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InForm Screening

SCR

Inform Screening (Scr) — [SCR] - Non-repeating form

Study ID: NNXXXX-XXXX		Integration
Subject initials [hidden]	|A3|	RT
Date of birth [hidden]	Req☑/Req☑/Req☑ (1900--2035)	
Age [read-only]	|N3|	RT

Oracle item design notes:
Key: [*] = Item is required.

Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

InForm Enrollment

ENR

Inform Enrollment (Enr) **[ENR] - Non-repeating form**

Study ID: NNXXXX-XXXX			Integration
*	Subject No. [read-only]	|N6|	P, RT

Oracle item design notes:
Key: [*] = Item is required.

Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

Date of Visit

Design Notes

For InForm studies: The options in 'Contact type must not be changed or removed as per FDA's requirement.
For Non-InForm studies: The options in 'Contact type must not be changed or removed as per FDA's requirement except for the option: 'Visit entered in error' option and this do not require PST approval.
Please also see 'Date of Visit (Single site version)' of this CRF (meant for CRO single site studies) if relevant.

V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, P13, V14, P15, V16, P17, V18, P19, V20, P21, V22, P23, V24, V25, V26, V27, V28, V29, V30, V31, V32,V-EOS

Date of Visit (DoV) **[VISIT_DATE_DOV] - Non-repeating**

Completed or partially completed visit:
Enter the date the participant attended the visit, select relevant contact type.

Missed visit:
If a scheduled visit was missed, please enter the planned visit date, select contact type 'Visit missed'.

Visit date entered in error:
If 'Date of visit' was entered in error, the date cannot be erased due to technical limitations. Instead, select contact type 'Visit entered in error', since the visit did not occur.

If the visit is later attended, update the Date of Visit, and contact type, as applicable.

Study ID: NNXXXX-XXXX			Integration
*	Date of visit	Req☑/Req☑/Req☑ (2024-2035)	CO
*	Contact type	○ Site visit ○ Telephone contact ○ Visit entered in error ○ Remote video contact ○ Off-site visit	CO

	○ Visit missed

Oracle item design notes:
Key: [*] = Item is required.

Visit P13, P15, P17, P19, P21, P23 should trigger only for participants which are in the algorithm group.

Informed Consent and Demography

Design Notes

For paediatric studies, please evaluate if trial specific CRF is needed, first item to be rephrased to: 'Date ~~and time~~ informed assent obtained', and mapped to DSDECOD=INFORMED ASSENT OBTAINED

Month included in the "Date of birth" should only be included on the CRF with explicit approval of the trial team (see CRF guidance). CDP will need to adjust the configuration and mapping rules accordingly.

V1

Informed Consent and Demography (Inf Cons/Demog) **[SUBJECT_INFO_2] - Non-repeating**

Study ID: NNXXXX-XXXX			Integration
*	~~Date and time informed consent obtained~~ Date child assent obtained	Req☑/Req☑/Req☑ (2024-2035) ~~Req☑:Req☑ 24-hour clock~~ ~~O N/A~~	C, CO
*	~~Date and time informed consent obtained by Parents/Legally Acceptable Representative (LAR) [de-activated]~~ Date informed consent obtained by Parents/Legally Acceptable Representative (LAR)	Req☑/Req☑/Req☑ (2024-2035) ~~Req☑:Req☑ 24-hour clock~~ ~~O N/A~~	CO
	Date informed consent obtained by Parents/Legally	Req☑/Req☑/Req☑ (2024-2035) ~~Req☑:Req☑ 24-hour clock~~	CO

	Acceptable Representative (LAR) *Only to be completed in countries where Informed Consent from both parents is required* ~~[de-activated]~~	○ N/A	

Demography			
	Date of birth (only for Argus interface) [hidden]	Req☑/Req☑/Req☑ (1900-2035)	A, R
*	Date of birth	UNK/Req☑/Req☑/Req☑ (1900-2035)	
	Sex (at birth) [read-only]	○ Male ○Female	A, R, RT
	~~Sex~~ ~~[de-activated]~~	~~'Male' or 'Female' to be defaulted~~	~~A, R~~
*	Subject self-reported ethnicity	○ Hispanic or Latino ○ Not Hispanic or Latino ○ Not reported	
	Ethnicity - Argus [hidden]	|A200|	A
*	Subject self-reported race *Select all that apply, but at least one.*	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Not reported	
	Race - Argus [hidden]	|A200|	A

Subject No. [read-only]	|N6|	A, R, CO, RT
~~**Rescreening**~~		
~~Previous Subject No.~~	~~|N6|~~	~~RT~~

Oracle item design notes:

Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, N: NEVAS, R: Reports, RT: RTSM

Sex (at birth): Populated by RTSM. Item to trigger Childbearing potential form to appear if response = Female.
Subject No.: Populated by RTSM and mapped from ENR to Inf Cons/Demog

Consent for Legal age

Non-Visit (Re-Consent)

Consent for Legal age (Reconsent) — **Non-Repeating Form**

Study ID: NNXXXX-XXXX
Complete this form if the minor reaches legal age while participating in the trial. If only the V-EOS remains after the participant has reached legal age, re-consenting is only required for human biosamples for future research as applicable, unless otherwise required by local regulations or IRB/IEC.

1	~~Date of re-consent obtained for main study~~ Date of consent for main study obtained after reaching legal age	[CONSENT_DATE_LEGAL] Req / Req / Req (2024-2035 ○ NA
2	Date of ~~re-consent~~ consent ~~obtained~~ for Biosamples for future research obtained after reaching legal age	Req☑/Req☑/Req☑ (2024-2035)
3	Date of consent for Genetic/Genomic Analysis on the biosamples for future analysis obtained after reaching legal age	Req☑/Req☑/Req☑ (2024-2035)

Only to be completed for FRANCE	

(Legal age is 16 only for United Kingdom and Sweden and 18 and above for the other countries)

Medical History/Concomitant Illness (Template for pre-printed diagnosis)

Design Notes
This CRF is to be used for studies pre-printing specific diseases on the CRF. First item is optional for non-InForm studies. Information for any diagnosis can be collected using three level radio control responses (L1-level, L2-level and L3-level) in item 'Diagnosis (with categories)'. Suggestions for different disease classes are in the CRF library and should be merged to one CRF. Data from L2-level is copied/mapped to item 'Diagnosis [hidden]'. It is important that terms pre-printed at L2-level are as per MedDRA dictionary due to ARGUS integration. Due to technical limitation in InForm EDC, only 3 levels of radio controls are possible on the CRF. No further levels can be added. Last option under each disease class is a free text option. This is to be used in case reported term does not match any of the pre-printed terms. Also, if the disease class is other than what has been listed for [L1], then last response in item 'Diagnosis (with categories)' (Other disease) can be used to enter free text for the reported diagnose. Collapse and unfold of different levels can be specified at study level depending on the number of diseases included in the study and how important they are to the study in question. If new pre-printed diseases are needed, it requires PST approval (please contact Standard Developer and KINC from Global Safety upfront). This form has ARGUS integration; hence changes are not allowed in other items than 'Diagnosis (with categories)'

V1

Medical History/Concomitant Illness (MedHx/ConIll)	**[MEDHIST_MEDDRA1]- Non-Repeating form**

Study ID: NNXXXX-XXXX			
*	Does the subject have, or has the subject previously had, any relevant conditions/illnesses?	○ Yes ○ No	R
If Yes is answered to the question above, fill in details below. If the subject receives concomitant medication for the treatment of the concomitant illness, fill in details in the Concomitant Medication form.			
	Seq. No. [read-only]	|N3|	A, R
*	Diagnosis ~~(with categories)~~	~~○ [L1] **<Disease Class 1>**~~ ~~○ [L2] <MedDRA term 1>~~ ~~○ [L3] <Supplemental information>~~ ~~○ [L3] <Supplemental information>~~ ~~○ [L3] <Supplemental information>~~ ~~○ [L2] <MedDRA term 2>~~ ~~○ [L3] <Supplemental information>~~ ~~○ [L3] <Supplemental information>~~ ~~○ [L3] <Supplemental information>~~ ~~○ [L2] <MedDRA term 3>~~ ~~○ [L3] <Supplemental information>~~ ~~○ [L3] <Supplemental information>~~ ~~○ [L3] <Supplemental information>~~ ~~○ [L2] Other <Disease Class 1> disorder, not listed above |A200|~~ ○ **Cardiovascular disorder** ○ Hypertension ○ Atrial fibrillation ○ Other cardiovascular disorder and outcome, not listed above |A200| ○ **Dyslipidaemia** ○ Hypercholesterolaemia ○ Hypertriglyceridemia ○ Combined hyperlipidaemia	

	○ Other dyslipidaemia, not listed above |A200| ○ **Eating disorder** ○ Bulimia nervosa ○ Anorexia nervosa ○ Binge eating ○ Other eating disorder, not listed above |A200| ○ **Gallbladder disease and procedure** ○ Cholelithiasis ○ Cholecystitis ○ Biliary colic ○ Cholecystectomy ○ Other gallbladder disease and disorder, not listed above |A200| ○ **Gastrointestinal disorder** ○ Gastrooesophageal reflux disease ○ Ulcerative colitis ○ Crohn's disease ○ Gastric ulcer ○ Other gastrointestinal disorder, not listed above |A200| ○ **Genitourinary tract disorder** ○ Menstrual disorder ○ Oligomenorrhoea ○ Polymenorrhoea ○ Amenorrhoea ○ Polycystic ovarian syndrome ○ Other genitourinary tract disorder, not listed above |A200| ○ **Glucose metabolism disorder** ○ 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)
- ○ Impaired fasting glucose (e.g. fasting plasma glucose 5.6-6.9 mmol/l (100-125 mg/dl))
- ○ Other glucosemetabolism disorder, not listed above |A200|

○ **Liver disease**
- ○ Metabolic dysfunction-associated steatotic liver disease (MASLD)
- ○ Metabolic dysfunction-associated steatohepatitis (MASH)
- ○ Other type of liver disease, not listed above |A200|

○ **Musculoskeletal system disorder**
- ○ Musculoskeletal pain
- ○ Other muskuloskeletal disorder, not listed above |A200|

○ **Pancreatic disease**
- ○ Acute pancreatitis
- ○ Chronic pancreatitis
- ○ Other pancreatic diseasse, not listed above |A200|

○ **Psychaitric disorder**
- ○ Depressive disorder
- ○ Bipolar disorder
- ○ Schizophrenia
- ○ Post-traumatic stress disorder
- ○ Anxiety disorder
- ○ Suicidal ideation
- ○ Suicide attempt
- ○ Sleep disorder
- ○ Substance abuse
- ○ Memory impaired
- ○ Concentration impaired
- ○ Other psychaitric disorder, not listed above |A200|

○ **Respiratory disorder**
- ○ Asthma
- ○ Obstructive sleep apnoea syndrome
- ○ Other respiratory disorder, not listed above |A200|

		○ **Thyroid disorder** ○ Hyperthyroidism ○ Hypothyroidism ○ Other thyroid disorder, not listed above |A200| ○ **Weight disorder** ○ Overweight ○ Obesity ○ Other weight disorder disorder, not listed above |A200| ○ [L1] **Other disease**, not listed above ○ [L2] |A200|	
	Diagnosis [hidden]	|A200|	A, R
*	Date of onset	Req/Unk☑/Req/Unk☑/Req☑ (1900-2035)	A, R
	~~Continuing?~~ ~~[deactivated]~~	~~○ Yes~~ ~~○ No~~	
	~~Date of resolution~~ ~~[deactivated]~~	~~Req/Unk☑/Req/Unk☑/Req/Unk☑ (1900-2030)~~	~~A, R~~
*	Continuing?	○ Yes ○ No Stop Date: Req/Unk☑/Req/Unk☑/Req/Unk☑ (1900-2035)	A, R

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

Seq. No: Calculated in InForm via rule.

Body Measurements_1

Design Notes
If different versions of this CRF are needed in the study across visits, please add the relevant questions from BODY_MEASUREMENT_1 to BODY_MEASUREMENT_2 or BODY_MEASUREMENT_3.

