_OPN_OBAS2, WGTHX_OPN_OBAS3
			Yes	1	citmWGTHX_OPN_OBAS1	
clWGTHX_LOSTLBS	String		Never	59	citmWGTHX_LOSTLBS1	WGTHX_LOSTLBS
			1-2	414	citmWGTHX_LOSTLBS2	
			3-5	415	citmWGTHX_LOSTLBS3	
			6-10	416	citmWGTHX_LOSTLBS4	
			>10	417	citmWGTHX_LOSTLBS5	
clWEIGHTLOSS1	String		self-directed (i.e., "on my own," using only books, websites, mobile apps, activity trackers or fitness monitors)	1	citmWEIGHTLOSS1	WEIGHTLOSS1
clWEIGHTLOSS2	String		weight loss program (e.g., Weight Watchers, insurance-offered program, dietary counselling, personal training, very-low-calorie diet, full meal replacement)	1	citmWEIGHTLOSS2	WEIGHTLOSS2
clWEIGHTLOSS3	String		over-the-counter weight loss aids	1	citmWEIGHTLOSS3	WEIGHTLOSS3
clWEIGHTLOSS4	String		Off-label prescription medications for obesity	1	citmWEIGHTLOSS4	WEIGHTLOSS4
clWEIGHTLOSS5	String		Prescription Anti-Obesity medications	1	citmWEIGHTLOSS5	WEIGHTLOSS5
clWEIGHTLOSS6	String		none of the above	1	citmWEIGHTLOSS1_5	WEIGHTLOSS6
clBARIATRIC1	String		considered pursuing bariatric surgery	1	citmBARIATRIC1	BARIATRIC1
clBARIATRIC2	String		discussed bariatric surgery with a healthcare provider	1	citmBARIATRIC2	BARIATRIC2
clBARIATRIC3	String		begun preparations for bariatric surgery	1	citmBARIATRIC3	BARIATRIC3
clBARIATRIC4	String		been offered bariatric surgery, but declined	1	citmBARIATRIC4	BARIATRIC4
clBARIATRIC5	String		none of the above	1	citmBARIATRIC5	BARIATRIC5
clNOYES_3_1	String		No	2	citmNOYES2_3_1	WGTHX_OBESITY_YN
			Yes	1	citmNOYES1_3_1	
clWGTHX_GAIN	String		No pattern	409	citmWGTHX_GAIN1	WGTHX_GAIN
			Gradual increase of weight	410	citmWGTHX_GAIN2	
			Sudden weight gain in relation to pregnancy	411	citmWGTHX_GAIN3	
			Sudden weight gain in relation to pharmacological treatment	412	citmWGTHX_GAIN4	
			Yo-yo pattern/weight cycling due to intermittent weight loss treatment (diet and exercise or pharmacological)	413	citmWGTHX_GAIN5	
clWGTHX_OBESYES	String		Mother	8	citmWGTHX_OBESYES1	WGTHX_OBESYES
			Father	9	citmWGTHX_OBESYES2	
clWGTHX_OBESYES2	String		Any sibling(s)	2	citmWGTHX_OBESYES3	WGTHX_OBESYES2
clWGTHX_OBESYES3	String		Any children	3	citmWGTHX_OBESYES4	WGTHX_OBESYES3

RDE Analytics: RD_WEIGHT_HIST

Data Variable RefName	RD Column Name	Column Data Type
grpWGTHX_YEAR	GRPWGTHX_YEAR_ND	VARCHAR2
grpWGTHX_YEAR - WGTHX_YEAR	WGTHX_YEAR	FLOAT
grpWGTHX_YEAR - WGTHX_UNIT	WGTHX_UNIT_C	VARCHAR2
	WGTHX_UNIT	VARCHAR2
WGTHX_BIRTH1	WGTHX_BIRTH1_C	VARCHAR2
	WGTHX_BIRTH1	VARCHAR2
	WGTHX_BIRTH1_ND	VARCHAR2
WGTHX_BIRTH1 - WGTHX_BIRTH	WGTHX_BIRTH	FLOAT
WGTHX_BIRTH1 - WGTHX_BIRTH_UNIT	WGTHX_BIRTH_UNIT_C	VARCHAR2
	WGTHX_BIRTH_UNIT	VARCHAR2
grpWGTHX_MAX	GRPWGTHX_MAX_ND	VARCHAR2
grpWGTHX_MAX - WGTHX_MAX	WGTHX_MAX	FLOAT
grpWGTHX_MAX - WGTHX_UNIT1	WGTHX_UNIT1_C	VARCHAR2
	WGTHX_UNIT1	VARCHAR2
WGTHX_YEARS	WGTHX_YEARS	NUMBER
	WGTHX_YEARS_ND	VARCHAR2
grpWGTHX_OPN_OBAS	GRPWGTHX_OPN_OBAS_ND	VARCHAR2
grpWGTHX_OPN_OBAS - WGTHX_OPN_OBAS1	WGTHX_OPN_OBAS1_C	VARCHAR2
	WGTHX_OPN_OBAS1	VARCHAR2
grpWGTHX_OPN_OBAS - WGTHX_OPN_OBAS2	WGTHX_OPN_OBAS2_C	VARCHAR2
	WGTHX_OPN_OBAS2	VARCHAR2
grpWGTHX_LEAST	GRPWGTHX_LEAST_ND	VARCHAR2
grpWGTHX_LEAST - WGTHX_LEAST	WGTHX_LEAST	FLOAT
grpWGTHX_LEAST - WGTHX_LEAST_UNIT	WGTHX_LEAST_UNIT_C	VARCHAR2
	WGTHX_LEAST_UNIT	VARCHAR2
WGTHX_LOSTLBS	WGTHX_LOSTLBS_C	VARCHAR2
	WGTHX_LOSTLBS	VARCHAR2
	WGTHX_LOSTLBS_ND	VARCHAR2
grpWGTHX_WEIGHTLOSS	GRPWGTHX_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
	*WEIGHTLOSS1_CITMWEIGHTLOSS1	VARCHAR2
grpWGTHX_WEIGHTLOSS - weight loss program (e.g., Weight Watchers, insurance-offered program, dietary counselling, personal training, very-low-calorie diet, full meal replacement)	*WEIGHTLOSS2_CITMWEIGHTLOSS2_C	VARCHAR2
	*WEIGHTLOSS2_CITMWEIGHTLOSS2	VARCHAR2
grpWGTHX_WEIGHTLOSS - over-the-counter weight loss aids	*WEIGHTLOSS3_CITMWEIGHTLOSS3_C	VARCHAR2
	*WEIGHTLOSS3_CITMWEIGHTLOSS3	VARCHAR2
grpWGTHX_WEIGHTLOSS - Off-label prescription medications for obesity	*WEIGHTLOSS4_CITMWEIGHTLOSS4_C	VARCHAR2
	*WEIGHTLOSS4_CITMWEIGHTLOSS4	VARCHAR2
grpWGTHX_WEIGHTLOSS - Prescription Anti-Obesity medications	*WEIGHTLOSS5_CITMWEIGHTLOSS5_C	VARCHAR2
	*WEIGHTLOSS5_CITMWEIGHTLOSS5	VARCHAR2
grpWGTHX_WEIGHTLOSS - none of the above	*WEIGHTLOSS6_CITMWEIGHTLOSS15_C	VARCHAR2
	*WEIGHTLOSS6_CITMWEIGHTLOSS15	VARCHAR2
grpWGTHX_BARIATRIC	GRPWGTHX_BARIATRIC_ND	VARCHAR2
grpWGTHX_BARIATRIC - considered pursuing bariatric surgery	BARIATRIC1_CITMBARIATRIC1_C	VARCHAR2
	BARIATRIC1_CITMBARIATRIC1	VARCHAR2
grpWGTHX_BARIATRIC - discussed bariatric surgery with a healthcare provider	BARIATRIC2_CITMBARIATRIC2_C	VARCHAR2
	BARIATRIC2_CITMBARIATRIC2	VARCHAR2
grpWGTHX_BARIATRIC - begun preparations for bariatric surgery	BARIATRIC3_CITMBARIATRIC3_C	VARCHAR2
	BARIATRIC3_CITMBARIATRIC3	VARCHAR2
grpWGTHX_BARIATRIC - been offered bariatric surgery, but declined	BARIATRIC4_CITMBARIATRIC4_C	VARCHAR2
	BARIATRIC4_CITMBARIATRIC4	VARCHAR2

¯IC - none of the above	BARIATRIC5_CITMBARIATRIC5_C	VARCHAR2
	BARIATRIC5_CITMBARIATRIC5	VARCHAR2
WGTHX_OBESE_TY	WGTHX_OBESITY_YN_C	VARCHAR2
	WGTHX_OBESITY_YN	VARCHAR2
	WGTHX_OBESITY_YN_ND	VARCHAR2
WGTHX_GAIN	WGTHX_GAIN_C	VARCHAR2
	WGTHX_GAIN	VARCHAR2
	WGTHX_GAIN_ND	VARCHAR2
WGTHX_PREG	WGTHX_PREG	NUMBER
	WGTHX_PREG_ND	VARCHAR2
grpWGTHX_OBESITY	GRPWGTHX_OBESITY_ND	VARCHAR2
grpWGTHX_OBESITY - Mother	*WGTHX_OBESYES_CITMWGTHXOBESYES1_C	VARCHAR2
	*WGTHX_OBESYES_CITMWGTHXOBESYES1	VARCHAR2
grpWGTHX_OBESITY - Father	*WGTHX_OBESYES_CITMWGTHXOBESYES2_C	VARCHAR2
	*WGTHX_OBESYES_CITMWGTHXOBESYES2	VARCHAR2
grpWGTHX_OBESITY - Any sibling(s)	*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
	*WGTHX_OBESYES3_WGTHX_OBESITY_NUM2	VARCHAR2
grpWGTHX_OBESITY - WGTHX_OBESITY_NUM2	WGTHX_OBESITY_NUM2	NUMBER
WGTHX_OPN_OBAS3	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.

: Childbearing Potential (ChBrPot) [CHILDBEAR_POTENTIAL]

Study ID:

1.*	Is the earing potential? [Subject of childbearing potential]	**[CHILDBEAR_POT_YN]** *[A:1]* Yes *[A:2]* No

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

: Pregnancy Test (Preg) [PREGVIS]

Study ID:
If Positive, ... t be discontinued from investigational medicinal product. The paper Pregnancy forms must also be completed.

#	Test	Test done?	Medium	Result	Date of test
1.a	PREGNANCY_TEST_RESULT		Urine		

1.1	Test *[hidden]* [Test]	**[PREGVIS_LBTPCD_L]** *[A:1]* PREGNANCY_TEST_RESULT
1.2	Test done? [Test done?]	**[PREGVIS_LBSTAT_K]** *[A:1]* Not Done
1.3	Medium *[read-only]* [Medium]	**[PREGVIS_LBSPEC_L]** *[A:4]* Urine
1.4	Result [Result]	**[PREGVIS_LBORRES_L]** *[A:1]* Positive *[A:2]* Negative
1.5	Date of test *[hidden]* [Date of test]	**[PREGVIS_LBDTC_D] (DD/MM/YYYY)** Req / Req / Req (2023-2030)

Key: = 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 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
clPREGVIS_LBTPCD	String		PREGNANCY_TEST_RESULT	1	citmPREGVIS_TEST	PREGVIS_LBTPCD_L
clPREGVIS_LBSTAT	String		Not Done	1	citmPREGVIS_ND	PREGVIS_LBSTAT_K
clPREGVIS_LBSPEC	String		Urine	4	citmPREGVIS_U	PREGVIS_LBSPEC_L
clPREGVIS_LBORRES	String		Positive	1	citmPREGVIS_POS	PREGVIS_LBORRES_L
			Negative	2	citmPREGVIS_NEG	

RDE Analytics: RD_PREGVIS

Data Variable RefName	RD Column Name	Column Data Type
RD_PREGVIS_SCTPREGVIS		
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_LBSPEC_L	PREGVIS_LBSPEC_L_C	VARCHAR2
	PREGVIS_LBSPEC_L	VARCHAR2
	PREGVIS_LBSPEC_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.

: Contraceptive counselling (Contraceptive counselling) [CONTRACEPTIVES_1]

Study ID:

1.*	Has th rovided contraceptive counselling at this visit? [contraceptive counselling]	**[CONTRA_COUNS_L]** *[A:1]* ○ Yes *[A:2]* ○ No *[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]	**[CONTRA_METHOD_YN_L]** *[A:1]* ○ **[METH_CONTRA_L]** Yes *[A:1]* ☐ Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation *[A:2]* ☐ Progestogen-only hormone contraception associated with inhibition of ovulation *[A:3]* ☐ Intrauterine device (IUD) *[A:4]* ☐ Intrauterine hormone-releasing system (IUS) *[A:5]* ☐ Bilateral tubal occlusion *[A:6]* ☐ Vasectomized partner *[A:7]* ☐ Sexual abstinence *[A:999]* ☐ **[CONTRA_METHOD_X]** Other (according to local legislation) Please specify: A200 *[A:2]* ○ No

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

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	citmCOTRA_COUNS_Y	CONTRA_COUNS_L
			No	2	citmCOTRA_COUNS_N	
			N/A, due to pregnancy	998	citmCOTRA_COUNS_NA	
clYESNO_5	String		Yes	1	citmYESNO1_5	CONTRA_METHOD_YN_L
			No	2	citmYESNO2_5	
clMETH_CONTRA	String		Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation	1	citmMETH_CONTRA_1	METH_CONTRA_L
			Progestogen-only hormone contraception associated with inhibition of ovulation	2	citmMETH_CONTRA_2	
			Intrauterine device (IUD)	3	citmMETH_CONTRA_3	
			Intrauterine hormone-releasing system (IUS)	4	citmMETH_CONTRA_4	
			Bilateral tubal occlusion	5	citmMETH_CONTRA_5	
			Vasectomized partner	6	citmMETH_CONTRA_6	
			Sexual abstinence	7	citmMETH_CONTRA_7	
			Other (according to local legislation)	999	citmMETH_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_CITMMETHCONTRA1_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHCONTRA1	VARCHAR2
CONTRA_METHOD_YN_L - Progestogen-only hormone contraception associated with inhibition of ovulation	*METH_CONTRA_L_CITMMETHCONTRA2_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHCONTRA2	VARCHAR2
CONTRA_METHOD_YN_L - Intrauterine device (IUD)	*METH_CONTRA_L_CITMMETHCONTRA3_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHCONTRA3	VARCHAR2
CONTRA_METHOD_YN_L - Intrauterine hormone-releasing system (IUS)	*METH_CONTRA_L_CITMMETHCONTRA4_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHCONTRA4	VARCHAR2
CONTRA_METHOD_YN_L - Bilateral tubal occlusion	*METH_CONTRA_L_CITMMETHCONTRA5_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHCONTRA5	VARCHAR2
CONTRA_METHOD_YN_L - Vasectomized partner	*METH_CONTRA_L_CITMMETHCONTRA6_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHCONTRA6	VARCHAR2
CONTRA_METHOD_YN_L - Sexual abstinence	*METH_CONTRA_L_CITMMETHCONTRA7_C	VARCHAR2
	*METH_CONTRA_L_CITMMETHCONTRA7	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.

	: Vital Signs (VS) [VITAL_SIGN_SINGLE]	
Study ID:		
Any clinical[b]	**erioration 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 / Req / Req (2023-2030)
Blood pressure and pulse [sctVS_SINGLE]		
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[b] Diastolic N3 mmHg[b]
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[b]
	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: Vital Signs

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**

RDE Analytics: RD_VITAL_SIGN_SINGLE

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

: Collection of Samples for Laboratory (Lab) [LAB_SAMPLE_TAKEN_3]

Study ID:
Collect bloc⁻ ⁻ving the procedures detailed in the laboratory manual.
When resul. _, 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).**

1.	Sample collection date *[hidden]* [Sample Collection Date]	**[ALL_SAMPLE_DATE_4] (DD/MM/YYYY)** Req / Req / Req (2020-2030)
2.	Sample collection date and time *[hidden]* [Sample Collection Date]	**[ALL_SAMPLE_DATE_TIME_4] (DD/MM/YYYY hh:mm)** Req / Req / Req (2020-2030) Req : Req *24-hour clock*
Blood [sctSAMPLE_TAKEN_YN_3_1]		
3.*	Have all blood samples been taken? [Blood Sample]	**[SAMPLE_TAKEN_YN_4]** *[A:1]* Yes *[A:2]* **[COMMENT_TEXT_YN_4]** No, comment A200

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
clSAMPLE_TAKEN_YN_4	String		Yes	1	citmSAMPLE_TAKEN_Y1_2	SAMPLE_TAKEN_YN_4
			No, comment	2	citmSAMPLE_TAKEN_N1_2	

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

: ECG (ECG) [ECG_2]

Study ID:
Visit 1: If c[illegible]ally 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, [illegible]ally 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).

1.	Date of examination *[hidden]* [Date of examination]	**[EXAM_DATE_ECG_2] (DD/MM/YYYY)** Req / Req / Req (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 / Req / Req (2022-2035) Req/Unk : Req/Unk *24-hour clock*
ECG Examination [sctECG_Exam2]		
3.*	Overall interpretation of ECG [Interpretation]	**[ECG_NORMAL_ABNORMAL_2]** *[A:1]* Normal *[A:2]* **[grpNORML_ABNORML_CODE_EC2]** Abnormal **[ABNORMAL_TEXT_EC2]** Specify abnormality: A200 **[CLIN_SIG_YN_5]** Clinically significant? *[A:1]* Yes *[A:2]* No

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
clECG_ABNORMAL_NORMAL_1	String		Normal	1	citmECG_NORMAL_2	ECG_NORMAL_ABNORMAL_2
			Abnormal	2	citmECG_ABNORMAL1_2	
clCLIN_SIG_YN_1	String		Yes	1	citmCLIN_SIG_Y	CLIN_SIG_YN_5
			No	2	citmCLIN_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

: Eye Examination (Eye Exam) [OPHTHALMOSCOPY_1]	
Study ID: Note: Exam[illegible] for T2D Participants	
1.* Date of examination [Date of Exam]	**[EXAM_DATE1] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
2.* **Right eye** Interpretation of eye examination [Right Eye]	**[RIGHT_NORM_ABN_1]** *[A:1]* Normal *[A:2]* **[grpRIGHT_ABNORM]** **[ABNORMAL_TEXT3_3]** Abnormal Specify Abnormality: A200 **[RIGHT_CLIN_SIG_YN]** Clinically significant? *[A:1]* Yes *[A:2]* No
3.* **Left eye** Interpretation of eye examination [Left Eye]	**[LEFT_NORM_ABN_1]** *[A:1]* Normal *[A:2]* **[grpLEFT_ABNORM]** **[ABNORMAL_TEXT3_1]** Abnormal Specify Abnormality: A200 **[LEFT_CLIN_SIG_YN]** Clinically significant? *[A:1]* Yes *[A:2]* No

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
clRIGHT_NORM_ABN_1	String		Normal	1	citmRIGHT_NORMAL_1	RIGHT_NORM_ABN_1
			Abnormal, Specify Abnormality	2	citmRIGHT_ABNORMAL_1	
clYESNO_3	String		Yes	1	citmYESNO1_3	RIGHT_CLIN_SIG_YN, LEFT_CLIN_SIG_YN
			No	2	citmYESNO2_3	
clLEFT_NORM_ABN_1	String		Normal	1	citmLEFT_NORMAL1	LEFT_NORM_ABN_1
			Abnormal, Specify Abnormality:	2	citmLEFT_ABNORMAL1	

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_ND	VARCHAR2
RIGHT_NORM_ABN_1	RIGHT_NORM_ABN_1_C	VARCHAR2
	RIGHT_NORM_ABN_1	VARCHAR2
	RIGHT_NORM_ABN_1_ND	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_ND	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

: Body measurements 1 (Body Meas) [BODY_MEASUREMENT_1]

Study ID:
Preferably, the 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_DATE3] (DD/MM/YYYY)** Req / Req / Req (2022-2035)
2.	Date and time of examination *[hidden]* [Exam Date & Time]	**[BODY_MEAS_DATE_TIME3] (DD/MM/YYYY hh:mm)** Req / Req / Req (2022-2035) Req/Unk : Req/Unk *24-hour clock*
3.	Was the subject fasting when the body measurement was done? *[hidden]* [Fasting?]	**[BM_FASTING]** *[A:1]* Yes *[A:2]* No
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]	**[grpHEIGHT1_4]** **[BODY_HEIGHT1_4]** **[HEIGHT_UNIT1_4]** 0 <= xxx.x *[A:340]* cm
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]	**[grpHEIGHT1_5]** **[BODY_HEIGHT1_5]** **[HEIGHT_UNIT1_5]** 0 <= xxx.x *[A:340]* cm
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]	**[grpHEIGHT1_6]** **[BODY_HEIGHT1_6]** **[HEIGHT_UNIT1_6]** 0 <= xxx.x *[A:340]* cm
7.	Mean Height (System calculated mean) *[read-only]* [Mean Height]	**[grpHEIGHT]** **[BODY_HEIGHT]** **[HEIGHT_UNIT]** xxx.x *[A:340]* cm
8.* ✔	Body weight (Measured at site visits without shoes, with an empty bladder and only wearing light clothing) [Body weight]	**[grpBODY_WEIGHT]** **[BODY_WEIGHT]** **[BODY_WEIGHT_UNIT]** xxx.x *[A:220]* kg *[A:700]* lb
9.	Body weight derived (calculated) *[hidden]* [Body Weight]	**[BODY_WEIGHT_DERIVE]** xxxxx. kg[b]
10.	Retired item - maintained on CRF due to legacy integration. Do not use *[hidden]* [retired item]	**[BMI_DERIVED]** xxx.xxx kg/m2[b]
11.	BMI (System calculated) *[read-only]* [BMI]	**[BMI_DERIVED_N]** xxx.x kg/m2[b]
12.	Waist circumference *[hidden]* [Waist]	**[grpWAIST_CIRCUMFERENCE]** **[WAIST_CIRCUMFERENCE]** **[WAIST_CIRCUM_UNIT]** xxxxxx. *[A:340]* cm
13.	Hip circumference *[hidden]* [Hip]	**[grpHIP_CIRCUMFERENCE]** **[HIP]** **[HIP_CIRCUM_UNIT]** xxxxxx. *[A:340]* cm

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
clFAST_YN	String		Yes	1	citmFAST_YN1	BM_FASTING
			No	2	citmFAST_YN2	
clHEIGHT_UNIT_1_4	String		cm	340	citmHEIGHT_UNIT_CM_1_1	HEIGHT_UNIT1_4
clHEIGHT_UNIT2_3	String		cm	340	citmHEIGHT_UNIT_CM_1_2	HEIGHT_UNIT1_5
clHEIGHT_UNIT1_6	String		cm	340	citmHEIGHT_UNIT_CM_1_3	HEIGHT_UNIT1_6
clHEIGHT_UNIT	String		cm	340	citmHEIGHT_UNIT_CM	HEIGHT_UNIT, WAIST_CIRCUM_UNIT, HIP_CIRCUM_UNIT
clBODY_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	GRPHEIGHT1_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	GRPHEIGHT1_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	GRPHEIGHT1_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
grpHE GH	GRPHEIGHT_ND	VARCHAR2
grpHEIGHT - OD 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	GRPWAIST_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

: Physical Examination (PE) [PHYSICAL_EXAM_4]

Study ID:
Visit 1: If cli[illegible]ally significant, record in the Medical History/Concomitant Illness form (MedHx/ConIll). If medication is taken remember to record in the Concomitant Medication form (CM).

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).

1. *	Was the physical examination performed? [PE Performed]	**[PE_EXAM_YN]** *[A:1]* ◯ Yes *[A:2]* ◯ No

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

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	citmPE_Y	PE_EXAM_YN
			No	2	citmPE_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

: Tanner Staging Male (Tanner Staging Male) [TAN_STAG_MALE]

Study ID: !

1.*	Genita [Genital Development]	**[GENIT_DEV]** *[A:1]* 1 *[A:2]* 2 *[A:3]* 3 *[A:4]* 4 *[A:5]* 5 *[A:997]* **[GEN_REA]** Not Done Specify Reason: A200
2.*	Left Testicular Volume [Left Testicular Volume]	**[TESTI_VOL_LEFT]** 0 < N2 ml[b]
3.*	Right Testicular Volume [Right Testicular Volume]	**[TESTI_VOL_RIGHT]** 0 < N2 ml[b]
4.*	Pubic Hair Development [Pubic Hair Development]	**[PUBIC_HAIR_DEV1]** *[A:1]* 1 *[A:2]* 2 *[A:3]* 3 *[A:4]* 4 *[A:5]* 5 *[A:997]* **[HAIR_REA]** Not Done Specify Reason: A200

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	PUBIC_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	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
PUBIC_HAIR_DEV1	PUBIC_HAIR_DEV1_C	VARCHAR2
	PUBIC_HAIR_DEV1	VARCHAR2
	PUBIC_HAIR_DEV1_ND	VARCHAR2
PUBIC_HAIR_DEV1 - HAIR_REA	HAIR_REA	VARCHAR2

: Tanner Staging Female (Tanner Staging Female) [TAN_STAG_FEMA]

Study ID: *

1.*	Breast	**[BREAST_DEVELOPMENT]** *[A:1]* ○ 1 *[A:2]* ○ 2 *[A:3]* ○ 3 *[A:4]* ○ 4 *[A:5]* ○ 5 *[A:997]* ○ **[BREAST_REA]** Not Done Specify Reason: A200
2.*	Pubic Hair Development [Pubic Hair Development]	**[PUBIC_HAIR_DEV]** *[A:1]* ○ 1 *[A:2]* ○ 2 *[A:3]* ○ 3 *[A:4]* ○ 4 *[A:5]* ○ 5 *[A:997]* ○ **[HAIR_REA1]** Not Done Specify Reason: A200

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
PUBIC_HAIR_DEV	PUBIC_HAIR_DEV_C	VARCHAR2
	PUBIC_HAIR_DEV	VARCHAR2
	PUBIC_HAIR_DEV_ND	VARCHAR2
PUBIC_HAIR_DEV - HAIR_REA1	HAIR_REA1	VARCHAR2

: DXA_SCAN (DXA_SCAN) [DXA_SCAN]

Study ID:

1.*	Has an performed? [Has an DXA Scan been performed?]	**[DXA_QUEST1]** *[A:1]* **[DXA_QUEST2] (DD/MM/YYYY)** Yes Date of DXA scan: Req / Req / Req (2023-2030) *[A:2]* **[DXA_OTH]** No, Specify reason: A200

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
clYESNOUNK_1	String		Yes	1	citmYESNOUNK1_1	DXA_QUEST1
			No	2	citmYESNOUNK2_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

: C-SSRS parental card (CSSRSparentalcard) [CSSRS_Parental_card]

Study ID: ſ
If the subje" v~~' to any question on the questionnaire the subject must be evaluated as soon as possible by a Mental Health Professional.

CSSRS [sctCSSRS1]		
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]** *[A:1]* Yes *[A:2]* No
2.*	Have you actually had any thoughts about killing yourself? [Have you actually had any thoughts about killing yourself?]	**[CSSRS2]** *[A:1]* Yes *[A:2]* No
If Yes to 2, answer question 3, 4, 5 and 6 [sctCSSRS2]		
3.	Have you thought about how you might do this? [Have you thought about how you might do this?]	**[CSSRS3]** *[A:1]* Yes *[A:2]* No
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]** *[A:1]* Yes *[A:2]* No
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]** *[A:1]* Yes *[A:2]* No
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]** *[A:1]* Yes *[A:2]* No
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]** *[A:1]* Yes *[A:2]* No

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
clYESNO_1	String		Yes	1	citmYESNO1_1	CSSRS1, CSSRS2, CSSRS3, CSSRS4, CSSRS5, CSSRS6, CSSRS7
			No	2	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

: C-SSRS Baseline (C-SSRS Baseline) [CSSRSBASELINE]

Study ID: [illegible]
Note: Gro[illegible]

SUICIDAL IDEATION [sctCSSRSBaseline]

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.

1.*	Wish to be Dead [Wish to be Dead]	**[CSSRSBASE_1]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSBASE_1_DESC]** Yes If yes, describe: A200
2.*	Non-Specific Active Suicidal Thoughts [Non-Specific Active Suicidal Thoughts]	**[CSSRSBASE_2]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSBASE_2_DESC]** Yes If yes, describe: A200
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]	**[CSSRSBASE_3]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSBASE_3_DESC]** Yes If yes, describe: A200
4.	Active Suicidal Ideation with Some Intent to Act, without Specific Plan [Active Suicidal Ideation with Some Intent to Act, without Specific Plan]	**[CSSRSBASE_4]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSBASE_4_DESC]** Yes If yes, describe: A200
5.	Active Suicidal Ideation with Specific Plan and Intent [Active Suicidal Ideation with Specific Plan and Intent]	**[CSSRSBASE_5]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSBASE_5_DESC]** Yes If yes, describe: A200

INTENSITY OF IDEATION [sctCSSRSBaseline1]

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:]	**[grpCSSRSBASE_MSIDEATION]** **[CSSRSBASE_MSIDEATION]** *[A:1]* ○ 1. Wish to be dead *[A:2]* ○ 2. Non-Specific Active Suicidal Thoughts *[A:3]* ○ 3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act *[A:4]* ○ 4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan *[A:5]* ○ 5. Active Suicidal Ideation with Specific Plan and Intent
7.	Frequency [Frequency]	**[CSSRSBASE_IDEA_1]** *[A:1]* ○ Less than once a week *[A:2]* ○ Once a week *[A:3]* ○ 2-5 times in week *[A:4]* ○ Daily or almost daily *[A:5]* ○ Many times each day
8.	Duration [Duration]	**[CSSRSBASE_IDEA_2]** *[A:1]* ○ Fleeting - few seconds or minutes *[A:2]* ○ Less than 1 hour/some of the time *[A:3]* ○ 1-4 hours/a lot of time *[A:4]* ○ 4-8 hours/most of day *[A:5]* ○ More than 8 hours/persistent or continuous
9.	Controllability [Controllability]	**[CSSRSBASE_IDEA_3]** *[A:1]* ○ Easily able to control thoughts *[A:2]* ○ Can control thoughts with little difficulty *[A:3]* ○ Can control thoughts with some difficulty *[A:4]* ○ Can control thoughts with a lot of difficulty *[A:5]* ○ Unable to control thoughts *[A:0]* ○ Does not attempt to control thoughts
10.	Deterrents [Deterrents]	**[CSSRSBASE_IDEA_4]** *[A:1]* ○ Deterrents definitely stopped you from attempting suicide *[A:2]* ○ Deterrents probably stopped you *[A:3]* ○ Uncertain that deterrents stopped you *[A:4]* ○ Deterrents most likely did not stop you *[A:5]* ○ Deterrents definitely did not stop you *[A:0]* ○ Does not apply
11.	Reasons for Ideation [Reasons for Ideation]	**[CSSRSBASE_IDEA_5]** *[A:1]* ○ Completely to get attention, revenge or a reaction from others *[A:2]* ○ Mostly to get attention, revenge or a reaction from others *[A:3]* ○ Equally to get attention, revenge or a reaction from others and to end/stop the pain. *[A:4]* ○ Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) *[A:5]* ○ Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) *[A:0]* ○ Does not apply

SUICIDAL BEHAVIOR [sctCSSRSBaseline3]

(Check all that apply, so long as these are separate events; must ask about all types)

12.	Actual Attempt [Actual Attempt]	**[CSSRSBASE_ATTEMPT]** *[A:2]* ○ No *[A:1]* ○ **[grpCSSRSBASE_ATTEMPT]** ⊟ Yes If yes, describe: **[CSSRSBASE_TOT_ATTEMPT]** Total # of Attempts N2 **[CSSRSBASE_TEXT_ATTEMPT]** describe: A200 **[CSSRSBASE_ENGAGED]** Has subject engaged in Non-Suicidal Self-Injurious Behavior? *[A:2]* ○ No *[A:1]* ○ Yes

	mpt: ɜmpt:]	**[CSSRSBASE_INTERRUPTED]** *[A:2]* No *[A:1]* **[grpCSSRSBASE_INTER]** Yes If yes, describe: **[CSSRSBASE_INTER]** Total # of interrupted N2 **[CSSRSBASE_INTER_TEXT]** describe: A200
14.	Aborted Attempt: [Aborted Attempt:]	**[CSSRSBASE_ABORTED]** *[A:2]* No *[A:1]* **[grpCSSRSBASE_ABORTED]** Yes If yes, describe: **[CSSRSBASE_NO_ABORTED]** Total # of interrupted: N2 **[CSSRSBASE_ABORTED_TEXT]** describe: A200
15.	Preparatory Acts or Behavior: [Suicide]	**[CSSRSBASE_BEHAVIOR]** *[A:2]* No *[A:1]* **[CSSRSBASE_BEHAVIOR_TEXT]** Yes If yes, describe: A200
16.	Suicidal Behavior: [Suicidal Behavior:]	**[CSSRSBASE_SUICIDE_BEH]** *[A:2]* No *[A:1]* Yes
Answer for Actual Attempts Only [sctCSSRSBaseline4]		
17.	Most Recent Attempt Actual Lethality/Medical Damage: [Most Recent]	**[grpCSSRSBASE_ATTEMPT_1]** Most Recent Attempt **[CSSRSBASE_ATTEM_DATE_1] (DD/MM/YYYY)** Req / Req / Req (2023-2030) **[CSSRSBASE_ATTEM_DAMAGE_1]** *[A:0]* **[CSSRSBASE_POTENTIAL_1]** 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:1]* 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
18.	Most Lethal Attempt Actual Lethality/Medical Damage: [Most Lethal]	**[grpCSSRSBASE_ATTEMPT_2]** Most Lethal Attempt **[CSSRSBASE_ATTEM_DATE_2] (DD/MM/YYYY)** Req / Req / Req (2023-2030) **[CSSRSBASE_ATTEM_DAMAGE_2]** *[A:0]* **[CSSRSBASE_POTENTIAL_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:1]* 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
19.	Initial/First Attempt Actual Lethality/Medical Damage: [Initial/First]	**[grpCSSRSBASE_ATTEMPT_3]** Initial/First Attempt **[CSSRSBASE_ATTEM_DATE_3] (DD/MM/YYYY)** Req / Req / Req (2023-2030) **[CSSRSBASE_ATTEM_DAMAGE_3]** *[A:0]* **[CSSRSBASE_POTENTIAL_3]** 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:1]* 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

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	Code	Codelist Item RefName	Data Variable RefName
clCSSRSBASE_1	String		No	2	citmCSSRSBASE_2	CSSRSBASE_1
			Yes	1	citmCSSRSBASE_1	
clCSSRSBASE_2	String		No	2	citmCSSRSBASE_2_1	CSSRSBASE_2
			Yes	1	citmCSSRSBASE_1_1	
clCSSRSBASE_1_2	String		No	2	citmCSSRSBASE_2_2	CSSRSBASE_3
			Yes	1	citmCSSRSBASE_1_2	
clCSSRSBASE_1_3	String		No	2	citmCSSRSBASE_2_3	CSSRSBASE_4
			Yes	1	citmCSSRSBASE_1_3	
clCSSRSBASE_1_4	String		No	2	citmCSSRSBASE_2_4	CSSRSBASE_5
			Yes	1	citmCSSRSBASE_1_4	
clCSSRSBASE_MSIDEATION	String		1. Wish to be dead	1	citmCSSRSBASE_MSIDEATION1	CSSRSBASE_MSIDEATION
			2. Non-Specific Active Suicidal Thoughts	2	citmCSSRSBASE_MSIDEATION2	
			3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act	3	citmCSSRSBASE_MSIDEATION3	

