

Mock CRF

Design Notes

In a few phase 1 studies, lab cannot deliver date (and time) and/or fasting information together with the results in normal load files. Then please use the ‘Collection of Samples for Laboratory (Date, Time, Fasting)’ standard CRF to collect this information.

Only include the section for Blood or Urine as needed. There is no need for PST approval before removing either section.

V1, V4, V5, V6, V7, V10, V12, V14, V16, V18, V19A, V21

Collection of Samples for Laboratory (Lab_1)

[LAB_SMPL_TKN] – Non-repeating form

Integration

Collect samples following the procedures detailed in the laboratory manual.

Blood

* Have blood samples been collected?	<input type="radio"/> Yes <input type="radio"/> No, none were collected
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Design Notes

In a few phase 1 studies, lab cannot deliver date (and time) and/or fasting information together with the results in normal load files. Then please use the 'Collection of Samples for Laboratory (Date, Time, Fasting)' standard CRF to collect this information.

Only include the section for Blood or Urine as needed. There is no need for PST approval before removing either section.

V2, V8, V19

Collection of Samples for Laboratory (Lab_2)

[LAB_SMPL_TKN_1] – Non-repeating form

Integration

Collect samples following the procedures detailed in the laboratory manual.

Blood

* Have blood samples been collected?	<input type="radio"/> Yes <input type="radio"/> No, none were collected
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Urine

* Have urine samples been collected?	<input type="radio"/> Yes <input type="radio"/> No, none were collected
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Collection of Samples for Laboratory _TS

Collection of Samples for Laboratory (Biosamples)

Design Notes
<p>In a few phase 1 studies, lab cannot deliver date (and time) and/or fasting information together with the results in normal load files. Then please use the ‘Collection of Samples for Laboratory (Date, Time, Fasting)’ standard CRF to collect this information.</p> <p>Only include the section for Blood or Urine as needed. There is no need for PST approval before removing either section.</p>

V2, V5, V8, V16, V19

Collection of Samples for Laboratory (Biosamples)	LAB_SMPL_TKN_2 – Non-repeating form
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		Integration
<i>Collect samples following the procedures detailed in the laboratory manual.</i>		
*	Have biosamples for future analysis been collected?	<div><input type="radio"/> Yes</div> <div><input type="radio"/> No, none were collected</div>

Contraception (Baseline)

V1

Contraception - (Contraception)

[CONTRACEPTION_BASE] - Non-repeating

		Integration
*	Has contraceptive counselling been provided?	<input type="radio"/> Yes <input type="radio"/> No
*	Is the subject using highly effective contraception as defined in the protocol? <i>Remember to update Concomitant Medication</i>	<input type="radio"/> Yes <ul style="list-style-type: none"> <input type="checkbox"/> Combined (oestrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation <input type="checkbox"/> Progestogen-only hormone contraception associated with inhibition of ovulation <input type="checkbox"/> Intrauterine device (IUD) <input type="checkbox"/> Intrauterine hormone-releasing system (IUS) <input type="checkbox"/> Bilateral tubal occlusion (including bilateral ligation) <input type="checkbox"/> Vasectomised partner <input type="checkbox"/> Same-sex partner(s) <input type="checkbox"/> Sexual abstinence <input type="radio"/> No

Form to be dynamically triggered from the 'Childbearing Potential' form for female subject and should only appear/filled in if the Childbearing potential is answered as YES.

Contraception (Follow-up)

v2, V4, V5, V6, V7, V8, V10, V12, V14, V16, V18, V19, V19A, V20

Contraception - (Contraception)**[CONTRACEPTION_FU] - Non-repeating**

		Integration
*	Has contraceptive counselling been provided at this visit?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Due to pregnancy <input type="radio"/> Subject no longer of childbearing potential <input type="radio"/> Other
*	Since last assessment, has the subject used highly effective contraception as defined in the protocol? <i>Remember to update Concomitant Medication</i>	<input type="radio"/> Yes <input type="checkbox"/> Combined (oestrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation <input type="checkbox"/> Progestogen-only hormone contraception associated with inhibition of ovulation <input type="checkbox"/> Intrauterine device (<i>IUD</i>) <input type="checkbox"/> Intrauterine hormone-releasing system (<i>IUS</i>) <input type="checkbox"/> Bilateral tubal occlusion (<i>including bilateral ligation</i>) <input type="checkbox"/> Vasectomised partner <input type="checkbox"/> Same-sex partner(s) <input type="checkbox"/> Sexual abstinence <input type="radio"/> No

Form to be dynamically triggered from the 'Childbearing Potential' form for female subject and should only appear/filled in if the Childbearing potential is answered as YES.