V1

Body Measurements 1 (Body Meas)		**[BODY_MEASUREMENT_1] – Non-repeating form**
Study ID: NNXXXX-XXXX Preferably, the measurement should be taken by the investigator, or the same qualified delegate, throughout the duration of the study		Integration
Date ~~and time~~ of examination[Hidden]	Req☑/Req☑/Req☑ (2024-2035) ~~Req/Unk ☑: Req/Unk ☑ 24-hour clock~~	R
~~Was the subject fasting when the body measurement was done?~~	~~O Yes~~ ~~O No~~	
* 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.)	|~~xxx~~xxx.X| O cm ~~O m O in~~	A, R

*	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.)	~~|xxx~~xxx.X| ○ cm ~~○ m ○ in~~	A, R
*	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.)	~~|xxx~~xxx.X| ○ cm ~~○ m ○ in~~	A, R
	Mean Height (System calculated mean)[read-only]	~~|xxx~~xxx.X| ○ cm ~~○ m ○ in~~	
*	Body weight (Measured at site visits without shoes, with an empty bladder and only wearing light clothing)	~~|xx~~xxx.X| ○ kg ○ lb	A, R
	BMI (System calculated) [read-only]	xxxxx.X| kg/m2	
	~~Waist circumference [de-activated]~~	~~|xxxxxx.| ○ cm ○ m ○ in~~	
	~~Hip circumference [de-activated]~~	~~|xxxxxx.| ○ cm ○ m ○ in~~	

Oracle item design notes:
Key: [*] = Item is required.

Body Measurements_1_1

Design Notes
If different versions of this CRF are needed in the study across visits, please add the relevant questions from BODY_MEASUREMENT_1 to BODY_MEASUREMENT_2 or BODY_MEASUREMENT_3.

V2, V7, V9, V12, V18, V24, V-EOS

Body Measurements 1_1 (Body Meas) **[BODY_MEASUREMENT_1_1] – Non-repeating form**

Study ID: NNXXXX-XXXX Preferably, the measurements should be taken by the investigator, or the same qualified delegate, throughout the duration of the study.			Integration
	Date ~~and time~~ of examination [Hidden]	Req☑/Req☑/Req☑ (2024-2035) ~~Req/Unk ☑: Req/Unk ☑ 24-hour clock~~	R
	~~Was the subject fasting when the body measurement was done?~~	~~O Yes~~ ~~O No~~	
*	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.)	|~~xxx~~xxx.X| O cm ~~O m O in~~	A, R
*	Height 2	|~~xxx~~xxx.X| O cm ~~O m O in~~	A, R

	(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 (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.)	|~~xxx~~xxx.X| ○ cm ~~○ m ○ in~~	A, R
*	Body weight (Measured at site visits without shoes, with an empty bladder and only wearing light clothing)	|~~xx~~xxx.X| ○ kg ○ lb	A, R
*	Waist circumference ~~(Item deactivated)~~ (Nearest 0.5 centimetre) (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. The participant should be asked to breathe normally.)	|~~xxx~~xxx.X| ○ cm ~~○ m ○ in~~	
	~~Hip circumference [de-activated]~~	~~|xxxxxx.| ○ cm ○ m ○ in~~	

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

Body Measurements_2

V5, V10, V11, V14, V16, V20, V22, V26, V28, V30, V32

Body Measurements (Body Meas) **[BODY_MEASUREMENT_2] – Non-repeating form**

Study ID: NNXXXX-XXXX Preferably, the measurements should be taken by the investigator, or the same qualified delegate, throughout the duration of the study.		Integration
	Date ~~and time~~ of examination[Hidden]	Req☑/Req☑/Req☑ (2024-2035) ~~Req/Unk ☑: Req/Unk ☑ 24-hour clock~~
	~~Was the subject fasting when the body measurement was done?~~	~~O Yes~~ ~~O No~~
*	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.)	|~~xxx~~xxx.X| O cm ~~O m O in~~
*	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.)	|~~xxx~~xxx.X| O cm ~~O m O in~~

*	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.)	|~~xxx~~xxx.X| ○ cm ~~○ m~~ ~~○ in~~
*	Body weight (Measured at site visits without shoes, with an empty bladder and only wearing light clothing)	|~~xx~~xxx.X| ○ kg ○ lb

Oracle item design notes:
Key: [*] = Item is required.

Body Measurements_3

V3, V4, V6, V8, V25, V27, V29, V31

Body Measurements (Body Meas) **[BODY_MEASUREMENT_3] – Non-repeating form**

Study ID: NNXXXX-XXXX Preferably, the measurements should be taken by the investigator, or the same qualified delegate, throughout the duration of the study.		Integration
	Date ~~and time~~ of examination [Hidden]	Req☑/Req☑/Req☑ (2024-2035) ~~Req/Unk ☑: Req/Unk ☑ 24-hour clock~~
*	Body weight (Measured at site visits without shoes, with an empty bladder and only wearing light clothing)	|~~xx~~xxx.X| ○ kg ○ lb

Oracle item design notes:
Key: [*] = Item is required.

Vital Signs

V1, V2, V12, V24, V-EOS

Vital Signs (VS) **[VITAL_SIGN_SINGLE] - Non-repeating form**

Study ID: NNXXXX-XXXX		Integration
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).		
~~**Date of examination**~~		
	~~Date of examination [de-activated]~~	~~Req☑/Req☑/Req☑ (2022-2035)~~
Blood pressure and pulse		
*	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)	Systolic / Diastolic |N3| mmHg / |N3| mmHg
*	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)	|N3| beats/min

Oracle item design notes:
Key: [*] = Item is required.

Physical Examination

Design Notes

This CRF is to be used when the protocol states that physical examination must be performed, and it has been decided by MEX and STAT that data should not be collected as these data are anyway collected as MH or AEs if clinically significant.
Deviation from this cannot be approved by PST. SIT to be involved.

See Guidance document for details on different guidance to investigator for different visits.

The text '<…>' should be updated to reflect the protocol.

V1

Physical Examination (PE) **[PHYSICAL_EXAM_4] – Non-repeating form**

Study ID: NNXXXX-XXXX	Integration
Visit 1: If abnormal, clinically significant, record in the Medical History/Concomitant Illness form (MedHx/ConIll). If medication is taken remember to record in the Concomitant Medication form (CM).	
* Was the physical examination performed?	○ Yes ○ No

ECG

Design Notes
The text '<…>' should be updated to reflect the protocol.

V1

ECG (ECG)	**[ECG_2] - Non-repeating form**

Study ID: NNXXXX-XXXX			Integration
Visits 1: If abnormal, clinically significant, record in the Medical History/Concomitant Illness form (MedHx/ConIll). If medication is taken remember to record in the Concomitant Medication form (CM).			
~~**<Time Point/Nominal Time>: <xxx> min**~~			
*	~~Date and time of examination~~ (Hidden)	~~Req☑/Req☑/Req☑ (2020-2030)~~ ~~Req☑:Req☑ 24-hour clock~~	
ECG Examination			
*	Overall interpretation of ECG	○ Normal ○ Abnormal Specify abnormality: |A200| Clinically significant? ○ Yes ○ No	

Oracle item design notes:
Key: [*] = Item is required.

Tanner Staging (Female)

V1, V7, V9, V12, V18, V24, V27, V30, V-EOS

Tanner Staging (Female) — **Non-repeating form**

Study ID: NNXXXX-XXXX		Integration
* 1	Breast Development	○ Stage 1 ○ Stage 2 ○ Stage 3 ○ Stage 4 ○ Stage 5 ○ Not Done Specify reason
* 2	Pubic Hair Development	○ Stage 1 ○ Stage 2 ○ Stage 3 ○ Stage 4 ○ Stage 5 ○ Not Done Specify reason

Form to be dynamically triggered from the Inf Cons/Demog form for female subjects only . Form should trigger at every required visit for female subjects

Tanner Staging (Male)

V1, V7, V9, V12, V18, V24, V27, V30, V-EOS

Tanner Staging (Male) — **Non-repeating form**

Study ID: NNXXXX-XXXX		Integration
* 1	Genital Development	○ Stage 1 ○ Stage 2 ○ Stage 3 ○ Stage 4 ○ Stage 5 ○ Not Done Specify reason
* 2	Left Testicular Volume	ml
*3	Right Testicular Volume	ml

*4 Pubic hair Development	○ Stage 1 ○ Stage 2 ○ Stage 3 ○ Stage 4 ○ Stage 5 ○ Not Done Specify reason

Form to be dynamically triggered from the Inf Cons/Demog form for Male subjects only. Form should trigger at every required visit for male subjects

Childbearing Potential

V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, P13, V14, P15, V16, P17, V18, P19, V20, P21, V22, P23, V24, V25, V26, V27, V28, V29, V30, V31, V32, V-EOS

Childbearing Potential (ChBrPot) **[CHILDBEAR_POTENTIAL] - Non-repeating form**

Study ID: NNXXXX-XXXX		Integration
	~~Date of evaluation [de-activated]~~	~~Req☑/Req☑/Req☑ (2022-2035)~~
*	Is the subject of childbearing potential?	○ Yes ○ No

Oracle item design notes:
Key: [*] = Item is required.

Form to be dynamically triggered from the Inf Cons/Demog form for female subjects.
'Is the subject of childbearing potential?': Item to trigger PregX form to appear if response = Yes. PREG VIS form to appear if response is Yes

Define which pregnancy form is to be used:
PREGLOG (non-visit related, repeating form) or
PREGVIS (visit related). Note that if PREGLOG is to be used then the Pregnancy VISIT holding that form is to be triggered.

Pregnancy Test_1

Design Notes

If only one medium is used for the first test, remove the other choice, and make item a defaulted value (non-InForm) or a fixed value in the fixed repeat table (InForm) – Do not remove/hide the medium.
If the Study Team confirms with full certainty, that the date of test is the same as the date of visit, then Date of test can be removed and replaced with trial specific expression in DMW.
InForm specific: Form to be dynamically triggered in all visits from the Childbearing Potential form if the response is Yes. Add edit check to ensure that when 'Not done' is empty then Date and Result and Specimen are complete, and vice versa.

V1, V2, V5, V8, V9, V10, V11, V12, V14, V16, V18, V20, V22, V24, V25, V26, V27, V28, V29, V30, V31, V32, V-EOS

Pregnancy Test (Preg) **[PREGVIS] – Non-repeating form**

Study ID: NNXXXX-XXXX Integration

If Positive, the subject must be discontinued from investigational medicinal product. The paper Pregnancy forms must also be completed.

Additional tests done to confirm pregnancy should be reported on the Pregnancy Test Log.

Pregnancy Test

Test [hidden]	**Test Done?**	**Medium**	**Result**	~~**Date of test**~~
○ PREGNANCY_TEST_RESULT	☐ Not done	○ URINE ~~○ BLOOD~~	○ Positive ○ Negative	~~Req☑/Req☑/Req☑ (2020-2030)~~

Oracle item design notes:
Key: [*] = Item is required.

Pregnancy Test_2

Design Notes

Do not hide the medium.
InForm specific: Pregnancy (Preg) visit holding this repeating form to be dynamically triggered from the Childbearing Potential form if the response is Yes. Add edit check to ensure that when Date or Result or Specimen is complete, the rest are complete as well

Non-Visit

Pregnancy Test Log (Preg Log) **[PREGLOG] – Repeating form**

Study ID: NNXXXX-XXXX Integration

If Positive, the subject must be discontinued from investigational medicinal product. The paper Pregnancy forms must also be completed.

Pregnancy Test

Test [hidden]	**Medium**	**Result**	**Date of test**
○ PREGNANCY_TEST_RESULT	○ URINE ~~○ BLOOD~~	○ Positive ○ Negative	Req☑/Req☑/Req☑ (2024-2035)

Oracle item design notes:
Key: [*] = Item is required.

Date of Menarche

V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, P13, V14, P15, V16, P17, V18, P19, V20, P21, V22, P23, V24, V25, V26, V27, V28, V29, V30, V31, V32, V-EOS

Date of Menarche (Menarche)	**Non-Repeating**

Study ID: NNXXXX-XXXX — Integration

Note: Female participants only, who reaches childbearing potential during the course of study.

*	Date of Menarche	[MENARCHE_DT] (DD/MM/YYYY) UNK/Req☑/Req☑/Req☑ (2024-2035)

Dynamic to be triggered, if the Childbearing potential is marked as Yes, from V2. Form should trigger only once at any of the respective visit when Childbearing potential is marked as Yes

Eligibility Criteria

Design Notes

The pull-down list for failed criteria text has only 80 characters limit, so either keep it as only numbers and alphabets, else make meaningful text of 80 characters. The full inclusion and exclusion criteria texts can be added in the section below for investigator reference only, if required.