			4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan	4	citmCSSRSBASE_MSIDEATION4	
			5. Active Suicidal Ideation with Specific Plan and Intent	5	citmCSSRSBASE_MSIDEATION5	
clCSSRSBA[CE]	String		Less than once a week	1	citmCSSRSBASE_IDEA_1	CSSRSBASE_IDEA_1
			Once a week	2	citmCSSRSBASE_IDEA_2	
			2-5 times in week	3	citmCSSRSBASE_IDEA_3	
			Daily or almost daily	4	citmCSSRSBASE_IDEA_4	
			Many times each day	5	citmCSSRSBASE_IDEA_5	
clCSSRSBASE_IDEA_2	String		Fleeting - few seconds or minutes	1	citmCSSRSBASE_IDEA_2_1	CSSRSBASE_IDEA_2
			Less than 1 hour/some of the time	2	citmCSSRSBASE_IDEA_2_2	
			1-4 hours/a lot of time	3	citmCSSRSBASE_IDEA_2_3	
			4-8 hours/most of day	4	citmCSSRSBASE_IDEA_2_4	
			More than 8 hours/persistent or continuous	5	citmCSSRSBASE_IDEA_2_5	
clCSSRSBASE_IDEA_3	String		Easily able to control thoughts	1	citmCSSRSBASE_IDEA_3_1	CSSRSBASE_IDEA_3
			Can control thoughts with little difficulty	2	citmCSSRSBASE_IDEA_3_2	
			Can control thoughts with some difficulty	3	citmCSSRSBASE_IDEA_3_3	
			Can control thoughts with a lot of difficulty	4	citmCSSRSBASE_IDEA_3_4	
			Unable to control thoughts	5	citmCSSRSBASE_IDEA_3_5	
			Does not attempt to control thoughts	0	citmCSSRSBASE_IDEA_3_0	
clCSSRSBASE_IDEA_4	String		Deterrents definitely stopped you from attempting suicide	1	citmCSSRSBASE_IDEA_4_1	CSSRSBASE_IDEA_4
			Deterrents probably stopped you	2	citmCSSRSBASE_IDEA_4_2	
			Uncertain that deterrents stopped you	3	citmCSSRSBASE_IDEA_4_3	
			Deterrents most likely did not stop you	4	citmCSSRSBASE_IDEA_4_4	
			Deterrents definitely did not stop you	5	citmCSSRSBASE_IDEA_4_5	
			Does not apply	0	citmCSSRSBASE_IDEA_4_0	
clCSSRSBASE_IDEA_5	String		Completely to get attention, revenge or a reaction from others	1	citmCSSRSBASE_IDEA_5_1	CSSRSBASE_IDEA_5
			Mostly to get attention, revenge or a reaction from others	2	citmCSSRSBASE_IDEA_5_2	
			Equally to get attention, revenge or a reaction from others and to end/stop the pain.	3	citmCSSRSBASE_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	citmCSSRSBASE_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	citmCSSRSBASE_IDEA_5_5	
			Does not apply	0	citmCSSRSBASE_IDEA_5_0	
clCSSRLAST_SUICIDE	String		No	2	citmCSSRLAST_SUICIDE_2	CSSRSBASE_ATTEMPT, CSSRSBASE_ENGAGED, CSSRSBASE_INTERRUPTED, CSSRSBASE_ABORTED, CSSRSBASE_SUICIDE_BEH
			Yes	1	citmCSSRLAST_SUICIDE_1	
clCSSRLAST_SUICIDE_2	String		No	2	citmCSSRLAST_SUICIDE_2	CSSRSBASE_BEHAVIOR
			Yes	1	citmCSSRLAST_SUICIDE_1	
clCSSRSBASE_ATTEM_DAMAGE_1	String		No physical damage or very minor physical damage	0	citmCSSRSBASE_ATTEM_DAMAGE_1_0	CSSRSBASE_ATTEM_DAMAGE_1,
			Minor physical damage	1	citmCSSRSBASE_ATTEM_DAMAGE_1_1	CSSRSBASE_ATTEM_DAMAGE_2,
			Moderate physical damage; medical attention needed	2	citmCSSRSBASE_ATTEM_DAMAGE_1_2	CSSRSBASE_ATTEM_DAMAGE_3
			Moderately severe physical damage; medical hospitalization and likely intensive care required	3	citmCSSRSBASE_ATTEM_DAMAGE_1_3	
			Severe physical damage; medical hospitalization with intensive care required	4	citmCSSRSBASE_ATTEM_DAMAGE_1_4	
			Death	5	citmCSSRSBASE_ATTEM_DAMAGE_1_5	
clCSSRSBASE_ATTEM_DAMAGE_2_1	String		Behavior not likely to result in injury	0	citmCSSRSLAST_ATTEM_DAMAGE_3_0	CSSRSBASE_POTENTIAL_1, CSSRSBASE_POTENTIAL_2, CSSRSBASE_POTENTIAL_3
			Behavior likely to result in injury but not likely to cause death	1	citmCSSRSLAST_ATTEM_DAMAGE_3_1	
			Behavior likely to result in death despite available medical care	2	citmCSSRSLAST_ATTEM_DAMAGE_3_2	

RDE Analytics: RD_CSSRSBASELINE

Data Variable RefName	RD Column Name	Column Data Type
CSSRSBASE_1	CSSRSBASE_1_C	VARCHAR2
	CSSRSBASE_1	VARCHAR2
	CSSRSBASE_1_ND	VARCHAR2
CSSRSBASE_1 - CSSRSBASE_1_DESC	CSSRSBASE_1_DESC	VARCHAR2
CSSRSBASE_2	CSSRSBASE_2_C	VARCHAR2
	CSSRSBASE_2	VARCHAR2
	CSSRSBASE_2_ND	VARCHAR2
CSSRSBASE_2 - CSSRSBASE_2_DESC	CSSRSBASE_2_DESC	VARCHAR2
CSSRSBASE_3	CSSRSBASE_3_C	VARCHAR2
	CSSRSBASE_3	VARCHAR2
	CSSRSBASE_3_ND	VARCHAR2
CSSRSBASE_3 - CSSRSBASE_3_DESC	CSSRSBASE_3_DESC	VARCHAR2
CSSRSBASE_4	CSSRSBASE_4_C	VARCHAR2
	CSSRSBASE_4	VARCHAR2
	CSSRSBASE_4_ND	VARCHAR2
CSSRSBASE_4 - CSSRSBASE_4_DESC	CSSRSBASE_4_DESC	VARCHAR2
CSSRSBASE_5	CSSRSBASE_5_C	VARCHAR2
	CSSRSBASE_5	VARCHAR2
	CSSRSBASE_5_ND	VARCHAR2
CSSRSBASE_5 - CSSRSBASE_5_DESC	CSSRSBASE_5_DESC	VARCHAR2
grpCSSRSBASE_MSIDEATION	GRPCSSRSBASE_MSIDEATION_ND	VARCHAR2
grpCSSRSBASE_MSIDEATION - CSSRSBASE_MSIDEATION	CSSRSBASE_MSIDEATION_C	VARCHAR2
	CSSRSBASE_MSIDEATION	VARCHAR2
CSSRSBASE_IDEA_1	CSSRSBASE_IDEA_1_C	VARCHAR2
	CSSRSBASE_IDEA_1	VARCHAR2
	CSSRSBASE_IDEA_1_ND	VARCHAR2
CSSRSBASE_IDEA_2	CSSRSBASE_IDEA_2_C	VARCHAR2
	CSSRSBASE_IDEA_2	VARCHAR2
	CSSRSBASE_IDEA_2_ND	VARCHAR2
CSSRSBASE_IDEA_3	CSSRSBASE_IDEA_3_C	VARCHAR2
	CSSRSBASE_IDEA_3	VARCHAR2
	CSSRSBASE_IDEA_3_ND	VARCHAR2
CSSRSBASE_IDEA_4	CSSRSBASE_IDEA_4_C	VARCHAR2
	CSSRSBASE_IDEA_4	VARCHAR2
	CSSRSBASE_IDEA_4_ND	VARCHAR2
CSSRSBASE_IDEA_5	CSSRSBASE_IDEA_5_C	VARCHAR2
	CSSRSBASE_IDEA_5	VARCHAR2
	CSSRSBASE_IDEA_5_ND	VARCHAR2
CSSRSBASE_ATTEMPT	CSSRSBASE_ATTEMPT_C	VARCHAR2
	CSSRSBASE_ATTEMPT	VARCHAR2
	CSSRSBASE_ATTEMPT_ND	VARCHAR2
CSSRSBASE_ATTEMPT - CSSRSBASE_TOT_ATTEMPT	CSSRSBASE_TOT_ATTEMPT	NUMBER

: PHQ-9 (PHQ9) [PHQ9]

Study ID: !
Note: Gro[illegible]

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
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
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
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
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
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
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
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
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
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
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]* ◯ Not difficult at all *[N:2]* ◯ Somewhat difficult *[N:3]* ◯ Very difficult *[N:4]* ◯ Extremely difficult

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
clPHQ	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	
clPHQ_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_ND	VARCHAR2
PHQ_7	PHQ_7_C	NUMBER
	PHQ_7	VARCHAR2
	PHQ_7_ND	VARCHAR2
PHQ_8	PHQ_8_C	NUMBER
	PHQ_8	VARCHAR2
	PHQ_8_ND	VARCHAR2
PHQ_9	PHQ_9_C	NUMBER
	PHQ_9	VARCHAR2
	PHQ_9_ND	VARCHAR2
grpPHQ_OFFICE	GRPPHQ_OFFICE_ND	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	NUMBER
	PHQ_TOTAL_SCORE_ND	VARCHAR2
PHQ_10	PHQ_10_C	NUMBER
	PHQ_10	VARCHAR2
	PHQ_10_ND	VARCHAR2

: Collection of Consent to Biosamples for Future Research (Collection Future Research) [COLLECTION_FUTURE_RESEARCH]	
Study ID:	
1.* Child a ıples for future analysis [Child assent for biosamples for future analysis]	**[DSTERM_1]** *[A:2]* No *[A:1]* **[grpDSTERM_1]** Yes **[DSSTDTC_1] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
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)]	**[DSTERM_2]** *[A:2]* No *[A:1]* **[grpDSTERM_2]** Yes **[DSSTDTC_2] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
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)]	**[DSTERM_3]** *[A:2]* No *[A:1]* **[grpDSTERM_3]** Yes **[DSSTDTC_3] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
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	citmDSTERM_1N	DSTERM_1
			Yes	1	citmDSTERM_1Y	
clDSTERM_YN_2	String		No	2	citmDSTERM_2N	DSTERM_2
			Yes	1	citmDSTERM_2Y	
clDSTERM_YN_3	String		No	2	citmDSTERM_3N	DSTERM_3
			Yes	1	citmDSTERM_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.

: Eligibility Criteria (Elig) [ELIG_CRIT_2]

Study ID:

To qualify f participation all eligibility criteria must be met by subject. The screening status should not be updated once the subject is randomised.

1.*	Screening status: Having evaluated all criteria, is the subject eligible to continue in the study? *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]	**[ELIG_STATUS]** *[A:1]* **[ELIG_DT] (DD/MM/YYYY)** Subject is eligible (Meets all eligibility requirements) Date subject is confirmed eligible Req / Req / Req (2023-2030) *[A:2]* Subject failed one or more eligibility requirements (Subject is a screen failure) *[A:3]* Eligibility evaluation was not completed
	Failed inclusion criterion	
2.		

Failed inclusion criteria Entry [sctELIG_INCL]

2.1	Failed inclusion criterion [Failed inclusion criterion]	**[ELIG_FAIL_INCL]** **[clFAIL_INCL]**
	Met exclusion criterion	
3.		

Met exclusion criteria Entry [sctELIG_EXCL]

3.1	Met exclusion criterion [Met exclusion criterion]	**[ELIG_MET_EXCL]** **[clMET_EXCL]**

Eligibility criteria [sctELIG_CRITERIA]

Inclusion Criteria
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 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 < 12 years
   b. Group Teens: 12 to < 18 years, and Tanner stage > 1
3. BMI, at screening and randomisation, corresponding to
   a. Group Kids: ≥95th percentile[a]
   b. Group Teens: ≥95th percentile[a] or ≥85th percentile[a] 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[b]
5. Body weight of >45 kg at screening and randomisation.

For participants with T2D at screening the following inclusion criteria apply in addition to criteria 1-5:
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

For participants assessed by DXA scan the following additional criteria must apply:
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^2 at screening

Exclusion Criteria

Obesity related
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 >1 year prior to screening, (2) adjustable gastric banding, if the band has been removed >1 year prior to screening, (3) intragastric balloon, if the balloon has been removed >1 year prior to screening or (4) duodenal-jejunal bypass liner (e.g., Endobarrier), if the sleeve has been removed >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 >5% within 90 days before screening irrespective of medical records

Mental health
6. History of major depressive disorder within 2 years before screening[b]
7. Diagnosis of other severe psychiatric disorders (e.g., schizophrenia, bipolar disorder)[b]
8. A lifetime history of suicidal attempt[b]
9. Suicidal behaviour within 30 days before screening[b]

Additional mental health for Group Teens
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

General Safety
12. History or presence of chronic pancreatitis[b]
13. Presence of acute pancreatitis within 180 days before screening[b]
14. Calcitonin ≥50 ng/L
15. Personal, or first-degree relative's, history of multiple endocrine neoplasia type 2 or medullary thyroid carcinoma[b]
16. Type 1 diabetes mellitus or monogenic diabetes
17. Renal impairment with estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73 m^2, as calculated by the Bedside Schwartz equation[c]
18. Presence or history of malignant neoplasms within the past 5 years prior to the day of screening[b]
19. Surgery scheduled for the duration of the study, except for 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 is 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 participating in any semaglutide study
26. Known history of heart disease (including history of clinically significant arrhythmias 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

Glycaemia-related
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

Diabetes related for participants with T2D
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

4.	End of the form *[read-only]* [Eligibility status]	**[ELIG_END]** *[A:1]*

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

Study Object Descriptions: Eligibility Criteria

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

Codelist Values Tables: Eligibility Criteria

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clELIG_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	
clFAIL_INCL	String		Inclusion Criteria 1	I1	citmFAIL_INCL_1	ELIG_FAIL_INCL
			Inclusion Criteria 2	I2	citmFAIL_INCL_2	
			Inclusion Criteria 3	I3	citmFAIL_INCL_3	
			Inclusion Criteria 4	I4	citmFAIL_INCL_4	
			Inclusion Criteria 5	I5	citmFAIL_INCL_5	
			Inclusion Criteria 6	I6	citmFAIL_INCL_6	
			Inclusion Criteria 7	I7	citmFAIL_INCL_7	
			Inclusion Criteria 8	I8	citmFAIL_INCL_8	
			Inclusion Criteria 9	I9	citmFAIL_INCL_9	
clMET_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	

			Exclusion Criteria 4	E4	citmMET_EXCL_4	
			Exclusion Criteria 5	E5	citmMET_EXCL_5	
			Exclusion Criteria 6	E6	citmMET_EXCL_6	
			Exclusion Criteria 7	E7	citmMET_EXCL_7	
			Exclusion Criteria 8	E8	citmMET_EXCL_8	
			Exclusion Criteria 9	E9	citmMET_EXCL_9	
			Exclusion Criteria 10	E10	citmMET_EXCL_10	
			Exclusion Criteria 11	E11	citmMET_EXCL_11	
			Exclusion Criteria 12	E12	citmMET_EXCL_12	
			Exclusion Criteria 13	E13	citmMET_EXCL_13	
			Exclusion Criteria 14	E14	citmMET_EXCL_14	
			Exclusion Criteria 15	E15	citmMET_EXCL_15	
			Exclusion Criteria 16	E16	citmMET_EXCL_16	
			Exclusion Criteria 17	E17	citmMET_EXCL_17	
			Exclusion Criteria 18	E18	citmMET_EXCL_18	
			Exclusion Criteria 19	E19	citmMET_EXCL_19	
			Exclusion Criteria 20	E20	citmMET_EXCL_20	
			Exclusion Criteria 21	E21	citmMET_EXCL_21	
			Exclusion Criteria 22	E22	citmMET_EXCL_22	
			Exclusion Criteria 23	E23	citmMET_EXCL_23	
			Exclusion Criteria 24	E24	citmMET_EXCL_24	
			Exclusion Criteria 25	E25	citmMET_EXCL_25	
			Exclusion Criteria 26	E26	citmMET_EXCL_26	
			Exclusion Criteria 27	E27	citmMET_EXCL_27	
			Exclusion Criteria 28	E28	citmMET_EXCL_28	
			Exclusion Criteria 29	E29	citmMET_EXCL_29	
			Exclusion Criteria 30	E30	citmMET_EXCL_30	
			Exclusion Criteria 31	E31	citmMET_EXCL_31	
			Exclusion Criteria 32	E32	citmMET_EXCL_32	
clELIG_END	String			1	citmELIG_END	ELIG_END

RDE Analytics: RD_ELIG_CRIT_2		
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
***RD_ELIG_CRIT_2_SCTELIG_INCL**		
ELIG_FAIL_INCL	ELIG_FAIL_INCL_C	VARCHAR2
	ELIG_FAIL_INCL	VARCHAR2
	ELIG_FAIL_INCL_ND	VARCHAR2
***RD_ELIG_CRIT_2_SCTELIG_EXCL**		
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]		
Study ID:		
1.	Date of *read-only* [Date of randomisation]	**[RANDOMISATION_DATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
2.	Randomisation No *[hidden]* [Randomisation No]	**[RANDOMISATION_NO]** N6
3.	Randomised to intervention arm *[hidden]* [Randomised to arm]	**[RAND_TRIAL_DRUG_CODE]** *[A:P]* Pseudo/blinded arm 1 *[A:PP]* Pseudo/blinded arm 2 *[A:PPP]* Pseudo/blinded arm 3 *[A:PPPP]* Pseudo/blinded arm 4 *[A:PPPPP]* Pseudo/blinded arm 5
4.	Stratification *[read-only]* [Stratification]	**[STRATUM_CODE]** *[A:1]* Group Kids,Male, Tanner Stage 1 *[A:2]* Group Kids,Male, Tanner Stage 2-3 *[A:3]* Group Kids,Male, Tanner Stage 4-5 *[A:4]* Group Kids,Female, Tanner Stage 1 *[A:5]* Group Kids,Female, Tanner Stage 2-3 *[A:6]* Group Kids,Female, Tanner Stage 4-5 *[A:7]* Group Teens,Male *[A:8]* Group Teens,Female
5.	Cohort No. *[hidden]* [Cohort No.]	**[COHORT]** *[A:12]* 1 *[A:13]* 2 *[A:14]* 3 *[A:15]* 4 *[A:16]* 5 *[A:17]* 6 *[A:18]* 7 *[A:19]* 8 *[A:20]* 9 *[A:21]* 10 *[A:22]* 1A *[A:23]* 2A *[A:24]* 3A *[A:25]* 4A *[A:26]* 5A *[A:27]* 6A *[A:28]* 7A *[A:29]* 8A *[A:30]* 9A *[A:31]* 10A *[A:32]* 1B *[A:33]* 2B *[A:34]* 3B *[A:35]* 4B *[A:36]* 5B *[A:37]* 6B *[A:38]* 7B *[A:39]* 8B *[A:40]* 9B *[A:41]* 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	citmSTRATUM_CODE_A	STRATUM_CODE
			Group Kids,Male, Tanner Stage 2-3	2	citmSTRATUM_CODE_B	
			Group Kids,Male, Tanner Stage 4-5	3	citmSTRATUM_CODE_C	
			Group Kids,Female, Tanner Stage 1	4	citmSTRATUM_CODE_D	
			Group Kids,Female, Tanner Stage 2-3	5	citmSTRATUM_CODE_E	
			Group Kids,Female, Tanner Stage 4-5	6	citmSTRATUM_CODE_F	
			Group Teens,Male	7	citmSTRATUM_CODE_G	
			Group Teens,Female	8	citmSTRATUM_CODE_H	
clCOHORT	String		1	12	citmCOHORT_1	COHORT
			2	13	citmCOHORT_2	
			3	14	citmCOHORT_3	
			4	15	citmCOHORT_4	
			5	16	citmCOHORT_5	
			6	17	citmCOHORT_6	
			7	18	citmCOHORT_7	
			8	19	citmCOHORT_8	
			9	20	citmCOHORT_9	
			10	21	citmCOHORT_10	
			1A	22	citmCOHORT_1A	
			2A	23	citmCOHORT_2A	
			3A	24	citmCOHORT_3A	
			4A	25	citmCOHORT_4A	
			5A	26	citmCOHORT_5A	
			6A	27	citmCOHORT_6A	
			7A	28	citmCOHORT_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

: First Date of Last Menstrual Cycle (Menstrual cycle) [MENSTRUAL_CYCLE]

Study ID:
Note: Fem~ ~~~~s only

sctMENSTRUAL_CYCLE [sctMENSTRUAL_CYCLE]

1.*	Did the subject menstruate? [Did the subject menstruate?]	**[MENSTRUAL_CYCLE_1]** *[A:1]* **[MENSTRUAL_CYCLE_DATE] (DD/MM/YYYY)** Yes Date Req / Req / Req (2023-2030) *[A:2]* No

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

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
clMENSTRUAL_CYCLE	String		Yes	1	citmMENSTRUAL_CYCLE_1	MENSTRUAL_CYCLE_1
			No	2	citmMENSTRUAL_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

: Body measurements (Body Meas) [BODY_MEASUREMENT_2]

Study ID:
Preferably, [illegible]nts 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 / Req / Req (2016-2025)
2.	Date and time of examination *[hidden]* [Exam Date & Time]	**[BODY_MEAS_DATE_TIME1] (DD/MM/YYYY hh:mm)** Req / Req / Req (2021-2030) Req/Unk : Req/Unk *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
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
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
6.	Mean height *(System calculated mean) [read-only]* [Mean height]	**[grpHEIGHT_MEAN1]** **[BODY_HEIGHT_MEAN1] [HEIGHT_MEAN_UNIT1]** xxx.x *[A:340]* cm
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
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
9.	Body weight derived (calculated) *[hidden]* [Body Weight]	**[BODY_WEIGHT_DERIVE_2]** xxxxx. kg[b]
10.	BMI (System Calculated) [BMI]	**[BMI_DERIVED_V2]** xxx.x kg/m2

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

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
clHEIGHT_UNIT_1	String		cm	340	citmHEIGHT_UNIT_CM_1	HEIGHT_UNIT1, HEIGHT_MEAN_UNIT1
clHEIGHT_UNIT2_2	String		cm	340	citmHEIGHT_UNIT_CM_1	HEIGHT_UNIT1_1, HEIGHT_UNIT1_2
clBODY_WEIGHT_UNIT_1	String		kg	220	citmBODY_WEIGHT_UNIT_KG_1	BODY_WEIGHT_UNIT1
			lb	700	citmBODY_WEIGHT_UNIT_LB_1	
clHEIGHT_UNIT1	String		cm	340	citmHEIGHT_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

: First Dose (First Dose) [DOSAGE_1]	
Study ID:	
1.* Date o estigational medicinal product (Semaglutide/Semaglutide placebo) [Date of first dose]	**[START_DATE_DOSE]** *[A:1]* **[START_DATE_FDOSE] (DD/MM/YYYY)** Req / Req / Req (2023-2030) *[A:998]* N/A
2. Date and time of first dose of investigational medicinal product *[hidden]* [Date and time of first dose]	**[START_DATE_TIME_DOSE]** *[A:1]* **[START_DATE_TIME_FDOSE] (DD/MM/YYYY hh:mm)** Req / Req / Req (2022-2035) Req : Req *24-hour clock* *[A:998]* N/A
3. First date and dose of investigational medicinal product *[hidden]* [First date and dose]	**[START_DATE_DOSE_1]** *[A:1]* **[grpDRUG_TYPE_DATE_DOSE]** **[START_DATE_FDOSE_1] (DD/MM/YYYY)** Req / Req / Req (2022-2035) **[grpDOSE_UNIT]** **[DOSE_2]** 0 < xxxx. **[DOSE_UNIT]** *[A:T1]* Unit 1 *[A:T2]* Unit 2 *[A:998]* N/A
4. Injection site *[hidden]* [Injection site]	**[INJ_LOCATION_CODE_1]** *[A:5]* Upper Arm (Arm) *[A:151]* Stomach (Abdominal skin) *[A:3]* Thigh
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: First Dose

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**

Codelist Values Tables: First Dose

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clSTART_DATE_DOSE	String		Date	1	citmSTART_DATE_DOSE	START_DATE_DOSE, START_DATE_TIME_DOSE, START_DATE_DOSE_1
			N/A	998	citmSTART_DATE_NA	
clFDOSE_UNIT	String		Unit 1	T1	citmFDOSE_UNIT1	DOSE_UNIT
			Unit 2	T2	citmFDOSE_UNIT2	
clINJ_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	

RDE Analytics: RD_DOSAGE_1

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

: Drug administration-Baseline (Drug Admin-Baseline) [DRUG_ADMIN_BASE]

Study ID: !
To be comp!^ **he participants 10 years old and above.

1.*	Who administered the drug [Who administered the drug]	**[DRUG_ADMIN_BASE1]** *[A:1]* ◯ Participant *[A:2]* ◯ Parent(s)/LAR (Legally Acceptable Representative) *[A:3]* ◯ Investigator/Site staff

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

Study Object Descriptions: Drug administration-Baseline

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
clDRUG_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

: Evaluation of glycaemic status (Eval Glycaemic Status) [EVAL_GLY_STAT]		
Study ID: Note: ONLY ···thout T2D. Please eval.. .'s glycaemic status based on all available information		
1.	Glycaemic status [Glycaemic status]	**[GLYCAEMIC_1_L]** *[A:418]* ◯ Normo-glycaemia *[A:419]* ◯ Pre-diabetes
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

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
clGLYCAEMIC_STATUS1	String		Normo-glycaemia	418	citmGLYCAEMIC_STATUS1_2	GLYCAEMIC_1_L
			Pre-diabetes	419	citmGLYCAEMIC_STATUS1_1	

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

: Mental Health Evaluation (Mental Health Evaluation) [MENTAL_HEALTH]

Study ID: †
If Question ' ¯nswered "YES" and event is clinically relevant fulfilling the criteria for adverse event reporting, report the event in AE form.

sctMENTAL_HEALTH [sctMENTAL_HEALTH]

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?]	**[grpMENTALHEALTH1]** **[MENTALHEALTH1S]** Subject *[A:1]* ◯ Yes *[A:2]* ◯ No **[MENTALHEALTH1LAR]** Subject's parent(s)/LAR *[A:1]* ◯ Yes *[A:2]* ◯ No
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 subject's parent(s)/LAR only) [Have the subject's parent(s)/LAR witnessed any clinically relevant changes in behaviour and/or school performance since last evaluation? (Investigator question to subject's parent(s)/LAR only)]	**[MENTALHEALTH2]** *[A:1]* ◯ Yes *[A:2]* ◯ No

sctMENTALHEALTH2 [sctMENTALHEALTH2]

If Questions 1 and /or 2 is answered "YES", Please complete questions 3 and 4

3.	Will the C-SSRS (parental card version) be completed? (Investigator discretion) If Yes, complete CSSRS parental card [C-SSRS (parental card version)] [Will the C-SSRS (parental card version) be completed? (Investigator discretion)]	**[MENTALHEALTH3]** *[A:1]* ◯ Yes *[A:2]* ◯ No
4.	Has the subject been referred to a Mental Health Professional? [Referred to a Mental Health Professional] [Has the subject been referred to a Mental Health Professional?]	**[MENTALHEALTH4]** *[A:1]* ◯ Yes *[A:2]* ◯ **[MENTALOTH]** ⊟ No Please provide reason A200

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
clYESNO	String		Yes	1	citmYESNO1	MENTALHEALTH1S, MENTALHEALTH1LAR, MENTALHEALTH2
			No	2	citmYESNO2	
clYESNO_1	String		Yes	1	citmYESNO1_1	MENTALHEALTH3, MENTALHEALTH4
			No	2	citmYESNO2_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

: X-Ray for Bone Age Assessment (X-ray bone age) [X_RAY]

Study ID:

1.*	Has an age assessment been taken? [Has an X-ray for bone age assessment been taken?]	**[XRAY_TAKEN]** *[A:1]* **[XRAY_DATE] (DD/MM/YYYY)** Yes Date of X-Ray: Req / Req / Req (2023-2030) *[A:2]* **[XRAY_REASON]** No *[A:1]* Epiphyseal closure *[A:2]* **[XRAY_TEXT]** Specify reason A200

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
clYESNO_2_1	String		Yes	1	citmYESNO1_2_1	XRAY_TAKEN
			No	2	citmYESNO2_2_1	
clXRAY_REASON	String		Epiphyseal closure	1	citmXRAY_REASON1	XRAY_REASON
			Specify reason	2	citmXRAY_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

	: Missed Assessment due to COVID-19 (Missed Assessment) [MISSD_ASSMNT]	
Study ID:		
sctMISSD_ 4ISSD_ASSMNT]		
1.*	Were any of the below assessments not done? [Any assessments not done]	**[MISSD_ASSMNT_YN]** *[A:1]* ◯ Yes *[A:2]* ◯ No

sctDOMAIN_1 [sctDOMAIN_1]

#	Domain 1	Assessment	Status	REASND
2.a	VS	Body measuremnt		COVID-19
2.b	VS	Waist circumference		COVID-19
2.c	VS	Blood pressure		COVID-19
2.d	VS	Height		COVID-19

sctDOMAIN_1 Entry [sctDOMAIN_1]		
2.1	Domain 1 *[hidden]* [Domain 1]	**[DOMAIN_1]** **[clDOMAIN_1]**
2.2	Assessment [Assessment]	**[ASSESSMENT_1]** **[clMISSED_ASSESSMENTS_1]**
2.3	Status [Status]	**[STAT]** *[A:1]* ☐ Not done
2.4	REASND *[hidden]* [REASND]	**[REASND_1]** *[A:1]* ◯ COVID-19

[sctDOMAIN_2]

#	Domain 2	Assessment	Status	REASND
3.a	PR	DXA Scan		COVID-19

Entry [sctDOMAIN_2]		
3.1	Domain 2 *[hidden]* [Domain 2]	**[DOMAIN_2]** **[clDOMAIN_1]**
3.2	Assessment [Assessment]	**[ASSESSMENT_2]** **[clMISSED_ASSESSMENTS_1]**
3.3	Status [Status]	**[STAT_1]** *[A:1]* ☐ Not done
3.4	REASND *[hidden]* [REASND]	**[REASND]** *[A:1]* ◯ COVID-19

[sctDOMAIN_3]

#	Domain 2	Assessment	Status	REASND
4.a	QS	Lab		COVID-19

Entry [sctDOMAIN_3]		
4.1	Domain 2 *[hidden]* [Domain 2]	**[DOMAIN_3]** **[clDOMAIN_1]**
4.2	Assessment [Assessment]	**[ASSESSMENT_3]** **[clMISSED_ASSESSMENTS_1]**
4.3	Status [Status]	**[STAT_3]** *[A:1]* ☐ Not done
4.4	REASND *[hidden]* [REASND]	**[REASND_3]** *[A:1]* ◯ COVID-19

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
clYESNO_1	String		Yes	1	citmYESNO1_1	MISSD_ASSMNT_YN
			No	2	citmYESNO2_1	
clDOMAIN_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	
clMISSED_ASSESSMENTS_1	String		Vital Signs	1	citmMISSED_ASSESSMENTS1	ASSESSMENT_1, ASSESSMENT_2, ASSESSMENT_3
			Body measuremnt	2	citmMISSED_ASSESSMENTS2	
			FIrst Dose	3	citmMISSED_ASSESSMENTS3	
			ECG	4	citmMISSED_ASSESSMENTS4	
			Last Dose	5	citmMISSED_ASSESSMENTS5	
			IWQOL-Lite-CT Physical Function	6	citmMISSED_ASSESSMENTS6	
			Short Form-36 (SF-36)	7	citmMISSED_ASSESSMENTS7	
			Waist circumference	8	citmMISSED_ASSESSMENTS8	
			Blood pressure	9	citmMISSED_ASSESSMENTS9	
			Height	10	citmMISSED_ASSESSMENTS10	
			DXA Scan	11	citmMISSED_ASSESSMENTS11	
			Lab	12	citmMISSED_ASSESSMENTS12	
clSTAT	String		Not done	1	NewCodelistItem_6	STAT, STAT_1, STAT_3
clREASND_1	String		COVID-19	1	COVID19	REASND_1, REASND, 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
***RD_MISSD_ASSMNT_SCTDOMAIN_1**		
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
***RD_MISSD_ASSMNT_SCTDOMAIN_2**		
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
***RD_MISSD_ASSMNT_SCTDOMAIN_3**		
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.

: Height-Repeated by 2nd personnel (HEIGHT_REPEATED) [HEIGHT_REPEATED]

Study ID:
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.)* [Height 1]	**[grpHEIGHT2_1]** **[BODY_HEIGHT2_1]** **[HEIGHT_UNIT2_1]** 0 <= xxx.x *[A:1]* cm
2. * ✔	Repeated Height 2 *(The height measurements must be performed by a second qualified person at site, who is blinded to the previous measurements.)* [Height 2]	**[grpHEIGHT2_2]** **[BODY_HEIGHT2_2]** **[HEIGHT_UNIT2_2]** 0 <= xxx.x *[A:1]* cm
3. * ✔	Repeated Height 3 *(The height measurements must be performed by a second qualified person at site, who is blinded to the previous measurements.)* [Height 3]	**[grpHEIGHT2_3]** **[BODY_HEIGHT2_3]** **[HEIGHT_UNIT2_3]** 0 <= xxx.x *[A:1]* cm
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

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_REPEATED	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
clHEIGHT_UNIT2_1	String		cm	1	citmHEIGHT_UNIT_CM_2_1	HEIGHT_UNIT2_1, HEIGHT_UNIT2_2, HEIGHT_UNIT2_3, HEIGHT_MEAN_UNIT2

RDE Analytics: RD_HEIGHT_REPEATED

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

: Treatment Discontinuation (Discontinuation) [TREAT_DISCONT]

Study ID:
Complete this ... **he IMP is temporarily discontinued.
If IMP is pe... ..ntinued use the End of IMP treatment form instead.

1.*	Discontinuation date [Discontinuation date]	**[DISCONT_DATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
2.*	Reasons for discontinuation [Reasons for discontinuation]	**[DISCONT_REASON]** *[A:1]* ☐ Safety concern as judged by the investigator *[A:2]* ☐ Suspicion of acute pancreatitis *[A:3]* ☐ Pregnancy *[A:5]* ☐ Intention of becoming pregnant *[A:8]* ☐ Tolerability not resolved by lowering dose *[A:20]* ☐ **[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
clDISCONT_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_CITMDISCONTREASON5_C	VARCHAR2
	*DISCONT_REASON_CITMDISCONTREASON5	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.

: Body measurements 3 (Body Meas) [BODY_MEASUREMENT_3]		
Study ID:		
1.	Date o *idden]* [Exam Date]	**[BODY_MEAS_DATE_3] (DD/MM/YYYY)** Req / Req / Req (2022-2035)
2.	Date and time of examination *[hidden]* [Exam Date & Time]	**[BODY_MEAS_DATE_TIME2] (DD/MM/YYYY hh:mm)** Req / Req / Req (2023-2030) Req/Unk : Req/Unk *24-hour clock*
3. * ✔	Body weight (Measured at site visits without shoes, with an empty bladder and only wearing light clothing) [Body weight]	**[grpBODY_WEIGHT2]** **[BODY_WEIGHT2] [BODY_WEIGHT_UNIT2]** xxx.x *[A:220]* kg *[A:700]* lb
4.	Body weight derived (calculated) *[hidden]* [Body Weight]	**[BODY_WEIGHT_DERIVE_3]** xxx.x kg[b]
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 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
clBODY_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]

#		Seq. No.	What dose was taken	What date was the dose taken	Rationale for the dose
1					

Study ID: NN9536-4512
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.

Dosing collection from last visit [sctDOSE]

1.	Seq. No. *[read-only]* [Seq. No.]	**[DOSE_SEQ_NO]** N2
2.* ✔	What dose was taken [What dose was taken]	**[DOSETAKENinmg]** **[DOSE1]** *[A:1]* 0.25 mg *[A:2]* 0.50 mg *[A:3]* 1.0 mg *[A:4]* 1.7 mg *[A:5]* 2.4 mg *[A:6]* Missed dose *[A:7]* Took study drug, do not remember dose *[A:999]* **[DOSETAKENOTHER_1]** Other, specify xx.xx
3.* ✔	What date was the dose taken [What date was the dose taken]	**[DOSESTARTDATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
4.* ✔	Rationale for the dose [Rationale for the dose]	**[RATIONALE]** *[A:1]* Dose escalation *[A:2]* Target dose/Maximum Tolerated Dose (MTD) reached *[A:3]* Re-initiate previous dose *[A:4]* Dose reduction due to tolerability/Adverse Event *[A:999]* **[RATIONALEOTHER]** Other, specify A128

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: 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: !

	Seq. No.	What dose was taken	What date was the dose taken	Rationale for the dose
1. ✔				

Dosing collection from last visit

1.1	Seq. No. *[read-only]* [Seq. No.]	**[DOSEPK_SEQ_NO]** N2
1.2* ✔	What dose was taken [What dose was taken]	**[grpPKDOSETAKEN]** **[DOSE2]** *[A:1]* 0.25 mg *[A:2]* 0.50 mg *[A:3]* 1.0 mg *[A:4]* 1.7 mg *[A:5]* 2.4 mg *[A:6]* Missed dose *[A:7]* Took study drug, do not remember dose *[A:999]* **[PK_DOSE_OTHER_1]** Other, specify xx.xx
1.3* ✔	What date was the dose taken [What date was the dose taken]	**[PKDOSESTARTDATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
1.4* ✔	Rationale for the dose [Rationale for the dose]	**[PKRATIONALE]** *[A:1]* Dose escalation *[A:2]* Target dose/Maximum Tolerated Dose (MTD) reached *[A:3]* Re-initiate previous dose *[A:4]* Dose reduction due to tolerability/Adverse Event *[A:999]* **[PK_RATIONAL_OTHER]** Other, Specify A200

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]* 0.25 mg *[A:2]* 0.50 mg *[A:3]* 1.0 mg *[A:4]* 1.7 mg *[A:5]* 2.4 mg *[A:6]* Missed dose *[A:7]* Took study drug, do not remember dose *[A:999]* **[PK_DOSE_OTHER_2]** Other, specify xx.xx
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 / Req / Req (2023-2030) NReq : NReq *24-hour clock*
4.* ✔	Rationale for the dose [Rationale for the dose]	**[PKRATIONALE2]** *[A:1]* Dose escalation *[A:2]* Target dose/Maximum Tolerated Dose (MTD) reached *[A:3]* Re-initiate previous dose *[A:4]* Dose reduction due to tolerability/Adverse Event *[A:999]* **[PK_RATIONAL_OTHER2]** Other, Specify A200

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]* 0.25 mg *[A:2]* 0.50 mg *[A:3]* 1.0 mg *[A:4]* 1.7 mg *[A:5]* 2.4 mg *[A:6]* Missed dose *[A:7]* Took study drug, do not remember dose *[A:999]* **[PK_DOSE_OTHER_3]** Other, specify xx.xx
6.* ✔	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]	**[PKDOSESTARTDATE3] (DD/MM/YYYY hh:mm)** Req / Req / Req (2023-2030) NReq : NReq *24-hour clock*
7.* ✔	Rationale for the dose [Rationale for the dose]	**[PKRATIONALE3]** *[A:1]* Dose escalation *[A:2]* Target dose/Maximum Tolerated Dose (MTD) reached *[A:3]* Re-initiate previous dose *[A:4]* Dose reduction due to tolerability/Adverse Event *[A:999]* **[PK_RATIONAL_OTHER3]** Other, Specify A200

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
clDOSE_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	

			Other, specify	999	citmDOSE9	
Rationa	[illegible]		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_DOSECOLLECTION_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	VARCHAR2
	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	VARCHAR2
PKRATIONALE3	PKRATIONALE3_C	VARCHAR2
	PKRATIONALE3	VARCHAR2
	PKRATIONALE3_ND	VARCHAR2
PKRATIONALE3 - PK_RATIONAL_OTHER3	PK_RATIONAL_OTHER3	VARCHAR2
***RD_DOSECOLLECTION_WITHPK_SCTDOSECOLLECTION_WITHPK**		
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.

: Drug administration (Drug Admin) [DRUG_ADMIN]

Study ID: †
To be comp†^ **he participants10 years old and above.

