MEDPACE

Sonoma Biotherapeutics

Protocol: SBT777101-01

eCRF Completion Guidelines

A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Activity of Single Ascending Doses of SBT777101 in Subjects with Rheumatoid Arthritis

VERSION HISTORY

VERSION DATE	VERSION NUMBER	AUTHOR	SUMMARY
13-Sep-2023	1.0	T.Nguyen	Initial Draft
			Revised draft following sponsor comments Updated Data Coordinator contact Added screenshots
			Added General Instructions section 8 – Navigating the Audit Trail
			Sponsor Approved Version 1.0
07-Mar-2024	2.0	T.Nguyen / S.Hall	Updated Schedule of Assessments with administrative changes Updated Dynamics per sponsor Updated fields on Eligibility form per sponsor Updated Adverse Event form to rearrange fields “Was the event related to a trial procedure?”, “If yes, specify:”, and “Did this Adverse Event lead to study discontinuation?”
			Added new field "Were any abnormal results clinically significant?" and updated screen note on Local Laboratory – Urinalysis form
			Dynamics - Updated dynamics for which forms appear if subject meets all SCR eligibility, IE, PRT2, LB_PREG, LB_MENO, ET, added dynamics for CE_IRR AE - Removed fields "ASTCT CRS grade:" and "ASTCT ICANS grade:". Added new fields: "Start time (24 hour clock):", "End time (24 hour clock):", "Check this box if this event is related to CRS:", and "Check this box if this event is related to Neurotoxicity/ICANS:". Updated CTCAE Grade to be required field and added dynamics note. Added N/A option for Grade. Updated "Infusion Related Reaction" field to "Infusion Related Reaction (IRR):" Updated "Check this box if this event is related to CRS:" to "Is this event related to CRS?" and "Check this box if this event is related to Neurotoxicity/ICANS:" to "Is this event related to Neurotoxicity/ICANS?" CE_CRS - Removed fields: “Start date:”, “Start Time (24 hr clock):”, “Is the event ongoing?”, “End date:”, “End time (24 hr clock):”. Added new fields "Associated Adverse Event #1:", "Associated Adverse Event #2:", "Associated Adverse Event #3:" and "ASTCT CRS grade:" CE_NEURO - R Removed fields: “Corresponding Primary Adverse Event Number:”, “Start date:”, “Start Time (24 hr clock):”, “Is the event ongoing?”, “End date:”, “End time (24 hr clock):”. Added new fields "Associated Adverse Event #1:", "Associated Adverse Event #2:", "Associated Adverse Event #3:" and "ASTCT ICANS grade:" DS_APHELIG - Added new fields "Date of Screen Failure at Apheresis:", "Primary Reason for Screen

VERSION DATE	VERSION NUMBER	AUTHOR	SUMMARY
			Failure at Apheresis:", and "Primary Reason for Screen Failure at Apheresis Other, Specify:" DS_PTELIG - Updated field "Did the subject meet all pre-infusion eligibility?" to "Did the subject meet all pre-infusion eligibility and approved for enrollment into the treatment period of the study?". Added new field "Date of Screen Failure at Pre-Treatment:". Update dynamics notes IEYN - Added new fields "Date of Screen Failure at Screening:", "Primary Reason for Screen Failure at Screening:", and "Primary Reason for Screen Failure at Screening Other, Specify:" PR_APHER - Removed all Second and Other Apheresis fields. Updated Initial Apheresis fields to removed "Initial". Added new fields to capture reason Apheresis not done and not successful. Added Start time and End time fields for Apheresis. CE_IRR - New form added GATE - Added new field "Were there any Infusion Related Reactions (IRR)?"
			General instructions – Updated section 2 #8 on SF limited casebooks, adding additional CRFs to SF casebook VS – Changed BMI to note that it is a read-only field AE – Added guidelines for AE changes in severity when an event is not a pre-existing condition

ELECTRONIC CASE REPORT FORM COMPLETION GUIDELINES

These electronic Case Report Form (eCRF) Completion Guidelines are organized to provide general instructions that apply to all eCRFs. If you have any questions regarding completion of the eCRFs, **please contact your Clinical Research Associate (CRA) or the Medpace Data Coordinator.**

CONTACT INFORMATION

The Medpace EDC Help Desk supports users with technical issues, such as system login failures.

EDC Help Desk
Phone: 1-800-730-5779, call and follow prompts to reach EDC Help Desk
or
Email: EDCHelp@medpace.com

Contact the Data Coordinator or Data Manager for study specific questions related to the EDC system, forms and queries.

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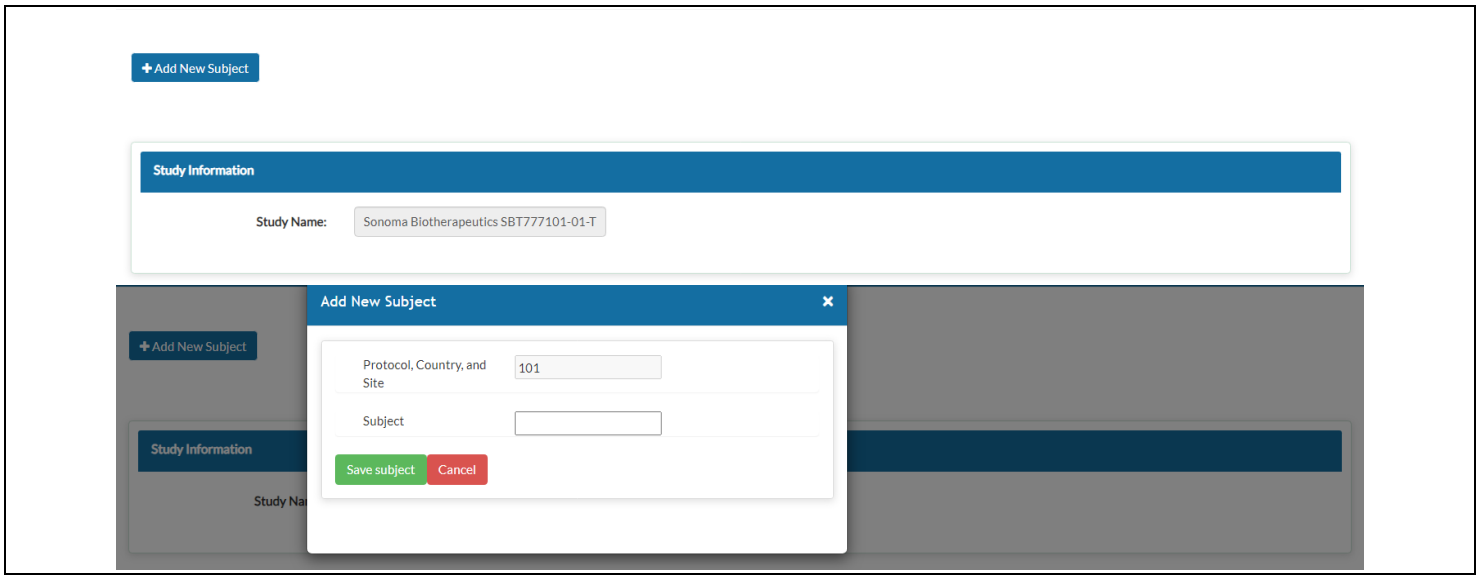
GENERAL INSTRUCTIONS

1. Electronic Data Capture System and Access

- Data will be entered in electronic Case Report Forms (eCRFs) in the ClinTrak® Electronic Data Capture (EDC) system via the following URL: https://clintrakedc.medpace.com
- Requests for access are made via ClinTrak® Systems Access Request Management (ARM) via the following URL: https://clintrak.medpace.com/ClinTrakARM/Account/Login
- All non-read only users must be trained prior to being granted access to the study within the EDC system.
- Training will be performed and documented within the EDC system. The training video links are within EDC and based on role. Users who have previously completed the required trainings are not required to repeat training.
- Training video link(s) will appear after initial login. Training acknowledgement will be required before accessing a study portal.
- Once training has been acknowledged, you may find your training certificate by accessing the 'My Profile' tab and clicking 'Print Training Certificate'. Save a copy of your training certificate with your study related documents.