Non-Visit Related (Eligibility)

Eligibility Criteria (Elig) **[ELIG_CRIT_2] - Non-repeating**

Study ID: NNXXXX-XXXX			Integration
To qualify for further study participation all eligibility criteria must be met by subject. *The screening status should not be updated once the subject is enrolled/~~randomised.~~*			
*	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*	○ Subject is eligible (Meets all eligibility requirements) Date subject is confirmed eligible Req☑/Req☑/Req☑ (2024-2035) ○ Subject failed one or more eligibility requirements (Subject is a screen failure) ○ Eligibility evaluation was not completed	CO

requirements (subject is a screen failure).	
Failed inclusion criteria – (Add Entry)	
Failed inclusion criterion	|Pull down list 1|
Met exclusion criteria – (Add Entry)	
Met exclusion criterion	|Pull down list 2|

Eligibility criteria

Inclusion Criteria

1. Informed consent 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:
    - The parent(s) or legally acceptable representative (LAR) of the participant must sign and date the Informed Consent Form, according to local requirements
    - The participant must sign and date the Child Assent Form or provide oral assent, according to local requirements
2. Age 12 to <15 years at the time of signing the informed consent
3 Body mass index (BMI) ≥95th percentile at screening
4 Body weight >60 kg at screening
5 History of at least one unsuccessful effort to lose sufficient body weight

For participants assessed by DXA scan the following additional criterion must apply:

6 Evaluation of the quality of the DXA scan must be performed and found acceptable by the imaging laboratory prior to enrolment at V2.

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:
    - Liposuction and/or abdominoplasty, if performed >1 year prior to screening

- Adjustable gastric banding, if the band has been removed >1 year prior to screening
- Intragastric balloon, if the balloon has been removed >1 year prior to screening
- Duodenal-jejunal bypass liner (e.g., Endobarrier), if the sleeve has been removed >1 year prior to screening

3 Uncontrolled thyroid disease as per investigator's discretion
4 Endocrine, hypothalamic, or syndromic obesity

Mental health related

5 History of depression within 2 years before screening
6 Diagnosis of other severe psychiatric disorders (e.g., schizophrenia, bipolar disorder)
7 A lifetime history of suicidal attempt
8 Suicidal behaviour within 30 days before screening
9 A Patient Health Questionnaire-9 (PHQ-9) score of ≥15 as assessed at screening
10 Suicidal ideation corresponding to type 4 or 5 on the Columbia-Suicide Severity Rating Scale (C-SSRS) within 30 days before screening

Glycaemia related

11 Glycated haemoglobin (HbA_{1c}) ≥48 mmol/mol (6.5%) as measured by the central laboratory at screening
12 History of type 1 or type 2 diabetes mellitus
13 Treatment with glucose-lowering agent(s) within 90 days before screening (except for metformin)

General Safety

14 Prepubertal status (Tanner stage 1)
15 Known or suspected hypersensitivity to study intervention(s) or related products
16 Previous participation in this study. Participation is defined as signed informed consent
17 Female who is pregnant, breast-feeding or intends to become pregnant or is of childbearing potential and not using adequate contraceptive method, as defined in Appendix 4 (Section **Error! Reference source not found.**)
18 Participation (i.e., signed informed consent) in any interventional clinical study within 90 days before screening
19 Other participant(s) from the same household participating in other semaglutide study(ies)
20 Calcitonin ≥50 ng/L as measured by central lab at screening
21 History of chronic pancreatitis
22 Acute pancreatitis within 180 days before screening

	23 Personal or first-degree relative(s) history of multiple endocrine neoplasia type 2 or medullary thyroid carcinoma 24 Impairment with estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m^2, as calculated by central lab at screening using the Bedside Schwartz equation 25 Presence or history of malignant neoplasms or in situ carcinomas (other than basal or squamous cell skin cancer) within 5 years before screening 26 Surgery scheduled for the duration of the study, except for minor surgical procedures, in the opinion of the investigator 27 Known or suspected abuse of alcohol or recreational drugs 28 Use of any medication with unknown or unspecified content within 90 days before screening 29 Known history of heart disease (including history of clinically significant arrhythmias or conduction of delays on electrocardiogram [ECG]) within 180 days before screening, new clinically significant arrhythmias or conduction delays on ECG identified at screening 30 Any disorder, unwillingness, or inability, which in the investigator's opinion might jeopardise the participant's safety or compliance with the protocol.		
	End of the form (Read-Only)	○	

DM and SDTM Programmer key guidance:

Detailed information on the below requirements is present in the CRF guidance document:

- The form needs to be completed for every subject in the study – question 1 should not be left blank for any subject.
- A new form must be deployed in InForm with new form ref name and criteria text in the event of protocol amendments that have changed criteria text.
- This form covers the screening period and should reflect the screen failure definition in the protocol, i.e., in/exclusion criteria failure.
- The last section does not collect data. It is meant to display the full text of the criteria used in the study in relation to screening / screening failure.

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

Control	Pull down value	Code
Pull down List 1	1. Inclusion Criteria 1 2. Inclusion Criteria 2 3. Inclusion Criteria 3 4. Inclusion Criteria 4 5. Inclusion Criteria 5	|1 |2 |n

	6. Inclusion Criteria 6	
Pull down List 2	1. Exclusion Criteria 1 2. Exclusion Criteria 2 3. Exclusion Criteria 3 4. Exclusion Criteria 4 5. Exclusion Criteria 5 6. Exclusion Criteria 6 7. Exclusion Criteria 7 8. Exclusion Criteria 8 9. Exclusion Criteria 9 10. Exclusion Criteria 10 11. Exclusion Criteria 11 12. Exclusion Criteria 12 13. Exclusion Criteria 13 14. Exclusion Criteria 14 15. Exclusion Criteria 15 16. Exclusion Criteria 16 17. Exclusion Criteria 17 18. Exclusion Criteria 18 19. Exclusion Criteria 19 20. Exclusion Criteria 20 21. Exclusion Criteria 21 22. Exclusion Criteria 22 23. Exclusion Criteria 23 24. Exclusion Criteria 24 25. Exclusion Criteria 25 26. Exclusion Criteria 26 27. Exclusion Criteria 27 28. Exclusion Criteria 28 29. Exclusion Criteria 29 30. Exclusion Criteria 30	E1 E2 En

End of Form: This item is just present because we cannot have a section note without an active item. so, to accommodate the criteria texts in the section note we have made an item in the end of the form, basically a dummy item. Please do not remove this item and update only the section notes for criteria.

First Dose ~~after Randomisation (Single IMP)~~

Design Notes

Even several items are black only the relevant item should be included at trial level.
The option allows the site to record N/A for subjects that were randomised in error (e.g. incorrect subject id in RTSM) or lost to follow or withdrew consent before the first dose was administered.
Two business units benefit from using this N/A:
Data management: A missing first dose date for a randomised subject will usually result in a query to site. The N/A allows the DM to know that the data was not missed during data entry.
Monitoring: CRAs depend on InForm reports on visit status to plan and track their activities. As the date of dose is a 'required item', leaving it blank will still cause the visit to appear as incomplete (even if the CRF is not started).

<IMP 1>: The name of the IMP can be added if needed.

V2

First Dose (First Dose) **[DOSAGE_1] - Non-repeating**

Study ID: NNXXXX-XXXX			Integration
*	Date ~~and time~~ of first dose of investigational medicinal product ~~<IMP 1>~~ (Semaglutide)	○ Req☑/Req☑/Req☑ (2024-2035) ~~Req☑:Req☑ 24-hour clock~~ ○ N/A	C, CO
	Date and time of first dose of investigational medicinal	○ Req☑/Req☑/Req☑ (2024-2035) Req☑:Req☑ *24-hour clock*	C, CO

product <IMP 1> (Semaglutide) [hidden]	○ N/A	
Date and first dose of investigational medicinal product <IMP 1> (Semaglutide) [hidden]	○ Req☑/Req☑/Req☑ (2024-2035) |0 < xxxx.| ○ <Unit 1> ○ <Unit 2> ○ N/A	~~C, CO~~
~~First date and dose of investigational medicinal product <IMP 1> [de-activated]~~	~~○ Req☑/Req☑/Req☑ (2020-2030)~~ ~~|0 < xxxx.| ○ <Unit 1>~~ ~~○ <Unit 2>~~ ~~○ N/A~~	~~CO~~
~~Injection site [de-activated]~~	~~○ Upper Arm (Arm)~~ ~~○ Thigh~~ ~~○ Stomach (Abdominal skin)~~	

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

DXA Scan (DXA Scan)

V1, V12 , V24

DXA Scan (DXA Scan)	Non-repeating

Study ID: NNXXXX-XXXX	Integration
* Has an DXA Scan been performed?	○ Yes Date of DXA Scan: Req☑/Req☑/Req☑ (2024-2035) ○ No, Specify reason: |A200|

Oracle item design notes:
Key: [*] = Item is required.

Form to be dynamically triggered only for USA and Belgium subjects.

SURGICAL PROCEDURES

Non-Visit

SURGICAL PROCEDURES (Procedure) **Repeating Form**

Study ID: NNXXXX-XXXX		Integration
* 1	Seq No	
* 2	Date of procedure	DD/MM/YYYY Req/Req/Req(2024/2035)
*3	Procedure name	○ Bariatric surgery ○ Bariatric gastric ballon insertion ○ Bariatric gastric ballon removal ○ Duodenal-Jejunal bypass sleeve therapy ○ Endoscopic sleeve gastroplasty ○ Gastric banding (includes laparoscopic adjustable gastric band) ○ Gastric band repositioning ○ Gastric banding reversal ○ Gastric bypass (roux-en-y) ○ Gastric bypass reversal ○ Duodenal switch ○ Other, Specify
*4	Reason for procedure	○ Adverse Event. AE. No

	○ Medical History/Concomitant Illness, enter Seq No Was the subject previously ineligible for procedure, now eligible due to weight loss ○ Yes ○ No ○ Other Specify reason

Adverse Event

Design Notes

'Randomisation no.' can be added in the case of a double-blinded, non-InForm, non-RTSM study if required by Safety Operation adviser.

The text '<…>' should be updated to reflect the protocol.

Non-Visit Related (AE)

Adverse Event (AE_MEDDRA3) **[AE] - Repeating form**

Study ID: NNXXXX-XXXX			Integration
	Adverse event number [read-only]	|0 < N3|	A,~~N~~,R
*	Onset date ~~and onset time~~ of AE	Req☑/Req☑/Req☑ (2024-2035) ~~Req/Unk☑:Req/Unk☑ *24-hour clock*~~	A,~~N~~,R
*	AE diagnosis (if known) or sign/symptom *Report only one sign/symptom per AE form.*	|A200|	A,~~N~~,R
Please refer to the protocol for detailed instructions on reporting requirements and timelines for Serious Adverse Events (SAEs)			

*	Is the AE serious? *If Yes, complete a SIF.*	○ No ○ Yes Seriousness criteria: Death ○ No ○ Yes Was an autopsy performed/planned? ○ No ○ Yes Life-threatening ○ No ○ Yes In-patient hospitalisation/prolongation of existing hospitalisation ○ No ○ Yes Date of admission: Req/Unk☑/Req/Unk☑/Req☑ (2024-2035) Date of discharge: Req/Unk☑/Req/Unk☑/Req☑ (2024-2035) Persistent or significant disability/incapacity ○ No ○ Yes Congenital anomaly/birth defect ○ No ○ Yes Important medical event ○ No ○ Yes	A,~~N~~,R
	Seriousness – Previous [hidden] Item is used for an electronic check that downgrading of seriousness does not occur.	|A20|	
*	Severity	○ Mild ○ Moderate ○ Severe	A,~~N~~,R
	Severity – Previous [hidden] Item is used for an electronic check that downgrading of severity does not occur.	|A20|	
*	Outcome of AE *If the adverse event has fatal outcome or if the sequela meets a seriousness criterion, the adverse event must be reported as a*	○ Recovered/resolved Date: Req☑/Req☑/Req☑ (2024-2035) ~~Time: Req/Unk☑:Req/Unk☑ *24-hour clock*~~ ○ Recovering/resolving Date: Req☑/Req☑/Req☑ (2024-2035) ~~Time: Req/Unk☑:Req/Unk☑ *24-hour clock*~~	A,~~N,~~R

	serious adverse event by also completing a SIF	○ Recovered/resolved with sequelae Date: Req☑/Req☑/Req☑ (2024-2035) ~~Time: Req/Unk☑:Req/Unk☑ *24-hour clock*~~ Describe sequelae |A200| ○ Not recovered/not resolved ○ Fatal Date: Req☑/Req☑/Req☑ (2024-2035) ~~Time: Req/Unk☑:Req/Unk☑ *24-hour clock*~~ ○ Unknown	
~~*~~	~~Does this AE qualify as an event for adjudication as defined in protocol? *If Yes, provide additional information in dedicated form(s)*~~	~~○ No~~ ~~○ Yes~~ ~~○ Acute coronary syndrome~~ ~~○ Acute pancreatitis~~ ~~○ Cerebrovascular event~~ ~~○ Coronary revascularisation procedure~~ ~~○ Heart failure~~ ~~○ Hypoglycaemic episode~~ ~~○ Kidney replacement therapy~~	~~N~~
~~*~~	~~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.*~~	~~○ No~~ ~~○ Yes~~	~~A,R~~
	~~If the AE PT search resulted in a match, select adverse event type [hidden]~~	~~○ Acute coronary syndrome~~ ~~○ Acute pancreatitis~~ ~~○ Cerebrovascular event~~ ~~○ Coronary revascularisation procedure~~ ~~○ Heart failure~~ ~~○ Hypoglycaemic episode~~ ~~○ Kidney replacement therapy~~	