1.*	Who administered the drug since last recorded. Please tick all that apply [Who administered the drug since last recorded. Please tick all that apply]	**[DRUG_ADMIN_1]** *[A:1]* ☐ Participant *[A:2]* ☐ Parent(s)/LAR (Legally Acceptable Representative) *[A:3]* ☐ Investigator/Site staff *[A:4]* ☐ **[DRUG_ADMIN_TEXT]** Other,specify A200

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

Study Object Descriptions: Drug administration

Type	RefName	Description
Form	DRUG_ADMIN	Visit: V6, V10,V14,V20,V24,V30

Codelist Values Tables: Drug administration

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clDRUG_ADMIN	String		Participant	1	citmDRUG_ADMIN1	DRUG_ADMIN_1
			Parent(s)/LAR (Legally Acceptable Representative)	2	citmDRUG_ADMIN2	
			Investigator/Site staff	3	citmDRUG_ADMIN3	
			Other	4	citmDRUG_ADMIN4	

RDE Analytics: RD_DRUG_ADMIN

Data Variable RefName	RD Column Name	Column Data Type
DRUG_ADMIN_1	DRUG_ADMIN_1_ND	VARCHAR2
DRUG_ADMIN_1 - Participant	*DRUG_ADMIN_1_CITMDRUGADMIN1_C	VARCHAR2
	*DRUG_ADMIN_1_CITMDRUGADMIN1	VARCHAR2
DRUG_ADMIN_1 - Parent(s)/LAR (Legally Acceptable Representative)	*DRUG_ADMIN_1_CITMDRUGADMIN2_C	VARCHAR2
	*DRUG_ADMIN_1_CITMDRUGADMIN2	VARCHAR2
DRUG_ADMIN_1 - Investigator/Site staff	*DRUG_ADMIN_1_CITMDRUGADMIN3_C	VARCHAR2
	*DRUG_ADMIN_1_CITMDRUGADMIN3	VARCHAR2
DRUG_ADMIN_1 - Other	*DRUG_ADMIN_1_DRUG_ADMIN_TEXT_C	VARCHAR2
	*DRUG_ADMIN_1_DRUG_ADMIN_TEXT	VARCHAR2
DRUG_ADMIN_1 - DRUG_ADMIN_TEXT	DRUG_ADMIN_TEXT	VARCHAR2

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

: Evaluation of glycaemic status (Eval glycaemic status) [EVAL_GLY_STAT_2]

Study ID:
Note: ONLY ···thout T2D.
Please eval.. .'s glycaemic status based on all available information

1.	Glycaemic status [Glycaemic status]	**[GLYCAEMIC_2]** *[A:418]* ◯ Normo-glycaemia *[A:419]* ◯ Pre-diabetes *[A:420]* ◯ Diagnosed with type 2 diabetes

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

Study Object Descriptions: Evaluation of glycaemic status

Type	RefName	Description
Form	EVAL_GLY_STAT_2	Visit: V14, V24, V30, V35

Codelist Values Tables: Evaluation of glycaemic status

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clGLYCAEMIC_STATUS2	String		Normo-glycaemia	418	citmGLYCAEMIC_STATUS2_1	GLYCAEMIC_2
			Pre-diabetes	419	citmGLYCAEMIC_STATUS2_2	
			Diagnosed with type 2 diabetes	420	citmGLYCAEMIC_STATUS2_3	

RDE Analytics: RD_EVAL_GLY_STAT_2

Data Variable RefName	RD Column Name	Column Data Type
GLYCAEMIC_2	GLYCAEMIC_2_C	VARCHAR2
	GLYCAEMIC_2	VARCHAR2
	GLYCAEMIC_2_ND	VARCHAR2

: C-SSRS Since Last Visit (C-SSRS Since Last Visit) [CSSRSLAST]

Study ID: I
Note: Gro[illegible]

SUICIDAL IDEATION [sctCSSRSLAST_1]

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.

1.*	Wish to be Dead [Wish to be Dead]	**[CSSRSLAST_1]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSLAST_1_DESC]** Yes If yes, describe: A200
2.*	Non-Specific Active Suicidal Thoughts [Non-Specific Active Suicidal Thoughts]	**[CSSRSLAST_2]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSLAST_2_DESC]** Yes If yes, describe: A200
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]	**[CSSRSLAST_3]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSLAST_3_DESC]** Yes If yes, describe: A200
4.	Active Suicidal Ideation with Some Intent to Act, without Specific Plan [Active Suicidal Ideation with Some Intent to Act, without Specific Plan]	**[CSSRSLAST_4]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSLAST_4_DESC]** Yes If yes, describe: A200
5.	Active Suicidal Ideation with Specific Plan and Intent [Active Suicidal Ideation with Specific Plan and Intent]	**[CSSRSLAST_5]** *[A:2]* ○ No *[A:1]* ○ **[CSSRSLAST_5_DESC]** Yes If yes, describe: A200

INTENSITY OF IDEATION [sctCSSRSLAST_2]

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:]	**[grpCSSRSLAT_MSIDEATION]** **[CSSRSLAT_MSIDEATION]** *[A:1]* ○ 1. Wish to be dead *[A:2]* ○ 2. Non-Specific Active Suicidal Thoughts *[A:3]* ○ 3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act *[A:4]* ○ 4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan *[A:5]* ○ 5. Active Suicidal Ideation with Specific Plan and Intent
7.	Frequency [Frequency]	**[CSSRSLAST_IDEA_1]** *[A:1]* ○ Less than once a week *[A:2]* ○ Once a week *[A:3]* ○ 2-5 times in week *[A:4]* ○ Daily or almost daily *[A:5]* ○ Many times each day
8.	Duration [Duration]	**[CSSRSLAST_IDEA_2]** *[A:1]* ○ Fleeting - few seconds or minutes *[A:2]* ○ Less than 1 hour/some of the time *[A:3]* ○ 1-4 hours/a lot of time *[A:4]* ○ 4-8 hours/most of day *[A:5]* ○ More than 8 hours/persistent or continuous
9.	Controllability [Controllability]	**[CSSRSLAST_IDEA_3]** *[A:1]* ○ Easily able to control thoughts *[A:2]* ○ Can control thoughts with little difficulty *[A:3]* ○ Can control thoughts with some difficulty *[A:4]* ○ Can control thoughts with a lot of difficulty *[A:5]* ○ Unable to control thoughts *[A:0]* ○ Does not attempt to control thoughts
10.	Deterrents [Deterrents]	**[CSSRSLAST_IDEA_4]** *[A:1]* ○ Deterrents definitely stopped you from attempting suicide *[A:2]* ○ Deterrents probably stopped you *[A:3]* ○ Uncertain that deterrents stopped you *[A:4]* ○ Deterrents most likely did not stop you *[A:5]* ○ Deterrents definitely did not stop you *[A:0]* ○ Does not apply
11.	Reasons for Ideation [Reasons for Ideation]	**[CSSRSLAST_IDEA_5]** *[A:1]* ○ Completely to get attention, revenge or a reaction from others *[A:2]* ○ Mostly to get attention, revenge or a reaction from others *[A:3]* ○ Equally to get attention, revenge or a reaction from others and to end/stop the pain. *[A:4]* ○ Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) *[A:5]* ○ Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) *[A:0]* ○ Does not apply

SUICIDAL BEHAVIOR [sctCSSRSLAST_2_1]

(Check all that apply, so long as these are separate events; must ask about all types)

12.	Actual Attempt: [Actual Attempt]	**[CSSRSLAST_ATTEMPT]** *[A:2]* ○ No *[A:1]* ○ **[grpCSSRSLAST_ATTEMPT]** Yes If yes, describe: **[CSSRSLAST_SU_ATTEMPT]** Total # of Attempts N2 **[CSSRSLAST_SU_ATTEMPT_TEXT]** If yes, describe: A200 **[CSSRLAST_SUICIDE]** Has subject engaged in Non-Suicidal Self-Injurious Behavior? *[A:2]* ○ No *[A:1]* ○ Yes

	mpt: [empt:]	**[CSSRLAST_INTER]** *[A:2]* No *[A:1]* **[grpCSSRLAST_BEHAVIOR]** Yes If yes, describe: **[CSSRLAST_INTERRUPTED]** Total # of Attempts N2 **[CSSRLAST_ABORTED_TEXT]** describe: A200
14.	Aborted Attempt: [Aborted Attempt:]	**[CSSRLAST_ABORT]** *[A:2]* No *[A:1]* **[grpCSSRLAST_ABORT]** Yes If yes, describe: **[CSSRLAST_NO_ABORT]** Total # of aborted N2 **[CSSRLAST_ABORT_TEXT]** describe: A200
15.	Preparatory Acts or Behavior: [Suicide]	**[CSSRLAST_BEHAVIOR]** *[A:2]* No *[A:1]* **[CSSRLAST_BEHAVIOR_TEXT]** Yes If yes, describe: A200
16.	Suicidal Behavior: [Suicidal Behavior:]	**[CSSRLAST_SUICIDE_BEH]** *[A:2]* No *[A:1]* Yes
17.	Suicide: [Suicide:]	**[CSSRLAST_SUICIDE_1]** *[A:2]* No *[A:1]* Yes
Answer for Actual Attempts Only [sctCSSRSLAST_4]		
18.	Most Lethal Attempt Actual Lethality/Medical Damage: [Most Lethal]	**[grpCSSRSLAST_ATTEMPT_1]** **[CSSRSLAST_ATTEM_DATE_1] (DD/MM/YYYY)** Req / Req / Req (2023-2030) **[CSSRSLAST_ATTEM_DAMAGE_1]** *[A:0]* **[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:1]* 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

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 Since Last Visit

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
clCSSRSLAST_1	String		No	2	citmCSSRSLAST_2_2	CSSRSLAST_1, CSSRSLAST_2, CSSRSLAST_3, CSSRSLAST_4, CSSRSLAST_5
			Yes	1	citmCSSRSLAST_2_1	
clCSSRSBASE_MSIDEATION	String		1. Wish to be dead	1	citmCSSRSBASE_MSIDEATION1	CSSRSLAT_MSIDEATION
			2. Non-Specific Active Suicidal Thoughts	2	citmCSSRSBASE_MSIDEATION2	
			3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act	3	citmCSSRSBASE_MSIDEATION3	
			4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan	4	citmCSSRSBASE_MSIDEATION4	
			5. Active Suicidal Ideation with Specific Plan and Intent	5	citmCSSRSBASE_MSIDEATION5	
clCSSRSLAST_IDEA_1	String		Less than once a week	1	citmCSSRSLAST_IDEA_1	CSSRSLAST_IDEA_1
			Once a week	2	citmCSSRSLAST_IDEA_2	
			2-5 times in week	3	citmCSSRSLAST_IDEA_3	
			Daily or almost daily	4	citmCSSRSLAST_IDEA_4	
			Many times each day	5	citmCSSRSLAST_IDEA_5	
clCSSRSLAST_IDEA_2	String		Fleeting - few seconds or minutes	1	citmCSSRSLAST_IDEA_2_1	CSSRSLAST_IDEA_2
			Less than 1 hour/some of the time	2	citmCSSRSLAST_IDEA_2_2	
			1-4 hours/a lot of time	3	citmCSSRSLAST_IDEA_2_3	
			4-8 hours/most of day	4	citmCSSRSLAST_IDEA_2_4	
			More than 8 hours/persistent or continuous	5	citmCSSRSLAST_IDEA_2_5	
clCSSRSLAST_IDEA_3	String		Easily able to control thoughts	1	citmCSSRSLAST_IDEA_3_1	CSSRSLAST_IDEA_3
			Can control thoughts with little difficulty	2	citmCSSRSLAST_IDEA_3_2	
			Can control thoughts with some difficulty	3	citmCSSRSLAST_IDEA_3_3	
			Can control thoughts with a lot of difficulty	4	citmCSSRSLAST_IDEA_3_4	
			Unable to control thoughts	5	citmCSSRSLAST_IDEA_3_5	
			Does not attempt to control thoughts	0	citmCSSRSLAST_IDEA_3_0	
clCSSRSLAST_IDEA_4	String		Deterrents definitely stopped you from attempting suicide	1	citmCSSRSLAST_IDEA_4_1	CSSRSLAST_IDEA_4
			Deterrents probably stopped you	2	citmCSSRSLAST_IDEA_4_2	
			Uncertain that deterrents stopped you	3	citmCSSRSLAST_IDEA_4_3	
			Deterrents most likely did not stop you	4	citmCSSRSLAST_IDEA_4_4	
			Deterrents definitely did not stop you	5	citmCSSRSLAST_IDEA_4_5	
			Does not apply	0	citmCSSRSLAST_IDEA_4_0	
clCSSRSLAST_IDEA_5	String		Completely to get attention, revenge or a reaction from others	1	citmCSSRSLAST_IDEA_5_1	CSSRSLAST_IDEA_5
			Mostly to get attention, revenge or a reaction from others	2	citmCSSRSLAST_IDEA_5_2	
			Equally to get attention, revenge or a reaction from others and to end/stop the pain.	3	citmCSSRSLAST_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	citmCSSRSLAST_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	citmCSSRSLAST_IDEA_5_5	
			Does not apply	0	citmCSSRSLAST_IDEA_5_0	

IPT	String		No	2	citmCSSRSLAST_2_2_1	CSSRSLAST_ATTEMPT
			Yes	1	citmCSSRSLAST_2_1_1	
clCSSRLAST	String		No	2	citmCSSRLAST_SUICIDE_2	CSSRLAST_SUICIDE, CSSRLAST_ABORT, CSSRLAST_SUICIDE_BEH
			Yes	1	citmCSSRLAST_SUICIDE_1	
clCSSRLAST_INTER	String		No	2	citmCSSRLAST_SUICIDE_2_1	CSSRLAST_INTER
			Yes	1	citmCSSRLAST_SUICIDE_1_1	
clCSSRLAST_SUICIDE_2	String		No	2	citmCSSRLAST_SUICIDE_2	CSSRLAST_BEHAVIOR
			Yes	1	citmCSSRLAST_SUICIDE_1	
clCSSRLAST_SUICIDE_1	String		No	2	citmCSSRLAST_SUICIDE_2_1_1	CSSRLAST_SUICIDE_1
			Yes	1	citmCSSRLAST_SUICIDE_1_1_1	
clCSSRSLAST_ATTEM_DAMAGE_1	String		No physical damage or very minor physical damage	0	citmCSSRSLAST_ATTEM_DAMAGE_1_0	CSSRSLAST_ATTEM_DAMAGE_1
			Minor physical damage	1	citmCSSRSLAST_ATTEM_DAMAGE_1_1	
			Moderate physical damage; medical attention needed	2	citmCSSRSLAST_ATTEM_DAMAGE_1_2	
			Moderately severe physical damage; medical hospitalization and likely intensive care required	3	citmCSSRSLAST_ATTEM_DAMAGE_1_3	
			Severe physical damage; medical hospitalization with intensive care required	4	citmCSSRSLAST_ATTEM_DAMAGE_1_4	
			Death	5	citmCSSRSLAST_ATTEM_DAMAGE_1_5	
clCSSRSBASE_ATTEM_DAMAGE_2_1	String		Behavior not likely to result in injury	0	citmCSSRSLAST_ATTEM_DAMAGE_3_0	CSSRSLAST_ATTEM_DAMAGE_2
			Behavior likely to result in injury but not likely to cause death	1	citmCSSRSLAST_ATTEM_DAMAGE_3_1	
			Behavior likely to result in death despite available medical care	2	citmCSSRSLAST_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	VARCHAR2
	CSSRSLAST_1_ND	VARCHAR2
CSSRSLAST_1 - CSSRSLAST_1_DESC	CSSRSLAST_1_DESC	VARCHAR2
CSSRSLAST_2	CSSRSLAST_2_C	VARCHAR2
	CSSRSLAST_2	VARCHAR2
	CSSRSLAST_2_ND	VARCHAR2
CSSRSLAST_2 - CSSRSLAST_2_DESC	CSSRSLAST_2_DESC	VARCHAR2
CSSRSLAST_3	CSSRSLAST_3_C	VARCHAR2
	CSSRSLAST_3	VARCHAR2
	CSSRSLAST_3_ND	VARCHAR2
CSSRSLAST_3 - CSSRSLAST_3_DESC	CSSRSLAST_3_DESC	VARCHAR2
CSSRSLAST_4	CSSRSLAST_4_C	VARCHAR2
	CSSRSLAST_4	VARCHAR2
	CSSRSLAST_4_ND	VARCHAR2
CSSRSLAST_4 - CSSRSLAST_4_DESC	CSSRSLAST_4_DESC	VARCHAR2
CSSRSLAST_5	CSSRSLAST_5_C	VARCHAR2
	CSSRSLAST_5	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	VARCHAR2
CSSRSLAST_IDEA_1	CSSRSLAST_IDEA_1_C	VARCHAR2
	CSSRSLAST_IDEA_1	VARCHAR2
	CSSRSLAST_IDEA_1_ND	VARCHAR2
CSSRSLAST_IDEA_2	CSSRSLAST_IDEA_2_C	VARCHAR2
	CSSRSLAST_IDEA_2	VARCHAR2
	CSSRSLAST_IDEA_2_ND	VARCHAR2
CSSRSLAST_IDEA_3	CSSRSLAST_IDEA_3_C	VARCHAR2
	CSSRSLAST_IDEA_3	VARCHAR2
	CSSRSLAST_IDEA_3_ND	VARCHAR2
CSSRSLAST_IDEA_4	CSSRSLAST_IDEA_4_C	VARCHAR2
	CSSRSLAST_IDEA_4	VARCHAR2
	CSSRSLAST_IDEA_4_ND	VARCHAR2
CSSRSLAST_IDEA_5	CSSRSLAST_IDEA_5_C	VARCHAR2
	CSSRSLAST_IDEA_5	VARCHAR2
	CSSRSLAST_IDEA_5_ND	VARCHAR2
CSSRSLAST_ATTEMPT	CSSRSLAST_ATTEMPT_C	VARCHAR2
	CSSRSLAST_ATTEMPT	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 - CSSRLAST_SUICIDE	CSSRLAST_SUICIDE_C	VARCHAR2
	CSSRLAST_SUICIDE	VARCHAR2
CSSRLAST_INTER	CSSRLAST_INTER_C	VARCHAR2
	CSSRLAST_INTER	VARCHAR2
	CSSRLAST_INTER_ND	VARCHAR2
CSSRLAST_INTER - CSSRLAST_INTERRUPTED	CSSRLAST_INTERRUPTED	NUMBER
CSSRLAST_INTER - CSSRLAST_ABORTED_TEXT	CSSRLAST_ABORTED_TEXT	VARCHAR2
CSSRLAST_ABORT	CSSRLAST_ABORT_C	VARCHAR2
	CSSRLAST_ABORT	VARCHAR2
	CSSRLAST_ABORT_ND	VARCHAR2
CSSRLAST_ABORT - CSSRLAST_NO_ABORT	CSSRLAST_NO_ABORT	NUMBER
CSSRLAST_ABORT - CSSRLAST_ABORT_TEXT	CSSRLAST_ABORT_TEXT	VARCHAR2
CSSRLAST_BEHAVIOR	CSSRLAST_BEHAVIOR_C	VARCHAR2
	CSSRLAST_BEHAVIOR	VARCHAR2
	CSSRLAST_BEHAVIOR_ND	VARCHAR2
CSSRLAST_BEHAVIOR - CSSRLAST_BEHAVIOR_TEXT	CSSRLAST_BEHAVIOR_TEXT	VARCHAR2
CSSRLAST_SUICIDE_BEH	CSSRLAST_SUICIDE_BEH_C	VARCHAR2
	CSSRLAST_SUICIDE_BEH	VARCHAR2
	CSSRLAST_SUICIDE_BEH_ND	VARCHAR2
CSSRLAST_SUICIDE_1	CSSRLAST_SUICIDE_1_C	VARCHAR2
	CSSRLAST_SUICIDE_1	VARCHAR2
	CSSRLAST_SUICIDE_1_ND	VARCHAR2
grpCSSRSLAST_ATTEMPT_1	GRPCSSRSLAST_ATTEMPT_1_ND	VARCHAR2
grpCSSRSLAST_ATTEMPT_1 - CSSRSLAST_ATTEM_DATE_1	CSSRSLAST_ATTEM_DATE_1	DATE

	CSSRSLAST_ATTEM_DATE_1_DTS	VARCHAR2
grpCSSR ast ttpm t 1 - CSSRSLAST_ATTEM_DAMAGE_1	CSSRSLAST_ATTEM_DAMAGE_1_C	VARCHAR2
	CSSRSLAST_ATTEM_DAMAGE_1	VARCHAR2
grpCSSRSLAST_ATTEMPT_1 - CSSRSLAST_ATTEM_DAMAGE_2	CSSRSLAST_ATTEM_DAMAGE_2_C	VARCHAR2
	CSSRSLAST_ATTEM_DAMAGE_2	VARCHAR2

: Adverse Events (AE) - Repeating Form [AE_MEDDRA3]

#		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								

Study ID: NN9536-4512

1. Adverse event number *[read-only]*
[AE No.]
[AE_NO_SEQ_NO]
0 < N3

2.* Onset date of AE
[AE Onset Date]
[AE_START_DATE] (DD/MM/YYYY)
Req / Req / Req (2023-2030)

3. Onset date and time of AE *[hidden]*
[AE Onset Date & Time]
[AE_START_DATE_TIME] (DD/MM/YYYY hh:mm)
Req / Req / Req (2022-2035)
Req/Unk : Req/Unk *24-hour clock*

4.* AE diagnosis (if known) or sign/symptom

Report only one sign/symptom per AE form
[AE Symptoms]
[MEDDRA_AE_TEXT]
A200

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] ◯ No
[A:1] ◯ **[grpAE_SERIOUS]**
Yes
Seriousness criteria:
[DEATH_YN]
Death *[A:2]* ◯ No *[A:1]* ◯ **[grpAUTOPSY_YN]**
Yes
[AUTOPSY_YN]
Was an autopsy performed/planned?
[A:2] ◯ No *[A:1]* ◯ Yes
[LIFE_THREAT_YN]
Life-threatening *[A:2]* ◯ No *[A:1]* ◯ Yes
[HOSPITAL_YN]
In-patient hospitalisation/prolongation of existing hospitalisation *[A:2]* ◯ No *[A:1]* ◯ **[grpADM_DISCH_DATE]**
Yes
[HOSP_ADMISSION_DATE] (DD/MM/YYYY)
Date of admission:
Req/Unk / Req/Unk / Req (2023-2030)
[HOSP_DISCHARGE_DATE] (DD/MM/YYYY)
Date of discharge:
Req/Unk / Req/Unk / Req (2023-2030)
[DISABI_INCAPACITY_YN]
Persistent or significant disability/incapacity *[A:2]* ◯ No *[A:1]* ◯ Yes
[CONGENI_BIRTH_DEF_YN]
Congenital anomaly/birth defect *[A:2]* ◯ No *[A:1]* ◯ Yes
[MEDICAL_EVENT_IMP_YN]
Important medical event *[A:2]* ◯ No *[A:1]* ◯ Yes

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] ◯ Mild
[A:2] ◯ Moderate
[A:3] ◯ Severe

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
[Outcome of AE]
[AE_OUTCOME_CODE]
[A:1] ◯ **[grpAE_OUTCOME_CODE1]**
Recovered/resolved
[AE_OUTCOME_CODE1] (DD/MM/YYYY)
Date: Req / Req / Req (2023-2030)
[A:11] ◯ **[grpAE_OUTCOME_CODE11]**
Recovering/resolving
[AE_OUTCOME_CODE11] (DD/MM/YYYY)
Date: Req / Req / Req (2023-2030)
[A:2] ◯ **[grpAE_OUTCOME_CODE2]**
Recovered/resolved with sequelae
[AE_SEQUELAE_DATE] (DD/MM/YYYY)
Date: Req / Req / Req (2023-2030)
[AE_SEQUELAE_TEXT]
Describe sequelae
A200
[A:12] ◯ Not recovered/not resolved
[A:9] ◯ **[grpAE_OUTCOME_CODE9]**
Fatal
[AE_OUTCOME_CODE9] (DD/MM/YYYY)
Date: Req / Req / Req (2023-2030)
[A:5] ◯ Unknown

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] ◯ **[grpAE_OUTCOME_CODE1A]**
Recovered/resolved
[AE_OUTCOME_CODE1A] (DD/MM/YYYY hh:mm)
Date and time:
Req / Req / Req (2022-2035)
Req/Unk : Req/Unk *24-hour clock*
[A:11] ◯ **[grpAE_OUTCOME_CODE11A]**
Recovering/resolving
[AE_OUTCOME_CODE11A] (DD/MM/YYYY hh:mm)
Date and time:
Req / Req / Req (2022-2035)
Req/Unk : Req/Unk *24-hour clock*
[A:2] ◯ **[grpAE_OUTCOME_CODE2A]**
Recovered/resolved with sequelae
[AE_SEQUELAE_DATE_TIME_A] (DD/MM/YYYY hh:mm)
Date and time:
Req / Req / Req (2022-2035)
Req/Unk : Req/Unk *24-hour clock*
[AE_SEQUELAE_TEXT_A]
Describe sequelae
A200
[A:12] ◯ Not recovered/not resolved
[A:9] ◯ **[grpAE_OUTCOME_CODE9A]**
Fatal
[AE_OUTCOME_CODE9A] (DD/MM/YYYY hh:mm)
Date and time:
Req / Req / Req (2022-2035)
Req/Unk : Req/Unk *24-hour clock*
[A:5] ◯ Unknown

	ılify as an event for adjudication as defined in protocol? *If Yes,* *additional information in dedicated form(s) [hidden]* [AE reuu ata]	**[AE_CATEGORY_MATCH_YN]** *[A:2]* No *[A:1]* **[AE_TYPE_CODE]** Yes *[A:ACUTE CORONARY SYNDROME]* Acute coronary syndrome *[A:PANCREATITIS]* Acute pancreatitis *[A:CEREBROVASCULAR EVENT]* Cerebrovascular event *[A:CORONARY ARTERY REVASCULARISATION]* Coronary revascularisation procedure *[A:HEART FAILURE]* Heart failure *[A:HYPOGLYCAEMIC EPISODE]* Hypoglycaemic episode *[A:EVT1]* <Event type 1> *[A:EVT2]* <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]* *[AESI]*	**[AESI_YN]** *[A:2]* No *[A:1]* Yes
13.	If the AE PT search resulted in a match, select adverse event category *[hidden]* [PT search]	**[PT_TRIAGE_YN]** *[A:CAT1]* Acute coronary syndrome *[A:CAT2]* Acute pancreatitis *[A:CAT3]* Cerebrovascular event *[A:CAT4]* Coronary revascularisation procedure *[A:CAT5]* Heart failure *[A:CAT6]* Hypoglycaemic episode *[A:CAT14]* Category 1 *[A:CAT15]* Category 2

Details of investigational medicinal product (IMP) given before AE onset [sctTRIAL_DRUG_INFO]

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	Action taken to product	Tech complaint related AE?	Action taken to product – Previous
14.a	Semaglutide/ Semaglutide placebo					

Details of investigational medicinal product (IMP) given before AE onset Entry [sctTRIAL_DRUG_INFO]

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*

14.1	Investigational Medicinal Product [IMP]	**[TRIAL_DRUG_CODE]** *[N:1]* Semaglutide/ Semaglutide placebo
14.2*	Product given? [Product given?]	**[PROD_ADM_YN]** *[A:1]* Yes *[A:2]* No
14.3	Causality [Causality]	**[AE_RELATION_CODE]** *[A:1]* Probable *[A:2]* Possible *[A:3]* Unlikely
14.4	Action taken to product [Action taken to product]	**[AE_DRUG_CHANGE_CODE]** *[A:24]* Drug interrupted *[A:25]* Drug withdrawn *[A:19]* Dose reduced *[A:20]* Dose increased *[A:21]* Dose not changed *[A:996]* Unknown *[A:998]* Not applicable
14.5	Is the AE related to a technical complaint? If yes, fill in the Technical Complaint form. [Tech complaint related AE?]	**[AE_TECH_RELATED_YN]** *[A:2]* No *[A:1]* Yes
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]	**[AE_DRUG_CHANGE_PREVIOUS]** A30

	Sequence number	Hypoglycaemic episode no.
15.		

Related hypoglycaemic episodes (if any) Entry [sct_REL_HYPO]

15.1	Sequence number *[read-only]* [Sequence number]	**[AE_HYPO_NO]** N3
15.2	Hypoglycaemic episode no. [Hypoglycaemic episode no.]	**[HYPO_NO]** 0 < N3
16.	Office use only *Item used for SAE notification [hidden]* [Office Use]	**[SAE_OFFICE]** N3
17.	Office use only *Item used to track changes in severity, action taken to product and seriousness. [hidden]* [Office Use]	**[SAE_OFFICE2]** N3
18.	Office use only *Item used to track changes in severity, action taken to product and seriousness. [hidden]* [Office Use]	**[SAE_OFFICE3]** N3

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	TED_YN	Integrations: A - please do not change the refname or format
Item	AE_DR_G_CHA_GE	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)		
sctAE_START		
AE_START_DATE	None	1

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	
clNOYES	String		No	2	citmNOYES2	DEATH_YN, AUTOPSY_YN, HOSPITAL_YN, DISABI_INCAPACITY_YN, CONGENI_BIRTH_DEF_YN, MEDICAL_EVENT_IMP_YN
			Yes	1	citmNOYES1	
clLIFE_THREATENING_YN	String		No	2	citmLIFE_THREATENING_N	LIFE_THREAT_YN
			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_CODE5	
clNOYES_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_ACS	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	HYPOGLYCAEMIC 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	
clTRIAL_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

	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 - DISABI_INCAPACITY_YN	DISABI_INCAPACITY_YN_C	VARCHAR2
	DISABI_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
***RD_AE_MEDDRA3_SCTTRIAL_DRUG_INFO**		
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
***RD_AE_MEDDRA3_SCT_REL_HYPO**		
AE_HYPO_NO	AE_HYPO_NO	NUMBER
	AE_HYPO_NO_ND	VARCHAR2

	HYPO_NO	NUMBER
	HYPO_NO_ND	VARCHAR2

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

: Safety Information Form (SIF) - Repeating Form [SIF]

#	SIF I	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

Related adverse event number(s) [sctAE_NO_SIF]

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	0 < N3	0 < N3	0 < N3	0 < N3	0 < N3	0 < N3	0 < N3	0 < N3	0 < N3	0 < N3

Investigator Information [sctSIF_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] No
[A:1] **[grpINCR_EXAC_SYMPT]**
Yes
[INCR_EXAC_SYMPT]
Did the condition worsen?
[A:1] Yes
[A:2] No
[A:996] Unknown
[A:996] 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] No
[A:1] Yes
[A:996] 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] **[grpAETIOLOGY_DISEASE]**
Underlying disease
[AETIOLOGY_DISEASE]
Specify:
A200

[A:2] **[grpAETIOLOGY_CONCOMMED]**
Concomitant medication
[AETIOLOGY_CONCOMMED]
Specify:
A200

[A:3] **[grpAETIOLOGY_OTHER]**
Other
[AETIOLOGY_OTHER]
Specify:
A200

[A:996] 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] No
[A:1] Yes
[A:996] 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] No
[A:1] **[grpSIF_RAND_DATE]**
Yes
[SIF_RAND_DATE] (DD/MM/YYYY)
Date:
Req / Req / Req (2023-2030)
[A:998] 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] No
[A:1] Yes
[A:996] 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]

		N2
14.2	Investigational Medicinal Product *[read-only]* [IMP]	**[SIF_TRIAL_DRUG_CODE]** *[N:1]* Semaglutide/Semaglutide placebo
14.3* ✔	Was product given at or prior to AE onset? [Was Product Given?]	**[PRODUCT_GIVEN_YN_SIF]** *[A:1]* Yes *[A:2]* No
14.4	Dose [Dose]	**[grpSIF_DOSE]** **[SIF_DOSE]** Dose: xxxx. **[SIF_UNIT]** Unit: **[clSIF_UNIT]** **[SIF_FREQ]** Frequency: **[clSIF_FREQ_CODE]**
14.5	Route [Route]	**[SIF_ROUTE_CODE]** **[clSIF_ROUTE_CODE]**
14.6	Start date of product [Start date of product]	**[SIF_TMT_STDT] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
14.7	Stop date, if product was interrupted / withdrawn [Stop date, if product was interrupted / withdrawn]	**[SIF_DC_TMT_DT] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
14.8	Start date and time of product *[hidden]* [Start date and time of product]	**[SIF_TMT_STDT_STTM] (DD/MM/YYYY hh:mm)** Req / Req / Req (2023-2030) Req/Unk : Req/Unk *24-hour clock*
14.9	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 / Req / Req (2023-2030) Req/Unk : Req/Unk *24-hour clock*
14.10	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_YNNA]** *[A:1]* Yes *[A:2]* No *[A:998]* N/A *[A:996]* Unknown
14.11	Was product reintroduced? [Was product reintroduced?]	**[TP_REINTRODUCED_YNNAUNK]** *[A:1]* **[grpSIF_DOSE_INFO]** Yes **[TP_REINTRODUCED_DATE] (DD/MM/YYYY)** Date: Req / Req / Req (2023-2030) **[SIF_REINTRO_DOSE_INFO]** Specify the dose after reintroduction: *[A:10]* Dose not changed *[A:11]* **[grpSIF_REINTRO_DOSE_RED]** Dose reduced **[SIF_REINTRO_DOSE_RED]** Reduced dose: xxxx. **[SIF_REINTRO_UNIT_RED]** Unit: **[clSIF_UNIT_1]** **[SIF_REINTRO_FREQ_RED]** Frequency: **[clSIF_FREQ_CODE]** *[A:12]* **[grpSIF_REINTRO_DOSE_INCR]** Dose increased **[SIF_REINTRO_DOSE_INCR]** Increased dose: xxxx. **[SIF_REINTRO_UNIT_INCR]** Unit: **[clSIF_UNIT_1]** **[SIF_REINTRO_FREQ_INCR]** Frequency: **[clSIF_FREQ_CODE]** **[AE_REAPPEAR_YNNAUNK]** Did the adverse event reappear after reintroduction? *[A:1]* Yes *[A:2]* No *[A:998]* N/A *[A:996]* Unknown *[A:2]* No *[A:998]* N/A *[A:996]* Unknown
14.12	Product name in Argus *[hidden]* [Product name in Argus]	**[SIF_TRIAL_DRUG_CODE_ARG]** *[N:1]* Blinded Semaglutide

	Date of assessment	Description of assessment	Result of assessment	Reference range
15.				