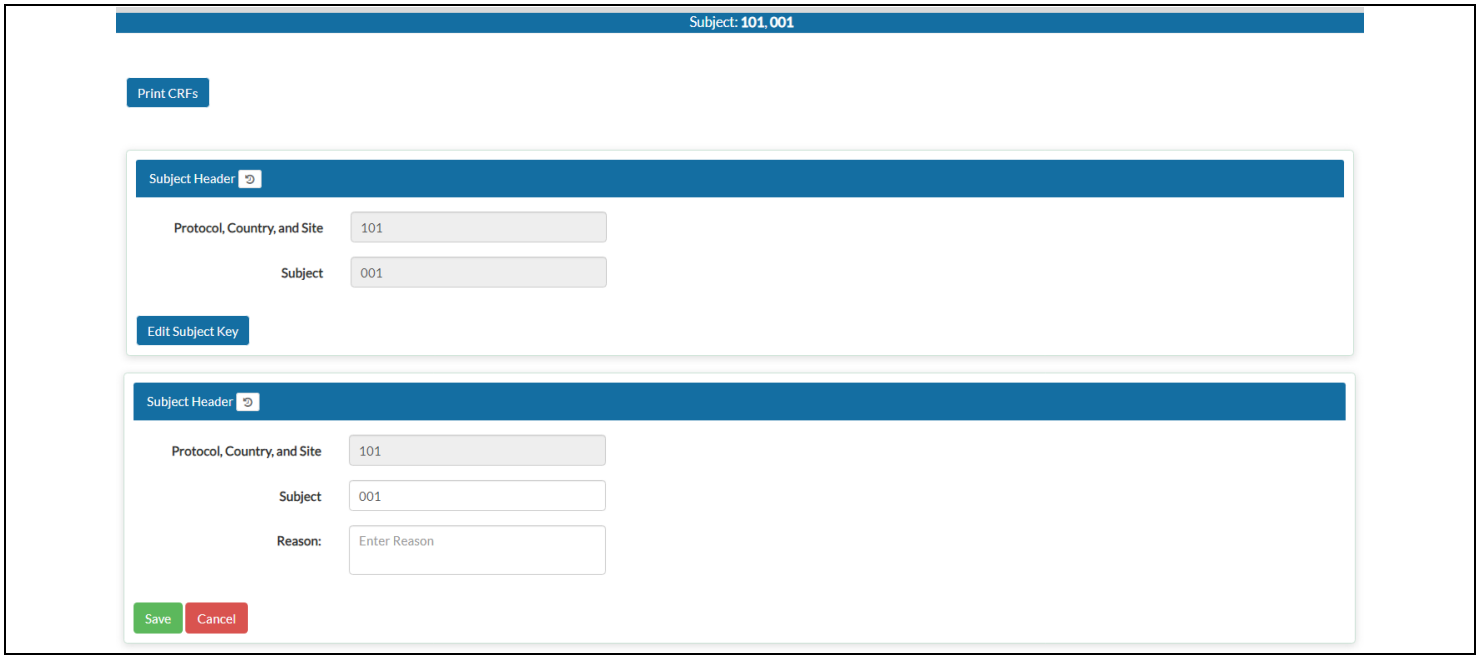
2. Adding A Subject In EDC

- The 9-character sequential subject number (**S01-XYY, ZZZ**), where S01 is the unique protocol identifier number, X is the country code, YY is the site number (01-99 assigned chronologically) and ZZZ is the subject identifier (001, 002, 003,…). Each subject ID is unique and cannot be reused.
- Subjects will be manually entered into EDC:



1. Click on the Data Entry tab located at the top of ClinTrak EDC.
2. Click the site name in the navigation tree.
3. Click **+Add New Subject**.
4. The Site field will be pre-populated with the assigned site number.
5. Enter the 3-digit subject identification number.
6. Click **Save Subject** to add the subject.
7. If enter correctly, the complete subject number for subject 001 at site 01 in the US should display as S01-101-001 in EDC.

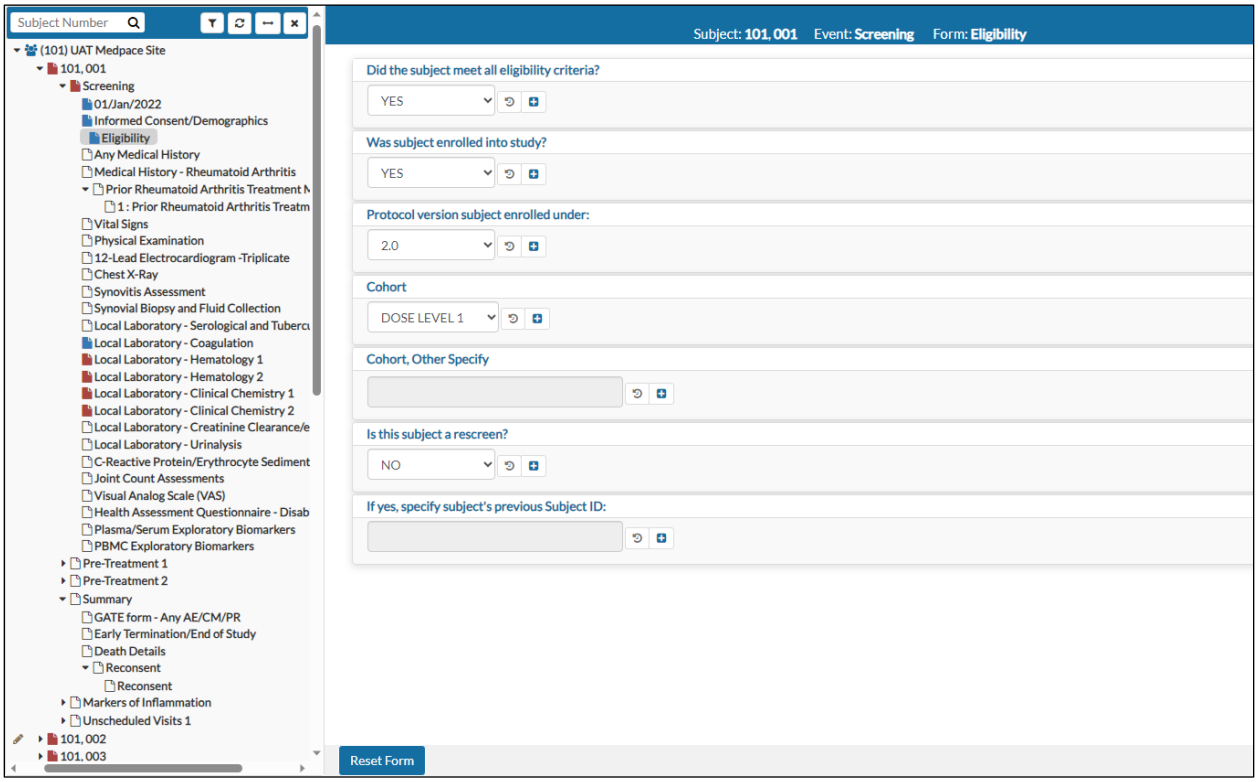
8. If for any reason the subject ID needs to be updated, select the subject in the navigation tree, click the **Edit Subject Key** button, update the **Subject** field, and provide a reason for the update.



- Screen Failures will have a limited casebook. The following eCRFs will need to be completed:
  - Date of Visit
  - Informed Consent/Demographics
  - Eligibility
  - Inclusion Not Met/Exclusion Criteria Met
  - Any Medical History
  - Medical History
  - Medical History - Rheumatoid Arthritis
  - Prior Rheumatoid Arthritis Treatment Medication
  - Synovitis Assessment
  - Synovial Biopsy and Fluid Collection
  - C-Reactive Protein/Erythrocyte Sedimentation Rate
  - Joint Count Assessments
  - Visual Analog Scale (VAS)
  - GATE form - Any AE/CM/PR (only record medications and procedures if used for treatment in an adverse event for Screen Failures)
  - Adverse Events

- Individuals who do not meet the criteria for participation in this study (screen failure) may be rescreened. Subjects may be rescreened up to 2 times, if deemed appropriate by the Principal Investigator. All screening assessments that led to screen failure must be repeated for rescreening.

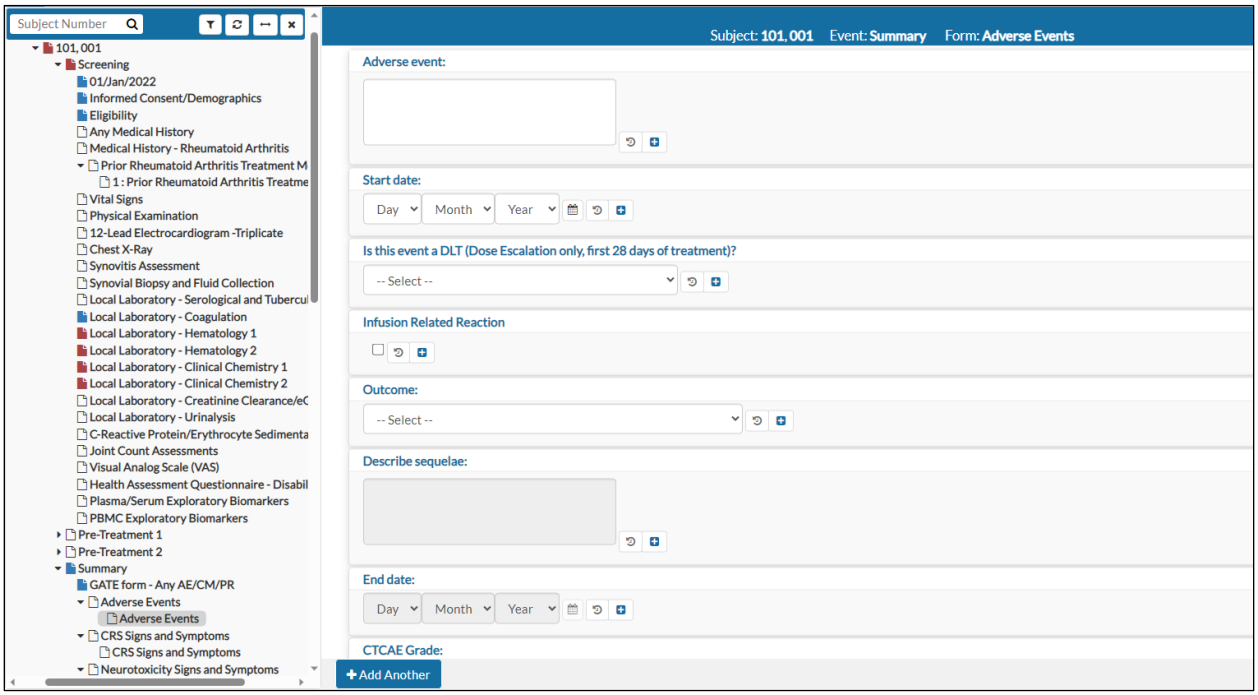
3. Navigating EDC and Completing eCRFs



- Navigate between subjects, visits, and eCRFs via the Navigation Tree, located in the left panel of the Data Entry tab
- In the Navigation Tree, use the arrows (▶) to locate the form on which you want to enter data. Click on the form name. The form will appear in the window on the right side of the screen.
- Once data entry is complete, click the green **Save** button in the lower left side of the screen. If data is entered into the form in error, click the red **Cancel All** button.
- If data entry needs to be updated after saved, select the field, enter new data, and click the green **Save** button in the lower left side of the screen.
- To correct the order of forms in the Navigation Tree, select the **Reset** button (↺) located at the top of the Navigation Tree window.
- If eCRF data is entered in error and needs to be cleared, click the **Reset Form** button located in the lower left side of the screen, enter a **Reason** for clearing data on the form, and click **Confirm**.
- Repeating forms: Multiple records can be added for repeating forms, such as Medical History, Adverse Events, and Prior and Concomitant Medications.