C-SSRS Baseline (C-SSRS Baseline)

V1

C-SSRS Baseline (C-SSRS Baseline)

[CSSRS_BASELINE] - Non-repeating

Integration

Suicidal Ideation

Ask questions 1 and 2. If both are negative, proceed to 'Suicidal Behaviour' section. If the answer to question 2 is 'Yes', ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is 'Yes', complete the 'Intensity of Ideation' section below.

* Wish to be Dead ☐ No
 ☐ Yes
 If yes, describe: |A200|

* Non-Specific Active Suicidal Thoughts ☐ No
 ☐ Yes
 If yes, describe: |A200|

Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act ☐ No
 ☐ Yes
 If yes, describe: |A200|

Active Suicidal Ideation with Some Intent to Act, without Specific Plan ☐ No
 ☐ Yes
 If yes, describe: |A200|

Active Suicidal Ideation with Specific Plan and Intent ☐ No
 ☐ Yes
 If yes, describe: |A200|

Intensity of Ideation

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe). Ask about time he/she was feeling the most suicidal.

Most Severe Ideation ☐ 1 (Wish to be dead)

	<input type="radio"/> 2 (<i>Non-Specific Active Suicidal Thoughts</i>) <input type="radio"/> 3 (<i>Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act</i>) <input type="radio"/> 4 (<i>Active Suicidal Ideation with Some Intent to Act, without Specific Plan</i>) <input type="radio"/> 5 (<i>Active Suicidal Ideation with Specific Plan and Intent</i>) Description of Ideation: A200
Frequency <i>How many times have you had these thoughts?</i>	<input type="radio"/> Less than once a week <input type="radio"/> Once a week <input type="radio"/> 2-5 times in week <input type="radio"/> Daily or almost daily <input type="radio"/> Many times each day
Duration <i>When you have the thoughts, how long do they last?</i>	<input type="radio"/> Fleeting - few seconds or minutes <input type="radio"/> Less than 1 hour/some of the time <input type="radio"/> 1-4 hours/a lot of time <input type="radio"/> 4-8 hours/most of day <input type="radio"/> More than 8 hours/persistent or continuous
Controllability <i>Could/can you stop thinking about killing yourself or wanting to die if you want to?</i>	<input type="radio"/> Easily able to control thoughts <input type="radio"/> Can control thoughts with little difficulty <input type="radio"/> Can control thoughts with some difficulty <input type="radio"/> Can control thoughts with a lot of difficulty <input type="radio"/> Unable to control thoughts <input type="radio"/> Does not attempt to control thoughts
Deterrents <i>Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?</i>	<input type="radio"/> Deterrents definitely stopped you from attempting suicide <input type="radio"/> Deterrents probably stopped you <input type="radio"/> Uncertain that deterrents stopped you <input type="radio"/> Deterrents most likely did not stop you <input type="radio"/> Deterrents definitely did not stop you <input type="radio"/> Does not apply
Reasons for Ideation <i>What sort of reasons did you have for thinking about wanting to die or killing yourself?</i>	<input type="radio"/> Completely to get attention, revenge or a reaction from others <input type="radio"/> Mostly to get attention, revenge or a reaction from others <input type="radio"/> Equally to get attention, revenge or a reaction from others and to end/stop the pain. <input type="radio"/> Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) <input type="radio"/> Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) <input type="radio"/> Does not apply
Suicidal Behaviour <i>Check all that apply, so long as these are separate events; must ask about all types</i>	

*	Actual Attempt	<input type="radio"/> No <input type="radio"/> Yes If yes, describe: A200 Total number of Attempts: N3 Has subject engaged in Non-Suicidal Self-Injurious Behaviour? <input type="radio"/> Yes <input type="radio"/> No
*	Interrupted Attempt	<input type="radio"/> No <input type="radio"/> Yes If yes, describe: A200 Total number of Interrupted Attempts: N3
*	Aborted Attempt	<input type="radio"/> No <input type="radio"/> Yes If yes, describe: A200 Total number of Aborted Attempts: N3
*	Preparatory Acts or Behaviour	<input type="radio"/> No <input type="radio"/> Yes If yes, describe: A200
*	Suicidal Behaviour	<input type="radio"/> No <input type="radio"/> Yes