Relevant assessments and laboratory data/vital signs (performed to confirm the event and/or its outcome) Entry [sctSIF_LAB]

15.1	Assessment index number *[hidden]* [Assessment index number]	**[SIF_ASSMENT_INDEX]** N3
15.2* ✔	Date of assessment [Date of assessment]	**[SIF_ASSMENT_DATE] (DD/MM/YYYY)** Req/Unk / Req / Req (2023-2030)
15.3* ✔	Description of assessment [Description of assessment]	**[SIF_ASSMENT_DESC]** A80
15.4* ✔	Result of assessment [Result of assessment]	**[grpSIF_ASSMENT_RESULT]** **[SIF_ASSENT_UNIT_RESULT]** 0 < xxxxxx. **[SIF_ASSMENT_UNIT]** *[A:1]* **[SIF_ASSMENT_UNIT_LIST]** **[clSIF_ASSMENT_UNIT_LIST]** *[A:999]* **[SIF_ASSMENT_UNIT_OTHER]** Other unit, specify: A25 **[SIF_ASSMENT_RESULT]** Specify if non-numeric result: A600
15.5 ✔	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_ASSMENT_REF_RANGE]** **[SIF_ASSMENT_REF_RANGE_L]** Lower normal limit A50 **[SIF_ASSMENT_REF_RANGE_H]** Upper normal limit A50 **[SIF_ASSMENT_NA]** *[A:996]* 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
nt = Concomitant Medication / Concomitant Medication.
Note: Sou ical settings made in InForm will override any settings made in Central Designer.
Note: Collapsible groups 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	grpAE_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_ASSMENT_INDEX	Populated with a rule, used in Argus integration
Item	SIF_ASSMENT_DATE	Integrations: A, R - please do not change the refname or format
Item	SIF_ASSMENT_DESC	Integrations: A, R - please do not change the refname or format
Item	grpSIF_ASSMENT_RESULT	Integrations: A, R - please do not change the refname or format
Item	grpSIF_ASSMENT_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
clCONDITION_BL_YNUK	String		No	2	citmCONDITION_BL_N	CONDITION_BL_YNUK
			Yes	1	citmCONDITION_BL_Y	
			Unknown	996	citmCONDITION_BL_UK	
clINCR_EXAC_SYMPT	String		Yes	1	citmINCR_EXAC_SYMPT_Y	INCR_EXAC_SYMPT
			No	2	citmINCR_EXAC_SYMPT_N	
			Unknown	996	citmINCR_EXAC_SYMPT_UK	
clSIF_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	
clAETIOLOGY	String		Underlying disease, specify:	1	citmAETIOLOGY_1	AETIOLOGY
			Concomitant medication, specify:	2	citmAETIOLOGY_2	
			Other, specify:	3	citmAETIOLOGY_3	
			Unknown	996	citmAETIOLOGY_4	
clSIF_CM_AE	String		No	2	citmSIF_CM2	SIF_CM_AE
			Yes	1	citmSIF_CM1	
			Unknown	996	citmSIF_CM996	
clSIF_RAND_YNNA	String		No	2	citmSIF_RAND_N	SIF_RAND
			Yes	1	clSIF_RAND_Y	
			N/A	998	citmSIF_RAND_NA	
clPREG_ONSET_YNNAUNK	String		No	2	citmPREG_ONSET_N	PREG_ONSET_YNUNK
			Yes	1	citmPREG_ONSET_Y	
			Unknown	996	citmPREG_ONSET_UNK	
clSIF_TRIAL_DRUG_CODE	Integer	1 - clSIF_TRIAL_DRUG_CODE	Semaglutide/Semaglutide placebo	1	citmSIF_TRIAL_DRUG_CODE1	SIF_TRIAL_DRUG_CODE
clPRODUCT_GIVEN_YN	String		Yes	1	citmPRODUCT_GIVEN_Y	PRODUCT_GIVEN_YN_SIF
			No	2	citmPRODUCT_GIVEN_N	
clSIF_UNIT	String		mg	160	citmSIF_UNIT13	SIF_UNIT
clSIF_FREQ_CODE	String		Once per week	21	citmSIF_FREQ_CODE_21	SIF_FREQ, SIF_REINTRO_FREQ_RED, SIF_REINTRO_FREQ_INCR
clSIF_ROUTE_CODE	String	1 - clSIF_ROUTE_CODE	Subcutaneous	058	citmSIF_ROUTE_CODES8	SIF_ROUTE_CODE
clAE_WD_AE_ABATE_YNNA	String		Yes	1	citmAE_WD_AE_ABATE_Y	AE_WD_AE_ABATE_YNNA
			No	2	citmAE_WD_AE_ABATE_N	
			N/A	998	citmAE_WD_AE_ABATE_NA	
			Unknown	996	citmAE_WD_AE_ABATE_UNK	
clTP_REINTRODUCED_YNNAUNK	String		Yes	1	citmTP_REINTRODUCED_Y	TP_REINTRODUCED_YNNAUNK
			No	2	citmTP_REINTRODUCED_N	
			N/A	998	citmTP_REINTRODUCED_NA	
			Unknown	996	citmTP_REINTRODUCED_UNK	
clSIF_REINTRO_DOSE_INFO	String		Dose not changed	10	citmSIF_REINTRO_DOSE_INFO_SAME	SIF_REINTRO_DOSE_INFO
			Dose reduced	11	citmSIF_REINTRO_DOSE_INFO_RED	
			Dose increased	12	citmSIF_REINTRO_DOSE_INFO_INCR	
clSIF_UNIT_1	String		mg	160	citmNEW_DAILY_DOSE4	SIF_REINTRO_UNIT_RED, SIF_REINTRO_UNIT_INCR
clAE_REAPPEAR_YNNAUNK	String		Yes	1	citmAE_REAPPEAR_Y	AE_REAPPEAR_YNNAUNK
			No	2	citmAE_REAPPEAR_N	

			N/A	998	citmAE_REAPPEAR_NA	
			Unknown	996	citmAE_REAPPEAR_UNK	
clSIF_TRIAL_DRU_CODE_ARG	Integer	1 - clSIF_TRIAL_DRUG_CODE_ARG	Blinded Semaglutide	1	citmSIF_TRIAL_DRUG_CODE_ARG1	SIF_TRIAL_DRUG_CODE_ARG
clSIF_ASSMENT_UN T	String		Unit pull down list 2	1	citmSIF_ASSMENT_UNIT_1	SIF_ASSMENT_UNIT
			OTHER	999	citmSIF_ASSMENT_UNIT_OTHR	
clSIF_ASSMENT_UNIT_LIST	String		pg	100	citmSIF_ASSMENT_UNIT_100	SIF_ASSMENT_UNIT_LIST
			pg/mL	101	citmSIF_ASSMENT_UNIT_101	
			pg/L	102	citmSIF_ASSMENT_UNIT_102	
			ng	120	citmSIF_ASSMENT_UNIT_120	
			ng/mL	121	citmSIF_ASSMENT_UNIT_121	
			ng/dL	122	citmSIF_ASSMENT_UNIT_122	
			ng/L	123	citmSIF_ASSMENT_UNIT_123	
			ug	140	citmSIF_ASSMENT_UNIT_140	
			ug/mL	141	citmSIF_ASSMENT_UNIT_141	
			ug/dL	142	citmSIF_ASSMENT_UNIT_142	
			ug/L	143	citmSIF_ASSMENT_UNIT_143	
			ug/100 mL	149	citmSIF_ASSMENT_UNIT_149	
			mg	160	citmSIF_ASSMENT_UNIT_160	
			mg/mL	161	citmSIF_ASSMENT_UNIT_161	
			mg/dL	162	citmSIF_ASSMENT_UNIT_162	
			mg/L	163	citmSIF_ASSMENT_UNIT_163	
			mg/g	169	citmSIF_ASSMENT_UNIT_169	
			mg/mmol	170	citmSIF_ASSMENT_UNIT_170	
			mg%	171	citmSIF_ASSMENT_UNIT_171	
			mg/uL	177	citmSIF_ASSMENT_UNIT_177	
			g	200	citmSIF_ASSMENT_UNIT_200	
			g/mL	201	citmSIF_ASSMENT_UNIT_201	
			g/dL	202	citmSIF_ASSMENT_UNIT_202	
			g/L	203	citmSIF_ASSMENT_UNIT_203	
			g/uL	208	citmSIF_ASSMENT_UNIT_208	
			g%	211	citmSIF_ASSMENT_UNIT_211	
			mmHg	321	citmSIF_ASSMENT_UNIT_321	
			uL	400	citmSIF_ASSMENT_UNIT_400	
			mL	420	citmSIF_ASSMENT_UNIT_420	
			dL	460	citmSIF_ASSMENT_UNIT_460	
			L	480	citmSIF_ASSMENT_UNIT_480	
			pmol	500	citmSIF_ASSMENT_UNIT_500	
			pmol/L	501	citmSIF_ASSMENT_UNIT_501	
			pmol/min	502	citmSIF_ASSMENT_UNIT_502	
			nmol	520	citmSIF_ASSMENT_UNIT_520	
			nmol/L	521	citmSIF_ASSMENT_UNIT_521	
			umol	540	citmSIF_ASSMENT_UNIT_540	
			umol/L	541	citmSIF_ASSMENT_UNIT_541	
			umol/mL	544	citmSIF_ASSMENT_UNIT_544	
			mmol	560	citmSIF_ASSMENT_UNIT_560	
			mmol/L	561	citmSIF_ASSMENT_UNIT_561	
			mmol/dL	564	citmSIF_ASSMENT_UNIT_564	
			nmol/mL	566	citmSIF_ASSMENT_UNIT_566	
			mU/L	806	citmSIF_ASSMENT_UNIT_806	
			U/mol	809	citmSIF_ASSMENT_UNIT_809	
			U	810	citmSIF_ASSMENT_UNIT_810	
			U/L	811	citmSIF_ASSMENT_UNIT_811	
			U/mL	812	citmSIF_ASSMENT_UNIT_812	
			U/IU	814	citmSIF_ASSMENT_UNIT_814	
			uU/mL	819	citmSIF_ASSMENT_UNIT_819	
			mIU/mL	826	citmSIF_ASSMENT_UNIT_826	
			IU	830	citmSIF_ASSMENT_UNIT_830	
			IU/L	831	citmSIF_ASSMENT_UNIT_831	
			IU/mL	832	citmSIF_ASSMENT_UNIT_832	
			mU/mL	835	citmSIF_ASSMENT_UNIT_835	
			mIU/L	833	citmSIF_ASSMENT_UNIT_833	
			%	850	citmSIF_ASSMENT_UNIT_850	
			NK	996	citmSIF_ASSMENT_UNIT_996	
			ND	997	citmSIF_ASSMENT_UNIT_997	
			NA	998	citmSIF_ASSMENT_UNIT_998	
			Dose Step	798	citmSIF_ASSMENT_UNIT_798	
clSIF_ASSMENT_NA	String		N/A	996	citmSIF_ASSMENT_NA	SIF_ASSMENT_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_GRPAETIOLOGY_DISEASE_C	VARCHAR2
	*AETIOLOGY_GRPAETIOLOGY_DISEASE	VARCHAR2
AETIOLOGY - AETIOLOGY_DISEASE	AETIOLOGY_DISEASE	VARCHAR2
AETIOLOGY - Concomitant medication, specify:	*AETIOLOGY_GRPAETIOLOGY_CONCOMMED_C	VARCHAR2
	*AETIOLOGY_GRPAETIOLOGY_CONCOMMED	VARCHAR2
AETIOLOGY - AETIOLOGY_CONCOMMED	AETIOLOGY_CONCOMMED	VARCHAR2
AETIOLOGY - Other, specify:	*AETIOLOGY_GRPAETIOLOGY_OTHER_C	VARCHAR2
	*AETIOLOGY_GRPAETIOLOGY_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
***RD_SIF_SCTTRIAL_DRUG_INFO_SIF**		
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

– YNNAUNK - SIF_REINTRO_UNIT_RED	SIF_REINTRO_UNIT_RED_C	VARCHAR2
	SIF_REINTRO_UNIT_RED	VARCHAR2
TP_REINTROD_CED_YNNAUNK - SIF_REINTRO_FREQ_RED	SIF_REINTRO_FREQ_RED_C	VARCHAR2
	SIF_REINTRO_FREQ_RED	VARCHAR2
TP_REINTRODUCED_YNNAUNK - SIF_REINTRO_DOSE_INCR	SIF_REINTRO_DOSE_INCR	FLOAT
TP_REINTRODUCED_YNNAUNK - SIF_REINTRO_UNIT_INCR	SIF_REINTRO_UNIT_INCR_C	VARCHAR2
	SIF_REINTRO_UNIT_INCR	VARCHAR2
TP_REINTRODUCED_YNNAUNK - SIF_REINTRO_FREQ_INCR	SIF_REINTRO_FREQ_INCR_C	VARCHAR2
	SIF_REINTRO_FREQ_INCR	VARCHAR2
TP_REINTRODUCED_YNNAUNK - AE_REAPPEAR_YNNAUNK	AE_REAPPEAR_YNNAUNK_C	VARCHAR2
	AE_REAPPEAR_YNNAUNK	VARCHAR2
SIF_TRIAL_DRUG_CODE_ARG	SIF_TRIAL_DRUG_CODE_ARG_C	NUMBER
	SIF_TRIAL_DRUG_CODE_ARG	VARCHAR2
	SIF_TRIAL_DRUG_CODE_ARG_ND	VARCHAR2
RD_SIF_SCTSIF_LAB		
SIF_ASSMENT_INDEX	SIF_ASSMENT_INDEX	NUMBER
	SIF_ASSMENT_INDEX_ND	VARCHAR2
SIF_ASSMENT_DATE	SIF_ASSMENT_DATE	DATE
	SIF_ASSMENT_DATE_DTS	VARCHAR2
	SIF_ASSMENT_DATE_DTR	VARCHAR2
	SIF_ASSMENT_DATE_ND	VARCHAR2
SIF_ASSMENT_DESC	SIF_ASSMENT_DESC	VARCHAR2
	SIF_ASSMENT_DESC_ND	VARCHAR2
grpSIF_ASSMENT_RESULT	GRPSIF_ASSMENT_RESULT_ND	VARCHAR2
grpSIF_ASSMENT_RESULT - SIF_ASSENT_UNIT_RESULT	SIF_ASSENT_UNIT_RESULT	FLOAT
grpSIF_ASSMENT_RESULT - SIF_ASSMENT_UNIT	SIF_ASSMENT_UNIT_C	VARCHAR2
	SIF_ASSMENT_UNIT	VARCHAR2
grpSIF_ASSMENT_RESULT - SIF_ASSMENT_UNIT_LIST	SIF_ASSMENT_UNIT_LIST_C	VARCHAR2
	SIF_ASSMENT_UNIT_LIST	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_NA	SIF_ASSMENT_NA_C	VARCHAR2
	SIF_ASSMENT_NA	VARCHAR2

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

: Medication Error, Misuse and Abuse (Misadministration) - Repeating Form [MISADMIN]

#	lo.	Related AE No.	Investigational medicinal product(s)	Type and reason	Other AE(s)	Any hypo(s)	Classification	Other relevant information
1								

Study ID: NN9536-4512

1. Event number *[read-only]*
[Event No.]
[MISADM_SEQ_NO]
N2

2.* Related adverse event number
[Related AE No.]
[MISADM_AE_NO]
N3

3.* Investigational medicinal product(s) involved in the misadministration
[Investigational medicinal product(s)]
[grpMISADM_IMP]
[MISADM_IMP1]
[A:1] ☐ Semaglutide/Semaglutide placebo

4.* Type of misadministration and the reason
[Type and reason]
[MISADM_TYP]
[A:1] ○ **[MISADM_ACCREAS]**
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_ACCCOM]**
Communication issues
[A:11] ○ Misunderstanding of 'instructions for use'
[A:12] ○ Misunderstanding of training/verbal instruction
[A:999] ○ **[MISADM_ACCOTH]**
Other, specify
A200
[A:2] ○ **[MISADM_INTREAS]**
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

5.* Did the subject experience any other adverse event(s) as a result of the misadministration?
[Other AE(s)]
[MISADM_AE_YN]
[A:2] ○ No
[A:1] ○ **[grpMISADM_AENO]**
Yes
[MISADM_AE1] [MISADM_AE2] [MISADM_AE3] [MISADM_AE4]
Adverse Event No.: N3 N3 N3 N3

6.* Did the subject experience any hypoglycaemic episode(s) as a result of the misadministration?
[Any hypo(s)]
[MISADM_HYPO_YN]
[A:2] ○ No
[A:1] ○ **[grpMISADM_HYPONO]**
Yes
[MISADM_HYPO1] [MISADM_HYPO2] [MISADM_HYPO3] [MISADM_HYPO4]
Hypoglycaemic Episode No.: N3 N3 N3 N3

7.* Classification
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]
[MISADM_CLASS]
[A:1] ○ **[MISADM_PROD]**
Wrong products administered/used
[A:999] ○ **[MISADM_PRODOTH]**
Other, specify
A200
[A:2] ○ **[MISADM_FREQ]**
Wrong frequency of administration
[A:1] ○ **[MISADM_FREQHIOTH]**
Higher frequency, specify
A200
[A:3] ○ **[MISADM_DOSE]**
Wrong dose administered
[A:1] ○ **[MISADM_OVERDOSEOTH]**
Overdose, specify
A200
[A:4] ○ **[MISADM_RUT]**
Wrong route of administration
[A:1] ○ Intravenous
[A:3] ○ Intramuscular
[A:999] ○ **[MISADM_RUTOTH]**
Other, specify
A200
[A:999] ○ **[MISADM_CLASSOTH]**
Other, specify
A200

8. Trial Products *[hidden]*
[Trial Products]
[MISADM_PRODLST]
[cIMISADM_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

	Comment
13.	

Other relevant information Entry [sctMISADMINCOMM]

13.1 Comment
[Comment]
[MISADM_COMM]
A200

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

Study C _riptions: Medication Error, Misuse and Abuse		
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_PRODLST	**Item DEACTIVATED**
Item	MISADM_FREQLOOTH	**Item DEACTIVATED**
Item	MISADM_UNDERDOSEOTH	**Item DEACTIVATED**
Item	MISADM_IMP2	**Item DEACTIVATED**
Item	MISADM_IMP3	**Item DEACTIVATED**

Codelist Values Tables: Medication Error, Misuse and Abuse					
Codelist RefName	**Codelist Data Type**	**Subset**	**Label**	**Code**	**Codelist Item RefName**	**Data Variable RefName**
clMISADM_IMP1	String		Semaglutide/Semaglutide placebo	1	citmMISADM_IMP1	MISADM_IMP1
clMISADM_TYP	String		Accidental misadministration:	1	citmMISADM_TYP_1	MISADM_TYP
			Intentional misadministration (Specify the subject's reason)	2	citmMISADM_TYP_2	
clMISADM_ACCREAS	String		Distraction	1	citmMISADM_ACCREAS1	MISADM_ACCREAS
			Poor eyesight	2	citmMISADM_ACCREAS2	
			Miscalculation	3	citmMISADM_ACCREAS3	
			Mix-up of products	4	citmMISADM_ACCREAS4	
			Dispensing error	5	citmMISADM_ACCREAS5	
			Incorrect handling of product	6	citmMISADM_ACCREAS6	
			Communication issues	7	citmMISADM_ACCREAS7	
			Other, specify	999	citmMISADM_ACCREAS999	
clMISADM_ACCCOM	String		Misunderstanding of 'instructions for use'	11	citmMISADM_ACCCOM_1	MISADM_ACCCOM
			Misunderstanding of training/verbal instruction	12	citmMISADM_ACCCOM_2	
clMIADM_INTREAS	String		For physical effect	8	citmMIADM_INTREA1	MISADM_INTREAS
			For psychological effect	9	citmMIADM_INTREA2	
			To cause harm	10	citmMIADM_INTREA3	
			Other, specify	999	citmMIADM_INTREA999	
clMISADM_AE_YN	String		No	2	citmMISADM_AE_N	MISADM_AE_YN
			Yes	1	citmMISADM_AE_Y	
clMISADM_HYPO_YN	String		No	2	citmMISADM_HYPO_N	MISADM_HYPO_YN
			Yes	1	citmMISADM_HYPO_Y	
clMISADM_CLASS	String		Wrong products administered/used	1	citmMISADM_CLASS_1	MISADM_CLASS
			Wrong frequency of administration	2	citmMISADM_CLASS_2	
			Wrong dose administered	3	citmMISADM_CLASS_3	
			Wrong route of administration	4	citmMISADM_CLASS_4	
			Other, specify	999	citmMISADM_CLASS_999	
clMISADM_PROD	String		Other, specify	999	citmMISADM_PROD_999	MISADM_PROD
clMISADM_FREQ	String		Higher frequency	1	citmMISADM_FREQ_1	MISADM_FREQ
clMISADM_DOSE	String		Overdose	1	citmMISADM_DOSE1	MISADM_DOSE
clMISADM_RUT	String		Intravenous	1	citmMISADM_RUT_1	MISADM_RUT
			Intramuscular	3	citmMISADM_RUT_3	
			Other	999	citmMISADM_RUT_999	
clMISADM_PRODLST	String		Product 2 instead of product 1	1	citmMISADM_PRODLST_1	MISADM_PRODLST
			Product 1 instead of product 2	2	citmMISADM_PRODLST_2	
clMISADM_IMP2	String		Investigational Medicinal product 2	2	citmMISADM_IMP2	MISADM_IMP2
clMISADM_IMP3	String		Investigational Medicinal product 3	3	citmMISADM_IMP3	MISADM_IMP3

RDE Analytics: RD_MISADMIN		
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
grpMISADM_IMP	GRPMISADM_IMP_ND	VARCHAR2
grpMISADM_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_ACCOTH	MISADM_ACCOTH	VARCHAR2
MISADM_TYP - MISADM_INTREAS	MISADM_INTREAS_C	VARCHAR2
	MISADM_INTREAS	VARCHAR2
MISADM_TYP - MISADM_INTOTH	MISADM_INTOTH	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_FREQHIOTH	MISADM_FREQHIOTH	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_RUTOTH	MISADM_RUTOTH	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
***RD_MISADMIN_SCTMISADMINCOMM**		
MISADM_COMM	MISADM_COMM	VARCHAR2
	MISADM_COMM_ND	VARCHAR2

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

: Malignant Neoplasm (Malignant Neoplasm) - Repeating Form [MALIGNANT_NEOPLASM]

#	Mali	n No.	Related AE No.	Specify type of event	Symptoms/signs	Investigation of event	Diagnosis imaging performed	Pathologic examination performed?	Pathologic examination performed	Diagnosis available	Results available	Treatment given	Any relevant risk/confounding factors identified	Undergone screening procedures	Years of exposure	Other relevant information (that confirms this event and/or its outcome, e.g. relevant biomarker and genetic testing)
1																

Study ID: NN9536-4512

1. Malignant Neoplasm event number *[read-only]*
[Malignant Neoplasm No.]
[NEO_SEQ_NO]
0 < N3

2.* ✔ Related adverse event number
[Related AE No.]
[NEO_AE_NO]
0 < N3

3.* ✔ Specify type of event
[Specify type of event]
[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:174]* Lower gastrointestinal tract (jejenum, 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]* **[grpNEO_LOCATION_SKIN]**
  Skin
  [NEO_LOCATION_SKIN_SPEC]
  - *[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

[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 (jejenum, 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]* **[grpNEO_LOCATION_SKIN2]**
  Skin
  [NEO_LOCATION_SKIN_SPEC2]
  - *[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

[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 (jejenum, 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]* **[grpNEO_LOCATION_SKIN3]**
  Skin
  [NEO_LOCATION_SKIN_SPEC3]
  - *[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]**

		Other Specify A200 *[A:4]* ◯ Metastasis of unknown primary neoplasm
4.* ✔	Were symptoms/signs (including test results) suggestive of this neoplasm present prior to administration of investigational medicinal product (IMP)? *Signs/symptoms includes results of study related procedures (physical examination, laboratory testing etc.) performed prior to first administration of IMP* [Symptoms/signs]	**[NEO_SYMP_SUGGEST_YN]** *[A:2]* ◯ No *[A:1]* ◯ **[grpNEO_DISEASE_WORSE_YN]** Yes **[NEO_SYMP_SUGGEST_TEXT]** Specify: A200 **[NEO_DISEASE_WORSENING_YN]** Did condition progress (worsen) during the study? *[A:2]* ◯ No *[A:1]* ◯ **[NEO_DISEASE_WORSE_TEXT]** Yes Specify: A200
5.* ✔	What led to investigation of the event? [Investigation of event]	**[NEO_INVESTIGA_EVENT_CODE]** *[A:1]* ◯ **[NEO_SIGN_SYMPTOM_TEXT]** Signs and symptoms Specify: A200 *[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
6.* ✔	Was diagnostic imaging performed? [Diagnosis imaging performed]	**[NEO_IMAGING_DIAGNOS_YN]** *[A:2]* ◯ No *[A:1]* ◯ **[grpNEO_IMAGING_DIAGNOSIS]** Yes **[NEO_IMAG_DIAG_ENDO]** *[A:110]* ☐ **[NEO_DIAGNO_METHOD_1_TEXT]** Endoscopy Specify imaging result(s) if applicable: A200 **[NEO_IMAG_DIAG_XRAY]** *[A:102]* ☐ **[NEO_DIAGNO_METHOD_2_TEXT]** X-ray Specify imaging result(s) if applicable: A200 **[NEO_IMAG_DIAG_ULTRA]** *[A:103]* ☐ **[NEO_DIAGNO_METHOD_3_TEXT]** Ultrasound Specify imaging result(s) if applicable: A200 **[NEO_IMAG_DIAG_CT]** *[A:104]* ☐ **[NEO_DIAGNO_METHOD_4_TEXT]** CT Scan Specify imaging result(s) if applicable: A200 **[NEO_IMAG_DIAG_MRI]** *[A:105]* ☐ **[NEO_DIAGNO_METHOD_5_TEXT]** MRI Specify imaging result(s) if applicable: A200 **[NEO_IMAG_DIAG_PET]** *[A:109]* ☐ **[NEO_DIAGNO_METHOD_6_TEXT]** PET scan Specify imaging result(s) if applicable: A200 **[NEO_IMAG_DIAG_PETCT]** *[A:107]* ☐ **[NEO_DIAGNO_METHOD_7_TEXT]** PET/CT scan Specify imaging result(s) if applicable: A200 **[NEO_IMAG_DIAG_PETMRI]** *[A:70]* ☐ **[NEO_DIAGNO_METHOD_8_TEXT]** PET/MRI scan Specify imaging result(s) if applicable: A200 **[NEO_IMAG_DIAG_PETSPEC]** *[A:108]* ☐ **[NEO_DIAGNO_METHOD_9_TEXT]** PET/SPECT scan Specify imaging result(s) if applicable: A200 **[NEO_IMAG_DIAG_OTH]** *[A:999]* ☐ **[NEO_DIAGNO_METHOD_10_TEXT]** Other Specify imaging result(s) if applicable: A200

		[A:996] Unknown
7.* ✔	Was i mination performed? *If Yes, , y to specify details below* [Pathologic examination performed?]	**[NEO_PATHOLOGIC_EXAM_YN]** *[A:2]* No *[A:1]* Yes

	Index No.	Date of examination	Pathologic examination	Specify result	Results of the pathologic examination
8.					

Pathologic examination performed Entry [sctPATHOLOGIC_EXAMINATION]

8.1	Assessment index number *[read-only]* [Index No.]	**[NEO_ASSMENT_INDEX]** N3
8.2* ✔	Date of examination [Date of examination]	**[NEO_EXAM_DATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
8.3* ✔	Pathologic examination based on [Pathologic examination]	**[NEO_SAMPLE_TYPE]** *[A:142]* Biopsy specimen *[A:143]* Surgical specimen *[A:1]* Blood
8.4* ✔	Specify results *(including immunostaining, receptor type (if applicable), pathological grading etc.)* [Specify result]	**[NEO_RESULT_TEXT]** A400
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]	**[NEO_PATH_EXAM_YN]** *[A:2]* No *[A:1]* **[grpPATH_EXAM]** Yes **[PATH_RESULTS]** *[A:61]* C-cell hyperplasia *[A:75]* Medullary microcarcinoma (carcinoma in situ) *[A:76]* Medullary carcinoma **[GEN_TEST_YN]** Has any genetic testing for multiple endocrine neoplasia (MEN) been performed? *[A:2]* No *[A:1]* **[GEN_TEST_CON]** Yes Describe the conclusions: A200 *[A:996]* Unknown
9.* ✔	Is a final pathologic diagnosis available? [Diagnosis available]	**[NEO_FINAL_PATHO_DIAG_YN]** *[A:2]* **[NEO_REASON_NOT_DONE_TEXT]** No Specify reason: A200 *[A:1]* **[NEO_FINAL_PATHO_DIA_TEX]** 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]* No *[A:1]* **[NEO_CLINICAL_STAGING_TEXT]** Yes Specify: A200
11.* ✔	Was any treatment(s) given for this condition? *Update concomitant medication as relevant* [Treatment given]	**[NEO_TREATMENT_YN]** *[A:2]* No *[A:1]* **[grpNEO_TREATMENT_Y]** Yes **[NEO_TREATMENT_2]** *[A:2]* Surgery **[NEO_TREATMENT_76]** *[A:76]* Radiation **[NEO_TREATMENT_5]** *[A:5]* Chemotherapy **[NEO_TREATMENT_77]** *[A:77]* Hormonal therapy **[NEO_TREATMENT_78]** *[A:78]* Observation **[NEO_TREATMENT_79]** *[A:79]* Palliative care **[NEO_TREATMENT_121]** *[A:121]* Immunotherapy **[NEO_TREATMENT_999]** *[A:999]* **[NEO_TREATMENT_OTH_TEXT]** Other Specify: A200
12.* ✔	Were there any relevant risk/confounding factors identified? [Any relevant risk/confounding factors identified]	**[NEO_RISK_CON_FACTOR_YN]** *[A:2]* No *[A:1]* **[grpNEO_RISK_CON_FACT_YES]** Yes **[NEO_RISK_CON_FA_1]** *[A:30]* **[NEO_RISK_CON_FA_1_TEXT]** Occupational exposure Specify: A200

[NEO_RISK_CON_FA_2]
[A:31] ☐ **[NEO_RISK_CON_FA_2_TEXT]**
Smoking
Specify:
A200

[NEO_RISK_CON_FA_3]
[A:32] ☐ **[NEO_RISK_CON_FA_3_TEXT]**
Sun exposure
Specify:
A200

[NEO_RISK_CON_FA_6]
[A:35] ☐ **[NEO_RISK_CON_FA_6_TEXT]**
Family history of neoplasm
Specify:
A200

[NEO_RISK_CON_FA_7]
[A:999] ☐ **[NEO_RISK_CON_FA_7_TEXT]**
Other
Specify:
A200

13.* ✔ Has the subject undergone screening procedures for this type of event prior to administration of investigational medicinal product?

Screening refers to e.g. national screening programmes for breast cancer or colorectal cancer.

Normal: no signs of disease
Abnormal: neoplasm observed
Indeterminate: possible indication of dysplasia/abnormal growth
[Undergone screening procedures]

[NEO_SCREENING_PROC_YN]
[A:2] ○ No
[A:1] ○ **[grpNEO_METHOD_CODE]**
Yes
[NEO_METHOD_CODE_IMAG]
Specify the latest type(s) of investigation:
[A:26] ☐ **[grp_NEO_METHOD_IMAG]**
Imaging
[NEO_PROCEDURE_1_DATE] (DD/MM/YYYY)
Date of investigation
Req/Unk / Req/Unk / Req (1900-2030)
[NEO_NORMAL_ABN_CODE_1]
Specify outcome
[A:1] ○ Normal
[A:2] ○ Abnormal
[A:80] ○ Indeterminate
[FOLLOW_UP_PLAN_YN_1]
Was a follow-up planned?
[A:2] ○ No
[A:1] ○ Yes
[NEO_METHOD_CODE_ENDO]
[A:110] ☐ **[grp_NEO_METHOD_ENDO]**
Endoscopy
[NEO_PROCEDURE_2_DATE] (DD/MM/YYYY)
Date of investigation
Req/Unk / Req/Unk / Req (1900-2030)
[NEO_NORMAL_ABN_CODE_2]
Specify outcome
[A:1] ○ Normal
[A:2] ○ Abnormal
[A:80] ○ Indeterminate
[FOLLOW_UP_PLAN_YN_2]
Was a follow-up planned?
[A:2] ○ No
[A:1] ○ Yes
[NEO_METHOD_CODE_BIOP]
[A:14] ☐ **[grp_NEO_METHOD_BIOP]**
Biopsy
[NEO_PROCEDURE_3_DATE] (DD/MM/YYYY)
Date of investigation
Req/Unk / Req/Unk / Req (1900-2030)
[NEO_NORMAL_ABN_CODE_3]
Specify outcome
[A:1] ○ Normal
[A:2] ○ Abnormal
[A:80] ○ Indeterminate
[FOLLOW_UP_PLAN_YN_3]
Was a follow-up planned?
[A:2] ○ No
[A:1] ○ Yes
[NEO_METHOD_CODE_LAB]
[A:15] ☐ **[grp_NEO_METHOD_LAB]**
Laboratory tests
[NEO_PROCEDURE_4_DATE] (DD/MM/YYYY)
Date of investigation
Req/Unk / Req/Unk / Req (1900-2030)
[NEO_NORMAL_ABN_CODE_4]
Specify outcome
[A:1] ○ Normal
[A:2] ○ Abnormal
[A:80] ○ Indeterminate
[FOLLOW_UP_PLAN_YN_4]
Was a follow-up planned?
[A:2] ○ No
[A:1] ○ Yes
[NEO_METHOD_CODE_OTH]
[A:999] ☐ **[grp_NEO_METHOD_OTH]**
Other
[NEO_PROCEDURE_5_DATE] (DD/MM/YYYY)
Date of investigation
Req/Unk / Req/Unk / Req (1900-2030)
[NEO_NORMAL_ABN_CODE_5]
Specify outcome
[A:1] ○ Normal
[A:2] ○ Abnormal
[A:80] ○ Indeterminate
[FOLLOW_UP_PLAN_YN_5]
Was a follow-up planned?
[A:2] ○ No
[A:1] ○ Yes
[A:996] ○ Unknown

14.* ✔ Has the subject previously been exposed to GLP-1 (receptor agonist drugs prior to trial start)?

If exposed less than 1 year, please enter 1 year
[Years of exposure]

[NEO_DRUG_CLASS_CODE_1]
[A:2] ○ No
[A:1] ○ **[grpNEO_DUR_YR_1]**
Yes
[NEO_DURATION_YEAR_1]
Number of years

		0 < N2 *[A:996]* Unknown
15.	Has th… …ously been exposed to [drug class]? *If exposed less than 1 year, please enter 1 year [hidden]* *[Years of exposure]*	**[NEO_DRUG_CLASS_CODE_2]** *[A:2]* No *[A:1]* **[grpNEO_DUR_YR_2]** Yes **[NEO_DURATION_YEAR_2]** Number of years 0 < N2 *[A:996]* Unknown
16.	Has the subject previously been exposed to [drug class]? *If exposed less than 1 year, please enter 1 year [hidden]* *[Years of exposure]*	**[NEO_DRUG_CLASS_CODE_3]** *[A:2]* No *[A:1]* **[grpNEO_DUR_YR_3]** Yes **[NEO_DURATION_YEAR_3]** Number of years 0 < N2 *[A:996]* Unknown

	Sequence number	Information date	Additional information
17.			

Other relevant information (that confirms this event and/or its outcome, e.g. relevant biomarker and genetic testing) Entry [sctNEO_LAB_REL_INFO]		
17.1	Sequence number *[read-only]* [Sequence number]	**[NEO_REL_NO]** N3
17.2* ✔	Date of Information [Information date]	**[NEO_INFO_DATE] {DD/MM/YYYY}** Req / Req / Req (2023-2030)
17.3* ✔	Additional information on event [Additional information]	**[NEO_INFO_OTH]** A200

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
clNEOPLASM_EVENT_CODE	String		New primary neoplasm (with or without metastasis)	1	citmEVENT_CODE_1	NEO_EVENT_CODE
			Recurrence of neoplasm	2	citmEVENT_CODE_2	
			Metastasis of previously diagnosed neoplasm	3	citmEVENT_CODE_3	
			Metastasis of unknown primary neoplasm	4	citmEVENT_CODE_4	
clNEO_LOC_CODE	String		Central nervous system	191	citmNEO_LOC_CODE191	NEO_LOCATION, NEO_LOCATION2, NEO_LOCATION3
			Upper respiratory system (nares, nasopharynx, oropharynx, larynx, vocal cords, glottis and trachea)	163	citmNEO_LOC_CODE163	
			Lower respiratory system (lungs including bronchi and bronchioles)	173	citmNEO_LOC_CODE173	
			Pleura	55	citmNEO_LOC_CODE55	
			Breast	177	citmNEO_LOC_CODE177	
			Upper gastrointestinal tract (oral cavity, oesophagus, stomach, duodenum)	164	citmNEO_LOC_CODE164	
			Lower gastrointestinal tract (jejenum, ileum, colorectal)	174	citmNEO_LOC_CODE174	
			Pancreas	167	citmNEO_LOC_CODE167	
			Liver	48	citmNEO_LOC_CODE48	
			Gallbladder (incl. extrahepatic bile ducts)	157	citmNEO_LOC_CODE157	
			Kidney	175	citmNEO_LOC_CODE175	
			Ureter	162	citmNEO_LOC_CODE162	
			Bladder (urinary bladder, urethra)	179	citmNEO_LOC_CODE179	
			Female reproductive system (uterus, cervix, endometrium, vagina, ovary)	176	citmNEO_LOC_CODE176	
			Male reproductive system (testis, penis, prostate)	171	citmNEO_LOC_CODE171	
			Skin	166	citmNEO_LOC_CODE166	
			Thyroid gland	165	citmNEO_LOC_CODE165	
			Other Endocrine glands (pituitary gland, parathyroid gland, adrenal gland, pineal gland)	168	citmNEO_LOC_CODE168	
			Bone	49	citmNEO_LOC_CODE49	
			Muscle	192	citmNEO_LOC_CODE192	
			Blood	178	citmNEO_LOC_CODE178	
			Lymph node	172	citmNEO_LOC_CODE172	
			Spleen	193	citmNEO_LOC_CODE193	
			Other	999	citmNEO_LOC_CODE999	
clNEO_LOC_SKIN_SPEC	String		Melanoma	170	citmNEO_LOC_SKIN_SPEC170	NEO_LOCATION_SKIN_SPEC
			Non-melanoma	169	citmNEO_LOC_SKIN_SPEC169	
clNEO_LOC_SKIN_SPEC2	String		Melanoma	170	citmNEO_LOC_SKIN_SPEC170_1	NEO_LOCATION_SKIN_SPEC2, NEO_LOCATION_SKIN_SPEC3
			Non-melanoma	169	citmNEO_LOC_SKIN_SPEC169_1	
clNEO_SYMP_SUGGEST_YN	String		No	2	citmNEO_SYMP_SUGGEST_YN2	NEO_SYMP_SUGGEST_YN
			Yes	1	citmNEO_SYMP_SUGGEST_YN1	
clNEO_DISEASE_WORSENING_YN	String		No	2	NEO_DISEASE_WORSENING_YN2	NEO_DISEASE_WORSENING_YN
			Yes	1	citmNEO_DISEASE_WORSENING_YN1	
clNEO_INVEST_EVEN_CODE	String		Signs and symptoms	1	citmNEO_INVE_EVENT_CODE1	NEO_INVESTIGA_EVENT_CODE
			Screening for specific disease	2	citmNEO_INVE_EVENT_CODE2	
			Incidental finding	3	citmNEO_INVE_EVENT_CODE3	
clNEO_SCREEN_DISEASE_CODE	String		Screening programme	3	citmNEO_SCR_DISEASE_CODE3	NEO_SCREEN_DISEASE_CODE
			Personal/family history of this type of neoplasm	2	citmNEO_SCR_DISEASE_CODE2	
clNOYESUNK	String		No	2	citmNOYESUNK2	NEO_IMAGING_DIAGNOS_YN, GEN_TEST_YN