GENERAL INSTRUCTIONS (CONTINUED)

Adding Repeating Forms

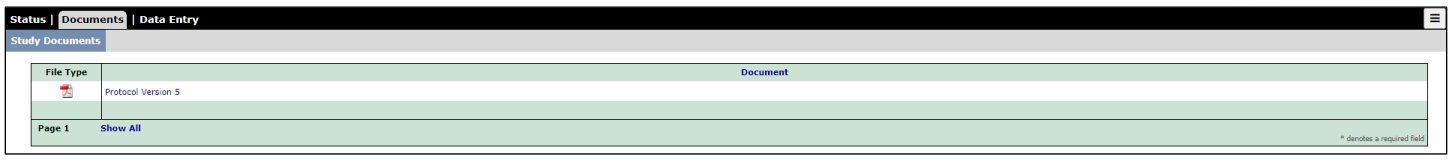


1. Locate the Gateway Form (e.g. Any Adverse Events?). This is typically a 'Yes' or 'No' question. Once 'Yes' is selected and saved, the first Repeating Form will appear in the Navigation Tree.
2. Click on the newly added form. The entry screen will appear in the window on the right side of the screen.
3. If additional forms are needed, click the **+Add Another** button, which appears in the lower left corner once the first form is saved.
4. Additional forms can also be added by clicking on the form name (e.g. Adverse Events) and clicking **Add Additional Form**

Deleting Repeating Forms

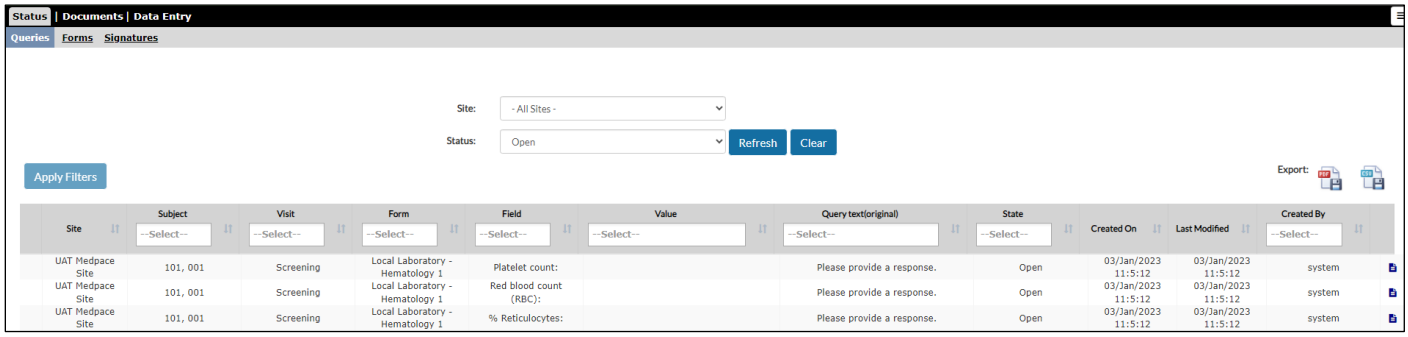
1. If the data on a repeating form is entered in error and needs to be cleared, click the **Delete** button located on the lower left side of the screen, enter a **Reason** for deleting the record, and click **Confirm**.
2. If a repeating form is deleted in error and needs to be restored, click the **Restore Form** button located on the lower left-hand side of the screen, enter a **Reason** for restoring, and click **Confirm**.

- If a subject terminates early from the study, do not enter any data in the eCRFs for events that were not performed.
- The eCRF Completion Guidelines locate in the Documents tab of the study portal.



- Protected health information (PHI) such as name, initials, full date of birth (as country specific regulations apply), etc. must not be entered into the CRF or be used in query responses.

4. Data Entry and Query Guidelines



- Data entry is expected to be completed in EDC within 5 business days of each visit.
- Queries should be reviewed and responded to within 5 days of the query generation.
- Query and data entry timelines can be shortened at study specific milestones, upon specific request, or during lock.
- All queries in a state of 'Open' require resolution from the site. To locate all 'Open' queries:
  1. Click on the Status tab located at the top of ClinTrak EDC. A table is provided listing all queries in an 'Open' state.
  2. Clicking on the ( ) icon at the end of each row takes the user directly to the entry screen where the query is located.
  3. A Query Status Indicator is located next to each field on the entry screen showing the status of the queries associated with that field. Red text and ( ) icon on a field indicate an open query that requires a response from the site coordinator.
- All changes and query responses made to the eCRFs require a reason for change, which will be tracked via the audit trail in the eCRF.
  1. When data changes are made, a Change Reason-Respond box will open asking for the reason for change.
  2. When responding to a query, a Query Response box will open asking for the response to the query.
  3. Once all necessary data changes are made and/or query responses are provided on the form, select **Save** in the lower left corner of the form.
  4. A complete history of changes and query responses can be viewed in the audit trail by clicking ( ) next to the field.

GENERAL INSTRUCTIONS (CONTINUED)

5. Data Entry Conventions

- Avoid using abbreviations.
- The date format is **DD/MMM/YYYY**. All Date fields will require a complete date unless 'UNK' is listed in the drop-down select box. For partial dates, a minimum of the year is required.
- All times must be entered in a **24-hour clock** format. Where applicable, '**UNK**' will be available if an unknown time is permitted. If only the hour is known, and the minutes are not, please enter the hour as appropriate and choose '**UNK**' for the minutes.
- Rounding convention: For decimal values, round to the nearest expected decimal place (e.g., 50.67 kg should be entered as 50.7 kg for a field in which only one decimal place is expected, per protocol. 50.679 kg should be entered as 50.68 kg for a field in which two decimal places are expected, per protocol, etc.).
- Drop-down select boxes will contain all possible responses for that field. You may select only one response from a drop-down select box. If 'Other' is selected from a drop-down select box, the system may allow entry into a corresponding 'Specify' text box, when applicable.

6. Unscheduled Visits

- Every subject added to a study is automatically provided with one optional Unscheduled (UNS) visit.
    1. If applicable, complete the associated Date of Visit eCRF.
    2. Click on the Unscheduled Visit 1 header in the Navigation Tree.
    3. All available forms for an Unscheduled visit will appear in the window on the right side of the screen. Click **Add Form** next to each form required for the UNS visit. The added form(s) will appear in the Navigation Tree under the Date of Visit eCRF.
- To add additional Unscheduled visits, click on the subject ID in the tree and click **Add** next to Unscheduled under Create Additional Events.

7. Principal Investigator Signature and Serious Adverse Event Reporting

- The Principal Investigator (PI) must electronically sign all subjects' Case Report Form books for database lock. If further corrections or changes are required after the Investigator signs, the system will automatically un-sign the case book and the Investigator will be required to re-sign.
- All Serious Adverse Events (SAEs) must be reported to Medpace Clinical Safety group and Sonoma Biotherapeutics through EDC within 24 hours of knowledge, if available. If it is not possible to access the EDC system within the required timeframe, send an email with the SAE to Medpace Safety at Medpace-safetynotification@medpace.com or call the Medpace SAE reporting line: +1-800-730-5779, dial 3 or +1-513-579-9911, dial 3 and fax/email the completed paper SAE form to Medpace within 24 hours of knowledge.
    - PI electronic signature is required for SAEs; the signature should occur as soon as possible after the SAE is reported and when updates are made.

8. Navigating the Audit Trail

- Navigation of the audit trail is explained in the EDC training video.
- The audit trail can be viewed by data item or at the form level. Click the item history icon next to the specific data item or generate form history report(s) from the visit/event screen to view the audit trail.
    - The audit trail shows the actions performed for that data field, such as data entry, data changes, and data cleaning activities (e.g., SDV and queries). User and timestamp are displayed for each action.

SCHEDULE OF ASSESSMENTS

		Screening Period	Pre-Treatment Period		Pre-Treatment Reassessment X Period (X = 1, and each new period adds 1)†		Treatment
† Indicates Repeating Visit or Form	Visit:	Screening Visit (SCR)	Pre-Treatment 1 (PRT1)	Pre-Treatment 2 (PRT2)	Pre-Treatment 1 (PRT1-X)	Pre-Treatment 2 (PRT2-X)	
	Day						1
	Visit Name (How visits will appear ins EDC)	Screening	Pre-Treatment Visit 1	Pre-Treatment Visit 2	Pre-Treatment Reassessment X Visit 1	Pre-Treatment Reassessment X Visit 2	W1D1
	Visit Window (Days)	-56 to -42	-41 to -11	-10 to -4	-41 to -11	-10 to -4	
Sheet	Form*						
DOV	Date of Visit	X	X	X	X	X	X
DM	Informed Consent/Demographics	X					
IEYN	Eligibility	X					
IE	Inclusion Not Met/Exclusion Criteria Met†	X					
MHYN	Any Medical History	X					
MH	Medical History†	X					
SU	Alcohol and Drugs Use	X					
MH_RA	Medical History - Rheumatoid Arthritis	X					
CM_OTMMED	Prior Rheumatoid Arthritis Treatment Medication†	X					
VS	Vital Signs	X		X		X	X
PE	Physical Examination	X		X		X	X
EG	12-Lead Electrocardiogram -Triplicate	X		X		X	
PR_XRAY	Chest X-Ray			X		X	
PE_SYNO	Synovitis Assessment	X		X		X	
LB_SYNO	Synovial Biopsy and Fluid Collection	X					
DS_APHELIG	Apheresis Eligibility		X		X		
PR_APHER	Apheresis		X		X		
LB_SERT	Local Laboratory - Serological and Tuberculosis Tests	X					
LB_PREG	Local Laboratory - Pregnancy	X		X		X	X
LB_MENO	Local Laboratory - Post Menopause	X					
LB_COAG	Local Laboratory - Coagulation	X		X		X	
LB_HEMA1	Local Laboratory - Hematology 1	X		X		X	
LB_HEMA2	Local Laboratory - Hematology 2	X		X		X	
LB_CHEM1	Local Laboratory - Clinical Chemistry 1	X		X		X	
LB_CHEM2	Local Laboratory - Clinical Chemistry 2	X		X		X	
LB_CRCL	Local Laboratory - Creatinine Clearance/eGFR	X					
LB_URIN	Local Laboratory - Urinalysis	X		X		X	
LB_LIPID	Local Laboratory - Lipid Tests			X		X	
LB_CRP	C-Reactive Protein/Erythrocyte Sedimentation Rate	X		X		X	