Answer for Actual Attempts Only

Most Recent Attempt	Most Recent Attempt Date: UNK/Req☑/: UNK/Req ☑/Req☑ (1900-2035) Actual Lethality/Medical Damage: <input type="radio"/> 0. No physical damage or very minor physical damage Potential Lethality: Only Answer If Actual Lethality=0 <input type="radio"/> 0 = Behaviour not likely to result in injury <input type="radio"/> 1 = Behaviour likely to result in injury but not likely to cause death <input type="radio"/> 2 = Behaviour likely to result in death despite available medical care <input type="radio"/> 1. Minor physical damage <input type="radio"/> 2. Moderate physical damage; medical attention needed <input type="radio"/> 3. Moderately severe physical damage; medical hospitalisation and likely intensive care required <input type="radio"/> 4. Severe physical damage; medical hospitalisation with intensive care required <input type="radio"/> 5. Death
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Most Lethal Attempt	<p>Most Lethal Attempt Date: UNK/Req☑/: UNK/Req ☑/Req☑ (1900-2035)</p> <p>Actual Lethality/Medical Damage:</p> <ul style="list-style-type: none"> ○ 0. No physical damage or very minor physical damage <ul style="list-style-type: none"> Potential Lethality: <i>Only Answer If Actual Lethality=0</i> <ul style="list-style-type: none"> ○ 0 = Behaviour not likely to result in injury ○ 1 = Behaviour likely to result in injury but not likely to cause death ○ 2 = Behaviour likely to result in death despite available medical care ○ 1. Minor physical damage ○ 2. Moderate physical damage; medical attention needed ○ 3. Moderately severe physical damage; medical hospitalisation and likely intensive care required ○ 4. Severe physical damage; medical hospitalisation with intensive care required ○ 5. Death
Initial/First Attempt	<p>Initial/First Attempt Date: UNK/Req☑/: UNK/Req ☑/Req☑ (1900-2035)</p> <p>Actual Lethality/Medical Damage:</p> <ul style="list-style-type: none"> ○ 0. No physical damage or very minor physical damage <ul style="list-style-type: none"> Potential Lethality: <i>Only Answer If Actual Lethality=0</i> <ul style="list-style-type: none"> ○ 0 = Behaviour not likely to result in injury ○ 1 = Behaviour likely to result in injury but not likely to cause death ○ 2 = Behaviour likely to result in death despite available medical care ○ 1. Minor physical damage ○ 2. Moderate physical damage; medical attention needed ○ 3. Moderately severe physical damage; medical hospitalisation and likely intensive care required ○ 4. Severe physical damage; medical hospitalisation with intensive care required ○ 5. Death

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

C-SSRS Since Last Visit (C-SSRS Since Last Visit)

V6, V8, V12, V16, V19, V19A

C-SSRS Since Last Visit (C-SSRS Since Last Visit)

[CSSRS_SLV] - Non-repeating

Integration

Suicidal Ideation

Ask questions 1 and 2. If both are negative, proceed to 'Suicidal Behaviour' section. If the answer to question 2 is 'Yes', ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is 'Yes', complete 'Intensity of Ideation' section below.

* Wish to be Dead ☐ No
 ☐ Yes
 If yes, describe: |A200|

* Non-Specific Active Suicidal Thoughts ☐ No
 ☐ Yes
 If yes, describe: |A200|

Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act ☐ No
 ☐ Yes
 If yes, describe: |A200|

Active Suicidal Ideation with Some Intent to Act, without Specific Plan ☐ No
 ☐ Yes
 If yes, describe: |A200|

Active Suicidal Ideation with Specific Plan and Intent ☐ No
 ☐ Yes
 If yes, describe: |A200|

Intensity of Ideation

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe Ideation ☐ 1 (Wish to be dead)