			Yes	1	citmNOYESUNK1	
			Unknown	996	citmNOYESUNK996	
cINEO_IMAG_DIAG_ENDO	String		Endoscopy	110	citmcINEO_IMAG_DIAG_ENDO	NEO_IMAG_DIAG_ENDO
cINEO_IMAG_DIAG_XRAY	String		X-ray	102	citmcI_NEO_IMAG_DIAG_XRAY	NEO_IMAG_DIAG_XRAY
cINEO_IMAG_DIAG_ULTRA	String		Ultrasound	103	citmNEO_IMAG_DIAG_ULTRA	NEO_IMAG_DIAG_ULTRA
cINEO_IMAG_DIAG_CT	String		CT scan	104	citmNEO_IMAG_DIAG_CT	NEO_IMAG_DIAG_CT
cIIMAG_IMAG_DIAG_MRI	String		MRI	105	citmIMAG_IMAG_DIAG_MRI	NEO_IMAG_DIAG_MRI
cINEO_IMAG_DIAG_PET	String		PET scan	109	citmNEO_IMAG_DIAG_PET	NEO_IMAG_DIAG_PET
cINEO_IMAG_DIAG_PETCT	String		PET/CT scan	107	citmNEO_IMAG_DIAG_PETCT	NEO_IMAG_DIAG_PETCT
cINEO_IMAG_DIAG_PETMRI	String		PET/MRI scan	70	citmNEO_IMAG_DIAG_PETMRI	NEO_IMAG_DIAG_PETMRI
cINEO_IMAG_DIAG_PETSPEC	String		PET/SPECT scan	108	citmNEO_IMAG_DIAG_PETSPEC	NEO_IMAG_DIAG_PETSPEC
cINEO_IMAG_DIAG_OTH	String		Other	999	citmNEO_IMAG_DIAG_OTH	NEO_IMAG_DIAG_OTH
cINOYES_1_1_1	String		No	2	citmNOYES2_1_1_1	NEO_PATHOLOGIC_EXAM_YN, FOLLOW_UP_PLAN_YN_1
			Yes	1	citmNOYES1_1_1_1	
cINEO_SAMPLE_TYPE	String		Biopsy specimen	142	citmNEO_SAMPLE_TYPE_142	NEO_SAMPLE_TYPE
			Surgical specimen	143	citmNEO_SAMPLE_TYPE_143	
			Blood	1	citmNEO_SAMPLE_TYPE_1	
cINOYES_1	String		No	2	citmNOYES2_1	NEO_PATH_EXAM_YN, NEO_RISK_CON_FACTOR_YN
			Yes	1	citmNOYES1_1	
cI_PATH_RESULTS	String		C-cell hyperplasia	61	citm_PATH_RESULTS_61	PATH_RESULTS
			Medullary microcarcinoma (carcinoma in situ)	75	citm_PATH_RESULTS_75	
			Medullary carcinoma	76	citm_PATH_RESULTS_76	
cINOYES_2	String		No	2	citmNOYES2_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	citmNOYES1_2	
cINOYES_3	String		No	2	citmNOYES2_3	NEO_TREATMENT_YN
			Yes	1	citmNOYES1_3	
cINEO_TRT_2	String		Surgery	2	citmNEO_TRT_2	NEO_TREATMENT_2
cINEO_TRT_76	String		Radiation	76	citmNEO_TRT_76	NEO_TREATMENT_76
cINEO_TRT_5	String		Chemotherapy	5	citmNEO_TRT_5	NEO_TREATMENT_5
cINEO_TRT_75	String		Hormonal therapy	77	citmNEO_TRT_75	NEO_TREATMENT_77
cINEO_TRT_78	String		Observation	78	citmNEO_TRT_78	NEO_TREATMENT_78
cINEO_TRT_79	String		Palliative care	79	citmNEO_TRT_79	NEO_TREATMENT_79
cINEO_TRT_121	String		Immunotherapy	121	citmNEO_TRT_121	NEO_TREATMENT_121
cINEO_TRT_999	String		Other	999	citmNEO_TRT_999	NEO_TREATMENT_999
cINEO_RISK_CON_FA_1	String		Occupational exposure	30	citmNEO_RISK_CON_FA_1	NEO_RISK_CON_FA_1
cINEO_RISK_CON_FA_2	String		Smoking	31	citmNEO_RISK_CON_FA_2	NEO_RISK_CON_FA_2
cINEO_RISK_CON_FA_3	String		Sun exposure	32	citmNEO_RISK_CON_FA_3	NEO_RISK_CON_FA_3
cINEO_RISK_CON_FA_6	String		Family history of neoplasm	35	citmNEO_RISK_CON_FA_6	NEO_RISK_CON_FA_6
cINEO_RISK_CON_FA_7	String		Other	999	citmNEO_RISK_CON_FA_7	NEO_RISK_CON_FA_7
cINOYESUNK_3	String		No	2	citmNOYESUNK_2	NEO_SCREENING_PROC_YN
			Yes	1	citmNOYESUNK_1	
			Unknown	996	citmNOYESUNK_996	
cINEO_METHOD_CODE_IMAG	String		Imaging	26	citmNEO_METHOD_CODE_IMAG	NEO_METHOD_CODE_IMAG
cINEO_NORMAL_ABN_CODE	String		Normal	1	citmNEO_NORMAL_ABN_CODE_1	NEO_NORMAL_ABN_CODE_1, NEO_NORMAL_ABN_CODE_2, NEO_NORMAL_ABN_CODE_3, NEO_NORMAL_ABN_CODE_4, NEO_NORMAL_ABN_CODE_5
			Abnormal	2	citmNEO_NORMAL_ABN_CODE_2	
			Indeterminate	80	citmNEO_NORMAL_ABN_CODE_80	
cINEO_METHOD_CODE_ENDO	String		Endoscopy	110	citmNEO_METHOD_CODE_ENDO	NEO_METHOD_CODE_ENDO
cINEO_METHOD_CODE_BIOP	String		Biopsy	14	citmNEO_METHOD_CODE_BIOP	NEO_METHOD_CODE_BIOP
cINEO_METHOD_CODE_LAB	String		Laboratory tests	15	citmNEO_METHOD_CODE_LAB	NEO_METHOD_CODE_LAB
cINEO_METHOD_CODE_OTH	String		Other	999	citmNEO_METHOD_CODE_OTH	NEO_METHOD_CODE_OTH
cINEO_DRUG_CLASS_1	String		No	2	citmDRUG_CLASS_1_N	NEO_DRUG_CLASS_CODE_1
			Yes	1	citmDRUG_CLASS_1_Y	
			Unknown	996	citmDRUG_CLASS_1_UNK	
cINEO_DRUG_CLASS_2	String		No	2	citmDRUG_CLASS_2_N	NEO_DRUG_CLASS_CODE_2
			Yes	1	citmDRUG_CLASS_2_Y	
			Unknown	996	citmDRUG_CLASS_2_UNK	
cINEO_DRUG_CLASS_3	String		No	2	citmDRUG_CLASS_3_N	NEO_DRUG_CLASS_CODE_3
			Yes	1	citmDRUG_CLASS_3_Y	
			Unknown	996	citmDRUG_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_SYMP_SUGGEST_TEXT	NEO_SYMP_SUGGEST_TEXT	VARCHAR2
N - NEO_DISEASE_WORSENING_YN	NEO_DISEASE_WORSENING_YN_C	VARCHAR2
	NEO_DISEASE_WORSENING_YN	VARCHAR2
NEO_SYMP_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_IMAG_DIAG_ENDO_NEO_DIAGNO_METHOD_1_TEXT	VARCHAR2
NEO_IMAGING_DIAGNOS_YN - NEO_DIAGNO_METHOD_1_TEXT	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_TEX	NEO_FINAL_PATHO_DIA_TEX	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_R S TON FTOR 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	VARCHAR2
NEO_SCREENING_PROC_YN	NEO_SCREENING_PROC_YN_C	VARCHAR2
	NEO_SCREENING_PROC_YN	VARCHAR2
	NEO_SCREENING_PROC_YN_ND	VARCHAR2
NEO_SCREENING_PROC_YN - Imaging	*NEO_METHOD_CODE_IMAG_GRP_NEO_METHOD_IMAG_C	VARCHAR2
	*NEO_METHOD_CODE_IMAG_GRP_NEO_METHOD_IMAG	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_1_DATE	NEO_PROCEDURE_1_DATE	DATE
	NEO_PROCEDURE_1_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_1_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_1	NEO_NORMAL_ABN_CODE_1_C	VARCHAR2
	NEO_NORMAL_ABN_CODE_1	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_1	FOLLOW_UP_PLAN_YN_1_C	VARCHAR2
	FOLLOW_UP_PLAN_YN_1	VARCHAR2
NEO_SCREENING_PROC_YN - Endoscopy	*NEO_METHOD_CODE_ENDO_GRP_NEO_METHOD_ENDO_C	VARCHAR2
	*NEO_METHOD_CODE_ENDO_GRP_NEO_METHOD_ENDO	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_2_DATE	NEO_PROCEDURE_2_DATE	DATE
	NEO_PROCEDURE_2_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_2_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_2	NEO_NORMAL_ABN_CODE_2_C	VARCHAR2
	NEO_NORMAL_ABN_CODE_2	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_2	FOLLOW_UP_PLAN_YN_2_C	VARCHAR2
	FOLLOW_UP_PLAN_YN_2	VARCHAR2
NEO_SCREENING_PROC_YN - Biopsy	*NEO_METHOD_CODE_BIOP_GRP_NEO_METHOD_BIOP_C	VARCHAR2
	*NEO_METHOD_CODE_BIOP_GRP_NEO_METHOD_BIOP	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_3_DATE	NEO_PROCEDURE_3_DATE	DATE
	NEO_PROCEDURE_3_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_3_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_3	NEO_NORMAL_ABN_CODE_3_C	VARCHAR2
	NEO_NORMAL_ABN_CODE_3	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_3	FOLLOW_UP_PLAN_YN_3_C	VARCHAR2
	FOLLOW_UP_PLAN_YN_3	VARCHAR2
NEO_SCREENING_PROC_YN - Laboratory tests	*NEO_METHOD_CODE_LAB_GRP_NEO_METHOD_LAB_C	VARCHAR2
	*NEO_METHOD_CODE_LAB_GRP_NEO_METHOD_LAB	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_4_DATE	NEO_PROCEDURE_4_DATE	DATE
	NEO_PROCEDURE_4_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_4_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_4	NEO_NORMAL_ABN_CODE_4_C	VARCHAR2
	NEO_NORMAL_ABN_CODE_4	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_4	FOLLOW_UP_PLAN_YN_4_C	VARCHAR2
	FOLLOW_UP_PLAN_YN_4	VARCHAR2
NEO_SCREENING_PROC_YN - Other	*NEO_METHOD_CODE_OTH_GRP_NEO_METHOD_OTH_C	VARCHAR2
	*NEO_METHOD_CODE_OTH_GRP_NEO_METHOD_OTH	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_PROCEDURE_5_DATE	NEO_PROCEDURE_5_DATE	DATE
	NEO_PROCEDURE_5_DATE_DTS	VARCHAR2
	NEO_PROCEDURE_5_DATE_DTR	VARCHAR2
NEO_SCREENING_PROC_YN - NEO_NORMAL_ABN_CODE_5	NEO_NORMAL_ABN_CODE_5_C	VARCHAR2
	NEO_NORMAL_ABN_CODE_5	VARCHAR2
NEO_SCREENING_PROC_YN - FOLLOW_UP_PLAN_YN_5	FOLLOW_UP_PLAN_YN_5_C	VARCHAR2
	FOLLOW_UP_PLAN_YN_5	VARCHAR2
NEO_DRUG_CLASS_CODE_1	NEO_DRUG_CLASS_CODE_1_C	VARCHAR2
	NEO_DRUG_CLASS_CODE_1	VARCHAR2
	NEO_DRUG_CLASS_CODE_1_ND	VARCHAR2
NEO_DRUG_CLASS_CODE_1 - NEO_DURATION_YEAR_1	NEO_DURATION_YEAR_1	NUMBER
NEO_DRUG_CLASS_CODE_2	NEO_DRUG_CLASS_CODE_2_C	VARCHAR2
	NEO_DRUG_CLASS_CODE_2	VARCHAR2
	NEO_DRUG_CLASS_CODE_2_ND	VARCHAR2
NEO_DRUG_CLASS_CODE_2 - NEO_DURATION_YEAR_2	NEO_DURATION_YEAR_2	NUMBER
NEO_DRUG_CLASS_CODE_3	NEO_DRUG_CLASS_CODE_3_C	VARCHAR2
	NEO_DRUG_CLASS_CODE_3	VARCHAR2
	NEO_DRUG_CLASS_CODE_3_ND	VARCHAR2
NEO_DRUG_CLASS_CODE_3 - NEO_DURATION_YEAR_3	NEO_DURATION_YEAR_3	NUMBER
***RD_MALIGNANT_NEOPLASM_SCTPATHOLOGIC_EXAMINATION**		
NEO_ASSMENT_INDEX	NEO_ASSMENT_INDEX	NUMBER
	NEO_ASSMENT_INDEX_ND	VARCHAR2
NEO_EXAM_DATE	NEO_EXAM_DATE	DATE
	NEO_EXAM_DATE_DTS	VARCHAR2
	NEO_EXAM_DATE_ND	VARCHAR2
NEO_SAMPLE_TYPE	NEO_SAMPLE_TYPE_C	VARCHAR2
	NEO_SAMPLE_TYPE	VARCHAR2
	NEO_SAMPLE_TYPE_ND	VARCHAR2
NEO_RESULT_TEXT	NEO_RESULT_TEXT	VARCHAR2
	NEO_RESULT_TEXT_ND	VARCHAR2
NEO_RESULT_TEXT1	NEO_RESULT_TEXT1	VARCHAR2
	NEO_RESULT_TEXT1_ND	VARCHAR2
NEO_RESULT_TEXT2	NEO_RESULT_TEXT2	VARCHAR2
	NEO_RESULT_TEXT2_ND	VARCHAR2
NEO_PATH_EXAM_YN	NEO_PATH_EXAM_YN_C	VARCHAR2
	NEO_PATH_EXAM_YN	VARCHAR2
	NEO_PATH_EXAM_YN_ND	VARCHAR2
NEO_PATH_EXAM_YN - PATH_RESULTS	PATH_RESULTS_C	VARCHAR2
	PATH_RESULTS	VARCHAR2
NEO_PATH_EXAM_YN - GEN_TEST_YN	GEN_TEST_YN_C	VARCHAR2
	GEN_TEST_YN	VARCHAR2
NEO_PATH_EXAM_YN - GEN_TEST_CON	GEN_TEST_CON	VARCHAR2
***RD_MALIGNANT_NEOPLASM_SCTNEO_LAB_REL_INFO**		
NEO_REL_NO	NEO_REL_NO	NUMBER

	NEO_REL_NO_ND	VARCHAR2
NEO_ N O D TE	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.

: Hepatic Event (Hepatic Event) - Repeating Form [HEPATIC_EVENT]

#		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?	Aetiology to the event?	Treatment(s)
1								

Study ID: NN9536-4512

1. Hepatic event number *[read-only]*
[Seq. No.]
[SEQ_NO_HEPATIC]
0 < N3

2.* Related adverse event number
[Related AE number]
[AE_NO_HEPATIC]
0 < N3

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_ENSEPH]
[A:212] ☐ Hepatic encephalopathy
[HEP_OTH]
[A:999] ☐ **[grpSYMPTOMS_OTH]**
Other
[HEP_CLIN_SYMP_OTH]
Specify:
A200

	Test	Test done?	Sample collection date	Result	Reference range
4.					

Laboratory Tests
Provide available results from locally analysed laboratory tests at time of this event Entry [sctHEPATIC_2]

4.1 Test
[Test]
[HEP_LAB_TEST_EVENT]
[clHEP_LPARM_CODE]

4.2* Test done?
[Test done?]
[HEP_LAB_TEST_YN]
[A:1] ○ Yes
[A:2] ○ No
[A:996] ○ Unknown

4.3 Sample collection date
[Sample collection date]
[HEP_COLLECTION_DATE] (DD/MM/YYYY)
Req / Req / Req (2023-2030)

4.4 Result
[Result]
[grp_HEP_RESULT]
[HEP_LVALUE]
Result xxxxx.
[HEP_LPARM_UNIT]
Unit **[clHEP_LPARM_UNIT]**

4.5 Reference range
[Reference range]
[grp_HEP_REF_RANGE]
[HEP_REF_RANGE_LOW]
Lower normal limit:
xxxxx.
[HEP_REF_RANGE_HIGH]
Upper normal limit:
xxxxx.

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

[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_CIRRHOSIS]
[A:135] ☐ Cirrhosis
[ABN_OTH]
[A:999] ☐ Other
[ABNORMAL_TEXT]
Specify:
A200

[A:996] ○ Unknown

	iy performed? formed?]	**[BIOSPY_YN]** *[A:2]* ○ No *[A:1]* ○ **[grpBIOPSY_Y]** Yes **[BIOPSY_DIAGNOS_TEXT]** Specify histological diagnosis: A200 *[A:996]* ○ Unknown
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?]	**[AETIOLOGY_YN]** *[A:2]* ○ No *[A:1]* ○ **[grpAETIOLOGY_Y]** Yes **[AETIOLOGY_CODE_136]** *[A:136]* ☐ Cardiovascular diseases or conditions (e.g. Hypoxic liver injury, Heart failure, Thromboembolic event, Severe hypotension, Right-sided heart failure). **[AETIOLOGY_CODE_137]** *[A:137]* ☐ Acute viral hepatitis **[AETIOLOGY_CODE_138]** *[A:138]* ☐ Chronic viral hepatitis **[AETIOLOGY_CODE_105]** *[A:105]* ☐ Non-alcoholic fatty liver disease **[AETIOLOGY_CODE_139]** *[A:139]* ☐ Decompensation of cirrhosis **[AETIOLOGY_CODE_140]** *[A:140]* ☐ Alcoholic liver disease **[AETIOLOGY_CODE_145]** *[A:145]* ☐ Binge drinking **[AETIOLOGY_CODE_141]** *[A:141]* ☐ Autoimmune hepatitis **[AETIOLOGY_CODE_142]** *[A:142]* ☐ Biliary or pancreatic disorders **[AETIOLOGY_CODE_143]** *[A:143]* ☐ Malignant disease **[AETIOLOGY_CODE_146]** *[A:146]* ☐ Extensive physical activity **[AETIOLOGY_CODE_144]** *[A:144]* ☐ **[DILI_AETIOLOGY_TEXT]** Potentially hepatotoxic agents within 30 days Other Specify: A200
8.	Drug-induced liver injury *[hidden]* [Drug-induced liver injury]	**[DILI_AETIOLOGY_CODE]** Potentially hepatotoxic agents within 30 days *[A:1]* ○ Potentially hepatotoxic agents within 30 days *[A:999]* ○ Other
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)]	**[TREATMENT_A_YN]** *[A:2]* ○ No *[A:1]* ○ **[grpTREATMENT_TYPE]** Yes **[TREATMENT_TYPE_131]** *[A:131]* ☐ Pharmaceutical treatment **[TREATMENT_TYPE_999]** *[A:999]* ☐ **[grpTRTMENT_OT]** Other **[TREATMENT_OTHER_1]** Specify: A200

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: Hepatic Event

Type	RefName	Description
Form	HEPATIC_EVENT	Visit: AE
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
clHEP_NY	String		No	2	citmHEP_NO	SYMPTOMS_A_YN
			Yes	1	citmHEP_YES	
clHEP_PRURITUS	String		Pruritus	209	citmPRURITUS	HEP_PRURITUS
clHEP_NAUSEA	String		Nausea	25	citmNAUSEA	HEP_NAUSEA
clHEP_VOMIT	String		Vomiting	71	citmVOMIT	HEP_VOMITING
clHEP_FATIGUE	String		Fatigue	65	citmFATIGUE	HEP_FATIGUE
clHEP_ABDOM	String		Abdominal pain	54	citmABDOM	HEP_ABDOMINAL
clHEP_GASTRO	String		Gastrointestinal bleeding	210	citmGASTRO	HEP_GASTRO
clHEP_JAUNDICE	String		Jaundice	73	citmJAUNDICE	HEP_JAUNDICE
clHEP_ASCITES	String		Ascites	211	citmASCITES	HEP_ASCITES
clHEP_ENSEPH	String		Hepatic encephalopathy	212	citmENSEPH	HEP_ENSEPH
clHEP_OTH	String		Other	999	citmHEP_OTH	HEP_OTH
clHEP_LPARM_CODE	String		Alanine Aminotransferase (ALT)	603	citmHEP_ALT	HEP_LAB_TEST_EVENT
			Aspartate Aminotransferase (AST)	604	citmHEP_AST	
			Gamma Glutamyl Transferase (GGT)	91	citmHEP_GGT	
			Total Bilirubin	605	citmHEP_BIL	
			Alkaline phosphatase (ALP)	606	citmHEP_ALP	
			INR	41	citmHEP_INR	
			Prothrombin time (PT)	134	citmHEP_PT	
			Albumin	42	citmHEP_ALB	
			Ammonia	135	citmHEP_AMM	
			Sodium	133	citmHEP_SOD	
			Potassium (K)	136	citmHEP_K	
			Creatinine	627	citmHEP_CREAT	
			C Reactive Protein (CRP)	619	citmHEP_CRP	
			WBC	618	citmHEP_WBC	
			Eosinophils	138	citmHEP_EOS	

			Platelets	139	citmHEP_PLATE	
clHEP_LA YN	String		Yes	1	citmHEP_LAB_Y	HEP_LAB_TEST_YN
			No	2	citmHEP_LAB_N	
			Unknown	996	citmHEP_LAB_UNK	
clHEP_LPARM_UNIT	String		U/L	811	citmHE_LAB_TESTU1	HEP_LPARM_UNIT
			mg/dL	162	citmLPARM_UNIT_162	
			umol/L	541	citmLPARM_UNIT_541	
			ratio	852	citmLPARM_UNIT_852	
			s	2	citmLPARM_UNIT_2	
			g/dL	202	citmLPARM_UNIT_202	
			g/L	203	citmLPARM_UNIT_203	
			mg/L	163	citmLPARM_UNIT_163	
			mmol/L	561	citmLPARM_UNIT_561	
			10^9/L	891	citmLPARM_UNIT_891	
			10^3/uL	893	citmLPARM_UNIT_893	
			cells/uL	154	citmLPARM_UNIT_154	
			mEq/L	840	citmLPARM_UNIT_840	
clIMAGING_YN_1	String		No	2	citm1MAGING_N	IMAGING_A_YN
			Yes	1	citm1MAGING_Y	
			Unknown	996	citm1MAGING_UNK	
clHEPA_IMAGE_ULTRA	String		Ultrasound	103	citmHEPA_IMAGE_ULTRA	METHOD_CODE_103
clHEPA_IMAGE_CT	String		CT Scan	104	citmHEPA_IMAGE_CT	METHOD_CODE_104
clHEPA_IMAGE_MRI	String		MRI	105	citmHEPA_IMAGE_MRI	METHOD_CODE_105
clHEPA_IMAGE_OT	String		Other	999	citmHEPA_IMAGE_OT	METHOD_CODE_999
clIMAGE_ABN_YN	String		No	2	citm1MAGE_ABN_N	IMAGING_FIND_A_YN
			Yes	1	citm1MAGE_ABN_Y	
clABN_GALL	String		Gallstones	129	citmABN_GALL	ABN_GALL
clABN_ASCITES	String		Ascites	130	citmABN_ASCITES	ABN_ASCITES
clABN_STEATOSIS	String		Steatosis	131	citmABN_STEATOSIS	ABN_STEATOSIS
clABN_LTUMOUR	String		Liver tumour	132	citmABN_LTUMOUR	ABN_LIV_TUMOUR
clABN_LCYST	String		Liver cyst	133	citmABN_LCYST	ABN_LIV_CYST
clABN_HP_VT	String		Hepatic/Portal vein thrombosis	134	citmABN_HP_VT	ABN_HP_VT
clABN_CIRRHOSIS	String		Cirrhosis	135	citmABN_CIRRHOSIS	ABN_CIRRHOSIS
clABN_OTH	String		Other	999	citmABN_OTH	ABN_OTH
clLIVER_BIOPSY	String		No	2	citmLBIOPSY_N	BIOSPY_YN
			Yes	1	citmLBIOPSY_Y	
			Unknown	996	citmLBIOPSY_UNK	
clAETIOLOGY_YN	String		No	2	citmAETIOLOGY_N	AETIOLOGY_YN
			Yes	1	citmAETIOLOGY_Y	
clHE_EVT_CAUSE1	String		Cardiovascular diseases or conditions (e.g. Hypoxic liver injury, Heart failure, Thromboembolic event, Severe hypotension, Right-sided heart failure).	136	citmHE_EVT_CAUSE1	AETIOLOGY_CODE_136
clHE_EVT_CAUSE2	String		Acute viral hepatitis	137	citmHE_EVT_CAUSE2	AETIOLOGY_CODE_137
clHE_EVT_CAUSE3	String		Chronic viral hepatitis	138	citmHE_EVT_CAUSE3	AETIOLOGY_CODE_138
clHE_EVT_CAUSE4	String		Non-alcoholic fatty liver disease	105	citmHE_EVT_CAUSE4	AETIOLOGY_CODE_105
clHE_EVT_CAUSE5	String		Decompensation of cirrhosis	139	citmHE_EVT_CAUSE5	AETIOLOGY_CODE_139
clHE_EVT_CAUSE6	String		Alcoholic liver disease	140	citmHE_EVT_CAUSE6	AETIOLOGY_CODE_140
clHE_EVT_CAUSE11	String		Binge drinking	145	citmHE_EVT_CAUSE11	AETIOLOGY_CODE_145
clHE_EVT_CAUSE7	String		Autoimmune hepatitis	141	citmHE_EVT_CAUSE7	AETIOLOGY_CODE_141
clHE_EVT_CAUSE8	String		Biliary or pancreatic disorders	142	citmHE_EVT_CAUSE8	AETIOLOGY_CODE_142
clHE_EVT_CAUSE9	String		Malignant disease	143	citmHE_EVT_CAUSE9	AETIOLOGY_CODE_143
clHE_EVT_CAUSE12	String		Extensive physical activity	146	citmHE_EVT_CAUSE12	AETIOLOGY_CODE_146
clHE_EVT_CAUSE10	String		Potentially hepatotoxic agents within 30 days	144	citmHE_EVT_CAUSE10	AETIOLOGY_CODE_144
clDILI_AETIOLOGY_CODE	String		Potentially hepatotoxic agents within 30 days	1	clDILI_AETIOLOGY_CODE_1	DILI_AETIOLOGY_CODE
			Other	999	clDILI_AETIOLOGY_CODE_999	
clTREATMENT_YN	String	1 - TREATMENT_A_YN	No	2	citmHEP_EVT_TRT_N	TREATMENT_A_YN
			Yes	1	citmHEP_EVT_TRT_Y	
clTRT_TYPE_131	String		Pharmaceutical treatment	131	citmTRT_131	TREATMENT_TYPE_131
clTRT_TYPE_999	String		Other	999	citmTRT_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_CITMPRURITUS_C	VARCHAR2
	HEP_PRURITUS_CITMPRURITUS	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_GRPSYMPTOMS_OTH_C	VARCHAR2
	HEP_OTH_GRPSYMPTOMS_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	VARCHAR2
	IMAGING_A_YN_ND	VARCHAR2
IMAGING_A_YN - Other	*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_CITMABNOTH_C	VARCHAR2
	ABN_OTH_CITMABNOTH	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	BIOPSY_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_SCTHEPATIC_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_LPARM_UNIT	HEP_LPARM_UNIT_C	VARCHAR2
	HEP_LPARM_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

	Ξ - HEP_REF_RANGE_HIGH	HEP_REF_RANGE_HIGH	FLOAT

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

: Gallbladder Disease (Gallbladder) - Repeating Form [GALLBLADDER]

#	bladder 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							

Study ID: NN9536-4512
Complete a Gallbladder Disease eCRF for each Adverse Event of biliary colic, cholecystitis and other forms of gallbladder disease.

1. Gallbladder Disease event number *[read-only]*
[Gallbladder Disease event number]
[GALL_SEQ_NO]
0 < N3

2.* Related adverse event number
[Related AE No.]
[GALL_AE_NO]
0 < N3

3.* Were any signs/symptoms present during the course of the event?
[Signs and Symptoms present]
[GALL_CLIN_SYMP_CODE_YN]
[A:2] No
[A:1] **[grpGALL_CLININ_SYMP_CODE]**
Yes
[GALL_CLINIC_SYMPTOM_ABPN]
[A:54] **[GALL_LOCATION_SUB_CODE]**
Abdominal pain
[A:107] Right upper quadrant
[A:156] Epigastric
[A:999] Other
[GALL_CLINIC_SYMPTOM_CODE]
[A:25] Nausea
[A:71] Vomiting
[A:72] Fever
[A:73] Jaundice/Icterus
[A:74] Murphy's sign
[A:999] Other

Laboratory tests
Provide available results from locally analysed laboratory tests at time of this event [sctGALL_LAB_TEST_EVENT]

#	Test	Test done?*	Sample collection date	Result	Reference range *Use same units for reference range as the reported result*
4.a	White blood count (WBC)				
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)				

Laboratory tests
Provide available results from locally analysed laboratory tests at time of this event Entry [sctGALL_LAB_TEST_EVENT]

4.1 Test
[Test]
[GALL_LAB_TEST]
[clGALL_LPARM_CODE]

4.2* Test done?
[Test done?]
[GALL_LAB_TEST_YN]
[A:1] Yes
[A:2] No
[A:996] Unknown

4.3 Sample collection date
[Sample collection date]
[GALL_COLLECTION_DATE] (DD/MM/YYYY)
Req / Req / Req (2023-2030)

4.4 Result
[Result]
[grpGALL_RESULT]
[GALL_LVALUE]
xxxxx.
[GALL_LPARM_UNIT]
[clGALL_LPARM_UNIT]

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]
[grpGALL_REF_RANGE]
[GALL_REF_RANGE_LOW]
Lower normal limit: xxxxx.
[GALL_REF_RANGE_HIGH]
Upper normal limit: xxxxx.

5.* Was imaging performed?
[Imaging performed?]
[GALL_IMAGING_YN]
[A:2] No
[A:1] **[grpGALL_IMAGING_YES]**
Yes
[GALL_METHOD_CODE]
[A:103] Ultrasound
[A:104] CT scan
[A:105] MRI
[A:48] Endoscopic retrograde cholangiopancreatogram (ERCP)
[A:999] Other
[IMAGING_INDICATION]
Primary indication for imaging
[A:1] Suspicion of pancreatitis
[A:2] Suspicion of gallbladder disease (including gallstones and cholecystitis)
[A:3] Unspecific GI symptoms
[A:999] Other
[GALLBLADDER_YN]
Were the imaging findings abnormal?
[A:2] No
[A:1] **[grpGALLBLADDER_CODE]**
Yes
[GALLBLADDER_CODE]
[A:1] Gallstone(s) in the gallbladder
[A:2] Gallstone(s) in the common bile duct
[A:3] Obstructive gallstone
[A:7] Indicating acute cholecystitis
[A:8] Indicating chronic cholecystitis
[A:4] Dilated common bile duct
[GALL_OTH]
[A:999] Other
[GALLBLADDER_OTHER]
Specify:
A200
[A:996] Unknown

6.* Was any treatment(s) given for this condition?
Update concomitant medication as relevant
[Was any treatment(s) given]
[GALL_TREATMENT_YN]
[A:2] No
[A:1] **[grp_GALL_TRT_CODE]**
Yes
[GALL_TREATMENT_CODE]
[A:70] Antibiotics
[A:71] I.V. fluids
[GALL_TREATMENT_CHOLECYST]
[A:72] **[GALL_CHOLECYST]**

		☐ Cholecystectomy *[A:6]* ◯ Elective surgery *[A:8]* ◯ Urgent surgery **[GALL_TREATMENT_ENDO]** *[A:73]* ☐ Endoscopic retrograde cholangiopancreatogram (ERCP) **[GALL_TREATMENT_SHOCK]** *[A:74]* ☐ Shock wave lithotripsy **[GALL_TREATMENT_MED]** *[A:75]* ☐ Medication to dissolve stones **[GALL_TREATMENT_OTH]** *[A:999]* ☐ Other
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?]	**[GALL_RISK_CON_FACTOR_YN]** *[A:2]* ◯ No *[A:1]* ◯ **[GALL_RISK_CON_FA_CODE]** ⊟ Yes *[A:12]* ☐ Family history of gallstones *[A:13]* ☐ Prior experience of similar pain *[A:14]* ☐ Gastric bypass surgery *[A:16]* ☐ Resection of the terminal ileum *[A:17]* ☐ Rapid weight loss *[A:999]* ☐ Other *[A:996]* ◯ Unknown

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
clGALL_SYMP_CODE_YN	String		No	2	citmGALL_SYMP_2	GALL_CLIN_SYMP_CODE_YN
			Yes	1	citmGALL_SYMP_1	
clGALL_CLINIC_SYMPTOM_PAIN	String		Abdominal pain	54	citmGALL_CLINIC_SYMPTOM_PAIN54	GALL_CLINIC_SYMPTOM_ABPN
clGALL_LOCATION_SUB_CODE	String		Right upper quadrant	107	citmLOCATION_SUB1_CODE	GALL_LOCATION_SUB_CODE
			Epigastric	156	citmLOCATION_SUB2_CODE	
			Other	999	citmLOCATION_SUB3_CODE	
clGALL_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	
clGALL_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	
clYESNOUNK	String		Yes	1	citmYESNOUNK1	GALL_LAB_TEST_YN
			No	2	citmYESNOUNK2	
			Unknown	996	citmYESNOUNK996	
clGALL_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	
clNOYESUNK	String		No	2	citmNOYESUNK2	GALL_IMAGING_YN, GALL_RISK_CON_FACTOR_YN
			Yes	1	citmNOYESUNK1	
			Unknown	996	citmNOYESUNK996	
clGALL_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	
clIMAGING_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	
clNOYES_1	String		No	2	citmNOYES2_1	GALLBLADDER_YN
			Yes	1	citmNOYES1_1	
clGALLBLADDER_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	
clGALL_OTH	String		Other	999	citmGALL_OTH999	GALL_OTH
clNOYES_1_1	String		No	2	citmNOYES2_1_1	GALL_TREATMENT_YN

			Yes	1	citmNOYES1_1_1	
clGALL_ ATMENT_CODE	String		Antibiotics	70	citmGALL_TREATMENT_1_CODE	GALL_TREATMENT_CODE
			I.V. fluids	71	citmGALL_TREATMENT_2_CODE	
clGALL_TREATMENT_CHOLECYST	String		Cholecystectomy	72	citmGALL_TREATMENT_CHOLECYST72	GALL_TREATMENT_CHOLECYST
clGALL_TREATMEN_SUB_CODE	String		Elective surgery	6	citmGALL_TREATMEN_SUB1_3_CODE	GALL_CHOLECYST
			Urgent surgery	8	citmGALL_TREATMEN_SUB2_3_CODE	
clGALL_TREATMENT_ENDO	String		Endoscopic retrograde cholangiopancreatogram (ERCP)	73	citmGALL_TREATMENT_ENDO73	GALL_TREATMENT_ENDO
clGALL_TREATMENT_SHOCK	String		Shock wave lithotripsy	74	citmGALL_TREATMENT_SHOCK74	GALL_TREATMENT_SHOCK
clGALL_TREATMENT_MED	String		Medication to dissolve stones	75	citmGALL_TREATMENT_MED75	GALL_TREATMENT_MED
clGALL_TREATMENT_OTH	String		Other	999	citmGALL_TREATMENT_OTH999	GALL_TREATMENT_OTH
clGALL_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

[illegible]N - Endoscopic retrograde cholangiopancreatogram (ERCP)	*GALL_TREATMENT_ENDO_CITMGALLTREATMENTENDO73_C	VARCHAR2
	*GALL_TREATMENT_ENDO_CITMGALLTREATMENTENDO73	VARCHAR2
GALL_TREATMENT_YN - Shock wave lithotripsy	*GALL_TREATMENT_SHOCK_CITMGALLTREATMENTSHOCK74_C	VARCHAR2
	*GALL_TREATMENT_SHOCK_CITMGALLTREATMENTSHOCK74	VARCHAR2
GALL_TREATMENT_YN - Medication to dissolve stones	*GALL_TREATMENT_MED_CITMGALLTREATMENTMED75_C	VARCHAR2
	*GALL_TREATMENT_MED_CITMGALLTREATMENTMED75	VARCHAR2
GALL_TREATMENT_YN - Other	*GALL_TREATMENT_OTH_CITMGALLTREATMENTOTH999_C	VARCHAR2
	*GALL_TREATMENT_OTH_CITMGALLTREATMENTOTH999	VARCHAR2
GALL_RISK_CON_FACTOR_YN	GALL_RISK_CON_FACTOR_YN_C	VARCHAR2
	GALL_RISK_CON_FACTOR_YN	VARCHAR2
	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_FA_CODE_CITMGALLRISKCONFA2CODE	VARCHAR2
GALL_RISK_CON_FACTOR_YN - Prior experience of similar pain	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA3CODE_C	VARCHAR2
	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA3CODE	VARCHAR2
GALL_RISK_CON_FACTOR_YN - Gastric bypass surgery	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA4CODE_C	VARCHAR2
	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA4CODE	VARCHAR2
GALL_RISK_CON_FACTOR_YN - Resection of the terminal ileum	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA6CODE_C	VARCHAR2
	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA6CODE	VARCHAR2
GALL_RISK_CON_FACTOR_YN - Rapid weight loss	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA7CODE_C	VARCHAR2
	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA7CODE	VARCHAR2
GALL_RISK_CON_FACTOR_YN - Other	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA8CODE_C	VARCHAR2
	*GALL_RISK_CON_FA_CODE_CITMGALLRISKCONFA8CODE	VARCHAR2
***RD_GALLBLADDER_SCTGALL_LAB_TEST_EVENT**		
GALL_LAB_TEST	GALL_LAB_TEST_C	VARCHAR2
	GALL_LAB_TEST	VARCHAR2
	GALL_LAB_TEST_ND	VARCHAR2
GALL_LAB_TEST_YN	GALL_LAB_TEST_YN_C	VARCHAR2
	GALL_LAB_TEST_YN	VARCHAR2
	GALL_LAB_TEST_YN_ND	VARCHAR2
GALL_COLLECTION_DATE	GALL_COLLECTION_DATE	DATE
	GALL_COLLECTION_DATE_DTS	VARCHAR2
	GALL_COLLECTION_DATE_ND	VARCHAR2
grpGALL_RESULT	GRPGALL_RESULT_ND	VARCHAR2
grpGALL_RESULT - GALL_LVALUE	GALL_LVALUE	FLOAT
grpGALL_RESULT - GALL_LPARM_UNIT	GALL_LPARM_UNIT_C	VARCHAR2
	GALL_LPARM_UNIT	VARCHAR2
grpGALL_REF_RANGE	GRPGALL_REF_RANGE_ND	VARCHAR2
grpGALL_REF_RANGE - GALL_REF_RANGE_LOW	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.