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

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 for Clinical Study form*

* **IMP**	* Product given prior the AE onset	Causality	Action taken to product	Tech complaint related AE	Action taken to product - Previous [hidden]	A, R
<~~IMP 1~~ Semaglutide B/ Semaglutide D>	○ Yes ○ No	○ Probable ○ Possible ○ Unlikely	○ Drug interrupted ○ Drug withdrawn ○ Dose reduced ○ Dose increased ○ Dose not changed ○ Unknown ○ Not applicable	○ No ○ Yes	|A30|	
~~<IMP 2>~~	~~○ Yes~~ ~~○ No~~	~~○ Probable~~ ~~○ Possible~~ ~~○ Unlikely~~	~~○ Drug interrupted~~ ~~○ Drug withdrawn~~ ~~○ Dose reduced~~ ~~○ Dose increased~~ ~~○ Dose not changed~~ ~~○ Unknown~~ ~~○ Not applicable~~	~~○ No~~ ~~○ Yes~~	~~|A30|~~	
~~<IMP 3>~~	~~○ Yes~~ ~~○ No~~	~~○ Probable~~ ~~○ Possible~~ ~~○ Unlikely~~	~~○ Drug interrupted~~ ~~○ Drug withdrawn~~ ~~○ Dose reduced~~ ~~○ Dose increased~~ ~~○ Dose not changed~~ ~~○ Unknown~~ ~~○ Not applicable~~	~~○ No~~ ~~○ Yes~~	~~|A30|~~	

	~~<IMP 4>~~	~~O Yes~~ ~~O No~~	~~O Probable~~ ~~O Possible~~ ~~O Unlikely~~	~~O Drug interrupted~~ ~~O Drug withdrawn~~ ~~O Dose reduced~~ ~~O Dose increased~~ ~~O Dose not changed~~ ~~O Unknown~~ ~~O Not applicable~~	~~O No~~ ~~O Yes~~	~~|A30|~~	
	~~<IMP 5>~~	~~O Yes~~ ~~O No~~	~~O Probable~~ ~~O Possible~~ ~~O Unlikely~~	~~O Drug interrupted~~ ~~O Drug withdrawn~~ ~~O Dose reduced~~ ~~O Dose increased~~ ~~O Dose not changed~~ ~~O Unknown~~ ~~O Not applicable~~	~~O No~~ ~~O Yes~~	~~|A30|~~	

~~**Details of investigational medical device**~~

*	~~Investigational medical device~~	~~* Investigational medical device used prior to the AE onset~~	~~Causality~~	~~Action taken for Investigational medical device~~	~~Tech complaint/device deficiency related AE~~	~~Action taken for Investigational medical device - Previous [hidden]~~	~~Ax~~
	~~<Investigational medical device 1>~~	~~O Yes~~ ~~O No~~	~~O Causal relationship~~ ~~O Probable~~ ~~O Possible~~ ~~O Not related~~	~~O No action~~ ~~O Device interrupted~~ ~~O Device withdrawn~~ ~~O Device adjusted~~ ~~O Unknown~~ ~~O Not applicable~~ ~~O Not changed~~ ~~O Use of device adjusted~~	~~O No~~ ~~O Yes~~	~~|A30|~~	
*	~~<Investigational medical device 2>~~	~~O Yes~~ ~~O No~~	~~O Causal relationship~~ ~~O Probable~~ ~~O Possible~~ ~~O Not related~~	~~O No action~~ ~~O Device interrupted~~ ~~O Device withdrawn~~ ~~O Device adjusted~~ ~~O Unknown~~ ~~O Not applicable~~ ~~O Not changed~~	~~O No~~ ~~O Yes~~	~~|A30|~~	

				~~O Use of device adjusted~~			
~~**Details of investigational related procedure**~~							
*	~~Investigational related procedure~~	~~* Investigational related procedure performed prior to the AE onset~~	~~Causality~~	~~Action taken due to the investigational related procedure~~	~~Action taken due to the investigational related procedure - Previous [hidden]~~		~~Ax~~
	~~<Investigational related procedure 1>~~	~~O Yes O No~~	~~O Causal relationship O Probable O Possible O Not related~~	~~O No action O Procedure interrupted O Unknown O Not applicable O Not changed~~	~~|A30|~~		
*	~~<Investigational related procedure 2>~~	~~O Yes O No~~	~~O Causal relationship O Probable O Possible O Not related~~	~~O No action O Procedure interrupted O Unknown O Not applicable O Not changed~~	~~|A30|~~		

~~**Related hypoglycaemic episode (if any) – Add Entry**~~ ~~If this AE is related to a hypoglycaemic episode, select 'Add Entry' and enter the hypoglycaemic episode number(s).~~			
~~**Sequence number**~~	~~**Hypoglycaemic episode no.**~~		
	~~Sequence number [read-only] [de-activated]~~	~~|N3|~~	~~Ax~~
	~~Hypoglycaemic episode no. [de-activated]~~	~~|N3|~~	
	Office use only [hidden] Item used for SAE notification	|N3|	
	Office use only [hidden]	|N3|	

Item used to track changes in severity, action taken to product, action taken for device, action taken due to procedure and seriousness.	

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

This form requires signature.
Adverse event number: Calculated in InForm via Rule
If 'Is the adverse event serious?' is answered Yes, SIF must appear, and an email notification must be sent.

Does this AE qualify as an event for adjudication? The event type selected is to trigger the availability of the adjudication event form of that event type.
The values from AE_TYPE_CODE_C column in DMW are mapped to the NEVAS model in DMW, and they need to be these below for NEVAS to work, If other values are needed: CTDM, Event Adjudication representative and EDC-CDP need to end-to-end evaluate the new values.

The standard values in AE_TYPE_CODE_C are following:

AE_TYPE_CODE	**AE_TYPE_CODE_C**
O Acute coronary syndrome	ACUTE CORONARY SYNDROME
O Acute pancreatitis	PANCREATITIS
O Cerebrovascular event	CEREBROVASCULAR EVENT
O Coronary revascularisation procedure	CORONARY ARTERY REVASCULARISATION
O Heart failure	HEART FAILURE
O Hypoglycaemic episode	HYPOGLYCAEMIC EPISODE
O Kidney replacement therapy	KIDNEY REPLACEMENT THERAPY

Does the AE fulfil an AE of special interest (AESI) criterion as defined in protocol? If response is Yes, SIF form must appear, and an email notification must be sent.

If the AT PT search resulted in a match, select event type to trigger selected adjudication forms. Hidden to site users, view-only to NN users, editable by 'EAG' role only.

SIF-Safety Information Form

Design Notes
Randomisation section: Only to be used for blinded studies. Section can be hidden for non-randomised studies. Remember then to delete the section title 'Randomisation'. The text '<…>' should be updated to reflect the protocol. Date of awareness: Due to an issue with EDC report the build in Central Designer/InForm must allow UNK for the date component. The issue will be solved in next CR with Oracle. Timing not known yet.

Non-Visit Related (AE)

Safety Information Form (SIF)	**[SIF] – Repeating form**

Study ID: NNXXXX-XXXX			Integration
Safety Information Form			
	Safety Information Form (SIF) number [read only]	|0 < N3|	A, R
Related adverse event number(s)			
*	Related AE number(s) *Multiple adverse event numbers may be added if several SAEs ~~or AESIs~~ occur as part of the same clinical picture or within the same hospitalisation period*	|0 < N3||0 < N3||0 < N3||0 < N3| |0 < N3||0 < N3||0 < N3||0 < N3| |0 < N3||0 < N3||0 < N3||0 < N3|	A, R

Investigator Information			
*	Investigator name	Given name: |A35| Middle name: |A15| Family name: |A50|	A, R
*	Date of awareness *Date site became aware of this event*	UNK/Req☑/Req☑/Req☑ (2024-2035)	A, R, CO
AE Information			
*	Was the condition recorded at baseline?	○ No ○ Yes Did the condition worsen? ○ Yes ○ No ○ Unknown ○ Unknown	A, R
*	Did the subject receive any treatment for the event? *If Yes, consider associating treatment drugs in the concomitant medication section below.*	○ No ○ Yes ○ Unknown	A, R
Investigators 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*	☐ Underlying disease Specify: |A200| ☐ Concomitant medication Specify: |A200| ☐ Other Specify: |A200| ☐ Unknown	A, R

	Unlikely or Possible on the AE form.		
Concomitant Medications			
*	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*	○ No ○ Yes ○ 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			
*	Event description	|A2000 – 5 rows visible| |A2000 – 5 rows visible|	A, R
~~**Randomisation**~~			
	~~Randomisation Number [deactivated]~~	~~|0 < N6|~~	*M*
~~*~~	~~Was the randomisation code broken by the Investigator? [deactivated]~~	~~○ No~~ ~~○ Yes~~ ~~Date: Req☑/Req☑/Req☑ (2022-2035)~~ ~~○ N/A~~	*mg*
Pregnancy			
*	Was the subject pregnant at onset of the event? *If Yes, fill in the Pregnancy forms*	○ No ○ Yes ○ Unknown	A, R

	Drug index number [hidden]	Investigational Medicinal Product [read-only]	* Product given prior the AE onset?	Dose	Route	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 [hidden]	A, R
		<~~IMP 1~~ Semaglutide B PDS290>	○ Yes ○ No	Dose: |xxxx.| Unit: |*Pull down unit List*| *mg* Frequency: |*Pull down Freq. List*| *Once per week*	|*Pull down Route List*| *Subcutaneous*	Req☑/Req☑/Req☑ (2024-2035) ~~Req☑/Unk Req☑/Unk 24-hour clock~~	Req☑/Req☑/Req☑ (2024-2035) ~~Req☑/Unk Req☑/Unk 24-hour clock~~	○ Yes ○ No ○ N/A ○ Unknown	○ Yes Date: Req☑/Req☑/Req☑ (2024-2035) Specify dose after reintroduction: ○ Dose not changed ○ Dose reduced Reduced dose: |xxxx.| Unit: |*Pull down Unit List*| Frequency: |*Pull down freq. List*| ○ Dose increased Increased dose: |xxxx.| Unit: |*Pull down unit list*| Frequency: |*pull down freq. List*| Did the adverse event reappear after reintroduction? ○ Yes ○ No ○ N/A ○ Unknown ○ No ○ N/A ○ Unknown	<~~Argus trial product 1~~ Semaglutide B FlexTouch >	
		<~~IMP 2~~ Semaglutide D DV3396 >	○ Yes ○ No	Dose: |xxxx.| Unit: |*Pull down unit List*| *mg* Frequency: |*Pull down Freq. List*| *Once per week*	|*Pull down Route List*| *Subcutaneous*	Req☑/Req☑/Req☑ (2024-2035) ~~Req☑/Unk Req☑/Unk 24-hour clock~~	Reqþ/Reqþ/Reqþ (2024-2035) ~~Reqþ/Unk Reqþ/Unk 24-hour clock~~	○ Yes ○ No ○ N/A ○ Unknown	○ Yes Date: Req☑/Req☑/Req☑ (2024-2035) Specify dose after reintroduction: ○ Dose not changed ○ Dose reduced Reduced dose: |xxxx.| Unit: |*Pull down Unit List*| Frequency: |*Pull down freq. List*| ○ Dose increased Increased dose: |xxxx.| Unit: |*Pull down unit list*| Frequency: |*pull down freq. List*| Did the adverse event reappear after reintroduction? ○ Yes ○ No ○ N/A ○ Unknown ○ No ○ N/A ○ Unknown	<~~Argus trial product 2~~ Semaglutide D DV3396 >	