	<input type="radio"/> 2 (Non-Specific Active Suicidal Thoughts) <input type="radio"/> 3 (Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act) <input type="radio"/> 4 (Active Suicidal Ideation with Some Intent to Act, without Specific Plan) <input type="radio"/> 5 (Active Suicidal Ideation with Specific Plan and Intent) Description of Ideation: A200
Frequency <i>How many times have you had these thoughts?</i>	<input type="radio"/> Less than once a week <input type="radio"/> Once a week <input type="radio"/> 2-5 times in week <input type="radio"/> Daily or almost daily <input type="radio"/> Many times each day
Duration <i>When you have the thoughts, how long do they last?</i>	<input type="radio"/> Fleeting - few seconds or minutes <input type="radio"/> Less than 1 hour/some of the time <input type="radio"/> 1-4 hours/a lot of time <input type="radio"/> 4-8 hours/most of day <input type="radio"/> More than 8 hours/persistent or continuous
Controllability <i>Could/can you stop thinking about killing yourself or wanting to die if you want to?</i>	<input type="radio"/> Easily able to control thoughts <input type="radio"/> Can control thoughts with little difficulty <input type="radio"/> Can control thoughts with some difficulty <input type="radio"/> Can control thoughts with a lot of difficulty <input type="radio"/> Unable to control thoughts <input type="radio"/> Does not attempt to control thoughts
Deterrents <i>Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?</i>	<input type="radio"/> Deterrents definitely stopped you from attempting suicide <input type="radio"/> Deterrents probably stopped you <input type="radio"/> Uncertain that deterrents stopped you <input type="radio"/> Deterrents most likely did not stop you <input type="radio"/> Deterrents definitely did not stop you <input type="radio"/> Does not apply
Reasons for Ideation <i>What sort of reasons did you have for thinking about wanting to die or killing yourself?</i>	<input type="radio"/> Completely to get attention, revenge or a reaction from others <input type="radio"/> Mostly to get attention, revenge or a reaction from others <input type="radio"/> Equally to get attention, revenge or a reaction from others and to end/stop the pain. <input type="radio"/> Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) <input type="radio"/> Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) <input type="radio"/> Does not apply
Suicidal Behaviour <i>Check all that apply, so long as these are separate events; must ask about all types</i>	

* Actual Attempt	<input type="radio"/> No <input type="radio"/> Yes If yes, describe: A200 Total number of Actual Attempts: N3 Has subject engaged in Non-Suicidal Self-Injurious Behavior? <input type="radio"/> Yes <input type="radio"/> No	
* Interrupted Attempt	<input type="radio"/> No <input type="radio"/> Yes If yes, describe: A200 Total number of Interrupted Attempts: N3	
* Aborted Attempt	<input type="radio"/> No <input type="radio"/> Yes If yes, describe: A200 Total number of Aborted Attempts: N3	
* Preparatory Acts or Behaviour	<input type="radio"/> No <input type="radio"/> Yes If yes, describe: A200	
* Suicidal Behaviour	<input type="radio"/> No <input type="radio"/> Yes	
* Suicide	<input type="radio"/> No <input type="radio"/> Yes	
Answer for Actual Attempts Only		
Most Lethal Attempt	Most Lethal Attempt Date: Req☑/Req☑/Req☑ (2025-2035) Actual Lethality/Medical Damage: <input type="radio"/> 0. No physical damage or very minor physical damage Potential Lethality: Only Answer If Actual Lethality=0 <input type="radio"/> 0 = Behaviour not likely to result in injury <input type="radio"/> 1 = Behaviour likely to result in injury but not likely to cause death <input type="radio"/> 2 = Behaviour likely to result in death despite available medical care <input type="radio"/> 1. Minor physical damage <input type="radio"/> 2. Moderate physical damage; medical attention needed <input type="radio"/> 3. Moderately severe physical damage; medical hospitalisation and likely intensive care required <input type="radio"/> 4. Severe physical damage; medical hospitalisation with intensive care required	

○ 5. Death

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

Evaluation of Antihypertensive and Lipid-Lowering Treatment, Project-specific

Evaluation of Antihypertensive and Lipid-Lowering Treatment

V19

Evaluation of Antihypertensive and Lipid-Lowering Treatment (Eval AH And LL Treat)

[EVALUATION_2]

Integration

If relevant, please indicate based on your medical judgment if there is a change in treatment intensity of antihypertensive or lipid-lowering medication(s) from randomisation (V2) to week 64 (V19).

The evaluation should be based on whether an overall change has occurred of antihypertensive or lipid-lowering medication(s) (i.e., either increase, decrease or no change) after reviewing all available relevant information e.g., changes in drug dose, drug class, number of drugs or a combination of these.