Note: *Form availability shown is for Enrollment through Week 1 Day 1 Treatment visits.*

SCHEDULE OF ASSESSMENTS (CONTINUED)

		Screening Period	Pre-Treatment Period		Pre-Treatment Reassessment X Period (X = 1, and each new period adds 1)†		Treatment
† Indicates Repeating Visit or Form	Visit:	Screening Visit (SCR)	Pre-Treatment 1 (PRT1)	Pre-Treatment 2 (PRT2)	Pre-Treatment 1 (PRT1-X)	Pre-Treatment 2 (PRT2-X)	
	Day						1
	Visit Name (How visits will appear ins EDC)	Screening	Pre-Treatment Visit 1	Pre-Treatment Visit 2	Pre-Treatment Reassessment X Visit 1	Pre-Treatment Reassessment X Visit 2	W1D1
	Visit Window (Days)	-56 to -42	-41 to -11	-10 to -4	-41 to -11	-10 to -4	
PE_JOINT	Joint Count Assessments	X		X		X	
QS_VAS	Visual Analog Scale (VAS)	X		X		X	
QS_ICE	Immune Effector Cell-Associated Encephalopathy (ICE) Score†			X		X	X
QS_HAQ	Health Assessment Questionnaire - Disability Index	X		X		X	
QS_FACIT	Functional Assessment of Chronic Illness Therapy - Fatigue			X		X	
PC	Pharmacokinetic Blood Samples			X		X	
LB_IMMUNO	PBMC Immunogenicity			X		X	
LB_ADA	Serum Anti-drug Antibody			X		X	
LB_EIMARKER	Plasma/Serum Exploratory Biomarkers	X		X		X	
LB_EBMARKER	PBMC Exploratory Biomarkers	X		X		X	
LB_RCL	Replication Competent Lentivirus			X		X	
DS_PTELIG	Pre-Treatment Eligibility			X		X	
EX	SBT777101 Administration						X
VISIT	Next Visit						X
GATE	GATE form - Any AE/CM/PR						
AE	Adverse Events†						
CE_CRS	CRS Signs and Symptoms†						
CE_NEURO	Neurotoxicity/ICANS Signs and Symptoms†						
CE_IRR	Infusion Related Reactions†						
CM	Prior & Concomitant Treatments/Medications†						
PR	Prior & Concomitant Procedures†						
LBYN_IMARKER	GATE - Markers						
LB_IMARKER	Markers of Inflammation†						
DS_EOS	Early Termination/End of Study						
DD	Death Details						
DS_RECON	Reconsent†						

Note: *Form availability shown is for Enrollment through Week 1 Day 1 Treatment visits.*

SCHEDULE OF ASSESSMENTS (CONTINUED)

		Safety Follow-Up															Early Termination			
† Indicates Repeating Visit or Form	Visit:	Week 1			Week 2		Week 3	Week 4	Week 6	Week 8	Week 10	Week 12	Week 18	Week 24	Week 36	Week 48/End of Study (ES)	Early Termination (ET)	Summary	Markers of Inflammation	Unscheduled† (UNS)
	Day	2	4/5	7	11	14	21	28	42	56	70	84	126	168	252	336				
	Visit Name (How visits will appear ins EDC)	W1D2	W1D4/5	W1D7	W2D11	W2D14	W3D21	W4D28	W6D42	W8D56	W10D70	W12D84	W18D126	W24D168	W36D252	End of Study	Early Termination	Summary	Markers of Inflammation	Unscheduled Visits
	Visit Window (Days)			±1	±1	±2	±2	±2	±2	±2	±2	±3	±7	±7	±7	±7				
Sheet	Form*																			
DOV	Date of Visit	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
DM	Informed Consent/Demographics																			
IEYN	Eligibility																			
IE	Inclusion Not Met/Exclusion Criteria Met†																			
MHYN	Any Medical History																			
MH	Medical History†																			
SU	Alcohol and Drugs Use																			
MH_RA	Medical History - Rheumatoid Arthritis																			
CM_OTMMED	Prior Rheumatoid Arthritis Treatment Medication†																			
VS	Vital Signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
PE	Physical Examination	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
EG	12-Lead Electrocardiogram -Triplicate			X		X										X	X			X
PR_XRAY	Chest X-Ray																			
PE_SYNO	Synovitis Assessment							X				X					X			
LB_SYNO	Synovial Biopsy and Fluid Collection							X				X					X			X
DS_APHELIG	Apheresis Eligibility																			
PR_APHER	Apheresis																			
LB_SERT	Local Laboratory - Serological and Tuberculosis Tests																			
LB_PREG	Local Laboratory - Pregnancy											X	X	X		X	X			X
LB_MENO	Local Laboratory - Post Menopause																			
LB_COAG	Local Laboratory - Coagulation												X	X		X				
LB_HEMA1	Local Laboratory - Hematology 1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
LB_HEMA2	Local Laboratory - Hematology 2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
LB_CHEM1	Local Laboratory - Clinical Chemistry 1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
LB_CHEM2	Local Laboratory - Clinical Chemistry 2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
LB_CRCL	Local Laboratory - Creatinine Clearance/eGFR																			
LB_URIN	Local Laboratory - Urinalysis									X					X	X	X			
LB_LIPID	Local Laboratory - Lipid Tests															X				
LB_CRP	C-Reactive Protein/Erythrocyte Sedimentation Rate	X		X		X	X	X	X	X	X	X	X	X	X	X	X			X

Note: *Form availability shown is for Week 1 Day 2 (Safety Follow-Up) through Early Termination/End of Study visits including Unscheduled visits.*

SCHEDULE OF ASSESSMENTS (CONTINUED)

		Safety Follow-Up															Early Termination			
† Indicates Repeating Visit or Form	Visit:	Week 1			Week 2		Week 3	Week 4	Week 6	Week 8	Week 10	Week 12	Week 18	Week 24	Week 36	Week 48/End of Study (ES)	Early Termination (ET)	Summary	Markers of Inflammation	Unscheduled† (UNS)
	Day	2	4/5	7	11	14	21	28	42	56	70	84	126	168	252	336				
	Visit Name (How visits will appear ins EDC)	W1D2	W1D4/5	W1D7	W2D11	W2D14	W3D21	W4D28	W6D42	W8D56	W10D70	W12D84	W18D126	W24D168	W36D252	End of Study	Early Termination	Summary	Markers of Inflammation	Unscheduled Visits
	Visit Window (Days)			±1	±1	±2	±2	±2	±2	±2	±2	±3	±7	±7	±7	±7				
Sheet	Form*																			
PE_JOINT	Joint Count Assessments					X		X		X		X	X	X		X	X			X
QS_VAS	Visual Analog Scale (VAS)					X		X		X		X	X	X		X	X			
QS_ICE	Immune Effector Cell-Associated Encephalopathy (ICE) Score†	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
QS_HAQ	Health Assessment Questionnaire - Disability Index					X		X		X		X	X	X		X	X			
QS_FACIT	Functional Assessment of Chronic Illness Therapy - Fatigue												X	X		X	X			
PC	Pharmacokinetic Blood Samples	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
LB_IMMUNO	PBMC Immunogenicity							X		X		X				X	X			X
LB_ADA	Serum Anti-drug Antibody							X		X		X				X	X			X
LB_EIMARKER	Plasma/Serum Exploratory Biomarkers	X		X		X	X	X	X	X	X	X	X	X	X	X	X			X
LB_EBMARKER	PBMC Exploratory Biomarkers	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
LB_RCL	Replication Competent Lentivirus											X		X		X				X
DS_PTELIG	Pre-Treatment Eligibility																			
EX	SBT777101 Administration																			
VISIT	Next Visit	X	X	X	X	X	X	X	X	X	X	X	X	X	X					
GATE	GATE form - Any AE/CM/PR																	X		
AE	Adverse Events†																	X		
CE_CRS	CRS Signs and Symptoms†																	X		
CE_NEURO	Neurotoxicity/ICANS Signs and Symptoms†																	X		
CE_IRR	Infusion Related Reactions†																	X		
CM	Prior & Concomitant Treatments/Medications†																	X		
PR	Prior & Concomitant Procedures†																	X		
LBYN_IMARKER	GATE - Markers																		X	
LB_IMARKER	Markers of Inflammation†																		X	
DS_EOS	Early Termination/End of Study																	X		
DD	Death Details																	X		
DS_RECON	Reconsent†																	X		

Note: *Form availability shown is for Week 1 Day 2 (Safety Follow-Up) through Early Termination/End of Study visits including Unscheduled visits.*

DYNAMICS

The only forms visible upon the initial entering of the patient in EDC are contained within the Screening and Summary folders. In the Screening folder, the only forms available are the Date of Visit, Informed Consent/Demographics, and Eligibility. In the Summary folder, the only form available is GATE form - Any AE/CM/PR.

Additional visits and/or forms may appear based on responses to existing form fields. An outline of the forms/visits expected to display based on certain responses is provided below. The “Trigger Form” is the form that is already available that contains the trigger question. The “Trigger Question” is the field that, depending on the response to it, will trigger additional forms/visits. The “Target Form” is the form that will become available based on the response to the trigger question. The response that will trigger the target form will be shown in [ ] brackets.