	Device index number [hidden]	Investigational medical device [read-only]	* Was the device used prior to the AE onset?	Operator/user of the device at time of the adverse event	Usage of device	Location of device	Ax
		<Investigational medical device 1>	O Yes O No	O Healthcare professional O Investigator O Subject O Other |A100|	O Initial use O Reuse of a reusable investigational device O Problem noted prior use O Reuse of a single use investigational device O Re-serviced/refurbished/fully refurbished O Other: |A100|	O Investigational/study site O Sponsor O Subject O Manufacturer O Discarded O Unknown O Other: |A100|	
		<Investigational medical device 2>	O Yes O No	O Healthcare professional O Investigator O Subject O Other |A100|	O Initial use O Reuse of a reusable investigational device O Problem noted prior use O Reuse of a single use investigational device O Re-serviced/refurbished/fully refurbished O Other: |A100|	O Investigational/study site O Sponsor O Subject O Manufacturer O Discarded O Unknown O Other: |A100|	

Relevant assessments and laboratory data/vital signs (performed to confirm the event and/or its outcome) - Add Entry			
	Assessment index number [hidden]	|N3|	
*	Date of assessment	Req/Unk☑/Req☑/Req☑ (2024-2035)	A, R
*	Description of assessment	|A80|	A, R
*	Result of assessment	|xxxxxx.| |Unit pull down list 2| Other unit, specify: |A25| Specify if non-numeric result: |A600 – 5 rows visible|	A, R
	Reference range *Use same unit for reference ranges as the reported result. If result of assessment is non-numeric N/A should be selected*	Lower normal limit |A50| Upper normal limit |A50| ○ N/A	A, R
	Office use only [hidden]	|N3|	
	Trial drug indication [hidden]	|A200| Obesity	

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

Date of awareness: Due to an issue with EDC report the build in Central Designer/InForm must allow UNK for the date component.
The issue will be solved in next CR with Oracle. Timing not known yet.

For study using EDC-Argus interface: Note that SIF Form is to be set-up to be associated with the CM form
The form requires signature
SIF number: Calculated in InForm via rule
Drug index number: Deactivated and hidden to all InForm users
Device index number: Deactivated and hidden to all InForm users
Units: Specific list of units, frequencies and routes pre-defined in tables below.
Product name: Must be preset in InForm (CTDM to get Argus product names from Global Safety)

Assessment index number: Populated by rule used in EDC-Argus integration
Trial drug indication: Populated by a rule in InForm (CTDM to get indication term from Global Safety)

CTDM: provide IMP specific information in table below. Add or delete unnecessary rows according to the study.
Item Units code lists
The IMP information is set-up in a fixed itemset in the SIF form.
There is a limitation to this: Inform EDC only allows for the same pull-down lists of units, frequency and route to be attached to **all** products within the fixed item set.
Study specific edit checks can be put in place to hit if the wrong unit, frequency or route is selected for a particular IMP.

Drug index number	IMP name	Units*	Frequency*	Route*	IMP name in Argus
1					
2					
3					
4					
5					

**see list of allowed ARGUS code values below*

Item Units (Unit): List of allowed units which can be used for unit pull-down list
(Global Safety controlled list)

No.	Unit	No.	Unit	No.	Unit	No.	Unit	No.	Unit	No.	Unit
100	Pg	149	ug/100 mL	202	g/dL	502	pmol/min	809	U/mol	833	mIU/L
101	pg/mL	160	mg	203	g/L	520	nmol	810	U	850	%
102	pg/L	161	mg/mL	208	g/uL	521	nmol/L	811	U/L	996	NK
120	Ng	162	mg/dL	211	g%	540	umol	812	U/mL	997	ND
121	ng/mL	163	mg/L	321	mmHg	541	umol/L	814	U/IU	998	NA
122	ng/dL	169	mg/g	400	uL	544	umol/mL	819	uU/mL	798	Dose Step
123	ng/L	170	mg/mmol	420	mL	560	mmol	826	mIU/mL		
140	Ug	171	mg%	460	dL	561	mmol/L	830	IU		
141	ug/mL	177	mg/uL	480	L	564	mmol/dL	831	IU/L		
142	ug/dL	200	g	500	pmol	566	nmol/mL	832	IU/mL		
143	ug/L	201	g/mL	501	pmol/L	806	mU/L	835	mU/mL		

*Note: when **Dose Step** is used a conversion into for instance mg must be applied, i.e. 1 dose step = 0,36 mg – of course depended on the actual IMP.*

Item Units (Frequency): List of allowed frequency codes which can be used for frequency pull-down list in the SIF form.
(Global Safety controlled list)

Seq. no.	Frequency
1	As needed
2	Once per day
3	Twice per day
4	3 times per day
5	4 times per day

6	5 times per day
7	6 times per day
21	Once per week
22	Twice per week
23	3 times per week
24	4 times per week
25	5 times per week
26	6 times per week
31	Once per month
32	Twice per month
33	3 times per month
34	4 times per month

Item Units (Route): List of allowed route codes which can be used for route pull-down list in the SIF form. (Global Safety controlled list. Numbers acc. to authority requirement).

No.	Route	No.	Route	No.	Route
001	Auricular (otic)	024	Intradiscal (intraspinal)	047	Ophthalmic
002	Buccal	025	Intrahepatic	048	Oral
003	Cutaneous	026	Intralesional	049	Oropharingeal
004	Dental	027	Intralymphatic	050	Other
005	Endocervical	028	Intramedullar (bone marrow)	051	Parenteral
006	Endosinusial	029	Intrameningeal	052	Periarticular
007	Endotracheal	030	Intramuscular	053	Perineural
008	Epidural	031	Intraocular	054	Rectal
009	Extra-amniotic	032	Intrapericardial	055	Respiratory (inhalation)
010	Hemodialysis	033	Intraperitoneal	056	Retrobulbar
011	Intra corpus cavernosum	034	Intrapleural	057	Sunconjunctival
012	Intra-amniotic	035	Intrasynovial	058	Subcutaneous
013	Intra-arterial	036	Intratumor	~~059~~	~~Subdermal~~
014	Intra-articular	037	Intrathecal	060	Sublingual
015	Intra-uterine	038	Intrathoracic	061	Topical
016	Intracardiac	~~039~~	~~Intratracheal~~	062	Transdermal
017	Intracavernous	040	Intravenous bolus	063	Transmammary
018	Intracerebral	041	Intravenous drip	064	Transplacental
~~019~~	~~Intracervical~~	042	Intravenous (not otherwise specified)	065	Unknown
020	Intracisternal	043	Intravesical	066	Urethral
021	Intracorneal	044	Iontophoresis	067	Vaginal
022	Intracoronary	045	Nasal		

023	Intradermal	046	Occlusive dressing technique		

Note: Due to redundancy the following codes should not be used, but the alternative code should be used instead:
Intracervical – use *Endocervical* instead
Intratracheal – use *Endotracheal* instead
Subdermal – use *Subcutaneous* instead

Consent for In-trial Interviews

Non-visit

Consent for In-trial interviews — **Non-repeating form**

Study ID: NNXXXX-XXXX		Integration
*	Child assent for In-trial Interviews	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035)
*	Consent for In-trial Interviews obtained by Parents/Legally Acceptable Representative (LAR) to allow child to be interviewed	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035)
	Consent for In-trial Interviews obtained by Parents/Legally Acceptable Representative (LAR) to allow child to be interviewed *Only to be completed in countries where Informed Consent from both parents is required*	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035) ○ NA

*	Consent for In-trial Interviews obtained by Parents/Legally Acceptable Representative (LAR) for their own participation	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035)

Oracle item design notes:
Key: [*] = Item is required.

Required only for US subjects

Withdrawal of consent to In-trial Interview

Non-visit

Withdrawal of consent to In-trial interview — **Non-repeating form**

Study ID: NNXXXX-XXXX		Integration
*	~~In-trial interview consent withdrawn?~~ Consent/assent for child's participation in in-trial interview withdrawn	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035)
*	Consent for parent/LAR's participation in in-trial interview withdrawn	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035)

Oracle item design notes:
Key: [*] = Item is required.

Required only for US subjects ~~and form should trigger dynamically when 'In-trial interview consent obtained?' is Yes~~

Medication Error, Misuse and Abuse

Design Notes

Due to EMA requirement around Medication, Misuse an Abuse and how NN handles these data in Safety Operation and Safety Surveillance, it is not allowed (even by PST) to change anything in this CRF (except deleting the optional green text).

The text '<…>' should be updated to reflect the protocol. fr

Non-Visit Related (AE)

Medication Error, Misuse and Abuse (Misadministration) **[MISADMIN] - Repeating form**

Study ID: NNXXXX-XXXX			Integration
*	Event number	|N2|	
*	Related adverse event number	|N3|	Ax, R
*	Investigational medicinal product(s) involved in the misadministration	☐ Semaglutide ~~☐ <Investigational medicinal product 2>~~ ~~☐ <Investigational medicinal product 3>~~	
*	Type of misadministration and the reason	○ Accidental misadministration ○ Distraction ○ Poor eyesight ○ Miscalculation ○ Mix-up of products ○ Dispensing error ○ Incorrect handling of product ○ Communication issues ○ Misunderstanding of 'instructions for use'	

		○ Misunderstanding of training/verbal instruction ○ Other, specify: |A200| ○ Intentional misadministration *(Specify the subject's reason)* ○ For physical effect ○ For psychological effect ○ To cause harm ○ Other, specify: |A200|
*	Did the subject experience any other adverse event(s) as a result of the misadministration?	○ No ○ Yes Adverse Event No.: |N3| |N3| |N3| |N3|
*	~~Did the subject experience any hypoglycaemic episode(s) as a result of the misadministration?~~	~~○ No~~ ~~○ Yes~~ ~~Hypoglycaemic Episode No.: |N3| |N3| |N3| |N3|~~
*	Classification *Incorrect dose due to mix-up of products should be reported under 'Wrong product administered/used'* *Incorrect dose due to wrong frequency of administration should be reported under 'Wrong frequency'*	○ Wrong products administered/used ~~○ [drop down list with products, e.g. <Product 2> instead of <Product 1>]~~ ○ Other, specify: |A200| ○ Wrong frequency of administration ○ Higher frequency, specify: |A200| ○ Lower frequency, specify: |A200| ○ Wrong dose administered ○ Overdose, specify: |A200| ~~○ Underdose, specify: |A200|~~ ○ Wrong route of administration ○ Intravenous ~~○ Subcutaneous~~ ○ Intramuscular ~~○ <study specific route>~~ ○ Other, specify: |A200| ○ Other, specify: |A200|
Other relevant information – (Add entry)		
	Comment	|A200|

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

Event number: Calculated in InForm

Technical Complaint for Clinical Study

Design Notes

In studies where 'Kit ID' is used in RTSM and 'DUN' is stated on the label, 'Kit ID' should be changed to 'Kit ID/DUN'. This does not impact any systems.

The text '<…>' should be updated to reflect the protocol.

Non-Visit Related

Technical Complaint for Clinical Study (Complaint) **[TECH_COMPL_FORM] – Repeating form**

Study ID: NNXXXX-XXXX		Integration
	Technical complaint number [read-only]	|0 < N3|
*	Product	○ ~~<Product 1>~~ Semaglutide B 1.5 mL, PDS290 pen-injector (all countries other than US) ~~○ <Product 2>~~ Semaglutide B 3.0 mL, PDS290 pen-injector (all countries other than US) ~~○ <Product 3>~~ Semaglutide D 0.5 mL, DV3396 pen-injector (US sites only) ~~○ <Product 4>~~ Semaglutide D 0.75 mL, DV3396 pen-injector (US sites only)
*	Batch, code or lot no. *Can be found on the label. Include batch, code or lot no., even if the technical complaint sample cannot be obtained.* ~~*For <Name(s) of SAMD according to protocol>, tick N/A.*~~	○ |A20| ○ N/A
*	Kit ID/DUN	○ |N7| ○ N/A

	Fill out one form per Kit ID/DUN. ~~*For <Name(s) of SAMD according to protocol>, tick N/A.*~~	
*	Onset date of the technical complaint	Req/Unk☑/Req/Unk ☑/Req ☑ (2024-2035)
*	Description of the technical complaint *Describe the affected product part and affected product function. Describe in detail how the fault has occurred.*	|A400|
Send the sample to Novo Nordisk for investigation		
*	Will the technical complaint sample be sent to Novo Nordisk for investigation? ~~*For complaints related to <Name(s) of SAMD according to protocol>, tick No.*~~ *If Yes, remember to include a print/copy of this form in the shipment of the sample(s).*	○ Yes ○ No, specify why: |A200|
*	Is the technical complaint related to adverse events (AEs)? *If Yes, Add Entry to specify details below.*	○ Yes ○ No

	Also fill in an Adverse Event form (AE).	