: Diabetic Retinopathy (Diab Retino) - Repeating Form [DIABETIC_RETINO]

#	E	Related adverse event number	Diabetic retinopathy identified	Current stage of diabetic retinopathy	Conditions found on eye examination	Other findings	Worsening in visual acuity	Disease verified	Treatment received?	Treatment given	Other treatment?
1											

Study ID: NN9838-4942
Note: T2D Participants only

1.	Diabetic retinopathy event number *[read-only]* [Evt. No.]	**[DIA_SEQ_NO]** 0 < N3
2.* ✔	Related adverse event number [Related adverse event number]	**[DIAB_RET_AE_NO]** 0 < N3
3.* ✔	How was this event of diabetic retinopathy identified? [Diabetic retinopathy identified]	**[EYE_IDENTIFY_CODE]** *[A:15]* ◯ Routine eye examination (not related to study) *[A:8]* ◯ Protocol scheduled eye examination *[A:19]* ◯ Unscheduled eye examination *[A:999]* ◯ **[grpID_OTH]** Other **[ID_OTHER]** Specify: A200

Current stage of diabetic retinopathy [sctDRET_EXAM]

#	Eye	Current stage*
4.a	Right	
4.b	Left	

Current stage of diabetic retinopathy Entry [sctDRET_EXAM]

4.1	Eye [Eye]	**[EYE_SIDE]** *[A:1]* ◯ Right *[A:2]* ◯ Left
4.2* ✔	Current stage of diabetic retinopathy [Current stage]	**[CURST_CODE]** *[A:125]* ◯ Mild non-proliferative diabetic retinopathy *[A:126]* ◯ Moderate-severe non-proliferative diabetic retinopathy *[A:123]* ◯ Proliferative diabetic retinopathy

Conditions found on eye examination [sctDRET_COND]

#	Condition	Finding*
5.a	Diabetic macular oedema	
5.b	Vitreous haemorrhage	
5.c	Traction retinal detachment	
5.d	Neovascular glaucoma	
5.e	Cataract	

Conditions found on eye examination Entry [sctDRET_COND]

5.1	Condition [Condition]	**[OTHFIND_CODE]** *[A:42]* ◯ Diabetic macular oedema *[A:30]* ◯ Vitreous haemorrhage *[A:39]* ◯ Traction retinal detachment *[A:40]* ◯ Neovascular glaucoma *[A:35]* ◯ Cataract
5.2* ✔	Finding [Finding]	**[DRET_FIND_YN]** *[A:2]* ◯ No *[A:1]* ◯ **[DRET_FIND_Y]** Yes *[A:1]* ◯ Right eye *[A:2]* ◯ Left eye *[A:3]* ◯ Both eyes (Bilateral)

Other findings [sctDRET_OTH_FIND]

#	Eye	Any other findings?*
6.a	Right	
6.b	Left	

Other findings Entry [sctDRET_OTH_FIND]

6.1	Eye [Eye]	**[EYE_SIDE_OTH]** *[A:1]* ◯ Right *[A:2]* ◯ Left
6.2* ✔	Any other findings? [Any other findings?]	**[DRET_OTH_FIND_YN]** *[A:2]* ◯ No *[A:1]* ◯ **[grpOTH_FIND_Y]** Yes **[DRET_OTH_FIND]** Specify A200

Worsening in visual acuity [sctDRET_VISACT]

#	Eye	Worsening in visual acuity?*
7.a	Right	
7.b	Left	

Worsening in visual acuity Entry [sctDRET_VISACT]

7.1	Eye [Eye]	**[EYE_SIDE_VISACT]** *[A:1]* ◯ Right *[A:2]* ◯ Left
7.2* ✔	Worsening in visual acuity (best corrected) in connection with event? [Worsening in visual acuity?]	**[DRET_VISACT_YN]** *[A:2]* ◯ No *[A:1]* ◯ **[grpVISACT_Y]** Yes **[DRET_VISACT_CODE]** 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
8.* ✔	Were the diabetes retinopathy and related conditions verified by an ophthalmologist? *Ophthalmologist is a medical doctor specialised in eye diseases* [Disease verified]	**[OPTHAL_VERIFY_YN]** *[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?]	**[DRET_TREAT_CONFIRM]** *[A:2]* ◯ No treatment, observation only *[A:1]* ◯ Yes

#	Treatment type	Treatment given?*
10.a	Focal/grid laser treatment/photocoagulation	
10.b	Scatter/pan-retinal laser treatment/photocoagulation	
10.c	Vitrectomy	
10.d	Anti-VEGF intravitreal agent	

	, pe]	**[EYE_TREATMENT_CODE]** *[A:129]* Focal/grid laser treatment/photocoagulation *[A:130]* Scatter/pan-retinal laser treatment/photocoagulation *[A:108]* Vitrectomy *[A:107]* Anti-VEGF intravitreal agent
10.2* ✔	Treatment given? [Treatment given?]	**[EYE_TRT_GIVEN_YN]** *[A:2]* No *[A:1]* **[EYE_TRT_GIVEN_Y]** Yes *[A:1]* Right eye *[A:2]* Left eye *[A:3]* Both eyes (Bilateral)

Other treatment? [sctDRET_OTH_TREAT]

#	Eye	Any other treatment?*
11.a	Right	
11.b	Left	

Other treatment? Entry [sctDRET_OTH_TREAT]

11.1	Eye [Eye]	**[EYE_SIDE_OTH_TRT]** *[A:1]* Right *[A:2]* Left
11.2* ✔	Any other treatment received? [Any other treatment?]	**[DRET_OTH_TREAT_YN]** *[A:2]* No *[A:1]* **[grpOTH_TREAT_Y]** Yes **[DRET_OTH_TREAT]** Specify A200

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, EYE_SIDE_OTH, EYE_SIDE_VISACT, EYE_SIDE_OTH_TRT
			Left	2	citmEYE_SIDE_2	
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	clTRT_GIVEN_N	EYE_TRT_GIVEN_YN
			Yes	1	clTRT_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

	OPTHAL_VERIFY_YN	VARCHAR2
	OPTHAL_VERIFY_YN_ND	VARCHAR2
DRET_TREAT_CONFIRM	DRET_TREAT_CONFIRM_C	VARCHAR2
	DRET_TREAT_CONFIRM	VARCHAR2
	DRET_TREAT_CONFIRM_ND	VARCHAR2
***RD_DIABETIC_RETINO_SCTDRET_EXAM**		
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
***RD_DIABETIC_RETINO_SCTDRET_COND**		
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
***RD_DIABETIC_RETINO_SCTDRET_OTH_FIND**		
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
***RD_DIABETIC_RETINO_SCTDRET_VISACT**		
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
***RD_DIABETIC_RETINO_SCTDRET_TRT_GIVEN**		
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
***RD_DIABETIC_RETINO_SCTDRET_OTH_TREAT**		
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.

: 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									

Study ID: NN9536-4512

1.	Pancreatitis event number *[read-only]* [Pancreatitis No.]	**[PANC_SEQ_NO]** 0 < N3
2.*	Related adverse event number [Related AE No.]	**[PANC_AE_NO]** 0 < N3
3.*	Did the subject have significant upper abdominal pain? [Upper abdominal pain]	**[ABDOMINAL_PAIN_YN]** *[A:2]* ◯ No *[A:1]* ◯ Yes
4.*	Were other signs/symptoms present during the course of the event? [Signs/symptoms]	**[PANC_SYMPTOMS_YN]** *[A:2]* ◯ No *[A:1]* ◯ **[PANC_CLINIC_SYMPT_CODE]** Yes *[A:25]* ☐ Nausea *[A:71]* ☐ Vomiting *[A:72]* ☐ Fever *[A:999]* ☐ Other *[A:996]* ◯ Unknown

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				
5.b	Total Lipase				
5.c	Alanine Aminotransferase (ALT)				
5.d	Aspartate Aminotransferase (AST)				
5.e	Total Bilirubin				
5.f	Alkaline Phosphatase (ALP)				
5.g	C Reactive Protein (CRP)				
5.h	White blood count (WBC)				
5.i	Blood glucose				

Laboratory Tests
Provide available results from locally analysed laboratory tests at time of this event Entry [sctPANC_LAB_TEST_EVENT]

5.1	Test [Test]	**[PANC_LAB_TEST]** **[clPANC_LPARM_CODE]**
5.2*	Test done? [Test done?]	**[PANC_LAB_TEST_YN]** *[A:1]* ◯ Yes *[A:2]* ◯ No *[A:996]* ◯ Unknown
5.3	Sample collection date [Sample collection date]	**[PANC_COLLECTION_DATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
5.4	Result [Result]	**[grpPANC_RESULT]** **[PANC_LVALUE_1]** xxxxx. **[PANC_LPARM_UNIT]** **[clPANC_LPARM_UNIT]**
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*]	**[grpPANC_REF_RANGE]** **[PANC_REF_RANGE_LOW]** Lower normal limit: xxxxx. **[PANC_REF_RANGE_HIGH]** Upper normal limit: xxxxx.
6.*	Was imaging performed? [Was imaging performed?]	**[PANC_IMAGING_YN]** *[A:2]* ◯ No *[A:1]* ◯ **[grpIMAGING_METHOD]** Yes **[PANC_METHOD_CODE]** *[A:103]* ☐ Ultrasound *[A:104]* ☐ CT scan *[A:105]* ☐ MRI *[A:999]* ☐ Other **[PANC_GALLSTONE_YN]** Was imaging consistent with presence of gallstones? *[A:2]* ◯ No *[A:1]* ◯ Yes **[ACUTE_PANCR_YN]** Was imaging consistent with acute pancreatitis? *[A:2]* ◯ No *[A:1]* ◯ **[ACUTE_PANCR_CODE]** Yes *[A:97]* ☐ Obstructive gallstone *[A:98]* ☐ Dilated common bile duct *[A:99]* ☐ Peri-pancreatic fluid *[A:100]* ☐ Oedematous or interstitial pancreatitis *[A:101]* ☐ Necrotising pancreatitis *[A:999]* ☐ Other **[CHRONIC_PANCR_YN]** Was imaging consistent with chronic pancreatitis? *[A:2]* ◯ No *[A:1]* ◯ **[CHRONIC_PANCR_CODE]** Yes *[A:102]* ☐ Calcification of pancreas *[A:103]* ☐ Atrophy of the pancreas *[A:104]* ☐ Dilatation of pancreatic ducts *[A:105]* ☐ Pseudocysts *[A:999]* ☐ Other *[A:996]* ◯ Unknown
7.*	Were any acute complications present during the course of the event? [Acute complications]	**[COMPLICATION_YN]** *[A:2]* ◯ No *[A:1]* ◯ **[PANC_COMPLICATION_CODE]** Yes *[A:141]* ☐ Sepsis *[A:142]* ☐ Gastrointestinal haemorrhage *[A:143]* ☐ Respiratory failure requiring ventilation *[A:144]* ☐ Renal failure requiring dialysis *[A:999]* ☐ Other *[A:996]* ◯ Unknown
8.*	What treatment(s) did the subject receive for this condition? *Standard treatment: e.g. pain killers, antibiotics, hospitalisation* [Treatment]	**[TREATMENT_TYPE_CODE]** *[A:30]* ◯ None *[A:61]* ◯ Standard treatment *[A:62]* ◯ Intensive care treatment *[A:999]* ◯ Other *[A:996]* ◯ Unknown
9.*	Were there any relevant risk/confounding factors identified? [Risk/confounding factors]	**[RISK_CON_FACTOR_YN]** *[A:2]* ◯ No

[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] Hypercalcaemia
[A:999] Other
[A:996] Unknown

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	Code	Codelist Item RefName	Data Variable RefName
clABDOMINAL_PAIN_YN	String		No	2	citmABDOMINAL_PAIN_YN1	ABDOMINAL_PAIN_YN
			Yes	1	citmABDOMINAL_PAIN_YN2	
clPANC_SYMPTOMS_YN	String		No	2	citmPANC_SYMPTOMS_YN1	PANC_SYMPTOMS_YN
			Yes	1	citmPANC_SYMPTOMS_YN2	
			Unknown	996	citmPANC_SYMPTOMS_YN3	
clPANC_CLINIC_SYMPT_CODE	String		Nausea	25	citmPANCCLINIC_SYMPT_1_CODE	PANC_CLINIC_SYMPT_CODE
			Vomiting	71	citmPANCCLINIC_SYMPT_2_CODE	
			Fever	72	citmPANCCLINIC_SYMPT_3_CODE	
			Other	999	citmPANCCLINIC_SYMPT_4_CODE	
clPANC_LPARM_CODE	String		Total Amylase	622	citmPANC_LPARM_CODE_AMY	PANC_LAB_TEST
			Total Lipase	92	citmPANC_LPARM_CODE_LIP	
			Alanine Aminotransferase (ALT)	603	citmPANC_LPARM_CODE_ALT	
			Aspartate Aminotransferase (AST)	604	citmPANC_LPARM_CODE_AST	
			Total Bilirubin	605	citmPANC_LPARM_CODE_TBIL	
			Alkaline Phosphatase (ALP)	606	citmPANC_LPARM_CODE_ALP	
			C Reactive Protein (CRP)	619	citmPANC_LPARM_CODE_CRP	
			White blood count (WBC)	618	citmPANC_LPARM_CODE_WBC	
			Blood glucose	316	citmPANC_LPARM_CODE_GLU	
clYESNOUNK	String		Yes	1	citmYESNOUNK1	PANC_LAB_TEST_YN
			No	2	citmYESNOUNK2	
			Unknown	996	citmYESNOUNK996	
clPANC_LPARM_UNIT	String		U/L	811	citmPANC_LPARM_UNIT_811	PANC_LPARM_UNIT
			mg/dL	162	citmPANC_LPARM_UNIT_162	
			umol/L	541	citmPANC_LPARM_UNIT_541	
			mg/L	163	citmPANC_LPARM_UNIT_163	
			ng/dL	122	citmPANC_LPARM_UNIT_122	
			nmol/L	521	citmPANC_LPARM_UNIT_521	
			10^3/uL	893	citmPANC_LPARM_UNIT_893	
			10^6/L	890	citmPANC_LPARM_UNIT_890	
			10^9/L	891	citmPANC_LPARM_UNIT_891	
			/mL	879	citmPANC_LPARM_UNIT_879	
			/uL	773	citmPANC_LPARM_UNIT_773	
			mmol/L	561	citmPANC_LPARM_UNIT_561	
clPANC_IMAGING_YN	String		No	2	citmPANC_IMAGING_YN1	PANC_IMAGING_YN
			Yes	1	citmPANC_IMAGING_YN2	
			Unknown	996	citmPANC_IMAGING_YN3	
clPANC_METHOD_CODE	String		Ultrasound	103	citmPANC_METHOD_1_CODE	PANC_METHOD_CODE
			CT scan	104	citmPANC_METHOD_2_CODE	
			MRI	105	citmPANC_METHOD_3_CODE	
			Other	999	citmPANC_METHOD_4_CODE	
clGALLSTONE_YN	String		No	2	citmGALLSTONE_YN2	PANC_GALLSTONE_YN
			Yes	1	citmGALLSTONE_YN1	
clPANC_GALLSTONE_YN	String		No	2	citmPANC_GALLSTONE_YN2	ACUTE_PANCR_YN
			Yes	1	citmPANC_GALLSTONE_YN1	
clACUTE_PANCR_CODE	String		Obstructive gallstone	97	citmACUTE_PANCR_1_CODE	ACUTE_PANCR_CODE
			Dilated common bile duct	98	citmACUTE_PANCR_2_CODE	
			Peri-pancreatic fluid	99	citmACUTE_PANCR_3_CODE	
			Oedematous or interstitial pancreatitis	100	citmACUTE_PANCR_4_CODE	
			Necrotising pancreatitis	101	citmACUTE_PANCR_5_CODE	
			Other	999	citmACUTE_PANCR_6_CODE	
clCHRONIC_PANCR_YN	String		No	2	citmCHRONIC_PANCR_YN1	CHRONIC_PANCR_YN
			Yes	1	citmCHRONIC_PANCR_YN2	
clCHRONIC_PANCR_CODE	String		Calcification of pancreas	102	citmCHRONIC_PANCR_1_CODE	CHRONIC_PANCR_CODE
			Atrophy of the pancreas	103	citmCHRONIC_PANCR_2_CODE	
			Dilatation of pancreatic ducts	104	citmCHRONIC_PANCR_3_CODE	
			Pseudocysts	105	citmCHRONIC_PANCR_4_CODE	
			Other	999	citmCHRONIC_PANCR_5_CODE	
clCOMPLICATION_YN	String		No	2	citmCOMPLICATION_YN1	COMPLICATION_YN
			Yes	1	citmCOMPLICATION_YN2	
			Unknown	996	citmCOMPLICATION_YN3	
clPANC_COMPLICATION_CODE	String		Sepsis	141	citmPANC_COMPLICATION_1_CODE	PANC_COMPLICATION_CODE
			Gastrointestinal haemorrhage	142	citmPANC_COMPLICATION_2_CODE	
			Respiratory failure requiring ventilation	143	citmPANC_COMPLICATION_3_CODE	
			Renal failure requiring dialysis	144	citmPANC_COMPLICATION_4_CODE	
			Other	999	citmPANC_COMPLICATION_5_CODE	
clTREATMENT_TYPE_CODE	String		None	30	citmTREATMENT_TYPE_CODE1	TREATMENT_TYPE_CODE
			Standard treatment	61	citmTREATMENT_TYPE_CODE2	
			Intensive care treatment	62	citmTREATMENT_TYPE_CODE3	

			Other	999	citmTREATMENT_TYPE_CODE4	
			Unknown	996	citmTREATMENT_TYPE_CODE5	
clRISK_CON_FACTOR_YN	String		No	2	citmRISK_CON_FACTOR_YN2	RISK_CON_FACTOR_YN
			Yes	1	citmRISK_CON_FACTOR_YN1	
			Unknown	996	citmRISK_CON_FACTOR_YN3	
clRISK_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	
			Hypertriglyceridemia	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_CITMPANCCLINICSYMPT1CODE_C	VARCHAR2
	*PANC_CLINIC_SYMPT_CODE_CITMPANCCLINICSYMPT1CODE	VARCHAR2
PANC_SYMPTOMS_YN - Vomiting	*PANC_CLINIC_SYMPT_CODE_CITMPANCCLINICSYMPT2CODE_C	VARCHAR2
	*PANC_CLINIC_SYMPT_CODE_CITMPANCCLINICSYMPT2CODE	VARCHAR2
PANC_SYMPTOMS_YN - Fever	*PANC_CLINIC_SYMPT_CODE_CITMPANCCLINICSYMPT3CODE_C	VARCHAR2
	*PANC_CLINIC_SYMPT_CODE_CITMPANCCLINICSYMPT3CODE	VARCHAR2
PANC_SYMPTOMS_YN - Other	*PANC_CLINIC_SYMPT_CODE_CITMPANCCLINICSYMPT4CODE_C	VARCHAR2
	*PANC_CLINIC_SYMPT_CODE_CITMPANCCLINICSYMPT4CODE	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_ND	VARCHAR2
RISK_CON_FACTOR_YN - Gallstones	*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
***RD_PANCREATITIS_SCTPANC_LAB_TEST_EVENT**		
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_LAB_TEST_YN_ND	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_LPARM_UNIT	PANC_LPARM_UNIT_C	VARCHAR2
	PANC_LPARM_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.

: Acute Kidney Injury (AKI) - Repeating Form [ACUTE_KIDNEY_INJURY]

#	Injury No.	Related AE No.	Event present itself?	Laboratory Tests 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?
1											

Study ID: NN9536-4512

1.	Acute Kidney Injury number *[read-only]* [Acute Kidney Injury No.]	**[RENAL_SEQ_NO]** 0 < N3
2.* ✔	Related adverse event number [Related AE No.]	**[RENAL_AE_NO]** 0 < N3
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

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]	**[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
4.2* ✔	Test done? [Test done?]	**[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]
4.4	Sample collection date [Sample collection date]	**[REN_SAMPLE_DATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
4.5	Result [Result]	**[grpREN_RESULT]** **[REN_LVALUE]** xxxxx. **[REN_LPARM_UNIT]** **[clREN_LPARM_UNIT]**
4.6	Reference range *Use same units for reference range as the reported result* [Reference range *Use same units for reference range as the reported result*]	**[grpREN_EVT_REF_RANGE]** **[REN_RES_LOW_RANGE]** Lower normal limit: xxxxx. **[REN_RES_HIGH_RANGE]** Upper normal limit: xxxxx.
4.7	Test Medium *[hidden]* [Test Medium]	**[TEST_MEDIUM_CODE]** *[A:3]* ◯ 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)					URINE
5.b	Estimated glomerular filtration rate (eGFR)					URINE

5.1	Test [Test]	**[REN_DESC_TEST_1]** *[A:48]* ◯ Measured glomerular filtration rate (mGFR) *[A:49]* ◯ Estimated glomerular filtration rate (eGFR)
5.2* ✔	Test done? [Test done?]	**[REN_EVT_YN_1]** *[A:1]* ◯ Yes *[A:2]* ◯ No *[A:996]* ◯ Unknown
5.3	Sample collection date [Sample collection date]	**[REN_SAMPLE_DATE_1] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
5.4	Result [Result]	**[grpREN_RESULT_1]** **[REN_LVALUE1]** xxxxx. **[REN_LPARM_UNIT_1]** **[clREN_LPARM_UNIT_1]**
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*]	**[grpREN_EVT_REF_RANGE_1]** **[REN_RES_LOW_RANGE_1]** Lower normal limit: xxxxx. **[REN_RES_HIGH_RANGE_1]** Upper normal limit: xxxxx.
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]	**[REN_DESC_TEST_2]** *[A:628]* ◯ Erythrocytes (urine dipstick) *[A:632]* ◯ Leukocytes (urine dipstick) *[A:629]* ◯ Albumin (urine dipstick)

		[A:47] Nitrite (urine dipstick) [A:630] Urine Culture [A:160] Urine microscopy
6.2* ✔	Test uu [Test done?]	**[REN_EVT_YN_2]** [A:1] Yes [A:2] No [A:996] Unknown
6.3	Sample collection date [Sample collection date]	**[REN_SAMPLE_DATE_2] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
6.4	Result	**[REN_LVALUE_2]** A200
6.5	Test Method *[hidden]* [Test Method]	**[TEST_METHOD]** [A:69] DIPSTICK [A:129] MICROBIAL CULTURE [A:130] MICROSCOPY
6.6	Test Medium *[hidden]* [Test Medium]	**[TEST_MEDIUM_CODE_2]** [A:4] URINE
7.* ✔	Has the subject received any nephrotoxic agents within the last 3 months? *Update concomitant medication as relevant* *[Nephrotoxic agents?]*	**[NEPHROTOXIC_AGENT_YN]** [A:2] No [A:1] **[grpNEPHROTOX_AG_CD]** Yes **[NEPHROTOX_AGENT_CODE]** [A:1] **[NEPHROTOX_AGENT_TEXT]** Aminoglycoside(s) Specify: A80 **[NEPHROTOX_AG_CODE1]** [A:2] **[NEPHROTOX_AGENT_TEXT_1]** Nonsteroidal anti-inflammatory drug(s) (NSAIDs) Specify: A80 **[NEPHROTOX_AG_CODE1_1]** [A:3] **[NEPHROTOX_AGENT_TEXT_2]** IV contrast Specify: A80 **[NEPHROTOX_AG_CODE1_2]** [A:4] **[NEPHROTOX_AGENT_TEXT_3]** Initiation of a renin-angiotensin-aldosterone system inhibitor(s) Specify: A80 **[NEPHROTOX_AG_CODE1_3]** [A:999] **[NEPHROTOX_AGENT_TEXT_4]** Other Specify: A200 [A:996] Unknown
8.* ✔	Was there evidence or suspicion of conditions which could explain or have contributed to the event? [Evidence or suspicion of conditions to event?]	**[CONDITION_YN]** [A:2] No [A:1] **[grpCONDITION_CODE1]** Yes **[CONDITION_CODE]** [A:4] Acute urinary tract infection **[CONDITION_CODE1]** [A:5] Chronic urinary tract infection **[CONDITION_CODE1_1]** [A:6] Post-renal obstructive disease **[CONDITION_CODE1_2]** [A:1] Hypertension **[CONDITION_CODE1_14]** [A:16] Recent volume depletion secondary to GI symptoms **[CONDITION_CODE1_15]** [A:15] Recent volume depletion due to other/unknown cause **[CONDITION_CODE1_13]** [A:14] Recent decrease in cardiac output or hypotension **[CONDITION_CODE1_3]** [A:7] Recent decrease in renal perfusion due to volume depletion, decreased cardiac output or hypotension **[CONDITION_CODE1_4]** [A:57] Progression of chronic kidney disease **[CONDITION_CODE1_5]** [A:9] Primary glomerulonephritis **[CONDITION_CODE1_6]** [A:10] Systemic autoimmune disease **[CONDITION_CODE1_7]** [A:11] Recent streptococcal infection **[CONDITION_CODE1_8]** [A:12] Renal artery stenosis **[CONDITION_CODE1_9]** [A:13] Renal vein thrombosis **[CONDITION_CODE1_11]** [A:29] Volume depletion for other reasons than gastrointestinal symptoms **[CONDITION_CODE1_12]** [A:56] Connective tissue disease or vasculitis **[CONDITION_CODE1_10]** [A:999] **[grp_CONDITION_OTHER]** Other **[CONDITION_OTHER]** Specify: A200 [A:996] Unknown
9.* ✔	Was imaging performed in relation to the event? [Was imaging performed in relation to the event?]	**[IMAGING_DIAGNOSIS_YN]** [A:2] No [A:1] **[grpIMAGING_DIAG_MET]** Yes **[IMAGING_DIAGNOSIS_METHOD]** [A:103] Ultrasound **[IMAGING_DIAG_MET1]** [A:104] CT scan **[IMAGING_DIAG_MET1_1]** [A:111] Renal angio-imaging (e.g. angiography, angio-CT, angio-MRI) **[IMAGING_DIAG_MET1_2]** [A:999]

		[grpMETHOD_TEXT] Other [METHOD_TEXT] Specify: A200 [SUM_IMAGE_RES] Summary of imaging results: A200 [A:996] Unknown
10.* ✔	Was a kidney biopsy performed in relation to the event? [Kidney biopsy diagnosis?]	[BIOPSY_DIAGNOSIS_YN] [A:2] No [A:1] [grpBIOPSY_DIAGNOSIS_TEXT] Yes [BIOPSY_DIAGNOSIS_TEXT] Summary of histology results A200 [A:996] Unknown
11.* ✔	Is there any family history of kidney disease? [Family history of kidney disease?]	[RELATIVE_HIST_YN1] [A:2] No [A:1] Yes [A:996] Unknown
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
clEVENT_PRESENT_CODE	String		Increase in serum creatinine ≥ 0.3 mg/dL within 48 hours	15	citmEVENT_PRESENT_CODE6	EVENT_PRESENT_CODE
			Increase in serum creatinine to ≥ 1.5 times baseline within 7 days	16	citmEVENT_PRESENT_CODE7	
			Urine volume < 0.5 mL/kg/h for 6 hours	17	citmEVENT_PRESENT_CODE3	
			Other	999	citmEVENT_PRESENT_CODE999	
clREN_DESC_TEST	String		Blood urea nitrogen (BUN)	93	citmREN_DESC_TEST93_1	REN_DESC_TEST
			Serum creatinine	627	citmREN_DESC_TEST627	
			Serum cystatin C	159	citmREN_DESC_TEST159	
			Urinary albumin/creatinine ratio (ACR)	155	citmREN_DESC_TEST155	
			Urine albumin	42	citmREN_DESC_TEST42	
			Urine protein	95	citmREN_DESC_TEST95	
			24-hour urine creatinine clearance	631	citmREN_DESC_TEST631	
clREN_EVT_YN	String		Yes	1	citmREN_EVT_YN1	REN_EVT_YN, REN_EVT_YN_1
			No	2	citmREN_EVT_YN2	
			Unknown	996	citmREN_EVT_YN996	
clREN_DESC_TEST_URINE	String		Random spot urine sample	115	citmREN_DES_TEST_URALB115	REN_DESC_TEST_PROC
			First morning urine sample	116	citmREN_DES_TEST_URALB116	
			Timed urine collection	117	citmREN_DES_TEST_URALB117	
clREN_LPARM_UNIT	String		mg/dL	162	citmREN_LPARM_UNIT_OTH_162	REN_LPARM_UNIT
			mmol/L	144	citmREN_LPARM_UNIT_OTH_144	
			umol/L	541	citmREN_LPARM_UNIT_OTH_541	
			mg/mmol	170	citmREN_LPARM_UNIT_OTH_170	
			mg/g	169	citmREN_LPARM_UNIT_OTH_169	
			g/L	203	citmREN_LPARM_UNIT_OTH_203	
			mL/min	145	citmREN_LPARM_UNIT_OTH_145	
			ug/L	143	citmREN_LPARM_UNIT_OTH_143	
clTEST_MED	String		BLOOD	3	citmTEST_MEDIUM_3	TEST_MEDIUM_CODE
			URINE	4	citmTEST_MEDIUM_4	
clREN_DESC_TEST_1	String		Measured glomerular filtration rate (mGFR)	48	citmREN_DESC_TEST48	REN_DESC_TEST_1
			Estimated glomerular filtration rate (eGFR)	49	citmREN_DESC_TEST49	
clREN_LPARM_UNIT_1	String		mg/dL	162	citmREN_LPARM_UNIT_OTH_162_1	REN_LPARM_UNIT_1
			mmol/L	144	citmREN_LPARM_UNIT_OTH_144_1	
			umol/L	541	citmREN_LPARM_UNIT_OTH_541_1	
			mg/mmol	170	citmREN_LPARM_UNIT_OTH_170_1	
			mg/g	169	citmREN_LPARM_UNIT_OTH_169_1	
			g/L	203	citmREN_LPARM_UNIT_OTH_203_1	
			mL/min	145	citmREN_LPARM_UNIT_OTH_145_1	
			ug/L	143	citmREN_LPARM_UNIT_OTH_143_1	
clTEST_MED_1	String		URINE	4	citmTEST_MEDIUM_4	TEST_MEDIUM_CODE_1
clREN_DESC_TEST_2	String		Erythrocytes (urine dipstick)	628	citmREN_DESC_TEST628	REN_DESC_TEST_2
			Leukocytes (urine dipstick)	632	citmREN_DESC_TEST632	
			Albumin (urine dipstick)	629	citmREN_DESC_TEST629	

			Nitrite (urine dipstick)	47	citmREN_DESC_TEST47	
			Urine Culture	630	citmREN_DESC_TEST630	
			Urine microscopy	160	citmREN_DESC_TEST630_1	
clREN_EVT_YN_1	String		Yes	1	citmREN_EVT_YN1_1	REN_EVT_YN_2
			No	2	citmREN_EVT_YN2_1	
			Unknown	996	citmREN_EVT_YN996_1	
clTEST_METHOD	String		DIPSTICK	69	citmTEST_METHOD_69	TEST_METHOD
			MICROBIAL CULTURE	129	citmTEST_METHOD_129	
			MICROSCOPY	130	citmTEST_METHOD_130	
clTEST_MED_2	String		URINE	4	citmTEST_MEDIUM_4	TEST_MEDIUM_CODE_2
clNOYESUNK_4	String		No	2	citmNOYESUNK2_3_1	NEPHROTOXIC_AGENT_YN, CONDITION_YN, IMAGING_DIAGNOSIS_YN, BIOPSY_DIAGNOSIS_YN, RELATIVE_HIST_YN1
			Yes	1	citmNOYESUNK1_3_1	
			Unknown	996	citmNOYESUNK996_3_1	
clNEPHROTOX_AGENT_CODE	String		Aminoglycoside(s)	1	citmNEPHROTOX_AGENT_CODE1	NEPHROTOX_AGENT_CODE
clNEPHROTOX_AG_CODE1	String		Nonsteroidal anti-inflammatory drug(s) (NSAIDs)	2	citmNEPHROTOX_AGENT_CODE2	NEPHROTOX_AG_CODE1
clNEPH_AG_CODE1_1	String		IV contrast	3	citmNEPHROTOX_AGENT_CODE3	NEPHROTOX_AG_CODE1_1
clNEPH_AG_CODE1_2	String		Initiation of a RAS blockade	4	citmNEPHROTOX_AGENT_CODE4	NEPHROTOX_AG_CODE1_2
clNEPH_AG_CODE1_3	String		Other potentially nephrotoxic drugs	999	citmNEPHROTOX_AGENT_CODE999	NEPHROTOX_AG_CODE1_3
clCONDITION_YN	String		Acute urinary tract infection	4	citmCONDITION_YN4	CONDITION_CODE
clCONDITION_YN1	String		Chronic urinary tract infection	5	citmCONDITION_YN5	CONDITION_CODE1
clCONDITION_YN1_1	String		Post-renal obstructive disease	6	citmCONDITION_YN6	CONDITION_CODE1_1
clCONDITION_YN1_2	String		Hypertension	1	citmCONDITION_YN1	CONDITION_CODE1_2
clCONDITION_YN1_14	String		Recent volume depletion secondary to GI symptoms	16	citmCONDITION_YN14	CONDITION_CODE1_14
clCONDITION_YN1_15	String		Recent volume depletion due to other/unknown cause	15	citmCONDITION_YN15	CONDITION_CODE1_15
clCONDITION_YN1_11	String		Recent decrease in cardiac output or hypotension	14	citmCONDITION_YN5_1	CONDITION_CODE1_13
clCONDITION_YN1_3	String		Recent decrease in renal perfusion due to volume depletion, decreased cardiac output or hypotension	7	citmCONDITION_YN7	CONDITION_CODE1_3
clCONDITION_YN1_4	String		Progression of chronic kidney disease	57	citmCONDITION_YN57	CONDITION_CODE1_4
clCONDITION_YN1_5	String		Primary glomerulonephritis	9	citmCONDITION_YN9	CONDITION_CODE1_5
clCONDITION_YN1_6	String		Systemic autoimmune disease	10	citmCONDITION_YN10	CONDITION_CODE1_6
clCONDITION_YN1_7	String		Recent streptococcal infection	11	citmCONDITION_YN11	CONDITION_CODE1_7
clCONDITION_YN1_8	String		Renal artery stenosis	12	citmCONDITION_YN12	CONDITION_CODE1_8
clCONDITION_YN1_9	String		Renal vein thrombosis	13	citmCONDITION_YN13	CONDITION_CODE1_9
clCONDITION_CODE1_11	String		Volume depletion for other reasons than gastrointestinal symptoms	29	citmCONDITION_YN29	CONDITION_CODE1_11
clCONDITION_CODE1_12	String		Connective tissue disease or vasculitis	56	citmCONDITION_YN56	CONDITION_CODE1_12
clCONDITION_YN1_10	String		Other, specify:	999	citmCONDITION_YN999	CONDITION_CODE1_10
clIMAG_DIAGNOSIS_METH	String		Ultrasound	103	citmIMAG_DIAG_METH103	IMAGING_DIAGNOSIS_METHOD
clIMAGING_DIAG_MET1	String		CT scan	104	citmIMAG_DIAG_METH104	IMAGING_DIAG_MET1
clIMAGING_DIAG_MET1_1	String		Renal angio-imaging (e.g. angiography, angio-CT, angio-MRI)	111	citmIMAG_DIAG_METH111	IMAGING_DIAG_MET1_1
clIMAGING_DIAG_MET1_2	String		Other	999	citmIMAG_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_14_CITMCONDITIONYN14_C	VARCHAR2
	*CONDITION_CODE1_14_CITMCONDITIONYN14	VARCHAR2
CONDITION_YN - Recent volume depletion due to other/unknown cause	*CONDITION_CODE1_15_CITMCONDITIONYN15_C	VARCHAR2
	*CONDITION_CODE1_15_CITMCONDITIONYN15	VARCHAR2

- :ent decrease in cardiac output or hypotension	*CONDITION_CODE1_13_CITMCONDITIONYN51_C	VARCHAR2
	*CONDITION_CODE1_13_CITMCONDITIONYN51	VARCHAR2
CONDITION_YN + ^screase in renal perfusion due to volume depletion, decreased cardiac output or hypotension	*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
***RD_ACUTE_KIDNEY_INJURY_SCTRENAL_LAB_TESTS**		
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_LPARM_UNIT	REN_LPARM_UNIT_C	VARCHAR2
	REN_LPARM_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
***RD_ACUTE_KIDNEY_INJURY_SCTRENAL_LAB_TESTS_1**		
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_LPARM_UNIT_1	REN_LPARM_UNIT_1_C	VARCHAR2
	REN_LPARM_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
[*]RD_ACUTE_EVT_INJURY_SCTRENAL_LAB_TESTS_2		
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.