Trigger Form	Trigger Form Question	Target Form
Eligibility	Did the subject meet all screening eligibility? [YES]	Screening folder: Any Medical History, Vital Signs, Physical Examination, 12-Lead Electrocardiogram -Triplicate, Local Laboratory - Serological and Tuberculosis Tests, Local Laboratory – Coagulation, Local Laboratory - Hematology (1&2), Local Laboratory - Clinical Chemistry (1&2), Local Laboratory – Urinalysis, Health Assessment Questionnaire - Disability Index, Local Laboratory - Creatinine Clearance/eGFR, Plasma/Serum Exploratory Biomarkers, PBMC Exploratory Biomarkers Summary folder: Early Termination/End of Study, Death Details, Reconsent Markers of Inflammation folder: GATE - Markers Pre-Treatment Visits 1, and Unscheduled
Eligibility	Primary Reason for Screen Failure at Screening phase: [FAILURE TO MEET TREATMENT ELIGIBILITY REQUIREMENTS]	Inclusion Not Met/Exclusion Criteria Met

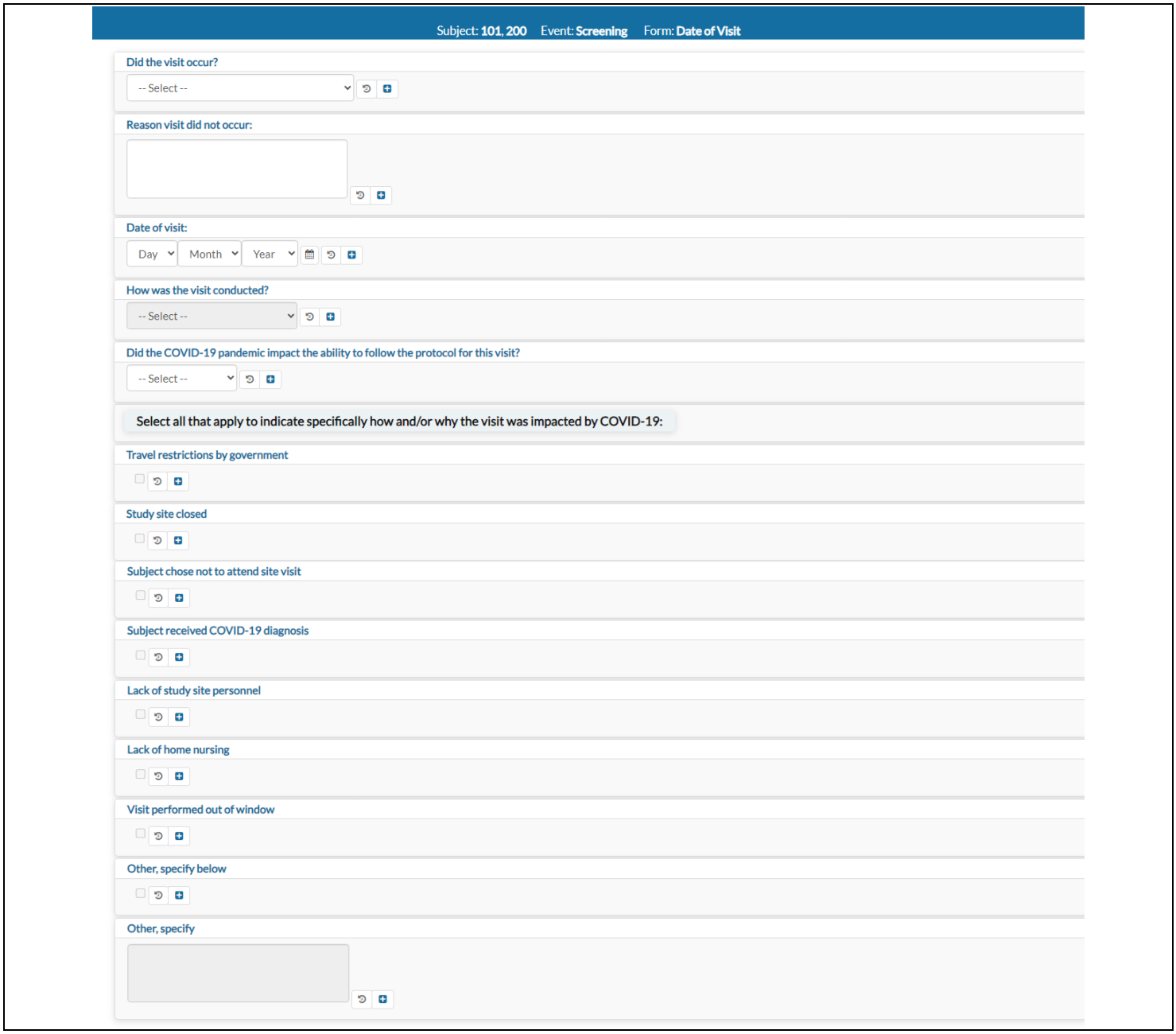
DYNAMICS (CONTINUED)

Trigger Form	Trigger Form Question	Target Form/Visit
Apheresis Eligibility	Did the subject meet all apheresis eligibility? [YES] at PRT1 or PRT1-X	Pre-Treatment Visits 2
Informed Consent/Demographics AND Eligibility	**Sex [FEMALE]** **Subject child bearing potential [POTENTIALLY ABLE TO BEAR CHILD] AND Did the subject meet all screening eligibility? [YES]**	**Local Laboratory - Pregnancy**
Informed Consent/Demographics AND Eligibility	Sex [FEMALE] Subject child bearing potential [POST-MENOPAUSAL] AND Did the subject meet all screening eligibility? [YES]	Local Laboratory - Post Menopause
Any Medical History	Has the subject experienced any past and/or concomitant diseases? [YES]	Medical History
Any Medical History	Does the subject have any past and/or concomitant use of alcohol and/or drugs of abuse within the previous year? [YES]	Alcohol and Drugs Use
GATE form - Any AE/CM/PR	Did the subject experience any adverse events? [YES]	Adverse Events
GATE form - Any AE/CM/PR	Did the subject take any prior or concomitant medications? [YES]	Prior & Concomitant Treatments/Medications
GATE form - Any AE/CM/PR	Did the subject have any prior or concomitant procedures? [YES]	Prior & Concomitant Procedures
GATE form - Any AE/CM/PR	Did the subject experience any adverse events? [YES] Were any of the adverse events related to CRS? [YES]	CRS Signs and Symptoms
GATE form - Any AE/CM/PR	Did the subject experience any adverse events? [YES] Were any of the adverse event related to Neurotoxicity? [YES]	Neurotoxicity Signs and Symptoms
GATE form - Any AE/CM/PR	Did the subject experience any adverse events? [YES] Were there any Infusion Related Reactions? [YES]	Infusion Related Reactions
GATE - Markers	Were Markers of Inflammation assessed? [YES]	Markers of Inflammation
Pre-Treatment Eligibility	Did the subject meet all pre-infusion eligibility and approved for enrollment into the treatment period of the study? [YES]	Week 1 Day 1 (W1D1)
Apheresis Eligibility	Did the subject meet all pre-infusion eligibility? [NO] Will the subject be eligible for reassessment at a later date? [YES]	Pre-Treatment Reassessment X Visit 1where X = 1, 2, 3,…

DYNAMICS (CONTINUED)

Trigger Form	Trigger Form Question	Target Form/Visit
Pre-Treatment Eligibility	Did the subject meet all pre-infusion eligibility? [NO] Will the subject be eligible for reassessment at a later date? [YES]	Pre-Treatment Reassessment X Visit 2 where X = 1, 2, 3,…
Next Visit	Is the subject continuing to the next visit? [YES]	Next visit of Week Y added (e.g. If “Yes” at W2D11, W2D14 is added) where Y = 1, 2, 3, 4, 6, 8, 10, 12, 18, 24, 36
Next Visit	Is the subject continuing to the next visit? [NO]	Early Termination visit
Next Visit	Is the subject continuing to the next visit? [YES] at Week 36 Day 252 (W36D252)	End of Study visit
Pre-Treatment Eligibility	Will the subject be eligible for reassessment at a later date? [NO] at PRT2 or any PRT2-X visit where X = 1, 2, 3,…	Early Termination visit

DATE OF VISIT



Did the visit occur?

Indicate **visit status** from the drop-down list:

- **No**
- **Yes, completed**
- **Yes, partially completed**

Note: *If "**No**" is selected, provide a response in the "**Reason visit did not occur:**" field*

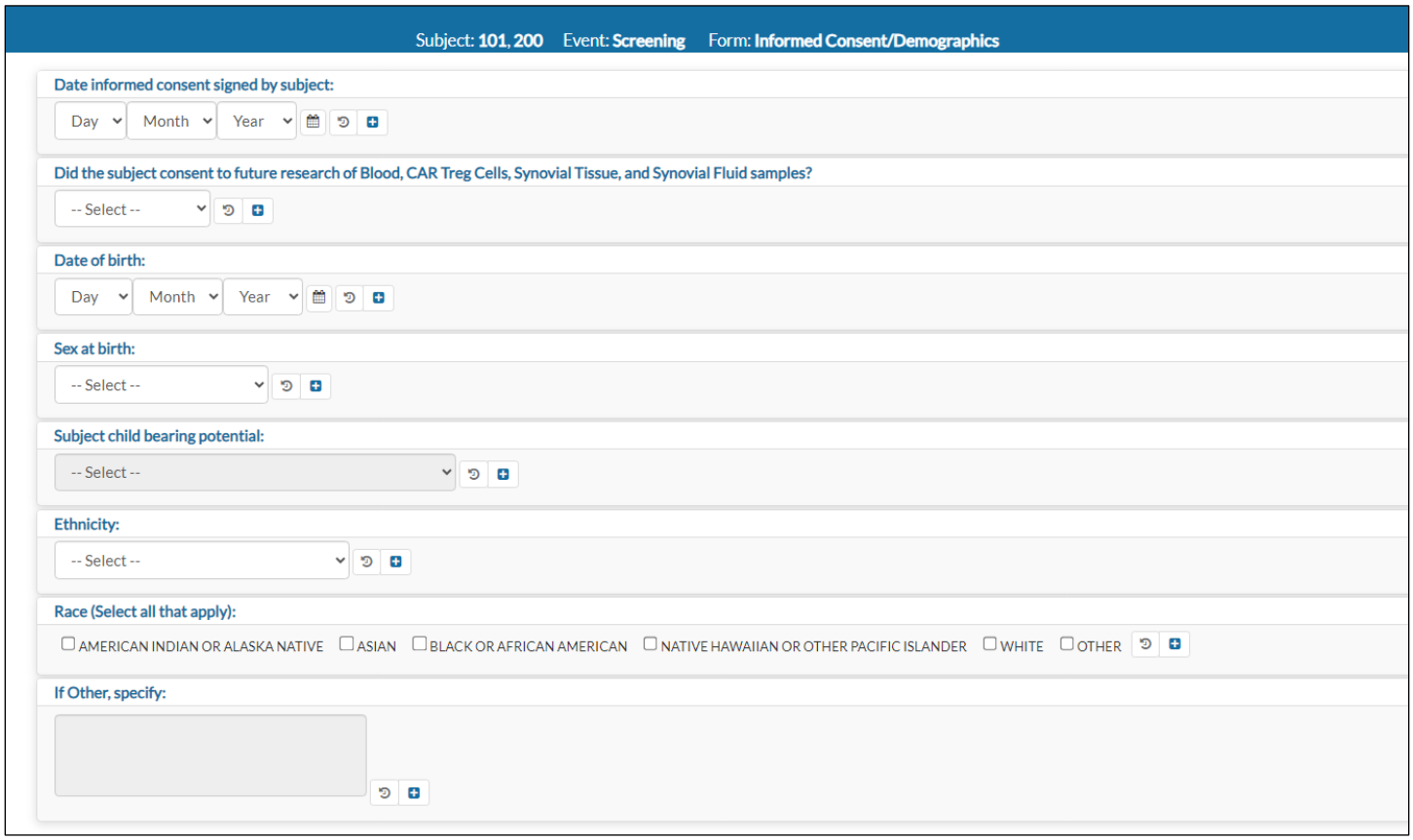
Date of visit:

Provide the **date of visit** in the **DD/MMM/YYYY** format. A complete date is required.

DATE OF VISIT (CONTINUED)

How was the visit conducted?	Indicate **how the visit was conducted** by selecting from the drop-down list: • **In Person** • **Telephone Call** • **Remote Audio** • **Remote Audio Video**
Did the COVID-19 pandemic impact the ability to follow the protocol for this visit?	Indicate if the **visit was impacted by COVID-19** from the drop-down list: **No** or **Yes**
Select all that apply to indicate specifically how and/or why the visit was impacted by COVID-19:	Select all applicable box(es) regarding **how the subject's participation was impacted by COVID-19** from the options provided: • **Travel restrictions by government** • **Study site closed** • **Subject chose not to attend site visit** • **Subject received COVID-19 diagnosis** • **Lack of study site personnel** • **Lack of home nursing** • **Visit performed out of window** • **Other, specify below** Note: *If "**Other, specify below**" is selected, provide a response in the "**Other, specify**" field*

INFORMED CONSENT/DEMOGRAPHICS



Date informed consent signed by subject:

Record the **date the subject signed the Informed Consent** in the **DD/MMM/YYYY** format. A complete date is required.

Did the subject consent to future research of Blood, CAR Treg Cells, Synovial Tissue, and Synovial Fluid samples?

Indicate if the **subject consented to future research of Blood, CAR Treg Cells, Synovial Tissue, and Synovial Fluid samples** by selecting **No** or **Yes**.

Date of birth:

Record the **date of birth** of the subject in the **DD/MMM/YYYY** format. A complete date is required unless country specific requirements prohibit a full date of birth to be recorded. At least a year is required for entry.

Sex at birth:

Select the subject's **sex at birth** from the drop-down list:

- **Female**
- **Male**
- **Undifferentiated**
- **Unknown**

INFORMED CONSENT/DEMOGRAPHICS (CONTINUED)

Subject child bearing potential:

Indicate if the **subject is of childbearing potential** by selecting from the drop-down list:

- **Post-menopausal**
- **Surgically sterile**
- **Potentially able to bear child**

Note: *This field is only enabled if "**Sex:**" is "**Female**" or "**Undifferentiated**"*
Note: *If "**Post-menopausal**" is selected, complete the **Local Laboratory - Post Menopause** eCRF*
Note: *If "**Potentially able to bear child**" is selected, complete the **Local Laboratory - Pregnancy** eCRF*

Ethnicity:

Indicate the subject's **Ethnicity** by selecting from the drop-down list:

- **Hispanic or Latino**
- **Not Hispanic or Latino**
- **Not Reported**
- **Unknown**

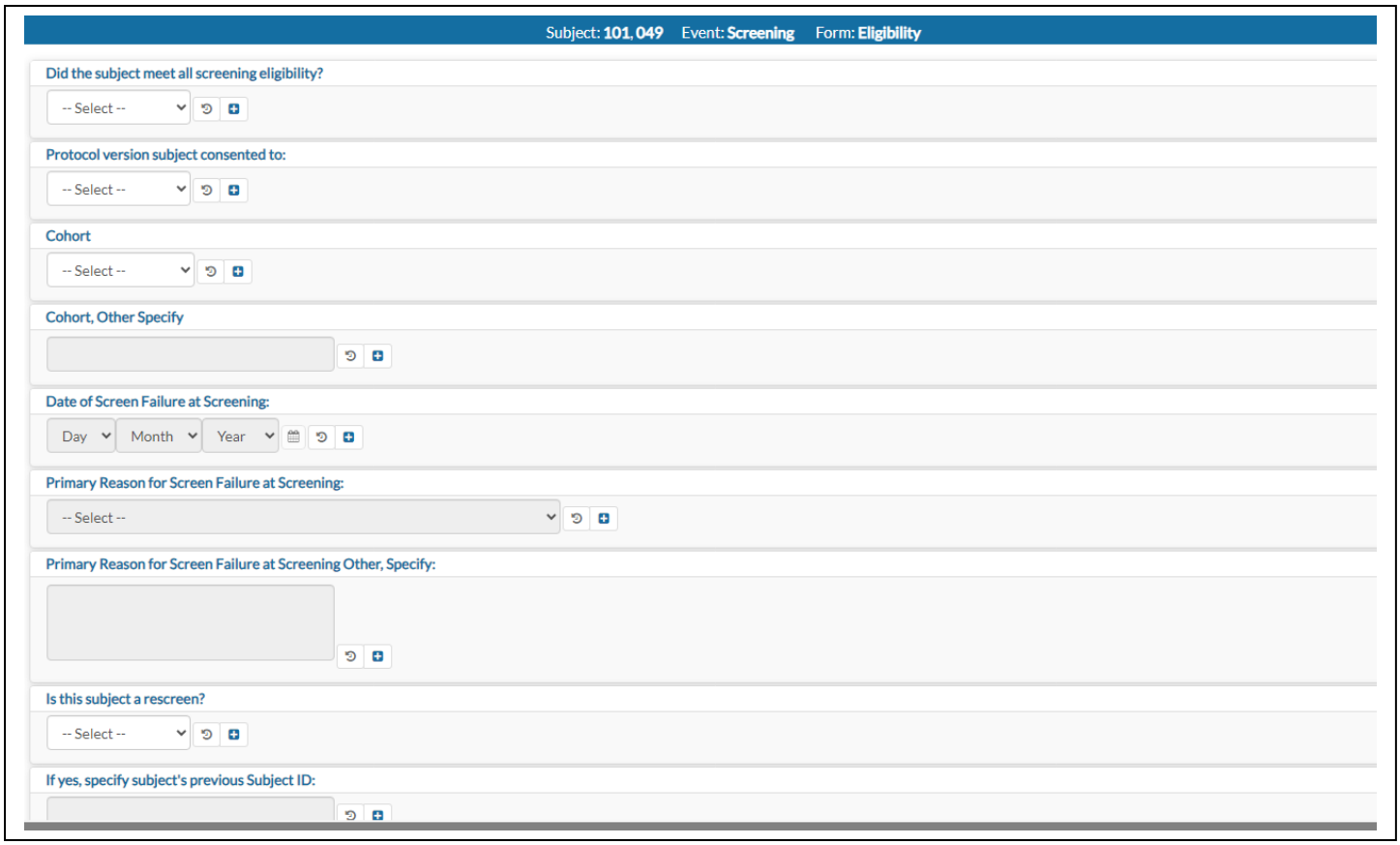
Race (Select all that apply):

Select all applicable box(es) for the subject's applicable **Race(s)**:

- **American Indian or Alaska Native**
- **Asian**
- **Black or African American**
- **Native Hawaiian or Other Pacific Islander**
- **White**
- **Other**

Note: *If the subject's race is not an option listed above, select "**Other**" and specify the race in the "**If Other, specify**" field*

ELIGIBILITY



Did the subject meet all screening eligibility?

Select **No** or **Yes**.