Related Adverse Event number(s) (Add Entry)		
*	Adverse Event number	|0<N3|
*	Is the technical complaint related to an SAE ~~and/or an AESI~~? *If Yes, fill in a Safety Information Form (SIF)*	○ Yes ○ No
~~Reporting of the technical complaint/device deficiency for <Name(s) of device(s)> according to the protocol.~~		
	~~Could the technical complaint/device deficiency have led to an SAE~~? *~~'Yes' should only be ticked if one of the below scenarios apply:~~* • *~~If suitable action had not been taken.~~* • *~~If intervention had not been made.~~* • *~~If the circumstances had been less fortunate~~* *~~If Yes, fill in a 'Device Deficiency that could have led to an SAE' form.~~* ~~[de-activated]~~	~~○ Yes~~ ~~○ No~~

Office use only [hidden] *Item is used for rule logic*	|N5|
Follow-up email sent date (office use only) [hidden]	Req☑/Req☑/Req☑ (2022-2035)
Office use only [hidden] *Item is used for rule logic*	|N5|
Description of the technical complaint, part 1 *(1-200 chars)* [hidden]	|A200|
Description of the technical complaint, part 2 *(201-400 chars)* [hidden]	|A200|

Oracle item design notes:
Key: [*] = Item is required

Technical complaint number: Calculated in InForm via rule
E-mail notification required upon submission and updates of the Technical Complaint for Clinical Study form. Notification to be sent to SafetyNotifications@novonordisk.com

Description of the technical complaint, part 1: Mapping of the characters 1-200 from item ‘Description of the technical complaint’. Read-only to DM only.
Description of the technical complaint, part 2: Mapping of the characters 201-400 from item ‘Description of the technical complaint’. Read-only to DM only.

Elevated Liver Enzymes (Central Lab)

Non-Visit Related

Elevated Liver Enzymes (Central Lab) - (Elevated Liver Enzymes) **[ELVTD_LVR_ENZ] – Repeating form**

Study ID: NNXXXX-XXXX Integration

Complete below questions in all cases where results from central laboratory meet one or more of the following criteria as stated in the protocol:

- *ALT >3 x ULN if baseline was normal or near normal; ALT >2 x above baseline or ALT >250 U/L if baseline was elevated*
- *AST >3 x ULN if baseline was normal or near normal; AST >2 x above baseline or AST >250 U/L if baseline was elevated*
- *ALP >2 x ULN if baseline was normal or near normal; ALP >2 x above baseline if baseline was elevated*

Where normal or near normal baseline is defined as ALT or AST ⩽ 1.5 x ULN, ALP ⩽ 1.5 x ULN and where elevated baseline is defined as ALT or AST > 1.5 x ULN, ALP > 1.5 x ULN.

	Elevated Liver Enzymes event number [read-only]	|0 < N3|
*	Sample collection date and time	Req☑/Req☑/Req☑ (2024-2035) Req☑:Req☑ *24-hour clock*
*	Possible aetiology for elevated liver enzymes *More than one option can be selected*	☐ Adverse Event *(most relevant AE),* enter Adverse Event no.: |0 < N3| ☐ Medical History/Concomitant Illness *(most relevant medical history/concomitant illness),* enter seq. no.: |0 < N3| ☐ Binge drinking ☐ Extensive physical activity ☐ Other Specify |A200|

Oracle item design notes:
Key: [*] = Item is required
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, IW: IWRS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

Mental Health Evaluation

V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, P13, V14, P15, V16, P17, V18, P19, V20, P21, V22, P23, V24, V25, V26, V27, V28, V29, V30, V31, V32, V-EOS

Mental Health Evaluation (Mental Health Evaluation) — [MENTAL_HEALTH] – Non-Repeating

Study ID: NNXXXX-XXXX
If any of question 1, 2 or 3 is answered “YES" and the event is clinically relevant fulfilling the criteria for adverse event reporting, report the event in AE form.

1*	Has the subject experienced or shown any clinically relevant deteriorations in mood since last evaluation? (Investigator question to both subject and subject's parent(s)/LAR, as applicable . *If the parent(s)/LAR is not available, please tick NA)*	○Subject ○Yes ○No ○Subject's parent(s)/LAR ○Yes ○No ○NA
*2	Has the subject experienced or shown any clinically relevant deteriorations in behaviour since last evaluation? (Investigator question to both subject and subject's parent(s)/LAR, as applicable. *If the parent(s)/LAR is not available, please tick NA)*	○Subject ○Yes ○No ○Subject's parent(s)/LAR ○Yes ○No ○NA
*3	Has the subject experienced or shown any clinically relevant deteriorations in school performance since last evaluation? (Investigator question to both subject and subject's parent(s)/LAR, as applicable. *If the parent(s)/LAR is not available, please tick NA)*	○Subject ○Yes ○No ○Subject's parent(s)/LAR

		○Yes ○No ○NA
If any of question 1, 2 or 3 is answered “YES", please complete question 4 and 5		
4	Will the C-SSRS Community Card be completed? (Investigator discretion) If Yes, complete CSSRS Community Card.	○Yes ○No
5	Has the subject been referred to a Mental Health Professional?	○Yes ○No If No, Please, provide reason

Key: [*] = Item is required

C-SSRS Community Card

V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, P13, V14, P15, V16, P17, V18, P19, V20, P21, V22, P23, V24, V25, V26, V27, V28, V29, V30, V31, V32, V-EOS

C-SSRS Community card	Non-Repeating

Study ID: NNXXXX-XXXX
If the subject answers 'Yes' to any question on the questionnaire 2-6, the subject must be evaluated as soon as possible by a Mental Health Professional.

CSSRS

1*	Have you wished you were dead or wished you could go to sleep and not wake up?	○Yes ○No
2*	Have you actually had any thoughts about killing yourself?	○Yes ○No
If Yes to 2, answer question 3, 4, 5 and 6		
3	Have you thought about how you might do this?	○Yes ○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?	○Yes ○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?	○Yes ○No

6	Have you done anything, started to do anything, or prepared to do anything to end your life? Examples: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, held a gun but changed your mind, cut yourself, tried to hang yourself, etc.	○Yes ○No

Study Object Descriptions: C-SSRS Community Card

Optional Section Notes

Type	RefName	Description		
Form	CSSRS	Dynamic form triggered when "Mental health evaluation" form Question# 4 is answered as "Yes".		

Key: [*] = Item is required

Weight History

V1

Weight History (Weight_Hx) — Non-repeating

Study ID: NNXXXX-XXXX
This form is used only to collect additional information to what would be recorded in the Medical History/Concomitant Illness eCRF.
Please ensure that all relevant medical history related to weight related comorbidities is recorded in the below form.

*	What was subject's weight a year ago?	xxx.x ○kg ○lb
*	What has been the subject's weight at birth?	xxx.x ○kg ○lb Unknown
*	What has been the subject's maximum weight?	xxx.x ○kg ○lb
*	How old was the subject at that time when he/she gained maximum weight?	years

*	How many times has the subject intentionally lost ≥ 11 lb/5 kg?"	○Never ○1-2 ○3-5 ○6-10 ○>10
*	Which of the following methods has the subject tried for weight loss (regardless of how much weight they lost)? (Tick all that apply)	☐ Self-directed (i.e., “on my own,” using only books, websites, mobile apps, activity trackers or fitness monitors) ☐ Weight loss program (e.g., Weight Watchers, insurance-offered program, dietary counselling, personal training, very-low-calorie diet, full meal replacement) ☐ Over-the-counter weight loss aids ☐ Prescription Anti-Obesity medications ☐ Liraglutide ☐ Orlistat ☐ Phentermine / -topiramate ☐ Phentermine ☐ Semaglutide ☐ Other (including drugs used off-label for weight loss) ☐ Don’t know ☐ None of the above
*	Regarding bariatric surgery, has the subject ever	☐ Considered pursuing bariatric surgery ☐ Discussed bariatric surgery with a healthcare provider ☐ Begun preparations for bariatric surge ☐ Been offered bariatric surgery, but declined ☐ None of the above
*	Did any of the subject’s biological relatives ever have overweight or obesity? (If unknown select ‘No’)	○No ○Yes

Key: [*] = Item is required

Socioeconomic status

V2

Socioeconomic status — **Non-repeating form**

Study ID: NNXXXX-XXXX

*	State education for parent1/LAR 1	○ Primary School ○ Middle School ○ High School ○ College/University ○ Master's Degree ○ Doctoral Degree ○ Prefer not to answer
	State education for parent2/LAR 2	○ Primary School ○ Middle School ○ High School ○ College/University ○ Master's Degree ○ Doctoral Degree ○ Prefer not to answer ○ NA

Key: [*] = Item is required

Living with parents/LAR

V2 , V12, V24, V-EOS

Living with parents/LAR — **Non-repeating form**

Study ID: NNXXXX-XXXX

*	Is the participant living with parents/LAR?	○ Yes ○ No

Key: [*] = Item is required

Hunger Single items

V2, EOS

Hunger Single Items	**Repeating form**

Study ID: NNXXXX-XXXX	
* Date and time	Req☑/Req☑/Req☑ (2024-2035) Req☑/Req☑/24-hour clock
* How hungry were you during the past 24 hours?	○ Not hungry at all ○ A little hungry ○ Moderately hungry ○ Quite hungry ○ Extremely hungry
* How hungry were you when you were the most hungry in the past 24 hours?	○ Not hungry at all ○ A little hungry ○ Moderately hungry ○ Quite hungry ○ Extremely hungry

Key: [*] = Item is required

Evaluation of Glycaemic Status

V2, V7, V9, V12, V18, V24, V-EOS

Evaluation of Glycaemic Status (Eval Glycaemic Status) — **Non-repeating**

Study ID: NNXXXX-XXXX — Integration

Please evaluate the subject's glycaemic status based on all available information.
If a participant is diagnosed with diabetes during the study, insulinoma associated-protein 2 (IA-2) antibodies and antiglutamic acid decarboxylase (anti-GAD) antibodies must be measured. Please refer to the protocol for further information.

Glycaemic status

- ○ Normo-glycaemia
- ○ Pre-diabetes
- ○ Diagnosed with type 2 diabetes

Tobacco, E-cigarettes and Nicotine Status

Design Notes
If both CRFs are present in a study: DM should check the 2 forms against each other. If 'NEVER SMOKED and SUTRT=TOBACCO then Tobacco section on Tobacco, Nicotine and E-cigarette Use CRF should not be filled in. Same logic for SUTRT=NICOTINE and SUTRT=E-CIGARETTE

V1

Tobacco, E-cigarettes and Nicotine Status ~~(Tobacco Status)~~ (Tobacco, E-cigarettes and Nicotine Status)) **[TOBACCO_STATUS ~~SU~~] Non-repeating**

Study ID: NNXXXX-XXXX		Integration
Tobacco (smoked)		
*	Tobacco status *Cigarettes, Heated tobacco, Beedi (Bidi), Cigars, Pipes, Cheroots, Cigarillos or other type of smoked tobacco* *Tobacco use is defined as smoking at least one cigarette or equivalent daily*	○ Never smoked ○ Previous smoker Smoking stop date: Req/Unk☑/Req/Unk☑/Req☑ (1900-2035) ○ Current smoker
E-cigarettes with nicotine		

*	E-cigarettes with nicotine status *Defined as at least 10 puffs daily*	○ Never used ○ Previous user E-cigarette using stop date: Req/Unk☑/Req/Unk☑/Req☑ (1900-2035) ○ Current user
Nicotine (non-smoked)		
*	Nicotine product status *Nicotine products include Nicotine patches, gum, spray, lozenge, inhaler, nicotine-snuff, snus or chewing tobacco* *Defined as at least 1 (patch, gum, spray, lozenge, inhaler, nicotine-snuff, snus or chewing tobacco) daily*	○ Never used nicotine products ○ Previously used nicotine products Nicotine products stop date: Req/Unk☑/Req/Unk☑/Req☑ (1900-2035) ○ Currently uses nicotine products

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, IW: IWRS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

Concomitant Medication

Design Notes

This CRF should be used for studies using pre-printed medication option. Phase 1 and NIS are allowed to use the new design, if necessary.
It enables studies to collect concomitant medication in a structured way. Information for any medication can be collected using two level radio control responses (L1 and L2) in item 'Medication'.