Please ensure consistency between the reported concomitant medication and your below evaluation.

1.* Has the subject received treatment for hypertension during the period between visit 2 and visit 22A?

- ☐ No
☐ Yes

If yes, please provide an answer in item 2.

2. Is the subject taking hypertension medication at this visit?

- ☐ No
☐ Yes

If yes, indicate the change in anti-hypertensive treatment intensity since visit 2.

Increase: Examples are:

*Increase in dose of existing medication
Initiation of medication (no medication at baseline)
Additional medication added on top of baseline medication
Changed to another medication with the purpose of increasing intensity*

Decrease: Examples are:

*Decrease in dose of existing medication
Discontinuation of some medications but not all
Changed to another medication with the purpose of decreasing intensity*

- If yes, please indicate the change in antihypertensives (in treatment intensity) from visit 2*
☐ Increase
☐ Decrease
☐ No change

<p>No change: Examples are: <i>Same medication dose and type as baseline</i> <i>Changed to different type of medication with same overall treatment intensity</i> <i>Change in doses of different medication, but overall same treatment intensity as baseline</i> <i>Includes involuntary treatment pauses in the treatment when subject otherwise should have continued</i></p>	
<p>3.* Was the subject treated with lipid-lowering agents during the period between visit 2 and visit 22A?</p> <p><i>If yes, please provide an answer in item 4.</i></p>	<p><input type="radio"/> No <input type="radio"/> Yes</p>
<p>4. Is the subject taking lipid-lowering agents at this visit?</p> <p>If yes, indicate the change in lipid-lowering medication intensity since visit 2.</p> <p>Increase: Examples are: <i>Increase in dose of existing medication</i> <i>Initiation of medication (no medication at baseline)</i> <i>Additional medication added on top of baseline medication</i> <i>Changed to another medication with the purpose of increasing intensity</i></p> <p>Decrease: Examples are: <i>Decrease in dose of existing medication</i> <i>Discontinuation of some medications but not all</i> <i>Changed to another medication with the purpose of decreasing intensity</i></p> <p>No change: Examples are: <i>Same medication dose and type as baseline</i> <i>Changed to different type of medication with same overall treatment intensity</i> <i>Change in doses of different medication, but overall same treatment intensity as baseline</i> <i>Includes involuntary treatment pauses in the treatment when subject otherwise should have continued</i></p>	<p><input type="radio"/> No <input type="radio"/> Yes</p> <p>If yes, please indicate the change in lipid-lowering agents (in treatment intensity) from visit 2</p> <p><input type="radio"/> Increase <input type="radio"/> Decrease <input type="radio"/> No change</p>

Hand Grip Test

Hand Grip Test

V2, V8, V19

Hand Grip Test (Hand Grip) [HAND_GRIP] -Non repeating form

The hand grip strength test must be performed according to the manual, and the result should be recorded to the nearest kilogram..		
		Integration
*	Is the subject right-handed, left-handed, or ambidextrous?	<div> <div> Right-handed </div> <div> Left-handed </div> <div> Ambidextrous </div> </div>
*	<div> <div>The highest values attained by right-hand grip strength scores</div> <div>Report the highest of three measurements</div> </div>	<div> <div> 0 < N3 ≤ 200 </div> <div>kg</div> </div>
*	<div> <div>The highest values attained by left-hand grip strength scores</div> <div>Report the highest of three measurements</div> </div>	<div> <div> 0 < N3 ≤ 200 </div> <div>kg</div> </div>

Key: [*] = Item is required.

MRI Scan Consent

V1

MRI Scan Consent (MRI Consent) [MRI_CONSENT] Non-repeating

		Integration
* MRI scan consent obtained?	<div><div><input type="radio"/> No</div><div><input type="radio"/> Yes</div></div> <div>Date consent obtained Req☑/Req☑/Req☑ (2025-2035)</div>	

Patient Health Questionnaire - PHQ-9

V1, V6, V8, V12, V16, V19, V19A

Patient Health Questionnaire - PHQ-9 (PHQ-9)

[PHQ9] - Non-repeating

		Integration
Over the last 2 weeks, how often have you been bothered by any of the following problems?		
* Little interest or pleasure in doing things	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day	
* Feeling down, depressed, or hopeless	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day	
* Trouble falling or staying asleep, or sleeping too much	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day	
* Feeling tired or having little energy	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day	
* Poor appetite or overeating	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day	