Note: *If "**No**" is selected, an **Inclusion Not Met/Exclusion Criteria Met** eCRF will appear. Please complete the form to indicate the criterion that the patient did not meet*

Protocol version subject consented to:

Select the **protocol version** the subject enrolled under from the drop-down list:

- **5.0**
- **6.0**
- **7.0**
- **8.0**
- **9.0**
- **10.0**

Cohort

Select the **cohort** the patient enrolled in from the drop-down list:

- **Dose Level 1**
- **Dose Level 2**
- **Dose Level 3**
- **Other**

Note: *If "**Other**" is selected, provide a response in the "**Cohort, Other Specify**" field*

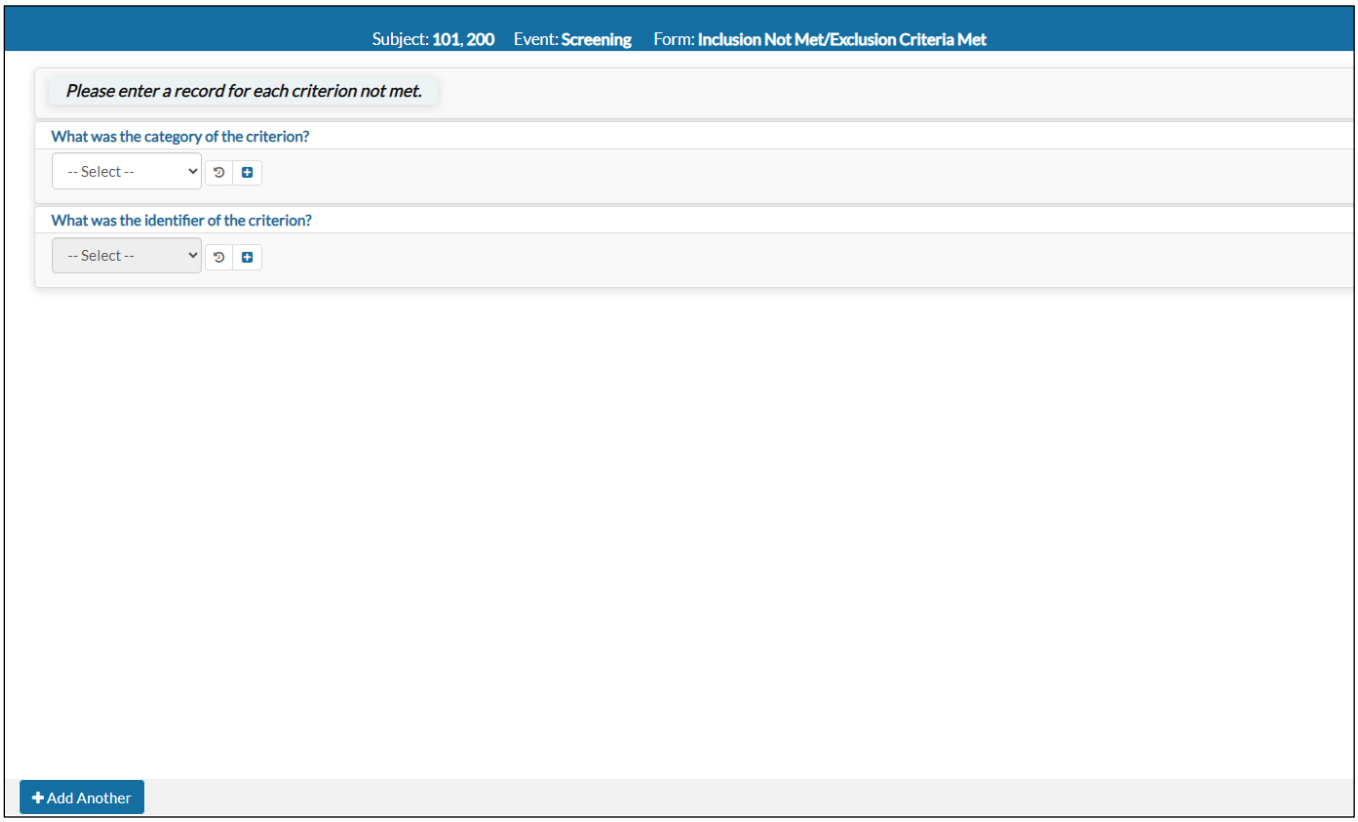
Date of Screen Failure at Screening:

Record the **date** of **Screen Failure at Screening phase** in the **DD/MMM/YYYY** format. A complete date is required.

ELIGIBITY (CONTINUED)

Primary Reason for Screen Failure at Screening:	Select the **primary reason** from the drop-down list: • **ADVERSE EVENT** • **FAILURE TO MEET TREATMENT ELIGIBILITY REQUIREMENTS** • **STUDY TERMINATED BY SPONSOR** • **WITHDRAWAL BY SUBJECT** • **OTHER** Note: If "**Other**" is selected, specify the reason in the "**Primary Reason for Screen Failure at Screening Other, Specify:**" field
Is this subject a rescreen?	Select **No** or **Yes**.
If yes, specify subject's previous Subject ID:	If the subject is a rescreened subject, provide the **previous subject number** in the **S01-XYY, ZZZ** format, where X is the country code, YY is the site number and ZZZ is the subject identifier. Note: *This field is only enabled if "**Is this subject a rescreen?**" is "**Yes**"*

INCLUSION NOT MET/EXCLUSION CRITERIA MET



Record any Inclusion criteria not met or Exclusion criteria met per protocol. This is a repeating form (multiple records can be added). Both Inclusion and Exclusion criteria can be captured if applicable.

Please enter a record for each criterion not met.

What was the category of the criterion?

Record whether the **criterion** that this patient did not meet was **Inclusion** or **Exclusion**.

What was the identifier of the criterion?

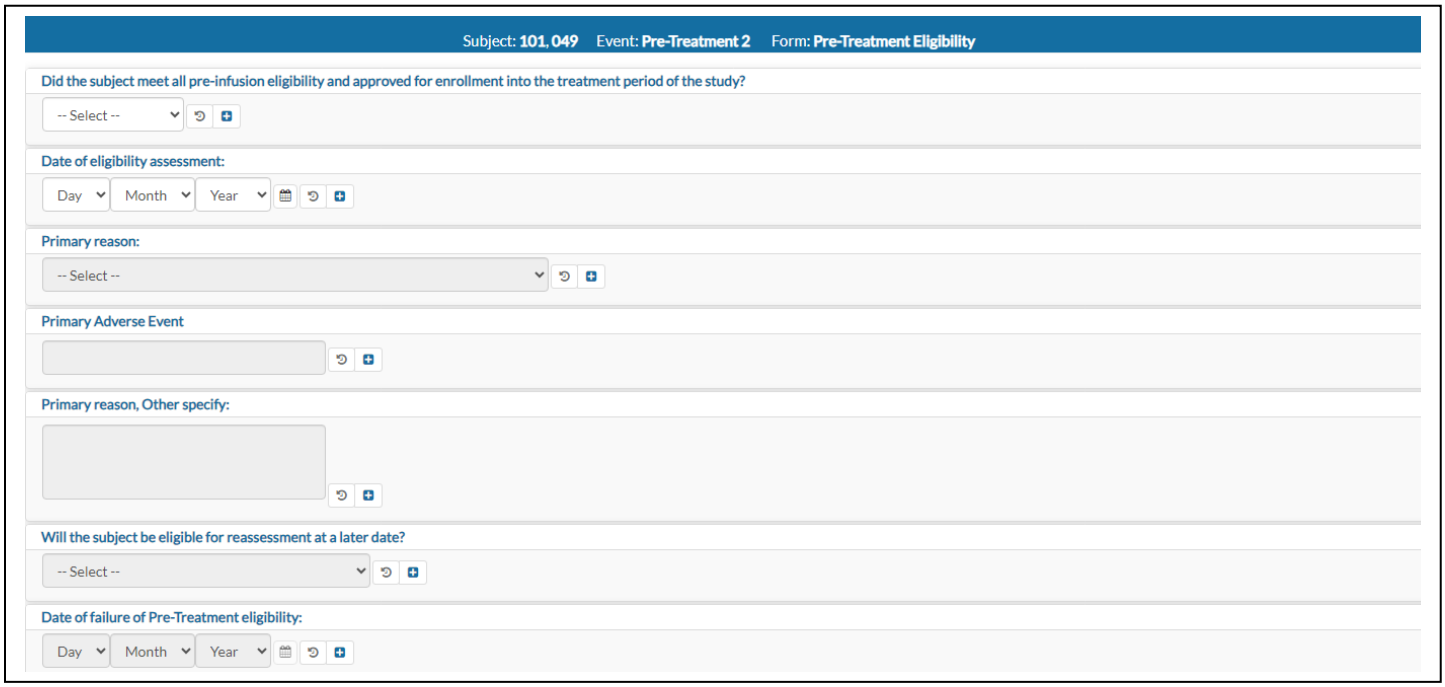
Select the **identifier of the criterion** from the dropdown list:

- **1**
- **2**
- **3**
- **4**
- **5**
- **6**
- **7**
- **8**
- **9**
- **10**
- **11**
- **12**
- **13**
- **14**
- **15**
- **16**
- **17**
- **18**
- **19**
- **20**
- **21**
- **22**
- **23**
- **24**
- **25**
- **26**
- **27**

Note: *Values **1-19** will only be available if the category is **Inclusion**, and values **1-27** will be available if the category is **Exclusion***

PRE-TREATMENT ELIGIBILITY

*Pre-Treatment Eligibility eCRF is available for completion at **Screening**, **Pre-Treatment Visit 2**, and **Pre-Treatment Reassessment X Visit 2 (where X = 1, 2, 3,…)** visits.*



Did the subject meet all pre-infusion eligibility and approved for enrollment into the treatment period of the study?

Select **No** or **Yes**.

Date of eligibility assessment:

Record the **date of eligibility assessment** in the **DD/MMM/YYYY** format. A complete date is required.