The item 'Medication' can be adjusted based on study/project need keeping the structure in levels: [L1] and [L2] respectively. The terms needed for [L1] and [L2] levels should be according to WHODrug dictionary and defined in close collaboration with IMD and Safety Surveillance Advisor.
Data from [L2] level of item 'Medication' is mapped directly to the hidden item 'Generic or Trade name' which is then transferred to standard OC question for coding as per WHODrug dictionary. It is important that terms defaulted at [L2] level are as per WHODrug dictionary as it is integrated to Argus through hidden item 'Generic or trade name'. It is not allowed to change structure of item 'Medication' or the hidden item 'Generic or trade name'.

The text '<…>' should be updated as needed for the specific study.

Non-Visit Related

Concomitant Medication (CM) **[CONCOM_MED_MEDDRA_1] – Repeating Form**

Study ID: NNXXXX-XXXX Integration

During the study from week 0 to week 294, the participant should not initiate any anti-obesity medication treatment which is not part of the study procedures.
If such treatment is initiated, the participant should be instructed to stop the treatment. (Refer section 6.8 in protocol)

	Seq. No. [read-only]	|N4|	A, R
*	Medication	○ Antihypertensive ○ Atenolol	

~~*<Optional guidance for which drug classes you need start dates, end dates and dose for L1 level>*~~	○ Amlodipine ○ Aliskiren ○ Azilsartan medoxomil ○ Benazepril ○ Bisoprolol ○ Bumetanide ○ Bendroflumethiazide ○ Canrenoate ○ Carvedilol ○ Captopril ○ Clonidine ○ Cilazapril ○ Candesartan ○ Delapril ○ Diltiazem ○ Eprosartan ○ Eplerenone ○ Enalapril ○ Furosemide ○ Felodipine ○ Filmasartan ○ Fosinopril ○ Hydralazine ○ Hydrochlorothiazide ○ Irbesartan ○ Imidapril ○ Indapamide ○ Labetalol ○ Lercanidipine ○ Losartan ○ Lisinopril ○ Metoprolol ○ Metolazone ○ Moxonidine ○ Methyldopa ○ Moexipril ○ Nadolol

- Nebivolol
- Nifdipine
- Olmesartan
- Perindopril
- Propanolol
- Quinapril
- Ramipril
- Sotalol
- Spironolactone
- Spirapril
- Timolol
- Terazosin
- Temocapril
- Telmisartan
- Trichlormethiazide
- Torasemide
- Trandolapril
- Valsartan
- Verapamil
- Zofenopril

- Lipid lowering
  - Alirocumab
  - Atorvastatin
  - Bezafibrate
  - Colesevelam
  - Colestyramine
  - Colestipol
  - Ciprofibrate
  - Evolocumab
  - Ezetimibe
  - Fluvastatin
  - Fenofibrate
  - Gemfibrozil
  - Lovastatin
  - Lovaza (Omega-3-triglucerides)

- OMEGA-3 TRIGLYCERIDES
- Pravastatin
- Pitavastatin
- Rosuvastatin
- Simvastatin
- Vascepa (Icosapent Ethyl)

- Antipsychotic medications
  - Acepromazine
  - Acetophenazine
  - Amisulpride
  - Aripiprazole
  - Asenapine
  - Butaperazine
  - Bromperidol
  - Benperidol
  - Brexpiprazole
  - Cariprazine
  - Chlorpromazine
  - Cyamemazine
  - Chlorproethazine
  - Clopenthixol
  - Chlorprothixene
  - Clotiapine
  - Clozapine
  - Dixyrazine
  - Droperidol
  - Fluanisone
  - Fluphenazine
  - Fluspirilene
  - Flupentixol
  - Haloperidol
  - iloperidone
  - Levomepromazine
  - Lithium
  - Lurasidone

	○ Loxapine ○ Levosulpiride ○ Mesoridazine ○ Mosapramine ○ Melperone ○ Moperone ○ Molindone ○ Olanzapine ○ Oxypertine ○ Promazine ○ Prochlorperazine ○ Pipotiazine ○ Penfluridol ○ Pipamperone ○ Pimozide ○ Paliperidone ○ Prothipendyl ○ Periciazine ○ Perazine ○ Pimavanserin ○ Quetiapine ○ Remoxipride ○ Risperidone ○ Sertindole ○ Sulpiride ○ Sultopride ○ Trifluprom azine ○ Thiopropazate ○ Trifluoperazine ○ Thioproperazine ○ Thioridazine ○ Tiapride ○ Trifluperidol ○ Tiotixene ○ Veralipride ○ Zuclopenthixol ○ Zotepine

	○ Ziprasidone ○ Anti-obesity medications ○ Amfepramone ○ Bupropion, Naltrexone ○ Cathine ○ Clobenzorex ○ Dexfenfluramine ○ Etilamfetamine ○ Ephedrine, Combinations ○ Fenfluramine ○ Lorcaserin ○ Mazindol ○ Mefenorex ○ Orlistat ○ Phentermine ○ Rimonabant ○ Sibutramine ○ Liraglutide ○ Sodium-Glucose Co-Transporter 2(SGLT2 Inhibitors) ○ Dapagliflozin ○ Canagliflozin ○ Empagliflozin ○ Ertugliflozin ○ Ipragliflozin ○ Sotagliflozin ○ Luseogliflozin ○ Biguanides ○ Metformin ○ Glinide ○ Thiazolidinedione ○ α-glucosidase inhibitors [AGI]

		○ Sulfonylureas ○ Other medications, not listed above |A200|	
	Generic or Trade name [hidden]	|A200|	A, R
	Country code [hidden]	|Pull down List 1|	
*	Start date ~~and time~~	Req/Unk☑/Req/Unk☑/Req☑ (1925-2035) ~~Req/Unk☑:/Req/Unk☑ 24-hour clock~~	A, R
*	Continuing?	○ Yes ○ No, Stop date ~~and time~~: Req/Unk☑/Req/Unk☑/Req☑ (2020-2035) ~~Req/Unk☑:/Req/Unk☑ 24-hour clock~~	A, R
*	Dose (Only for antihypertensive, lipid-lowering, antipsychotic medication, antidiabetic, and anti-obesity medications)	|xxxxxx.| ○ mg ○ mL ○ µg ○ g ○ U ○ IU ~~○ <Unit 1>~~ ~~○ <Unit 2>~~ ○ Other unit, specify: |A40|	A, R
*	Frequency (Only for antihypertensive, lipid-lowering, antipsychotic medication, antidiabetic, and anti-obesity medications)	○ Daily ○ Weekly ~~○ <Frequency 1>~~ ○ Other frequency, specify: |A50|	A, R

	~~Total daily dose [de-activated]~~	~~|xxxxxx.|~~ ~~O mg~~ ~~O mL~~ ~~O µg~~ ~~O g~~ ~~O U~~ ~~O IU~~ ~~O <Unit 1>~~ ~~O Other unit, specify |A10|~~	~~A, R~~
	~~Route [de-activated]~~	~~|Pull down List 3|~~	
*	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*	O Adverse Event, enter Adverse Event no.: |0 < N3| O Medical History/Concomitant Illness, enter seq. no.: |0 < N3| O Prophylactic O Other, specify: |A200|	
	Generic or Trade name concatenated with country code [hidden]	|A200|	

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

- Seq. No.: Calculated in InForm via rule.
- Country code: Used for coding purpose. Edit rights to be given to DM only. Item not to be visible to site staff.
- Generic or Trade name concatenated with country code: Used for coding purpose. Populated by InForm by concatenating item ‘Generic or Trade name’ and ‘Country code. Item not to be visible to site staff.
- For study using EDC-Argus interface: Form is to be set-up associated with the SIF.
- A de-activated item ‘CONCOM_ROUTE_TEXT’ is not present in the form above but currently exists in Central Designer and is needed for EDC-Argus integration. Hence, it will appear in the specifications received from Oracle.

- Primary indication:
  If any new response or sub-responses are added to this item, then it needs to be evaluated in the Implementation group meeting.

EDC Mapping rule:
Hidden item Generic or Trade name to be populated from item Medication [L2] level. If [L2] is selected as free text, then map the free text. Do not map the text in parenthesis.

Collection of Consent to Biosamples for Future Research

Design Notes
The text '<…>' should be updated to reflect the protocol.

V1

Collection of Consent to Biosamples for Future Research (Collection Future Research)		**[COLLECTION_FUTURE_RESEARCH] Non-repeating form**
Study ID: NNXXXX-XXXX		Integration
	~~Consent Obtained~~	~~O No~~ ~~O Yes~~
*	Child assent for biosamples for future analysis	O No O Yes Req☑/Req☑/Req☑ (2024-2035)
*	Consent for biosamples for future analysis obtained by Parents/Legally Acceptable Representative (LAR)	O No O Yes Req☑/Req☑/Req☑ (2024-2035)
	Consent for biosamples for future analysis obtained by Parents/Legally Acceptable Representative (LAR) *Only to be completed in countries where Informed*	O No O Yes Req☑/Req☑/Req☑ (2024-2035) O NA

	Consent from both parents is required	
	Child assent to Genetic/Genomic Analysis on the biosamples for future analysis? *Only to be completed for FRANCE*	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035)
	Parents/Legally Acceptable Representative (LAR) consent to Genetic/Genomic Analysis on the biosamples for future analysis? *Only to be completed for FRANCE*	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035)
	Did the Parents/Legally Acceptable Representative (LAR) consent to Genetic/Genomic Analysis on the biosamples for future analysis? Only to be completed in countries where Informed Consent from both parents is required. *Only to be completed for FRANCE*	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035) ○ NA

	~~<xxxx Consent> obtained~~	~~○ No~~ ~~○ Yes~~ ~~Req☑/Req☑/Req☑ (2022-2035)~~

~~<xxxx Consent> obtained [de-activated]~~	~~O No~~ ~~O Yes~~ ~~Req☑/Req☑/Req☑ (2022-2035)~~

Oracle item design notes:
Key: [*] = Item is required.

Withdrawal of Consent to Biosamples for Future Research

Design Notes
The text '<…>' should be updated to reflect the protocol.

Non-visit related (Consent)

Withdrawal of Consent to Biosamples for Future Research (Withdrawal Future Research)	**[WITHDRAWAL_FUTURE_RESEARCH] Non-repeating form**

Study ID: NNXXXX-XXXX		Integration
*	Biosamples Consent withdrawn	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035)
	Biosamples Consent to Genetic/Genomic Analysis withdrawn *Only to be completed for FRANCE*	○ No ○ Yes Req☑/Req☑/Req☑ (2024-2035)

	~~<xxxx Consent> obtained~~	~~○ No~~ ~~○ Yes~~ ~~Req☑/Req☑/Req☑ (2022-2035)~~

~~<xxxx Consent> obtained [de-activated]~~	~~O No~~ ~~O Yes~~ ~~Req☑/Req☑/Req☑ (2022-2035)~~

Oracle item design notes:
Key: [*] = Item is required.

Allocation to Maintenance group

Design Notes
The text '<…>' should be updated to reflect the protocol.

V12

Allocation to Maintenance group			Non-repeating form
Study ID: NNXXXX-XXXX			Integration
*	Which group is the subject allocated to for the maintenance phase ~~(Hidden)~~ Read Only	○ Dose Tapering Algorithm group ○ Non-Algorithm group	RTSM

Dynamic should be triggered for dose tapering algorithm form at V14, V16, V18 and V20 only for subjects which are in dose tapering algorithm group

Visit P13, P15, P17, P19, P21, P23 should trigger only for subjects which are in dose tapering algorithm group

Key: [*] = Item is required.

Dose at the end of initial treatment phase

Dose at the end of initial treatment phase	**Non-repeating form**

Design Notes
The text '<…>' should be updated to reflect the protocol.