*	Feeling bad about yourself - or that you are a failure or have let yourself or your family down	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
*	Trouble concentrating on things, such as reading the newspaper or watching television	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
*	Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
*	Thoughts that you would be better off dead or of hurting yourself in some way	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
*	Total score	N2
	If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	<input type="radio"/> Not difficult at all <input type="radio"/> Somewhat difficult <input type="radio"/> Very difficult <input type="radio"/> Extremely difficult

Weight history (Adults) V1.0

Weight History (Adults)

Design Notes

If any new approved obesity medication is added, remember to evaluate the need for new submission values and topic codes in the IG.

V1

Weight History – (Weight Hx)

[WEIGHT_HIST] - Non-repeating

Study ID: NNXXXX-XXXX

Integration

This form is only to be used for information not collected in the Medical History/Concomitant Illness CRF.

- | | |
|---|--|
| <p>* What was the subject's weight a year ago?</p> <p><i>For female subjects: If the subject was pregnant, how much did she weigh before the pregnancy?</i></p> | <p> xxx.x <input type="radio"/> kg <input type="radio"/> lb</p> |
| <p>* What has been the subject's maximum weight?</p> <p><i>For female subjects: exclude times when the subject was pregnant</i></p> | <p> xxx.x <input type="radio"/> kg <input type="radio"/> lb</p> |

*	How old was the subject when they reached their maximum weight?	N3 Years
*	In the subject's own opinion, when did they first develop overweight?	<input type="radio"/> In childhood <input type="radio"/> In adolescence <input type="radio"/> In adulthood
	When was the onset of overweight? <i>For female subjects only</i>	In relation to a pregnancy <input type="radio"/> Before <input type="radio"/> After <input type="radio"/> Subject has not been pregnant In relation to menopause <input type="radio"/> Before <input type="radio"/> After
*	What has been the lowest weight of the subject as an adult?	xxx.x <input type="radio"/> kg <input type="radio"/> lb
*	How many times has the subject intentionally lost ≥ 11 lb/5 kg?	<input type="radio"/> 0 <input type="radio"/> 1-2 <input type="radio"/> >3
	Has the subject ever considered bariatric surgery?	<input type="radio"/> No <input type="radio"/> Yes Provide further details regarding bariatric surgery: <input type="checkbox"/> Discussed bariatric surgery with a healthcare provider <input type="checkbox"/> Begun preparations for bariatric surgery <input type="checkbox"/> Been deemed ineligible for bariatric surgery due to health risks <input type="checkbox"/> Been offered bariatric surgery, but declined <input type="checkbox"/> Undergone bariatric surgery
	Does the subject have any family history of overweight or obesity?	<input type="radio"/> No <input type="radio"/> Yes

<i>This is only related to genetic family relations</i>	
* Has the subject tried any weight loss methods, regardless of how much weight they lost?	<input type="radio"/> No <input type="radio"/> Yes Which of the following methods has the subject tried for weight loss? <input type="checkbox"/> Self-directed <input type="checkbox"/> Weight loss program <input type="checkbox"/> Over-the-counter weight loss aids <input type="checkbox"/> Weight loss device or procedure <input type="checkbox"/> Intra gastric balloon <input type="checkbox"/> Endoscopic sleeve gastroplasty <input type="checkbox"/> Adjustable gastric banding <input type="checkbox"/> Sleeve gastrectomy <input type="checkbox"/> Roux-en-Y Gastric Bypass <input type="checkbox"/> Biliopancreatic diversion with duodenal switch <input type="checkbox"/> One Anastomosis Gastric Bypass or similar (e.g. mini gastric bypass) <input type="checkbox"/> Liposuction and/or abdominoplasty <input type="checkbox"/> Unknown weight loss device or procedure <input type="checkbox"/> Prescription medications for obesity
<i>If 'Weight loss device or procedure' is selected in the question above, fill in details below for device or procedure</i> <i>If 'Prescription medications for obesity' is selected in the question above, fill in details below for each medication selected.</i>	
(Add entry)	
Seq. No. [read-only]	N3
Name of the previous prescription medication for obesity <i>Only drugs that are not part of the subject's current treatment are to be reported here. All current treatments are to be reported on the Concomitant</i>	<input type="radio"/> Phentermine <input type="radio"/> Orlistat <input type="radio"/> Naltrexone/bupropion <input type="radio"/> Lorcaserin <input type="radio"/> Phentermine/topiramate <input type="radio"/> Liraglutide <input type="radio"/> Fenfluramine <input type="radio"/> Amfepramone <input type="radio"/> Dexfenfluramine