: Concomitant Medication (CM) - Repeating Form [CONCOM_MED_MEDDRA_1]

#		Medication	Start date	Continuing?	Dose	Rescue medication (Only applicable for T2D subjects with a central HbA1c value above 8.5% (69 mmol/mol))	Frequency	Route	Primary Indication
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

2.* Medication

[Medication]

[SCAT]

[A:1] **[SCAT1_L2]**
Antihypertensive therapy and diuretics
- *[A:1]* Atenolol
- *[A:11]* Amlodipine
- *[A:58]* Aliskiren
- *[A:56]* Azilsartan medoxomil
- *[A:38]* Benazepril
- *[A:2]* Bisoprolol
- *[A:23]* Bumetanide
- *[A:18]* Bendroflumethiazide
- *[A:27]* Canrenoate
- *[A:5]* Carvedilol
- *[A:37]* Captopril
- *[A:30]* Clonidine
- *[A:43]* Cilazapril
- *[A:50]* Candesartan
- *[A:46]* Delapril
- *[A:15]* Diltiazem
- *[A:54]* Eprosartan
- *[A:26]* Eplerenone
- *[A:33]* Enalapril
- *[A:22]* Furosemide
- *[A:13]* Felodipine
- *[A:57]* Filmasartan
- *[A:39]* Fosinopril
- *[A:32]* Hydralazine
- *[A:17]* Hydrochlorothiazide
- *[A:51]* Irbesartan
- *[A:44]* Imidapril
- *[A:20]* Indapamide
- *[A:6]* Labetalol
- *[A:14]* Lercanidipine
- *[A:49]* Losartan
- *[A:35]* Lisinopril
- *[A:3]* Metoprolol
- *[A:21]* Metolazone
- *[A:29]* Moxonidine
- *[A:28]* Methyldopa
- *[A:47]* Moexipril
- *[A:10]* Nadolol
- *[A:4]* Nebivolol
- *[A:12]* Nifdipine
- *[A:53]* Olmesartan
- *[A:36]* Perindopril
- *[A:8]* Propanolol
- *[A:40]* Quinapril
- *[A:34]* Ramipril
- *[A:9]* Sotalol
- *[A:25]* Spironolactone
- *[A:45]* Spirapril
- *[A:7]* Timolol
- *[A:31]* Terazosin
- *[A:48]* Temocapril
- *[A:55]* Telmisartan
- *[A:19]* Trichlormethiazide
- *[A:24]* Torasemide
- *[A:42]* Trandolapril
- *[A:52]* Valsartan
- *[A:16]* Verapamil
- *[A:41]* Zofenopril

[A:2] **[SCAT2_L2]**
Antiobesity Preparations, Excl. Diet Products
- *[A:3]* Amfepramone
- *[A:13]* Bupropion, Naltrexone
- *[A:7]* Cathine
- *[A:8]* Clobenzorex
- *[A:4]* Dexfenfluramine
- *[A:6]* Etilamfetamine
- *[A:12]* Ephedrine, Combinations
- *[A:2]* Fenfluramine
- *[A:11]* Lorcaserin
- *[A:5]* Mazindol
- *[A:9]* Mefenorex
- *[A:14]* Orlistat
- *[A:1]* Phentermine
- *[A:15]* Rimonabant
- *[A:10]* Sibutramine
- *[A:16]* Liraglutide

[A:3] **[SCAT3_L2]**
Lipid modifying agents
- *[A:9]* Alirocumab
- *[A:2]* Atorvastatin
- *[A:14]* Bezafibrate
- *[A:10]* Colesevelam
- *[A:11]* Colestyramine
- *[A:12]* Colestipol
- *[A:16]* Ciprofibrate
- *[A:8]* Evolocumab
- *[A:17]* Ezetimibe
- *[A:6]* Fluvastatin
- *[A:13]* Fenofibrate
- *[A:15]* Gemfibrozil
- *[A:5]* Lovastatin
- *[A:19]* Lovaza (Omega-3-triglucerides)
- *[A:20]* OMEGA-3 TRIGLYCERIDES
- *[A:3]* Pravastatin
- *[A:7]* Pitavastatin
- *[A:4]* Rosuvastatin
- *[A:1]* Simvastatin
- *[A:21]* Vascepa (Icosapent Ethyl)

		[A:4] **[SCAT4_L2]** Sodium-Glucose Co-Transporter 2(SGLT2 Inhibitors) *[A:1]* Dapagliflozin *[A:2]* Canagliflozin *[A:3]* Empagliflozin *[A:4]* Ertugliflozin *[A:5]* Ipragliflozin *[A:6]* Sotagliflozin *[A:7]* Luseogliflozin *[A:5]* **[SCAT5_L2]** Biguanides *[A:1]* Metformin *[A:6]* Glinide *[A:7]* Thiazolidinedione *[A:8]* α-glucosidase inhibitors [AGI] *[A:9]* Sulfonylureas *[A:999]* **[SCAT_OTH]** Other medications, not listed above A200
3.	Generic or Trade name *[hidden]* [Drug Name]	**[INV_DRUG1_TEXT]** A200
4.	Country Code *[hidden]* [Country Code]	**[COUNTRY_ISO_CODE]** **[clCOUNTRY_ISO_CODE]**
5.*	Start date [Start date]	**[CONCOM_START_DATE] (DD/MM/YYYY)** Req/Unk / Req/Unk / Req (1925-2030)
6.	Start date and time *[hidden]* [Start date and time]	**[CONCOM_START_DATE_TIME] (DD/MM/YYYY hh:mm)** Req/Unk / Req/Unk / Req (1900-2035) Req/Unk : Req/Unk *24-hour clock*
7.*	Continuing? [Continuing?]	**[CONCOM_STOP_DATE]** *[A:1]* Yes *[A:2]* **[STOP_DATE_CM] (DD/MM/YYYY)** No, Stop date Req/Unk / Req/Unk / Req (2023-2030)
8.	Continuing? *[hidden]* [Continuing?]	**[CONCOM_STOP_DATE_TIME]** *[A:1]* Yes *[A:2]* **[STOP_DATE_NCM_1] (DD/MM/YYYY hh:mm)** No, Stop date and time Req/Unk / Req/Unk / Req (2022-2035) Req/Unk : Req/Unk *24-hour clock*
9.	Dose (Only for the weight-related co-morbidities like diabetes, hypertension, and dyslipidaemia) [Dose]	**[grpDOSE]** **[DOSE]** Dose 0 < xxxxxx. **[CONCOM_UNIT2]** Unit *[A:160]* mg *[A:420]* mL *[A:140]* ug *[A:200]* g *[A:830]* IU *[A:999]* **[CONCOM_UNIT2_999]** Other unit, specify: A10
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))]	**[RESCUE_MED]** *[A:1]* Yes *[A:2]* No
11.	Frequency [Frequency]	**[grpFREQUENCY_CODE]** **[FREQUENCY_CODE]** *[A:1]* Daily *[A:2]* Weekly *[A:999]* **[FREQUENCY_OTHER_TEXT]** Other frequency, specify: A50
12.	Total Daily Dose *[hidden]* [Total Daily Dose]	**[grpTOTAL_DAILY_DOSE]** **[TOTAL_DAILY_DOSE]** 0 < xxxxxx. **[CONCOM_UNIT]** Unit *[A:160]* mg *[A:420]* mL *[A:140]* ug *[A:200]* g *[A:830]* IU *[A:999]* **[CONCOM_UNIT999]** Other unit, specify: A10
13.	Route (Only for the weight-related co-morbidities like diabetes, hypertension, and dyslipidaemia) [Route]	**[grpCONCOM_ROUTE_CODE]** **[CONCOM_ROUTE_CODE]** **[clCONCOM_ROUTE_CODE]**
14.	Administered during surgery *[hidden]* [Administered during surgery]	**[ADM_SURG_YN]** *[A:1]* Yes *[A:2]* No
15.*	Primary Indication *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]	**[grpPRIM_INDICATION]** **[PRIM_INDICATION_1]** *[A:1]* **[PRIM_INDICATION_AE_NO_1]** Adverse Event, enter Adverse Event no. 0 < N3 *[A:2]* **[PRIM_INDICATION_MED_HIST_1]** Medical History/Concomitant Illness, enter seq. no. 0 < N3 *[A:13]* **[PRIM_INDICATION_COVID_AE]** COVID-19 treatment, enter Adverse Event no. 0 < N3 *[A:14]* COVID-19 vaccine *[A:15]* COVID-19 prophylactic *[A:6]* Prophylactic *[A:999]* **[PRIM_INDICATION_OTHER_1]** Other, specify: A200
16.	Primary Indication *[hidden]* [Primary Indication]	**[PRIM_INDICATION]** *[A:1]* **[PRIM_INDICATION_AE_NO]** Adverse Event, enter Adverse Event no. 0 < N3 *[A:2]* **[PRIM_INDICATION_MED_HIST]** Medical History/Concomitant Illness, enter seq. no. 0 < N3 *[A:6]* Prophylactic *[A:999]* **[PRIM_INDICATION_OTHER]** Other, specify: A200

	'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]* ◯ Diabetic retinopathy *[A:6]* ◯ Diabetic neuropathy *[A:5]* ◯ Diabetic nephropathy *[A:7]* ◯ 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]* ◯ Complication 1 text *[A:2]* ◯ Complication 2 text *[A:3]* ◯ Complication 3 text *[A:4]* ◯ Complication 4 text *[A:5]* ◯ Complication 5 text *[A:6]* ◯ 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]* ◯ No *[A:1]* ◯ **[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	citmSCAT1_L1	SCAT
			Antiobesity Preparations, Excl. Diet Products	2	citmSCAT2_L1	
			Lipid modifying agents	3	citmSCAT3_L1	
			Sodium-Glucose Co-Transporter 2(SGLT2 Inhibitors)	4	citmSCAT4_L1	
			Biguanides	5	citmSCAT12_L1	
			Glinide	6	citmSCAT14_L1	
			Thiazolidinedione	7	citmSCAT15_L1	
			α-glucosidase inhibitors [AGI]	8	citmSCAT16_L1	
			Sulfonylureas	9	citmSCAT17_L1	
			Other medications	999	citmSCAT999	
clSCAT1_L2	String		Atenolol	1	citmSCAT1_L2_1	SCAT1_L2
			Amlodipine	11	citmSCAT1_L2_2	
			Aliskiren	58	citmSCAT1_L2_3	
			Azilsartan medoxomil	56	citmSCAT1_L2_4	
			Benazepril	38	citmSCAT1_L2_5	
			Bisoprolol	2	citmSCAT1_L2_6	
			Bumetanide	23	citmSCAT1_L2_7	
			Bendroflumethiazide	18	citmSCAT1_L2_8	
			Canrenoate	27	citmSCAT1_L2_9	
			Carvedilol	5	citmSCAT1_L2_10	
			Captopril	37	citmSCAT1_L2_11	
			Clonidine	30	citmSCAT1_L2_12	
			Cilazapril	43	citmSCAT1_L2_13	

			Candesartan	50	citmSCAT1_L2_14	
			Delapril	46	citmSCAT1_L2_15	
			Diltiazem	15	citmSCAT1_L2_16	
			Eprosartan	54	citmSCAT1_L2_17	
			Eplerenone	26	citmSCAT1_L2_18	
			Enalapril	33	citmSCAT1_L2_19	
			Furosemide	22	citmSCAT1_L2_20	
			Felodipine	13	citmSCAT1_L2_21	
			Filmasartan	57	citmSCAT1_L2_22	
			Fosinopril	39	citmSCAT1_L2_23	
			Hydralazine	32	citmSCAT1_L2_24	
			Hydrochlorothiazide	17	citmSCAT1_L2_25	
			Irbesartan	51	citmSCAT1_L2_26	
			Imidapril	44	citmSCAT1_L2_27	
			Indapamide	20	citmSCAT1_L2_28	
			Labetalol	6	citmSCAT1_L2_29	
			Lercanidipine	14	citmSCAT1_L2_30	
			Losartan	49	citmSCAT1_L2_31	
			Lisinopril	35	citmSCAT1_L2_32	
			Metoprolol	3	citmSCAT1_L2_33	
			Metolazone	21	citmSCAT1_L2_34	
			Moxonidine	29	citmSCAT1_L2_35	
			Methyldopa	28	citmSCAT1_L2_36	
			Moexipril	47	citmSCAT1_L2_37	
			Nadolol	10	citmSCAT1_L2_38	
			Nebivolol	4	citmSCAT1_L2_39	
			Nifdipine	12	citmSCAT1_L2_40	
			Olmesartan	53	citmSCAT1_L2_41	
			Perindopril	36	citmSCAT1_L2_42	
			Propanolol	8	citmSCAT1_L2_43	
			Quinapril	40	citmSCAT1_L2_44	
			Ramipril	34	citmSCAT1_L2_45	
			Sotalol	9	citmSCAT1_L2_46	
			Spironolactone	25	citmSCAT1_L2_47	
			Spirapril	45	citmSCAT1_L2_48	
			Timolol	7	citmSCAT1_L2_49	
			Terazosin	31	citmSCAT1_L2_50	
			Temocapril	48	citmSCAT1_L2_51	
			Telmisartan	55	citmSCAT1_L2_52	
			Trichlormethiazide	19	citmSCAT1_L2_53	
			Torasemide	24	citmSCAT1_L2_54	
			Trandolapril	42	citmSCAT1_L2_55	
			Valsartan	52	citmSCAT1_L2_56	
			Verapamil	16	citmSCAT1_L2_57	
			Zofenopril	41	citmSCAT1_L2_58	
clSCAT2_L2	String		Amfepramone	3	citmSCAT2_L2_1	SCAT2_L2
			Bupropion, Naltrexone	13	citmSCAT2_L2_2	
			Cathine	7	citmSCAT2_L2_3	
			Clobenzorex	8	citmSCAT2_L2_4	
			Dexfenfluramine	4	citmSCAT2_L2_5	
			Etilamfetamine	6	citmSCAT2_L2_6	
			Ephedrine, Combinations	12	citmSCAT2_L2_7	
			Fenfluramine	2	citmSCAT2_L2_8	
			Lorcaserin	11	citmSCAT2_L2_9	
			Mazindol	5	citmSCAT2_L2_10	
			Mefenorex	9	citmSCAT2_L2_11	
			Orlistat	14	citmSCAT2_L2_12	
			Phentermine	1	citmSCAT2_L2_13	
			Rimonabant	15	citmSCAT2_L2_14	
			Sibutramine	10	citmSCAT2_L2_15	
			Liraglutide	16	citmSCAT2_L2_16	
clSCAT3_L2	String		Alirocumab	9	citmSCAT3_L2_1	SCAT3_L2
			Atorvastatin	2	citmSCAT3_L2_2	
			Bezafibrate	14	citmSCAT3_L2_3	
			Colesevelam	10	citmSCAT3_L2_4	
			Colestyramine	11	citmSCAT3_L2_5	
			Colestipol	12	citmSCAT3_L2_6	
			Ciprofibrate	16	citmSCAT3_L2_7	
			Evolocumab	8	citmSCAT3_L2_8	
			Ezetimibe	17	citmSCAT3_L2_9	
			Fluvastatin	6	citmSCAT3_L2_10	
			Fenofibrate	13	citmSCAT3_L2_11	
			Gemfibrozil	15	citmSCAT3_L2_12	
			Lovastatin	5	citmSCAT3_L2_13	
			Lovaza (Omega-3-triglucerides)	19	citmSCAT3_L2_14	
			OMEGA-3 TRIGLYCERIDES	20	citmSCAT3_L2_15	
			Pravastatin	3	citmSCAT3_L2_16	
			Pitavastatin	7	citmSCAT3_L2_17	
			Rosuvastatin	4	citmSCAT3_L2_18	
			Simvastatin	1	citmSCAT3_L2_19	
			Vascepa (Icosapent Ethyl)	21	citmSCAT3_L2_20	
clSCAT4_L2	String		Dapagliflozin	1	citmSCAT4_L2_1	SCAT4_L2
			Canagliflozin	2	citmSCAT4_L2_2	
			Empagliflozin	3	citmSCAT4_L2_3	
			Ertugliflozin	4	citmSCAT4_L2_4	
			Ipragliflozin	5	citmSCAT4_L2_5	
			Sotagliflozin	6	citmSCAT4_L2_6	
			Luseogliflozin	7	citmSCAT4_L2_7	
clSCAT5_L2	String		Metformin	1	citmSCAT5_L2_1	SCAT5_L2

ɔE	String		Afghanistan, AF	AF	AfghanistanAF	COUNTRY_ISO_CODE
			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	
			Cameroon, CM	CM	CameroonCM	
			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	CocircteDivoireCI	
			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	SaintPierreandMiquelonPM
			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
			Åland Islands, AX	AX	AringlandIslandsAX
clCONTINUING_YN	String		Yes	1	citmCONTINUING_Y	CONCOM_STOP_DATE, CONCOM_STOP_DATE_TIME
			No	2	citmCONTINUING_N	
clCONCOM_UNIT	String		mg	160	citmCONCOM_UNIT160	CONCOM_UNIT2, CONCOM_UNIT
			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	RESCUE_MED
			No	2	citmRESCUE_MED2	
clFREQUENCY_CODE	String		Daily	1	citmFREQUENCY_CODE1	FREQUENCY_CODE
			Weekly	2	citmFREQUENCY_CODE2	
			Other, specify	999	citmFREQUENCY_CODE999	
clCONCOM_ROUTE_CODE	String		Subcutaneous	304	citmCONCOM_ROUTE_CODE304	CONCOM_ROUTE_CODE
			Oral	288	citmCONCOM_ROUTE_CODE048	
			Other	999	citmCONCOM_ROUTE_CODE999	
clADM_SURG_YN	String		Yes	1	clADM_SURG_Y	ADM_SURG_YN
			No	2	clADM_SURG_N	
clPRIM_IND	String		Adverse Event	1	citmPRIM_IND_1	PRIM_INDICATION_1
			Medical History/Concomitant Illness	2	citmPRIM_IND_2	
			COVID-19 treatment	13	citmPRIM_IND_13	

			COVID-19 vaccine	14	citmPRIM_IND_14	
			COVID-19 prophylactic	15	citmPRIM_IND_15	
			Prophylactic	6	citmPRIM_IND_6	
			Other	999	citmPRIM_IND_OTH	
clPRIM_INDICATION	String		Adverse Event, enter Adverse Event no.	1	citmPRIM_INDICATION_AE_NO	PRIM_INDICATION
			Medical History/Concomitant Illness, enter seq. no	2	citmPRIM_INDICATION_MED_HIST	
			Prophylactic	6	citmPRIM_INDICATION_PRO	
			Other, specify	999	citmPRIM_INDICATION_SPECIFY_OTHER	
clPRIM_INDICATION_CODE	String		Diabetic retinopathy	4	clPRIM_INDICATION_CODE4	PRIM_INDICATION_CODE
			Diabetic neuropathy	6	clPRIM_INDICATION_CODE6	
			Diabetic nephropathy	5	clPRIM_INDICATION_CODE5	
			Macroangiopathy (including peripheral vascular disease)	7	clPRIM_INDICATION_CODE7	
clCOMPLICATION_CODE	String		Complication 1 text	1	citmCOMPLICATION_CODE1	COMPLICATION_CODE
			Complication 2 text	2	citmCOMPLICATION_CODE2	
			Complication 3 text	3	citmCOMPLICATION_CODE3	
			Complication 4 text	4	citmCOMPLICATION_CODE4	
			Complication 5 text	5	citmCOMPLICATION_CODE5	
			Complication 6 text	6	citmCOMPLICATION_CODE6	
clMED_COVID_19	String		No	2	citmMED_COVID_19_N	MED_COVID_19
			Yes	1	citmMED_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 - SCAT5_L2	SCAT5_L2_C	VARCHAR2
	SCAT5_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.

: 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									

Study ID: NN9536-4512

1.	Technical complaint number *[read-only]* [Seq. No.]	**[COMPLAINT_NO]** N3
2.*	Product [Product]	**[COMPLAINT_SAMPL_CODE]** *[A:1]* Semaglutide/Semaglutide placebo, 0.5 ml single dose pen-injector (For US Sites) *[A:2]* Semaglutide/Semaglutide placebo, 0.75 ml single dose pen-injector (For US Sites) *[A:3]* Semaglutide/Semaglutide placebo, 1.5 ml PDS290 pen injector (EU and International Sites) *[A:4]* Semaglutide/Semaglutide placebo, 3 ml PDS290 pen injector (EU and International Sites)
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]* **[BATCH_ID]** A20 *[A:998]* N/A
4.*	Kit ID/DUN *Fill out one form per Kit ID/DUN.* *[DUN]*	**[DUN_ID2]** *[A:1]* **[DUN_ID_2]** N7 *[A:998]* N/A
5.*	Onset date of technical complaint [Onset date]	**[TC_START_DATE] (DD/MM/YYYY)** Req/Unk / Req/Unk / Req (2023-2030)
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

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_SAMPL_RETURN_YN]** *[A:1]* Yes *[A:2]* **[COM_SAMP_RETURN_TEXT]** No, specify why: A200
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]* Yes *[A:2]* No

	AE number	SAE related
9.		

Related Adverse Event number(s) Entry [sctAE_NO_SAE_MEST_REL_REL_INFO]

9.1*	Adverse Event number [AE number]	**[AE_NO_2]** 0 < N3
9.2*	Is the technical complaint related to SAE? *If Yes, fill in a Safety Information Form (SIF)* [SAE related]	**[TC_RELAT_SAE_AESI_YN]** *[A:1]* Yes *[A:2]* No

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]* Yes *[A:2]* No **[TC_INTERVENTION]** Intervention had not been made? *[A:1]* Yes *[A:2]* No **[TC_CIRCUMSTANCES]** The circumstances had been less fortunate? *[A:1]* Yes *[A:2]* 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]* Yes *[A:2]* 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 / Req / Req (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 ODE	Populated by a rule in Inform

Codelist Va ues 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	citmCOMPLAINT_SAMPL_1	COMPLAINT_SAMPL_CODE
			Semaglutide/Semaglutide placebo, 0.75 ml single dose pen-injector (For US Sites)	2	citmCOMPLAINT_SAMPL_2	
			Semaglutide/Semaglutide placebo, 1.5 ml PDS290 pen injector (EU and International Sites)	3	citmCOMPLAINT_SAMPL_3	
			Semaglutide/Semaglutide placebo, 3 ml PDS290 pen injector (EU and International Sites)	4	citmCOMPLAINT_SAMPL_4	
clBATCH_ID	String			1	citmBATCH_ID	BATCH_ID2
			N/A	998	citmBATCH_NA	
clDUN_ID	String			1	citmDUN_ID	DUN_ID2
			N/A	998	citmDUN_NA	
clCOMP_SAMPL_RETURN_YN	String		Yes	1	citmCOMP_SAMPL_RETURN_Y	COMP_SAMPL_RETURN_YN
			No	2	citmCOMPLE_SAMPL_RETURN_N	
clAE_RELATION_YN	String		Yes	1	citmAE_RELATION_Y	AE_RELATION_YN
			No	2	citmAE_RELATION_N	
clTC_RELAT_SAE_MESI_YN	String		Yes	1	citmTC_RELAT_SAE_MESI_Y	TC_RELAT_SAE_AESI_YN
			No	2	citmTC_RELAT_SAE_MESI_N	
clTC_SUITABLE_ACTION	String		Yes	1	citmTC_SUITABLE_ACTION1	TC_SUITABLE_ACTION
			No	2	citmTC_SUITABLE_ACTION2	
clTC_INTERVENTION	String		Yes	1	citmTC_INTERVENTION1	TC_INTERVENTION
			No	2	citmTC_INTERVENTION2	
clTC_CIRCUMSTANCES	String		Yes	1	citmTC_CIRCUMSTANCES1	TC_CIRCUMSTANCES
			No	2	citmTC_CIRCUMSTANCES2	
clPEN_ERR	String		Yes	1	citmPEN_ERR_Y	PEN_USE_ERR
			No	2	citmPEN_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_MESI_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.

: 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	Result	Date of test
1.a	PREGNANCY_TEST_RESULT	Urine		

Pregnancy Test Entry [sctPREGLOG]

1.1	Test *[hidden]* [Test]	**[PREGLOG_LBTPCD_L]** *[A:1]* PREGNANCY_TEST_RESULT
1.2	Medium *[read-only]* [Medium]	**[PREGLOG_LBSPEC_L]** *[A:4]* Urine
1.3	Result [Result]	**[PREGLOG_LBORRES_L]** *[A:1]* Positive *[A:2]* Negative
1.4	Date of test [Date of test]	**[PREGLOG_LBDTC_D] (DD/MM/YYYY)** Req / Req / Req (2023-2030)

Key: = 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
clPREGLOG_LBTPCD	String		PREGNANCY_TEST_RESULT	1	citmPREGLOG_TEST	PREGLOG_LBTPCD_L
clPREGLOG_LBSPEC	String		Urine	4	citmPREGLOG_U	PREGLOG_LBSPEC_L
clPREGLOG_LBORRES	String		Positive	1	citmPREGLOG_POS	PREGLOG_LBORRES_L
			Negative	2	citmPREGLOG_NEG	

RDE Analytics: RD_PREGLOG

Data Variable RefName	RD Column Name	Column Data Type
RD_PREGLOG_SCTPREGLOG		
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

: Withdrawal of Consent to Biosamples for Future Research (Withdrawal Future Research) [WITHDRAWAL_FUTURE_RESEARCH]

Study ID:

1.*	Biosam thdrawn [Biosamples Consent withdrawn]	**[WITH_DSTERM_1]** *[A:2]* No *[A:1]* **[grpWITH_DSTERM_1]** Yes **[DSSTDTC_4] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
2.	xxxx Consent withdrawn *[hidden]* [xxxx Consent withdrawn]	**[WITH_DSTERM_2]** *[A:2]* No *[A:1]* **[grpWITH_DSTERM_2]** Yes **[DSSTDTC_5] (DD/MM/YYYY)** Req / Req / Req (2022-2035)
3.	xxxx Consent withdrawn *[hidden]* [xxxx Consent withdrawn]	**[WITH_DSTERM_3]** *[A:2]* No *[A:1]* **[grpWITH_DSTERM_3]** Yes **[DSSTDTC_6] (DD/MM/YYYY)** Req / Req / Req (2022-2035)

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_DSTERM_2	**Item DEACTIVATED**
Item	WITH_DSTERM_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
clDSTERM_YN_4	String		No	2	citmDSTERM_4N	WITH_DSTERM_1
			Yes	1	citmDSTERM_4Y	
clDSTERM_YN_5	String		No	2	citmDSTERM_5N	WITH_DSTERM_2
			Yes	1	citmDSTERM_5Y	
clDSTERM_YN_6	String		No	2	citmDSTERM_6N	WITH_DSTERM_3
			Yes	1	citmDSTERM_6Y	

RDE Analytics: *RD_WITHDRAWAL_FUTURE_RESEARCH

Data Variable RefName	RD Column Name	Column Data Type
WITH_DSTERM_1	WITH_DSTERM_1_C	VARCHAR2
	WITH_DSTERM_1	VARCHAR2
	WITH_DSTERM_1_ND	VARCHAR2
WITH_DSTERM_1 - DSSTDTC_4	DSSTDTC_4	DATE
	DSSTDTC_4_DTS	VARCHAR2
WITH_DSTERM_2	WITH_DSTERM_2_C	VARCHAR2
	WITH_DSTERM_2	VARCHAR2
	WITH_DSTERM_2_ND	VARCHAR2
WITH_DSTERM_2 - DSSTDTC_5	DSSTDTC_5	DATE
	DSSTDTC_5_DTS	VARCHAR2
WITH_DSTERM_3	WITH_DSTERM_3_C	VARCHAR2
	WITH_DSTERM_3	VARCHAR2
	WITH_DSTERM_3_ND	VARCHAR2
WITH_DSTERM_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.

: Hypoglycaemic Episode (Hypo) - Repeating Form [HYPO_5_PAED]

#	Seq.	te & 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

Part 1 [sctHYPO_5]

1. Hypoglycaemic episode number *[read-only]*
[Seq. No.]
[HYPOS_SEQ_NO]
0 < N3

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_STDTTM] (DD/MM/YYYY hh:mm)
Req / Req / Req (2023-2030)
Req/Unk : Req/Unk *24-hour clock*

3.* **Lowest** glucose value recorded during the hypoglycaemic episode
Report 'Not done' if diary response is 'Unknown'.
[Lowest glucose value]
[HYPOS_LOWEST]
[A:1] **[grpHYPOS_LOWEST]**
[HYPOS_GLUC_LEVEL] [HYPOS_GLUC_UNIT]
0 <= xxxx. *[A:561]* mmol/L *[A:162]* mg/dL
[A:997] Not done

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 / Req / Req (2023-2030)
Req/Unk : Req/Unk *24-hour clock*

5.* Did the hypoglycaemic episode occur in relation to physical activity?
[Related to physical activity]
[HYPOS_PHYS_ACT]
[A:1] Yes
[A:2] No
[A:996] Unknown

6.* Was the subject asleep when the hypoglycaemic episode occurred?
[Was the subject asleep]
[HYPOS_ASLEEP_YN]
[A:1] **[HYPOS_SYMWAKE_YN]**
Yes
Did the symptoms of the hypoglycaemic episode wake up the subject?
[A:1] Yes *[A:2]* No
[A:2] No

7. Were there any symptoms? *[hidden]*
[Symptomatic]
[SYMPTOM_EPISODE_YN]
[A:1] Yes
[A:2] 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] Yes
[A:2] No

IMP Details [sctHYPO_5_TRT]

#	Investigational medicinal product	Date and time of last dose*	Dose and unit*
9.a	Semaglutide/ Semaglutide placebo		

IMP Details Entry [sctHYPO_5_TRT]

9.1 Investigational medicinal product
[Investigational medicinal product]
[HYPOS_ECTRT]
[A:1] Semaglutide/ Semaglutide placebo

9.2* Date and time of last dose
[Date and time of last dose]
[HYPOS_ECSTDAT] (DD/MM/YYYY hh:mm)
Req / Req / Req (2023-2030)
Req/Unk : Req/Unk *24-hour clock*

9.3* Dose and unit
[Dose and unit]
[grpHYPOS_ECDOSE]
[HYPOS_ECDOSE] [HYPOS_ECDOSU]
xxxxx.x *[A:1]* mg

Drug of interest Details [sctHYPO_5_TRT2]

#	Medication	Date and time of last dose*	Dose and unit*
10.a	Metformin		
10.b	Basal Insulin		

Drug of interest Details Entry [sctHYPO_5_TRT2]

10.1 Medication
[Medication]
[HYPOS_CMTRT]
[A:113] Metformin *[A:4]* Basal Insulin

10.2* Date and time of last dose
[Date and time of last dose]
[HYPOS_CMSTDAT] (DD/MM/YYYY hh:mm)
Req / Req / Req (2023-2030)
Req/Unk : Req/Unk *24-hour clock*

10.3* Dose and unit
[Dose and unit]
[grpHYPOS_CMDOSE]
[HYPOS_CMDOSE] [HYPOS_CMDOSU]
xxxxx.x *[A:1]* mg *[A:2]* U

11.* Date and time of last main meal (not including snacks) before the hypoglycaemic episode
Report date and time as Unk/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 / Req/Unk / Req/Unk (2023-2030)
Req/Unk : Req/Unk *24-hour clock*

12.* Is the hypoglycaemic episode a Serious Adverse Event (SAE)?
[SAE]
[HYPOS_SAE_YN]
[A:2] No
[A:1] **[HYPOS_RELAE]**
Yes
Enter primary AE no: 0 < N3

Part 2 [sctHYPO_5_2]

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]
[grpHYPOS_SYM]
[HYPOS_SYM_NAUS]
[A:1] Feeling sick (nausea)
[HYPOS_SYM_SHAK]
[A:2] Feeling shaky (shakiness)
[HYPOS_SYM_SWT]
[A:3] Feeling sweaty (sweatiness)
[HYPOS_SYM_AGIT]
[A:4] Feeling anxious (agitation)
[HYPOS_SYM_TIRED]
[A:5] Feeling tired (tiredness)
[HYPOS_SYM_IRR]
[A:6] Feeling short-tempered (irritability)
[HYPOS_SYM_HUN]
[A:7] Feeling hungry (hunger)
[HYPOS_SYM_CONC]
[A:8] Finding it hard to think (poor concentration)
[HYPOS_SYM_DEC]
[A:9] Not able to make a decision (poor judgement and confusion)
[HYPOS_SYM_MEM]
[A:10] Cannot remember things that happened recently (problems with short-term memory)
[HYPOS_SYM_DIZ]
[A:11] Feeling your head spin and unsteady walking (dizziness and unsteady gait)
[HYPOS_SYM_ERR]
[A:12] Behaviour which is not normal (erratic behaviour)
[HYPOS_SYM_PALP]
[A:13] Rapid or irregular heartbeat (palpitations)
[HYPOS_SYM_HDACH]
[A:14] Headache
[HYPOS_SYM_NMARE]
[A:15] Nightmares
[HYPOS_SYM_TRMB]

		[A:16] ☐ Trembling **[HYPOS_SYM_HEAR]** *[A:17]* ☐ Hearing problems (difficulty hearing) **[HYPOS_SYM_SIGT]** *[A:18]* ☐ Sight problems (blurred or double vision, disturbed colour vision) **[HYPOS_SYM_CRY]** *[A:19]* ☐ Non-stop crying (inconsolable crying) **[HYPOS_SYM_SPCH]** *[A:20]* ☐ Slurred speech **[HYPOS_SYM_PALE]** *[A:21]* ☐ Extreme pale skin (pallor) **[HYPOS_SYM_OTH]** *[A:999]* ☐ Other
14.	Was a medical person helping the subject to handle the hypoglycaemic episode? [Medical person helping]	**[HYPOS_MEDHELP_YN]** *[A:1]* ◯ Yes *[A:2]* ◯ No *[A:996]* ◯ Unknown
15.	Where was the subject treated for the hypoglycaemic episode? [Where was the subject treated]	**[grpHYPOS_TRTINCLIN]** **[HYPOS_TRTINCLIN]** *[A:11]* ☐ **[HYPOS_AMBUL_YN]** In clinic, emergency room or hospital Was the subject transported by ambulance? *[A:1]* ◯ Yes *[A:2]* ◯ No **[HYPOS_TRTOTHLOC]** *[A:999]* ☐ Other
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
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
18.	What type of treatment was given to the subject during the hypoglycaemic episode? [Type of treatment]	**[grpHYPOS_TRT]** **[HYPOS_TRTCARB]** *[A:1]* ☐ Something to eat or drink (carbohydrates) **[HYPOS_TRTGGON]** *[A:2]* ☐ Glucagon injection **[HYPOS_TRTGLUC]** *[A:4]* ☐ IV glucose **[HYPOS_TRTOTH]** *[A:999]* ☐ Other
19.	Did the subject feel better after the treatment? [Did the subject feel better after the treatment]	**[HYPOS_BETRAFTTRT_YN]** *[A:1]* ◯ Yes *[A:2]* ◯ No
20.	Which of the following factors does the subject think may have contributed to the hypoglycaemic episode? [Contributing factors]	**[grpHYPOS_FACTORS]** **[HYPOS_DIETCNG]** *[A:1]* ☐ Change of diet **[HYPOS_MISDMEAL]** *[A:2]* ☐ Missed meal **[HYPOS_PHYACT]** *[A:5]* ☐ Physical activity **[HYPOS_ALCH]** *[A:18]* ☐ Drinking alcohol **[HYPOS_DOSCLCERR]** *[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_DEVUSEERR]** *[A:20]* ☐ Made a mistake when using the device **[HYPOS_OTHFACT]** *[A:999]* ☐ Other **[HYPOS_UNKFACT]** *[A:996]* ☐ Unknown
21.	Office use only *[hidden]* [HypoOfficeOnly]	**[Hypo_OFFICE5]** 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: Hypo
Item	HYPO5_SEQ_NO	Calculated in InForm via rule
Item	HYPO5_STOP_DTTM	**Item DEACTIVATED**
Item	SYMPTOM_EPISODE_YN	**Item DEACTIVATED**
Item	HYPO5_RELAE	Integrations: A, R - please do not change the refname or format
Item	Hypo_OFFICE5	Item used for email

Keys (navigation)/Uniqueness: Hypoglycaemic Episode

Item	Unique	Order #
HYPO_5_PAED (Repeating form)		
sctHYPO_5		
HYPO5_STDTTM	None	1

Codelist Values Tables: Hypoglycaemic Episode

Codelist RefName	Codelist Data Type	Subset	Label	Code	Codelist Item RefName	Data Variable RefName
clHYPO5_LOWEST	String		Done	1	citmGLUC_LOW_1	HYPO5_LOWEST
			Not done	997	citmGLUC_LOW_997	
clHYPO5_GLUCLOW_U	String		mmol/L	561	citmGLUC_UNIT_MMOLL	HYPO5_GLUC_UNIT
			mg/dL	162	citmGLUC_UNIT_MGDL	
clPHYACT_YN	String		Yes	1	citmPHYACT_Y	HYPO5_PHYS_ACT
			No	2	citmPHYACT_N	
			Unknown	996	citmPHYACT_UNK	
clASLEEP_YN	String		Yes	1	citmASLEEP_Y	HYPO5_ASLEEP_YN
			No	2	citmASLEEP_N	
clSYMWAKE_YN	String		Yes	1	citmSYMWAKE_Y	HYPO5_SYMWAKE_YN
			No	2	citmSYMWAKE_N	
clSYMPTOM_EPISODE_YN	String		Yes	1	citmSYMPTOM_EPISODE_Y	SYMPTOM_EPISODE_YN