V12

Study ID: NNXXXX-XXXX	Integration

*	What dose is the subject on at the end of initial treatment phase *(For subjects entering dose tapering algorithm, the dose to be added should be the dose **before** entering the algorithm)*	○ 0.0 mg ○ 0.25 mg ○ 0.5 mg ○ 1.0 mg ○ 1.7 mg ○ 2.4 mg
	If the dose is not 2.4 mg, then please specify the primary reason for the dose	○ Lack of tolerability ○ Health concern related to magnitude of weight loss ○ IMP has been disconitinued ~~(also to be chosen if dose has been tapered to 0 mg)~~

	○ At the investigator's discretion ○ Other, please specify

Key: [*] = Item is required.

Dose at the end of maintenance phase

Dose at the end of maintenance phase	**Non-repeating form**

Design Notes
The text '<…>' should be updated to reflect the protocol.

V24

Study ID: NNXXXX-XXXX	Integration

*	What dose is the subject on at the end of maintenance phase	○ 0.0 mg ○ 0.25 mg ○ 0.5 mg ○ 1.0 mg ○ 1.7 mg ○ 2.4 mg

	If the dose is not 2.4 mg, then please specify the primary reason for the dose	○ Lack of tolerability ○ Health concern related to magnitude of weight loss ○ IMP has been discontinued (also to be chosen if dose has been tapered to 0 mg) ○ At the investigator's discretion ○ Other, please specify
*	Which dose is prescribed at this visit?	○ 0.0 mg ○ 0.25 mg ○ 0.5 mg ○ 1.0 mg ○ 1.7 mg ○ 2.4 mg

Key: [*] = Item is required.

Dose at the end of study

Dose at the end of study	**Non-repeating form**

Design Notes
The text '<…>' should be updated to reflect the protocol.

V-EOS

Study ID: NNXXXX-XXXX	Integration

*	What dose is the subject on at the end of study	○ 0.0 mg ○ 0.25 mg ○ 0.5 mg ○ 1.0 mg ○ 1.7 mg

	○ 2.4 mg
If the dose is not 2.4 mg, then please specify the primary reason for the dose	○ Lack of tolerability ○ Health concern related to magnitude of weight loss ○ IMP has been discontinued (also to be chosen if dose has been tapered to 0 mg) ○ At the investigator's discretion ○ Other, please specify

Key: [*] = Item is required.

Dose Tapering Algorithm

weight Algorithm	**Non-repeating form**

Design Notes
The text '<…>' should be updated to reflect the protocol. Only applicable for participants in dose tapering algorithm group

V14, V16, V18, V20

Study ID: NNXXXX-XXXX	Integration

*	Is the subject following dose tapering algorithm?	○ Yes

	○ No,please specify ⊖ Date of stopping algorithm Req☑/Req☑/Req☑ (2024-2035) ⊖ Reason for stopping algorithm (Tick all that apply) ⊖ ☐ Recurrence of BMI within obesity range (≥ the 95th percentile for age and sex) ⊖ ☐ A clinically significant BMI increase of 10% from the BMI at initiation of maintenance phase (V12) ⊖ ☐ A health concern (including mental health) related to continued tapering of dose ⊖ Please specify

Key: [*] = Item is required.

Dose during continued treatment phase

Dose during continued treatment phase	**Non-repeating form**

Design Notes
The text '<…>' should be updated to reflect the protocol. Dose during continued treatment phase

V25.V26, V27, V28, V29, V30 ,V31, V32,

*	Is the subject still on the dose prescribed at the latest visit?	○ Yes ○ No If no,then please specify the dose the subject is on ○ 0.0 mg ○ 0.25 mg ○ 0.5 mg ○ 1.0 mg ○ 1.7 mg ○ 2.4 mg
*	Which dose was prescribed at this visit?	○ 0.0 mg ○ 0.25 mg ○ 0.5 mg ○ 1.0 mg ○ 1.7 mg ○ 2.4 mg

Key: [*] = Item is required.

End of IMP Treatment

Design Notes

For the question 'Has the subject completed the planned study intervention?', (Adverse event no.), 'AE no.' is not to be collected in phase 1 studies.

The text '<…>' should be updated to reflect the protocol.

Non-Visit Related (End IMP)

End of IMP Treatment (End of IMP Treat) **[END_OF_TREATMENT] - Non-repeating**

Study ID: NNXXXX-XXXX Integration

This form is only to be completed once the subject has **permanently stopped** taking investigational medicinal product (IMP).
Please remember to register the discontinuation of IMP in RTSM, if applicable.

*	Date of last dose of investigational medicinal product ~~<IMP 1>~~(Semaglutide)	○ Req☑/Req☑/Req☑ (2024-2035) ○ N/A	C, CO
	~~Date of last dose of investigational medicinal product <IMP 2> [de-activated]~~	~~○ Req☑/Req☑/Req☑ (2021-2030)~~ ~~○ N/A~~	
	~~Date and time of last dose of investigational medicinal product <IMP 1> [de-activated]~~	~~○ Req☑/Req☑/Req☑ (2019-2030)~~ ~~Req☑:Req☑ *24-hour clock*~~ ~~○ N/A~~	
*	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. (***If a subject in the dose tapering algorithm group is still tapered to zero by the end of the study, the response should also be 'Yes'***.)* *Select 'No' if the subject has **permanently** discontinued*	○ Yes ○ No **Primary** reason for discontinuation of investigational medicinal product(s): ○ Adverse Event ○ Adverse event no.: |0 < N3| ~~○ Hypoglycaemic episode no. (only if not reported on AE form): |0 < N3|~~ ○ Protocol deviation ○ Included in the trial in violation of the inclusion and/or exclusion criteria ○ Intention of becoming pregnant ○ Simultaneous use of an approved or non-approved investigational medicinal product in another clinical trial ~~○ <study specific criterion> <Diagnosis of type 1 diabetes>~~ ~~○ <study specific criterion <Suspicion of acute pancreatitis>~~ ○ Other, specify: |A200| ○ Lack of efficacy ~~○ <trial specific criterion>~~ ~~○ <trial specific criterion>~~ ~~○ Other, specify: |A200|~~ ○ Lost to follow-up ○ Pregnancy	C

IMP before the end of planned intervention and/or if the subject has not attended the last planned visit in the intervention period. *(***Exception is if a subject in the dose tapering algorithm is still tapered to zero by the end of the study – in such case, please select 'Yes')**	~~O~~Technical problems ~~Specify |A200|~~ O At the discretion of the Investigator Specify |A200| O Site closure O Epi/Pandemic Specify: |A200| O Other *(only to be selected if none of the above options are applicable)* O Withdrawal of consent ~~O <study specific criterion>~~ O Other, specify |A200|

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

End of Study

Non-Visit Related (End of Study)

End of Study (End Study) **[END_OF_TRIAL_2] - Non-repeating form**

Study ID: NNXXXX-XXXX			Integration
This form is to be completed at the end of subject participation in the clinical study (e.g. study completion, screening failure, ~~run-in criteria failure, randomisation criteria failure~~, ~~discontinuation~~ Withdrawal from study)			
*	Date subject's participation ended in the study	Req☑/Req☑/Req☑ (2024-2035)	C, N, CO
*	Specify **primary** reason participation ended	○ Subject completed the study ○ Screen failure *(defined as subject not eligible for participation according to in/exclusion criteria)* ~~○ Failing to meet randomisation requirements~~ ~~○ Run-in criteria failure~~	C, N, CO

If the subject participation ended prior to ~~randomisation~~ enrollment, complete the RTSM Screening Failure session.	~~O Randomisation criteria failure~~ ~~O Protocol specified withdrawal criteria met~~ ~~O Dosing day exclusion criteria~~ ~~O <study specific criterion>~~ ~~O <study specific criterion>~~ O Withdrawal of consent by subject, specify reason, if available: |A200| O Withdrawal of consent by subject's parent or subject's legally acceptable representative (LAR) Specify reason, if available: |A200| O Lost to follow-up Specify reason, if available: |A200| O Investigator decision Specify reason, if available: |A200| O Site closure O Epi/Pandemic Specify: |A200| O Death	

	IMPACT interface (calculated) [hidden]	Null field date: Req☑/Req☑/Req☑ (2022-2035) Discontinuation date: Req☑/Req☑/Req☑ (2022-2035) Discontinuation code: |A15|	P
	InForm subject status (calculated) [hidden]	|Pull down List 1| [ ] Completed [ ] Did not complete	InForm Special Item
	InForm subject discontinuation flag (calculated) [hidden]	|Pull down List 2| [ ] Screening failure [ ] Discontinuation from trial	InForm Special Item

Oracle item design notes:
Key: [*] = Item is required.
Integration: A: Argus, Ax: Forms attached in Argus, C: CPR Dashboard, CO: COSMOS, P: Impact, N: NEVAS, R: Reports, RT: RTSM

Contraceptive counselling (Contraceptive counselling)

Contraceptive Counselling	Non-repeating form

V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V14, V16, V18, V20, V22, V24, V25, V26, V27, V28, V29, V30, V31, V32, V-EOS

Study ID: NNXXXX-XXXX	
* Has the subject been provided	○Yes

contraceptive counselling at this visit?	○ No ○ N/A, due to pregnancy

Key: [*] = Item is required

Dynamic to be added. If childbearing potential is Yes, then trigger this form

Case Book Sign Off

Non-Visit Related

Case Book Sign Off (Sign Off) **[TERM] - Non-repeating form**

Study ID: NNXXXX-XXXX		Integration
*	Prepare the case book for sign off	☐

General item design notes:
Key: [*] = Item is required.

This form is minimum content. If a field is not used state “NA”. Additions to the form are acceptable.

CRF Version	**CRF Date**	**Reason for Update and Description of Update**	**CRF Design Coordinator/ CRF Designer** (Initials)
1.0	23-Feb-2024	New document	MURJ
2.0	21-Jun-2024	• Withdrawal of consent to In-trial interview: Question item text updated	MURJ

		• Withdrawal of consent to In-trial interview: Supporting Text ‘and form should trigger dynamically when ‘In-trial interview consent obtained?’ is Yes’ is deleted • Allocation Maintenance Group: Hidden text is deleted and ‘Read only’ is added under question item ‘Which group is the subject allocated to for the maintenance phase’ • Weight History Form: Under Prescription Anti-Obesity medications for Phentermine/topiramate slash deleted hyphen added as Phentermine-topiramate • Tobacco, E-cigarettes and Nicotine Status: Form Short name and REFNAME updated • Dose Tapering Algorithm: Bulletin removed from date and reason and please specify • End of initial treatment phase : Text (also to be chosen if dose has been tapered to 0 mg)” deleted • End of IMP Treatment: Diagnosis of type 1 diabetes and Suspicion of acute pancreatitis striked out as it is not required	
3.0	20-Nov-2024	• **Collection of Consent to Biosamples for Future Research**: Below question items added to the form	MURJ

		1. Child assent to Genetic/Genomic Analysis on the biosamples for future analysis? *Only to be completed for FRANCE* 2. Parents/Legally Acceptable Representative (LAR) consent to Genetic/Genomic Analysis on the biosamples for future analysis? *Only to be completed for FRANCE*. 3.Parents/Legally Acceptable Representative (LAR) consent to Genetic/Genomic Analysis on the biosamples for future analysis? Only to be completed in countries where Informed Consent from both parents is required. *Only to be completed for FRANCE* 4: Radio-button- NA added under 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 • **Withdrawal of consent to Biosamples for Future Research**. Below question item added to the form 1. Biosamples Consent to Genetic/Genomic Analysis withdrawn	

		Only to be completed for FRANCE. • **Consent for Legal age:** Below question item update/added to the form 1. Question item#1 text updated 2. Question item#2 text updated 3.New question item added: Date of consent for Genetic/Genomic Analysis on the biosamples for future analysis obtained after reaching legal age *Only to be completed for FRANCE* 4. Note updated: (Legal age is 16 only for United Kingdom and Sweden and 18 and above for the other countries) • **Consent for In-trial Interviews**: 1: Radio-button- NA added under Consent for In-trial Interviews obtained by Parents/Legally Acceptable Representative (LAR) to allow child to be interviewed Only to be completed in countries where Informed Consent from both parents is required • **Dose Tapering Algorithm:** The text "(Tick all that apply) "added next to'Reason for stopping algorithm'. Also Selecting more than one option for 'Reason for stopping algorithm'will be enabled in EDC. Also radio buttons is replaced with check box for all of the options under Reason for	

		stopping algorithm	