<p><i>Medication form. 'Other' is including drugs used off-label for weight loss</i></p>	<ul style="list-style-type: none"> <input type="radio"/> Mazindol <input type="radio"/> Etilamfetamine <input type="radio"/> Cathine <input type="radio"/> Clobenzorex <input type="radio"/> Mefenorex <input type="radio"/> Sibutramine <input type="radio"/> Setmelanotide <input type="radio"/> Ephedrine <input type="radio"/> Rimonabant <input type="radio"/> Tirzepatide <input type="radio"/> Semaglutide <input type="radio"/> ←New approved obesity medication→ <input type="radio"/> Other
<p>What were the reason(s) for discontinuing the prescription medication?</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Lack of tolerability <input type="checkbox"/> Lack of effect <input type="checkbox"/> Reached personal weight goal Specify personal weight goal: xxxxx. <input type="radio"/> kg <input type="radio"/> lb <input type="checkbox"/> Cost of treatment <input type="checkbox"/> Other

General item design notes:

Key: [*] = Item is required.

Oracle item design notes:

Seq. no: Calculated in InForm via rule.

Edit checks: If 'Prescription medications for obesity' is selected in the question 'Which of the following methods has the subject tried for weight loss?', then ensure that at least one entry should be present in the prescription medication details section.

Unplanned Procedures

Non-Visit Related

Unplanned Procedures - (Unplanned Proc Bariatric) [XXXXXXXX] - Repeating

Study ID:XXXXXX		Integration
Seq. No. [read-only]	N4	
* Date of procedure	Req☑/Req☑/Req☑ (2025-2035)	
* Procedure type	<div><div>○ Weight loss surgery</div><div><div>○ Bariatric gastric balloon insertion</div><div>○ Bariatric gastric balloon removal</div><div>○ Endoscopic sleeve gastropasty</div><div>○ Endoscopic sleeve gastropasty reversal</div><div>○ Gastric banding (includes laparoscopic adjustable gastric band)</div><div>○ Gastric band repositioning</div><div>○ Gastric band removal</div><div>○ Sleeve gastrectomy</div><div>○ Gastric bypass (roux-en-y, OAGB or similar)</div><div>○ Gastric bypass reversal</div><div>○ Biliopancreatic diversion with duodenal switch</div><div>○ Liposuction</div><div>○ Other</div></div><div>Specify: A200 </div><div><div>○ Knee surgery</div><div><div>○ Baker's cyst excision</div><div>○ Right</div><div>○ Left</div><div>○ Bilateral</div></div><div>j Knee joint debridement</div></div></div>	Keep this question "Weight loss surgery" item as default

	<input type="radio"/> Right <input type="radio"/> Left <input type="radio"/> Bilateral ; Arthroplasty revision <input type="radio"/> Right <input type="radio"/> Left <input type="radio"/> Bilateral <input type="radio"/> Partial knee joint replacement <input type="radio"/> Right <input type="radio"/> Left <input type="radio"/> Bilateral <input type="radio"/> Total knee joint replacement <input type="radio"/> Right <input type="radio"/> Left <input type="radio"/> Bilateral <input type="radio"/> Other Specify: A200 <input type="radio"/> Hip surgery <input type="radio"/> Partial hip replacement <input type="radio"/> Total hip replacement <input type="radio"/> Other Specify: A200 <input type="radio"/> Obstructive sleep apnoea surgery <input type="radio"/> Septoplasty <input type="radio"/> Turbinoplasty <input type="radio"/> Tonsillectomy <input type="radio"/> Adenoidectomy <input type="radio"/> Other Specify: A200
* Reason for procedure	<input type="radio"/> Adverse Event, enter Adverse Event number: 0 < N3 <input type="radio"/> Medical History/Concomitant Illness, enter number: 0 < N3 Was the subject previously ineligible for procedure, now eligible due to weight loss? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Other Specify: A200

Key: [*] = Item is required.