			No	2	citmSYMPTOM_EPISODE_N	
clSEV_H[illegible]	String		Yes	1	citmSEV_HYPO_Y	HYPO5_SEVERE_YN
			No	2	citmSEV_HYPO_N	
clHYPO5_ECTRT	String		Semaglutide/ Semaglutide placebo	1	citmHYPO5_ECTRT_1	HYPO5_ECTRT
clHYPO5_ECDOSU	String		mg	1	citmHYPO5_UNIT1	HYPO5_ECDOSU
clHYPO5_CMTRT	String		Metformin	113	citmHYPO5_CMTRT_1	HYPO5_CMTRT
			Basal Insulin	4	citmHYPO5_CMTRT_2	
clHYPO5_CMDOSU	String		mg	1	citmHYPO5_CMUNIT1	HYPO5_CMDOSU
			U	2	citmHYPO5_CMUNIT2	
clHYPO5_SAE_YN	String		No	2	citmHYPO5_SAE_N	HYPO5_SAE_YN
			Yes	1	citmHYPO5_SAE_Y	
clHYPO5_SYM_NAUS	String		Feeling sick (nausea)	1	citmHYPO5_SYM_NAUS	HYPO5_SYM_NAUS
clHYPO5_SYM_SHAK	String		Feeling shaky (shakiness)	2	citmHYPO5_SYM_SHAK	HYPO5_SYM_SHAK
clHYPO5_SYM_SWT	String		Feeling sweaty (sweatiness)	3	citmHYPO5_SYM_SWT	HYPO5_SYM_SWT
clHYPO5_SYM_AGIT	String		Feeling anxious (agitation)	4	citmHYPO5_SYM_AGIT	HYPO5_SYM_AGIT
clHYPO5_SYM_TIRED	String		Feeling tired (tiredness)	5	citmHYPO5_SYM_TIRED	HYPO5_SYM_TIRED
clHYPO5_SYM_IRR	String		Feeling short-tempered (irritability)	6	citmHYPO5_SYM_IRR	HYPO5_SYM_IRR
clHYPO5_SYM_HUN	String		Feeling hungry (hunger)	7	citmHYPO5_SYM_HUN	HYPO5_SYM_HUN
clHYPO5_SYM_CONC	String		Finding it hard to think (poor concentration)	8	citmHYPO5_SYM_CONC	HYPO5_SYM_CONC
clHYPO5_SYM_DEC	String		Not able to make a decision (poor judgement and confusion)	9	citmHYPO5_SYM_DEC	HYPO5_SYM_DEC
clHYPO5_SYM_MEM	String		Cannot remember things that happened recently (problems with short-term memory)	10	citmHYPO5_SYM_MEM	HYPO5_SYM_MEM
clHYPO5_SYM_DIZ	String		Feeling your head spin and unsteady walking (dizziness and unsteady gait)	11	citmHYPO5_SYM_DIZ	HYPO5_SYM_DIZ
clHYPO5_SYM_ERR	String		Behaviour which is not normal (erratic behaviour)	12	citmHYPO5_SYM_ERR	HYPO5_SYM_ERR
clHYPO5_SYM_PALP	String		Rapid or irregular heartbeat (palpitations)	13	citmHYPO5_SYM_PALP	HYPO5_SYM_PALP
clHYPO5_SYM_HDACH	String		Headache	14	citmHYPO5_SYM_HDACH	HYPO5_SYM_HDACH
clHYPO5_SYM_NMARE	String		Nightmares	15	citmHYPO5_SYM_NMARE	HYPO5_SYM_NMARE
clHYPO5_SYM_TRMB	String		Trembling	16	citmHYPO5_SYM_TRMB	HYPO5_SYM_TRMB
clHYPO5_SYM_HEAR	String		Hearing problems (difficulty hearing)	17	citmHYPO5_SYM_HEAR	HYPO5_SYM_HEAR
clHYPO5_SYM_SIGT	String		Sight problems (blurred or double vision, disturbed colour vision)	18	citmHYPO5_SYM_SIGT	HYPO5_SYM_SIGT
clHYPO5_SYM_CRY	String		Non-stop crying (inconsolable crying)	19	citmHYPO5_SYM_CRY	HYPO5_SYM_CRY
clHYPO5_SYM_SPCH	String		Slurred speech	20	citmHYPO5_SYM_SPCH	HYPO5_SYM_SPCH
clHYPO5_SYM_PALE	String		Extreme pale skin (pallor)	21	citmHYPO5_SYM_PALE	HYPO5_SYM_PALE
clHYPO5_SYM_OTH	String		Other	999	citmHYPO5_SYM_OTH	HYPO5_SYM_OTH
clHYPO5_MEDHELP_YN	String		Yes	1	citmHYPO5_MEDHELP_1	HYPO5_MEDHELP_YN
			No	2	citmHYPO5_MEDHELP_2	
			Unknown	996	citmHYPO5_MEDHELP_996	
clHYPO5_TRTINCLIN	String		In clinic, emergency room or hospital	11	citmHYPO5_TRTINCLIN	HYPO5_TRTINCLIN
clHYPO5_AMBUL_YN	String		Yes	1	citmHYPO5_AMBUL_Y	HYPO5_AMBUL_YN
			No	2	citmHYPO5_AMBUL_N	
clHYPO5_TRTOTHLOC	String		Other	999	citmHYPO5_TRTOTHLOC	HYPO5_TRTOTHLOC
clHYPO5_SEIZUR_YN	String		Yes	1	citmHYPO5_SEIZUR_Y	HYPO5_SEIZUR_YN
			No	2	citmHYPO5_SEIZUR_N	
clHYPO5_UNCONCOMA_YN	String		Yes	1	citmHYPO5_UNCONCOMA_Y	HYPO5_UNCONCOMA_YN
			No	2	citmHYPO5_UNCONCOMA_N	
clHYPO5_TRTCARB	String		Something to eat or drink (carbohydrates)	1	citmHYPO5_TRTCARB	HYPO5_TRTCARB
clHYPO5_TRTGGON	String		Glucagon injection	2	citmHYPO5_TRTGGON	HYPO5_TRTGGON
clHYPO5_TRTGLUC	String		IV glucose	4	citmHYPO5_TRTGLUC	HYPO5_TRTGLUC
clHYPO5_TRTOTH	String		Other	999	citmHYPO5_TRTOTH	HYPO5_TRTOTH
clHYPO5_BETRAFTTRT_YN	String		Yes	1	citmHYPO5_BETRAFTTRT_Y	HYPO5_BETRAFTTRT_YN
			No	2	citmHYPO5_BETRAFTTRT_N	
clHYPO5_DIETCNG	String		Change of diet	1	citmHYPO5_DIETCNG	HYPO5_DIETCNG
clHYPO5_MISDMEAL	String		Missed meal	2	citmHYPO5_MISDMEAL	HYPO5_MISDMEAL
clHYPO5_PHYACT	String		Physical activity	5	citmHYPO5_PHYACT	HYPO5_PHYACT
clHYPO5_ALCH	String		Drinking alcohol	18	citmHYPO5_ALCH	HYPO5_ALCH
clHYPO5_DOSCLCERR	String		Made a mistake in calculating the dose of diabetes medication	8	citmHYPO5_DOSCLCERR	HYPO5_DOSCLCERR
clHYPO5_ACCHIDOS	String		Accidentally took too high dose of diabetes medication	9	citmHYPO5_ACCHIDOS	HYPO5_ACCHIDOS
clHYPO5_MEDMIXUP	String		Mixed up the diabetes medications	10	citmHYPO5_MEDMIXUP	HYPO5_MEDMIXUP
clHYPO5_DEVUSEERR	String		Made a mistake when using the device	20	citmHYPO5_DEVUSEERR	HYPO5_DEVUSEERR
clHYPO5_OTHFACT	String		Other	999	citmHYPO5_OTHFACT	HYPO5_OTHFACT
clHYPO5_UNKFACT	String		Unknown	996	citmHYPO5_UNKFACT	HYPO5_UNKFACT

RDE Analytics: RD_HYPO_5_PAED

Data Variable RefName	RD Column Name	Column Data Type
HYPO5_SEQ_NO	HYPO5_SEQ_NO	NUMBER
	HYPO5_SEQ_NO_ND	VARCHAR2
HYPO5_STDTTM	HYPO5_STDTTM	DATE
	HYPO5_STDTTM_DTS	VARCHAR2
	HYPO5_STDTTM_DTR	VARCHAR2
	HYPO5_STDTTM_ND	VARCHAR2
HYPO5_LOWEST	HYPO5_LOWEST_C	VARCHAR2
	HYPO5_LOWEST	VARCHAR2
	HYPO5_LOWEST_ND	VARCHAR2
HYPO5_LOWEST - HYPO5_GLUC_LEVEL	HYPO5_GLUC_LEVEL	FLOAT
HYPO5_LOWEST - HYPO5_GLUC_UNIT	HYPO5_GLUC_UNIT_C	VARCHAR2
	HYPO5_GLUC_UNIT	VARCHAR2
HYPO5_STOP_DTTM	HYPO5_STOP_DTTM	DATE
	HYPO5_STOP_DTTM_DTS	VARCHAR2
	HYPO5_STOP_DTTM_DTR	VARCHAR2
	HYPO5_STOP_DTTM_ND	VARCHAR2
HYPO5_PHYS_ACT	HYPO5_PHYS_ACT_C	VARCHAR2
	HYPO5_PHYS_ACT	VARCHAR2
	HYPO5_PHYS_ACT_ND	VARCHAR2
HYPO5_ASLEEP_YN	HYPO5_ASLEEP_YN_C	VARCHAR2
	HYPO5_ASLEEP_YN	VARCHAR2
	HYPO5_ASLEEP_YN_ND	VARCHAR2
HYPO5_ASLEEP_YN - HYPO5_SYMWAKE_YN	HYPO5_SYMWAKE_YN_C	VARCHAR2
	HYPO5_SYMWAKE_YN	VARCHAR2
SYMPTOM_EPISODE_YN	SYMPTOM_EPISODE_YN_C	VARCHAR2
	SYMPTOM_EPISODE_YN	VARCHAR2

	SYMPTOM_EPISODE_YN_ND	VARCHAR2
HYPO5_S...	HYPO5_SEVERE_YN_C	VARCHAR2
	HYPO5_SEVERE_YN	VARCHAR2
	HYPO5_SEVERE_YN_ND	VARCHAR2
HYPO5_MLDAT	HYPO5_MLDAT	DATE
	HYPO5_MLDAT_DTS	VARCHAR2
	HYPO5_MLDAT_DTR	VARCHAR2
	HYPO5_MLDAT_ND	VARCHAR2
HYPO5_SAE_YN	HYPO5_SAE_YN_C	VARCHAR2
	HYPO5_SAE_YN	VARCHAR2
	HYPO5_SAE_YN_ND	VARCHAR2
HYPO5_SAE_YN - HYPO5_RELAE	HYPO5_RELAE	NUMBER
grpHYPO5_SYM	GRPHYPO5_SYM_ND	VARCHAR2
grpHYPO5_SYM - Feeling sick (nausea)	*HYPO5_SYM_NAUS_CITMHYPO5SYMNAUS_C	VARCHAR2
	*HYPO5_SYM_NAUS_CITMHYPO5SYMNAUS	VARCHAR2
grpHYPO5_SYM - Feeling shaky (shakiness)	*HYPO5_SYM_SHAK_CITMHYPO5SYMSHAK_C	VARCHAR2
	*HYPO5_SYM_SHAK_CITMHYPO5SYMSHAK	VARCHAR2
grpHYPO5_SYM - Feeling sweaty (sweatiness)	*HYPO5_SYM_SWT_CITMHYPO5SYMSWT_C	VARCHAR2
	*HYPO5_SYM_SWT_CITMHYPO5SYMSWT	VARCHAR2
grpHYPO5_SYM - Feeling anxious (agitation)	*HYPO5_SYM_AGIT_CITMHYPO5SYMAGIT_C	VARCHAR2
	*HYPO5_SYM_AGIT_CITMHYPO5SYMAGIT	VARCHAR2
grpHYPO5_SYM - Feeling tired (tiredness)	*HYPO5_SYM_TIRED_CITMHYPO5SYMTIRED_C	VARCHAR2
	*HYPO5_SYM_TIRED_CITMHYPO5SYMTIRED	VARCHAR2
grpHYPO5_SYM - Feeling short-tempered (irritability)	*HYPO5_SYM_IRR_CITMHYPO5SYMIRR_C	VARCHAR2
	*HYPO5_SYM_IRR_CITMHYPO5SYMIRR	VARCHAR2
grpHYPO5_SYM - Feeling hungry (hunger)	*HYPO5_SYM_HUN_CITMHYPO5SYMHUN_C	VARCHAR2
	*HYPO5_SYM_HUN_CITMHYPO5SYMHUN	VARCHAR2
grpHYPO5_SYM - Finding it hard to think (poor concentration)	*HYPO5_SYM_CONC_CITMHYPO5SYMCONC_C	VARCHAR2
	*HYPO5_SYM_CONC_CITMHYPO5SYMCONC	VARCHAR2
grpHYPO5_SYM - Not able to make a decision (poor judgement and confusion)	*HYPO5_SYM_DEC_CITMHYPO5SYMDEC_C	VARCHAR2
	*HYPO5_SYM_DEC_CITMHYPO5SYMDEC	VARCHAR2
grpHYPO5_SYM - Cannot remember things that happened recently (problems with short-term memory)	*HYPO5_SYM_MEM_CITMHYPO5SYMMEM_C	VARCHAR2
	*HYPO5_SYM_MEM_CITMHYPO5SYMMEM	VARCHAR2
grpHYPO5_SYM - Feeling your head spin and unsteady walking (dizziness and unsteady gait)	*HYPO5_SYM_DIZ_CITMHYPO5SYMDIZ_C	VARCHAR2
	*HYPO5_SYM_DIZ_CITMHYPO5SYMDIZ	VARCHAR2
grpHYPO5_SYM - Behaviour which is not normal (erratic behaviour)	*HYPO5_SYM_ERR_CITMHYPO5SYMERR_C	VARCHAR2
	*HYPO5_SYM_ERR_CITMHYPO5SYMERR	VARCHAR2
grpHYPO5_SYM - Rapid or irregular heartbeat (palpitations)	*HYPO5_SYM_PALP_CITMHYPO5SYMPALP_C	VARCHAR2
	*HYPO5_SYM_PALP_CITMHYPO5SYMPALP	VARCHAR2
grpHYPO5_SYM - Headache	*HYPO5_SYM_HDACH_CITMHYPO5SYMHDACH_C	VARCHAR2
	*HYPO5_SYM_HDACH_CITMHYPO5SYMHDACH	VARCHAR2
grpHYPO5_SYM - Nightmares	*HYPO5_SYM_NMARE_CITMHYPO5SYMNMARE_C	VARCHAR2
	*HYPO5_SYM_NMARE_CITMHYPO5SYMNMARE	VARCHAR2
grpHYPO5_SYM - Trembling	*HYPO5_SYM_TRMB_CITMHYPO5SYMTRMB_C	VARCHAR2
	*HYPO5_SYM_TRMB_CITMHYPO5SYMTRMB	VARCHAR2
grpHYPO5_SYM - Hearing problems (difficulty hearing)	*HYPO5_SYM_HEAR_CITMHYPO5SYMHEAR_C	VARCHAR2
	*HYPO5_SYM_HEAR_CITMHYPO5SYMHEAR	VARCHAR2
grpHYPO5_SYM - Sight problems (blurred or double vision, disturbed colour vision)	*HYPO5_SYM_SIGT_CITMHYPO5SYMSIGT_C	VARCHAR2
	*HYPO5_SYM_SIGT_CITMHYPO5SYMSIGT	VARCHAR2
grpHYPO5_SYM - Non-stop crying (inconsolable crying)	*HYPO5_SYM_CRY_CITMHYPO5SYMCRY_C	VARCHAR2
	*HYPO5_SYM_CRY_CITMHYPO5SYMCRY	VARCHAR2
grpHYPO5_SYM - Slurred speech	*HYPO5_SYM_SPCH_CITMHYPO5SYMSPCH_C	VARCHAR2
	*HYPO5_SYM_SPCH_CITMHYPO5SYMSPCH	VARCHAR2
grpHYPO5_SYM - Extreme pale skin (pallor)	*HYPO5_SYM_PALE_CITMHYPO5SYMPALE_C	VARCHAR2
	*HYPO5_SYM_PALE_CITMHYPO5SYMPALE	VARCHAR2
grpHYPO5_SYM - Other	*HYPO5_SYM_OTH_CITMHYPO5SYMOTH_C	VARCHAR2
	*HYPO5_SYM_OTH_CITMHYPO5SYMOTH	VARCHAR2
HYPO5_MEDHELP_YN	HYPO5_MEDHELP_YN_C	VARCHAR2
	HYPO5_MEDHELP_YN	VARCHAR2
	HYPO5_MEDHELP_YN_ND	VARCHAR2
grpHYPO5_TRTINCLIN	GRPHYPO5_TRTINCLIN_ND	VARCHAR2
grpHYPO5_TRTINCLIN - In clinic, emergency room or hospital	*HYPO5_TRTINCLIN_HYPO5_AMBUL_YN_C	VARCHAR2
	*HYPO5_TRTINCLIN_HYPO5_AMBUL_YN	VARCHAR2
grpHYPO5_TRTINCLIN - HYPO5_AMBUL_YN	HYPO5_AMBUL_YN_C	VARCHAR2
	HYPO5_AMBUL_YN	VARCHAR2
grpHYPO5_TRTINCLIN - Other	*HYPO5_TRTOTHLOC_CITMHYPO5TRTOTHLOC_C	VARCHAR2
	*HYPO5_TRTOTHLOC_CITMHYPO5TRTOTHLOC	VARCHAR2
HYPO5_SEIZUR_YN	HYPO5_SEIZUR_YN_C	VARCHAR2
	HYPO5_SEIZUR_YN	VARCHAR2
	HYPO5_SEIZUR_YN_ND	VARCHAR2
HYPO5_UNCONCOMA_YN	HYPO5_UNCONCOMA_YN_C	VARCHAR2
	HYPO5_UNCONCOMA_YN	VARCHAR2
	HYPO5_UNCONCOMA_YN_ND	VARCHAR2
grpHYPO5_TRT	GRPHYPO5_TRT_ND	VARCHAR2
grpHYPO5_TRT - Something to eat or drink (carbohydrates)	*HYPO5_TRTCARB_CITMHYPO5TRTCARB_C	VARCHAR2
	*HYPO5_TRTCARB_CITMHYPO5TRTCARB	VARCHAR2
grpHYPO5_TRT - Glucagon injection	*HYPO5_TRTGGON_CITMHYPO5TRTGGON_C	VARCHAR2
	*HYPO5_TRTGGON_CITMHYPO5TRTGGON	VARCHAR2
grpHYPO5_TRT - IV glucose	*HYPO5_TRTGLUC_CITMHYPO5TRTGLUC_C	VARCHAR2
	*HYPO5_TRTGLUC_CITMHYPO5TRTGLUC	VARCHAR2
grpHYPO5_TRT - Other	*HYPO5_TRTOTH_CITMHYPO5TRTOTH_C	VARCHAR2
	*HYPO5_TRTOTH_CITMHYPO5TRTOTH	VARCHAR2
HYPO5_BETRAFTTRT_YN	HYPO5_BETRAFTTRT_YN_C	VARCHAR2
	HYPO5_BETRAFTTRT_YN	VARCHAR2
	HYPO5_BETRAFTTRT_YN_ND	VARCHAR2
grpHYPO5_FACTORS	GRPHYPO5_FACTORS_ND	VARCHAR2
grpHYPO5_FACTORS - Change of diet	*HYPO5_DIETCNG_CITMHYPO5DIETCNG_C	VARCHAR2
	*HYPO5_DIETCNG_CITMHYPO5DIETCNG	VARCHAR2
grpHYPO5_FACTORS - Missed meal	*HYPO5_MISDMEAL_CITMHYPO5MISDMEAL_C	VARCHAR2

	*HYPO5_MISDMEAL_CITMHYPO5MISDMEAL	VARCHAR2
grpHYPO [illegible] physical activity	*HYPO5_PHYACT_CITMHYPO5PHYACT_C	VARCHAR2
	*HYPO5_PHYACT_CITMHYPO5PHYACT	VARCHAR2
grpHYPO5_FACTORS - Drinking alcohol	HYPO5_ALCH_CITMHYPO5ALCH_C	VARCHAR2
	HYPO5_ALCH_CITMHYPO5ALCH	VARCHAR2
grpHYPO5_FACTORS - Made a mistake in calculating the dose of diabetes medication	*HYPO5_DOSCLCERR_CITMHYPO5DOSCLCERR_C	VARCHAR2
	*HYPO5_DOSCLCERR_CITMHYPO5DOSCLCERR	VARCHAR2
grpHYPO5_FACTORS - Accidentally took too high dose of diabetes medication	*HYPO5_ACCHIDOS_CITMHYPO5ACCHIDOS_C	VARCHAR2
	*HYPO5_ACCHIDOS_CITMHYPO5ACCHIDOS	VARCHAR2
grpHYPO5_FACTORS - Mixed up the diabetes medications	*HYPO5_MEDMIXUP_CITMHYPO5MEDMIXUP_C	VARCHAR2
	*HYPO5_MEDMIXUP_CITMHYPO5MEDMIXUP	VARCHAR2
grpHYPO5_FACTORS - Made a mistake when using the device	*HYPO5_DEVUSEERR_CITMHYPO5DEVUSEERR_C	VARCHAR2
	*HYPO5_DEVUSEERR_CITMHYPO5DEVUSEERR	VARCHAR2
grpHYPO5_FACTORS - Other	*HYPO5_OTHFACT_CITMHYPO5OTHFACT_C	VARCHAR2
	*HYPO5_OTHFACT_CITMHYPO5OTHFACT	VARCHAR2
grpHYPO5_FACTORS - Unknown	*HYPO5_UNKFACT_CITMHYPO5UNKFACT_C	VARCHAR2
	*HYPO5_UNKFACT_CITMHYPO5UNKFACT	VARCHAR2
Hypo_OFFICE5	HYPO_OFFICE5	NUMBER
	HYPO_OFFICE5_ND	VARCHAR2
***RD_HYPO_5_PAED_SCTHYPO_5_TRT**		
HYPO5_ECTRT	HYPO5_ECTRT_C	VARCHAR2
	HYPO5_ECTRT	VARCHAR2
	HYPO5_ECTRT_ND	VARCHAR2
HYPO5_ECSTDAT	HYPO5_ECSTDAT	DATE
	HYPO5_ECSTDAT_DTS	VARCHAR2
	HYPO5_ECSTDAT_DTR	VARCHAR2
	HYPO5_ECSTDAT_ND	VARCHAR2
grpHYPO5_ECDOSE	GRPHYPO5_ECDOSE_ND	VARCHAR2
grpHYPO5_ECDOSE - HYPO5_ECDOSE	HYPO5_ECDOSE	FLOAT
grpHYPO5_ECDOSE - HYPO5_ECDOSU	HYPO5_ECDOSU_C	VARCHAR2
	HYPO5_ECDOSU	VARCHAR2
***RD_HYPO_5_PAED_SCTHYPO_5_TRT2**		
HYPO5_CMTRT	HYPO5_CMTRT_C	VARCHAR2
	HYPO5_CMTRT	VARCHAR2
	HYPO5_CMTRT_ND	VARCHAR2
HYPO5_CMSTDAT	HYPO5_CMSTDAT	DATE
	HYPO5_CMSTDAT_DTS	VARCHAR2
	HYPO5_CMSTDAT_DTR	VARCHAR2
	HYPO5_CMSTDAT_ND	VARCHAR2
grpHYPO5_CMDOSE	GRPHYPO5_CMDOSE_ND	VARCHAR2
grpHYPO5_CMDOSE - HYPO5_CMDOSE	HYPO5_CMDOSE	FLOAT
grpHYPO5_CMDOSE - HYPO5_CMDOSU	HYPO5_CMDOSU_C	VARCHAR2
	HYPO5_CMDOSU	VARCHAR2

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

: 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
2.*	Date of procedure [Date]	**[PRO_DATE] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
3.*	Procedure Name [Name]	**[DIAG1_CATEG]** *[A:2]* **[DIAG_TERM10]** Bariatric surgery *[A:1]* Bariatric gastric balloon insertion *[A:2]* Bariatric gastric balloon removal *[A:3]* Duodenal-jejunal bypass sleeve therapy *[A:4]* Endoscopic sleeve gastroplasty *[A:5]* Gastric banding (includes laparoscopic adjustable gastric band) *[A:6]* Gastric band repositioning *[A:7]* Gastric banding reversal *[A:8]* Gastric bypass (roux-en-y) *[A:9]* Gastric bypass reversal *[A:10]* Duodenal switch *[A:99]* **[DIAG_TERM10OTH]** Other, specify A200 *[A:1]* **[DIAG_TERM9]** Knee surgery *[A:4]* **[DIAGTERM94]** Partial knee replacement *[A:1]* Right *[A:2]* Left *[A:3]* Bilateral *[A:5]* **[DIAGTERM95]** Total knee replacement *[A:1]* Right *[A:2]* Left *[A:3]* Bilateral *[A:99]* **[DIAGTERM9OTH]** Other, specify A200 *[A:3]* **[DIAG_TERM11_L]** Hip Surgery *[A:1]* Partial hip replacement *[A:2]* Total hip replacement *[A:3]* **[DIAG_TERM11OTH_X]** Other, specify: A200
4.	Baker's cyst excision *[hidden]* [Baker's cyst excision]	**[DIAGTERM91]** *[A:1]* Right *[A:2]* Left *[A:3]* Bilateral
5.	Joint debridement *[hidden]* [Joint debridement]	**[DIAGTERM92]** *[A:1]* Right *[A:2]* Left *[A:3]* Bilateral
6.	Revision arthroplasty *[hidden]* [Revision arthroplasty]	**[DIAGTERM93]** *[A:1]* Right *[A:2]* Left *[A:3]* Bilateral
7.*	Reason for procedure [Reason for procedure]	**[REAS_PROC]** *[A:86]* **[AE_NO]** Adverse Event,enter Adverse Event no. N3 *[A:2]* **[grp_MH_NO1]** Medical History/Concomitant Illness, enter seq. no. **[MH1_NO1]** N3 **[SUB_GRP_MH_NO1]** Was the subject previously ineligible for procedure, now eligible due to weight loss? *[A:1]* Yes *[A:2]* No *[A:99]* **[REAS_OTH]** Other, specify A200

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
clPROCEDURE_NAME	String		Bariatric surgery	2	citmPROC_NAME2	DIAG1_CATEG
			Knee Surgery	1	citmPROC_NAME1	
			Hip Surgery	3	citmPROC_NAME3	
clDIAGTERM10	String		Bariatric gastric balloon insertion	1	citmDIAGTERM101	DIAG_TERM10
			Bariatric gastric balloon removal	2	citmDIAGTERM102	
			Duodenal-jejunal bypass sleeve therapy	3	citmDIAGTERM103	
			Endoscopic sleeve gastroplasty	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	

			Other, specify	99	citmDIAGTERM111	
clDIAGTE M9	ring		Partial knee replacement	4	citmDIAGTERM94	DIAG_TERM9
			Total knee replacement	5	citmDIAGTERM95	
			Other, specify	99	citmDIAGTERM9OTH	
clSUB_DIAG_TERM91	String		Right	1	citmSUB_DIAG_TERM911	DIAGTERM94, DIAGTERM95, DIAGTERM91, DIAGTERM92, DIAGTERM93
			Left	2	citmSUB_DIAG_TERM912	
			Bilateral	3	citmSUB_DIAG_TERM913	
clDIAGTERM11_L	String		Partial hip replacement	1	citmDIAGTERM11_L_1	DIAG_TERM11_L
			Total hip replacement	2	citmDIAGTERM11_L_2	
			Other	3	citmDIAGTERM11_L_3	
clAE_MH_OTH	String		Adverse event	86	citmAENO_1	REAS_PROC
			Medical History/Concomitant Illness	2	citmMHNO_1	
			Other, specify	99	citmOTH_99	
clYESNO_4	String		Yes	1	citmYESNO1_4	SUB_GRP_MH_NO1
			No	2	citmYESNO2_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 - DIAGTERM9OTH	DIAGTERM9OTH	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

: Consent for Legal age (Reconsent) [RECONSENT]		
Study ID: Complete this ... minor reaches legal age while participating in the trial and has only signed an age specific informed assent 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]	**[CONSENT_DATE_LEGAL] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
2.	Date of re-consent obtained for Biosamples for future research [Biosample consent]	**[BIOSAMPLE_CONSENT1] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Study Object Descriptions: Consent for Legal age

Type	RefName	Description
Form	RECONSENT	Non-visit (This form will be collected for administrative purpose and mapped to OC but not in SDTM)

RDE Analytics: RD_RECONSENT

Data Variable RefName	RD Column Name	Column Data Type
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

: Date of Menarche (Menarche) [PUBERTAL_STATUS_2]	
Study ID: Note: Female only, who reaches childbearing potential during the course of study.	
1.* Date of Menarche [Date of Menarche]	**[MENARCHE_DT] (DD/MM/YYYY)** Req/Unk / Req / Req (2023-2030)

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 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_DTS	VARCHAR2
	MENARCHE_DT_DTR	VARCHAR2
	MENARCHE_DT_ND	VARCHAR2

: End of IMP Treatment (End of IMP Treatment) [END_OF_TREATMENT]

Study ID:
This form is completed once the subject has **permanently stopped** taking investigational medicinal product (IMP).

Please remember to register the discontinuation of IMP in RTSM, if applicable.

1.* ✔	Date of last dose of investigational medicinal product (Semaglutide/Semaglutide placebo) [Last date on IMP]	**[LAST_TRIAL_PROD_DATE_1]** *[A:1]* ◯ **[LAST_TRIAL_PROD_DATE_P1] (DD/MM/YYYY)** Req / Req / Req (2023-2030) *[A:998]* ◯ N/A
2.	Date of last dose of investigational medicinal product (IMP 2) *[hidden]* [Last date on IMP]	**[LAST_TRIAL_PROD_DATE_2]** *[A:1]* ◯ **[LAST_TRIAL_PROD_DATE_P2] (DD/MM/YYYY)** Req / Req / Req (2022-2035) *[A:998]* ◯ N/A
3.	Date and time of last dose of investigational medicinal product *[hidden]* [Last date and time on IMP]	**[LAST_TRIAL_PROD_TIME_1]** *[A:1]* ◯ **[LAST_TRIAL_PROD_TIME_2] (DD/MM/YYYY hh:mm)** Req / Req / Req (2022-2035) Req : Req *24-hour clock* *[A:998]* ◯ N/A
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]	**[TREAT_COMPLETION_YN]** *[A:1]* ◯ Yes *[A:2]* ◯ **[DISCONT_REASON_1]** No **Primary** reason for discontinuation of investigational medicinal product(s): *[A:11]* ◯ **[AE_HYPO_1]** Adverse Event *[A:11]* ◯ **[grpAE_NO_2]** Adverse event no.: **[AE_NO1_1]** 0 < N3 *[A:71]* ◯ **[grpHYPO_NO_1]** Hypoglycaemic episode no. (only if not reported on AE form): **[HYPO_NO1_1]** 0 < N3 *[A:29]* ◯ **[PD_SUB_REASON_CODE]** Protocol deviation *[A:201]* ◯ Included in the study in violation of the inclusion and/or exclusion criteria *[A:203]* ◯ Intention of becoming pregnant *[A:727]* ◯ Simultaneous use of an approved or non-approved investigational medicinal product in another clinical trial *[A:T1]* ◯ Calcitonin ≥50 ng/L *[A:T2]* ◯ Suspicion of acute pancreatitis *[A:T3]* ◯ Diagnosis of type 1 diabetes *[A:999]* ◯ **[PD_SUB_REASON_OTHER]** Other, specify A200 *[A:39]* ◯ Lack of efficacy *[A:12]* ◯ Lost to follow-up *[A:4]* ◯ Pregnancy *[A:38]* ◯ **[INV_DIS_OTH]** At the discretion of the Investigator Specify A200 *[A:152]* ◯ Site closure *[A:153]* ◯ **[DISCONT_REASON_EPI]** Epi/Pandemic Specify A200 *[A:999]* ◯ **[DISCONT_REA_SUB_OT]** Other (only to be selected if none of the above options are applicable) *[A:46]* ◯ Withdrawal of consent *[A:999]* ◯ **[DISCONT_REASON_OTHER_1]** Other, specify A200
5.	Lack of efficacy *[hidden]* [Lack of efficacy]	**[LE_SUB_REASON_CODE_1]** *[A:T1]* ◯ Trial specific criterion *[A:T2]* ◯ Trial specific criterion *[A:999]* ◯ Other
6.	Other, specify *[hidden]*	**[LE_SUB_REASON_OTHER_1]** A200
7.	Technical problems Specify *[hidden]*	**[TP_SUB_REASON_SPEC_1]** A200
8.	Hidden item – used for IMPACT interface for Withdrawal from treatment *[hidden]* [IMPACT - Withdrawal from treatment]	**[grpIMPACT_EOTREAT]** **[IMPACT_TREAT_DT] (DD/MM/YYYY)** IMPACT Withdrawal date Req / Req / Req (2023-2030) **[IMPACT_TREAT_REAS]** IMPACT With. Reas. Code A50

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	
clLAST_PROD	String		Date	1	citmLAST_PROD_DT_P2	LAST_TRIAL_PROD_DATE_2
			N/A	998	citmLAST_PROD_NA_P2	
clLAST_PROD_DT	String		Date and time	1	citmLAST_PROD_DTTM	LAST_TRIAL_PROD_TIME_1
			N/A	998	citmLAST_PROD_NA	
clTREAT_COMPLETION_YN	String		Yes	1	citmTREAT_COMPLETION_Y	TREAT_COMPLETION_YN
			No	2	citmTREAT_COMPLETION_N	
clDISCONT_REASON_1	String	1 - clDISCONT_REASON_1	Adverse Event	11	citmDISCONT_REASON11_1	DISCONT_REASON_1
			Protocol deviation	29	citmDISCONT_REASON13_1	
			Lack of efficacy	39	citmDISCONT_REASON39_1	
			Lost to follow-up	12	citmDISCONT_REASON12_1	
			Pregnancy	4	citmDISCONT_REASON4_1	
			At the discretion of the Investigator	38	citmDISCONT_REASON38	
			Site closure	152	citmDISCONT_REASON152	
			Epi/Pandemic	153	citmDISCONT_REASON153	
			Other	999	citmDISCONT_REASON999_1	
clAE_HYPO_1	String		Adverse event no.	11	citmAE_1	AE_HYPO_1
			Hypoglycaemic episode no.	71	citmHYPO_1	
clPD_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	
clSUB_REAS_OT	String	1 - clSUB_REAS_OT	Withdrawal of consent	46	citmSUB_REASON_OT46	DISCONT_REA_SUB_OT
			Other, specify	999	citmSUB_REASON_OT999	
clLE_SUB_REASON_1	String		Trial specific criterion	T1	citmLE_SUB_REASONT1_1	LE_SUB_REASON_CODE_1
			Trial specific criterion	T2	citmLE_SUB_REASONT2_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_REA_SUB_OT	DISCONT_REA_SUB_OT_C	VARCHAR2
	DISCONT_REA_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

: End of Study (End of Study) [END_OF_TRIAL_2]

Study ID:
This form is to be completed at the end of subject participation in the clinical study (e.g. study completion, screening failure, Withdrawal from study)

1.* ✔	Date subject's participation ended in the study [Date subject's participation ended in the study]	**[TRIAL_COMPL_DT_YN_2] (DD/MM/YYYY)** Req / Req / Req (2023-2030)
2.* ✔	Specify primary reason participation ended If the subject participation ended prior to randomisation, complete the RTSM Screening Failure session. [Specify primary reason participation ended]	**[TRIAL_COMPLETION_YN_2]** *[A:2]* ○ Subject completed the study *[A:11]* ○ Screen failure *(defined as subject not eligible for participation according to in/exclusion criteria)* *[A:14]* ○ **[WITHDR_CONS_REAS]** Withdrawal of consent by subject Specify reason, if available A200 *[A:13]* ○ **[WITHDR_CONS_LAR]** Withdrawal of consent by subject's parent or subject's legally acceptable representative (LAR) Specify reason, if available A200 *[A:6]* ○ **[LOST_FU_REASON]** Lost to follow-up Specify reason, if available A200 *[A:8]* ○ **[INVEST_DECIS_REAS]** Investigator decision Specify reason, if available A200 *[A:152]* ○ Site closure *[A:153]* ○ **[EPI_PAN_SPECIFY]** Epi/Pandemic Specify A200 *[A:3]* ○ Death
3.	Failing to meet randomisation requirements *[hidden]* [Failing to meet randomisation requirements]	**[FAIL_RAND_REQ]** *[A:122]* ○ Run-in criteria failure *[A:126]* ○ Randomisation criteria failure
4.	Hidden item – used for IMPACT interface *[hidden]* [Hidden item – used for IMPACT interface]	**[grpIMPACT_INTERFACE]** **[IMPACT_A_NUL] (DD/MM/YYYY)** Null field Req / Req / Req (2023-2030) **[IMPACT_B_DATE] (DD/MM/YYYY)** Discontinuation Date Req / Req / Req (2023-2030) **[IMPACT_C_REAS]** Discontinuation code A15
5.	Hidden item – used for InForm subject status flags *[hidden]* [Hidden item – used for InForm subject status flags]	**[STATUS_FLG]** **[clSTATUS_FLG]**
6.	Hidden item – used for InForm subject discontinuation flags *[hidden]* [Hidden item – used for InForm subject discontinuation flags]	**[STATUS_DISC_REAS]** **[clSTATUS_DISC_REAS]**

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 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
clTRIAL_COMPLETION_YN_2	String	1 - clTRIAL_COMPLETION_YN_3	Subject completed the study	2	citmTRIAL_COMPL_2	TRIAL_COMPLETION_YN_2
			Screen failure *(defined as subject not eligible for participation according to in/exclusion criteria)*	11	citmTRIAL_COMPL_11	
			Withdrawal of consent by subject	14	citmTRIAL_COMPL_14	
			Withdrawal of consent by subject's parent or subject's legally acceptable representative (LAR)	13	citmTRIAL_COMPL13	
			Lost to follow-up	6	citmTRIAL_COMPL6	
			Investigator decision	8	citmTRIAL_COMPL_8	
			Site closure	152	citmTRIAL_COMPL_152	
			Epi/Pandemic	153	citmTRIAL_COMPL_153	
			Death	3	citmTRIAL_COMPL_3	
clFAIL_RAND_REQ	String		Run-in criteria failure	122	citmFAIL_RAND_REQ_122	FAIL_RAND_REQ
			Randomisation criteria failure	126	citmFAIL_RAND_REQ_126	
clSTATUS_FLG	String		Completed	C	citmSTATUS_FLG_C	STATUS_FLG
			Did not complete	NC	citmSTATUS_FLG_NC	
clSTATUS_DISC_REAS	String		Screening Failure	SF	citmSTATUS_DISC_REAS_SF	STATUS_DISC_REAS
			Discontinuation from trial	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_ND	VARCHAR2
grpIMPAC NTERF 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

: Case Book Sign Off (Sign Off) [TERM]		
Study ID:		
1.*	Prepar [Sign off] for sign off	**[itmCBSign]** *[A:1]* ☐
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	Data Variable RefName
clCBSign_1	String			1	citmCBSign_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 Sc	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 evtV24.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV18.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV1.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP9.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV22.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP23.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP21.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV35.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP34.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV8.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP7.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV33.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV28.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV16.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP32.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP5.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV4.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV20.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV2.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV26.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP15.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP29.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV6.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV30.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP13.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP27.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP19.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV10.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtV12.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP25.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE evtP3.VISIT_DATE_DOV.sctVISIT_DATE.VISIT_DATE
Randomization field (Randomization)	Item	Unassigned	Unassigned

ected Health Information Table 2		
Item RefN	**Section RefName**	**Form RefName**
No items h	as "Personal/Protected Health Information".	
Please note: 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.		

ns For Study Design:
No unit con

for Study:	
No Review	n defined.

ions Summary Table:
No in-place been defined.

s for Study Design:
No custom n defined.