Primary reason:

Select the **primary reason** from the dropdown list:

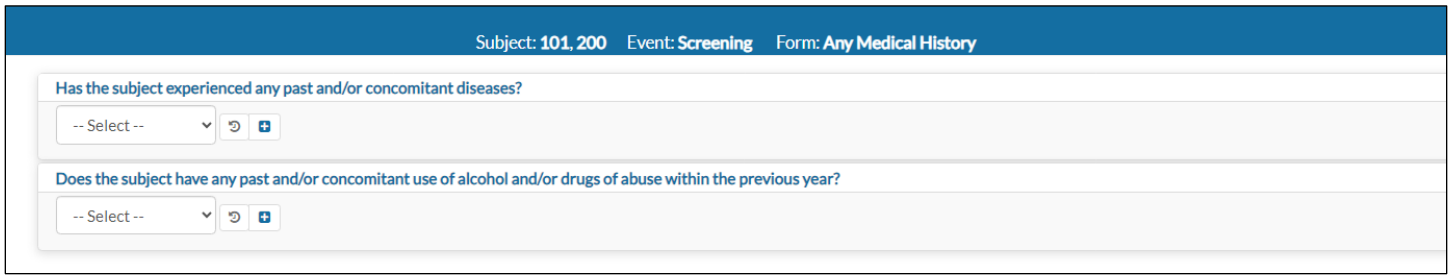
- **ADVERSE EVENT**
- **MEDICAL HISTORY**
- **CONCOMITANT MEDICATION**
- **CLINICALLY SIGNIFICANT RESULTS FROM LABS OR ASSESSMENTS**
- **DAS28 less than 3.2**
- **OTHER**

Note: *This field is only enabled if "**Did the subject meet all pre-infusion eligibility and approved for enrollment into the treatment period of the study?**" is "**No**"*
Note: *If "**Adverse Event**" is selected, provide an Adverse Event number in the "**Primary Adverse Event**" field*
Note: *If "**Other**" is selected, provide a response in the "**Primary reason, Other specify:**" field*

PRE_TREATMENT ELIGIBITY (CONTINUED)

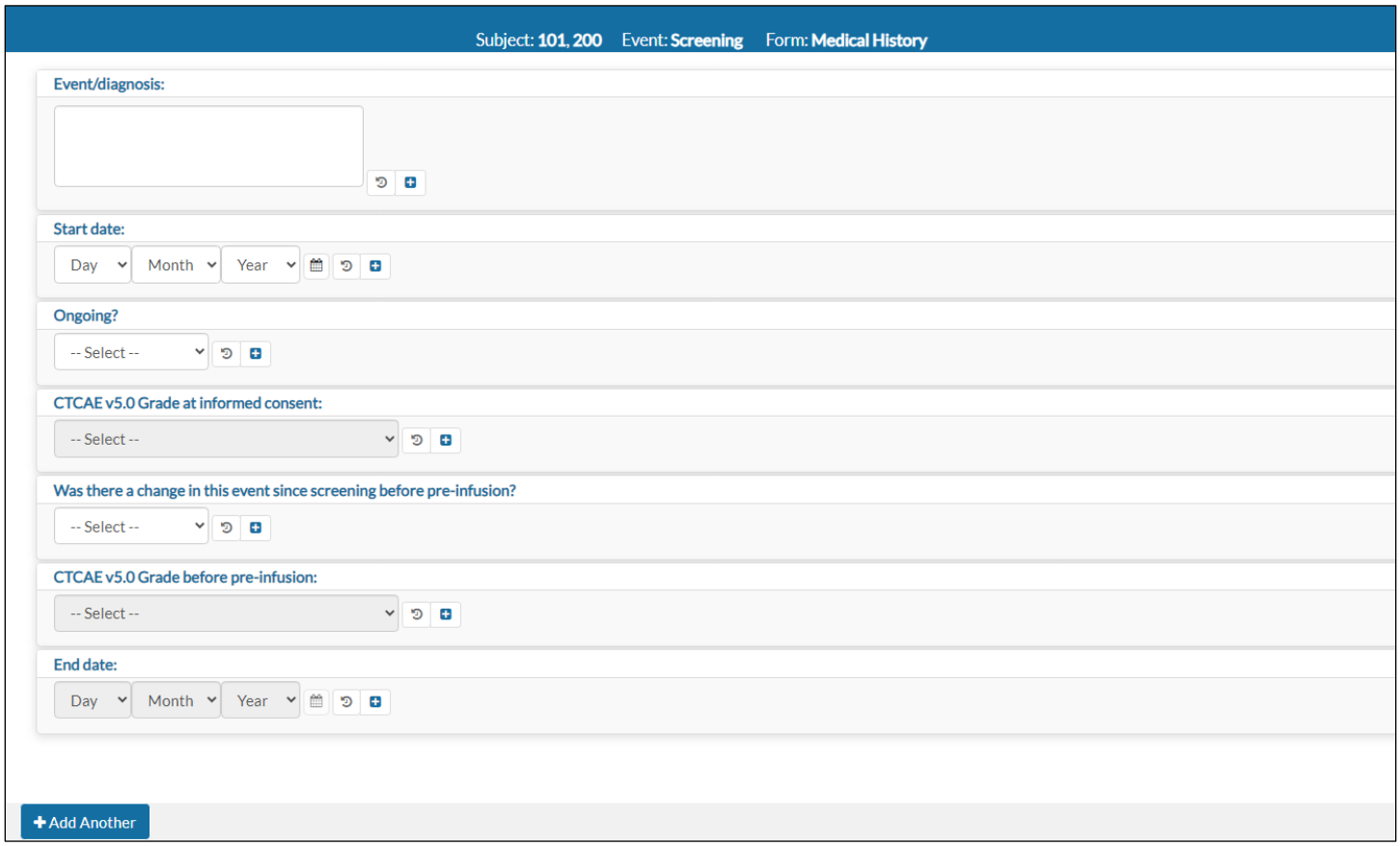
Will the subject be eligible for reassessment at a later date?	Indicate if the **subject will be eligible for reassessment at a later date** by selecting from the drop-down list: • **No** • **Yes** • **Not applicable at this time** Note: *This field is only enabled if "**Did the subject meet all pre-infusion eligibility and approved for enrollment into the treatment period of the study?"** is "**No**"*
Date of failure of Pre-Treatment eligibility:	Record the **date of failure of Pre-Treatment eligibility** in the **DD/MMM/YYYY** format. A complete date is required. *This field is only enabled if "**Will the subject be eligible for reassessment at a later date?"** is "**No**"*

ANY MEDICAL HISTORY



Has the subject experienced any past and/or concomitant diseases?	Select **No** or **Yes**. A response is required. Note: *If **Yes** is selected, a **Medical History** eCRF will appear for completion*
Does the subject have any past and/or concomitant use of alcohol and/or drugs of abuse within the previous year?	Select **No** or **Yes**. A response is required. Note: *If **Yes** is selected, an **Alcohol and Drugs Use** eCRF will appear for completion*

MEDICAL HISTORY



This is a repeating form (multiple records can be added).

Event/diagnosis:

In the field provided, record the **event or diagnosis**.

- Record only one event or diagnosis per record.
- Conditions/diagnoses with an onset on or after the Day 1 visit or baseline condition that worsens thereafter should be reported on the Adverse Events eCRF.
- If applicable, please specify the exact location of the body concerned by the Medical History (i.e. Left, Right or Bilateral). Also, if necessary, enter if the Medical History is “chronic” or “acute”.
- When applicable, report the stage/grade of the event (ex: for retinopathy, nephropathy, tumors etc.).

Start date:

Record the **start date** of the event/diagnosis in the **DD/MMM/YYYY** format.
Note: *A year is required for start date. “**Unknown**” is an available selection for Day and Month*

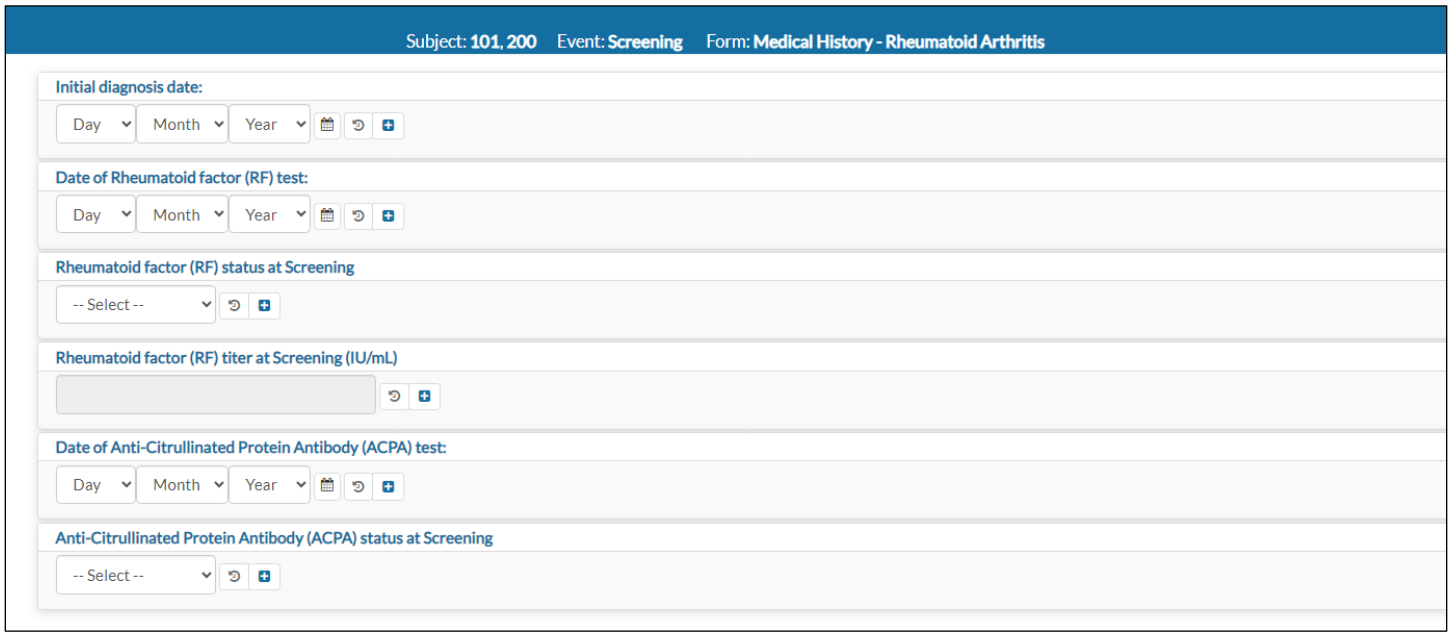
Ongoing?

Select **No** or **Yes** to indicate if the event/diagnosis is currently **ongoing**.
Note: *If the medical history changes/updates from ongoing to resolved during the study, update this field accordingly*

MEDICAL HISTORY (CONTINUED)

CTCAE v5.0 Grade at informed consent:	Select the **severity** of the event/diagnosis from the dropdown list according to the CTCAE v5.0 Grade scale: • **GRADE 1 – MILD** • **GRADE 2 – MODERATE** • **GRADE 3 – SEVERE** • **GRADE 4 – LIFE THREATENING** • **UNKNOWN** Note: *This field is only enabled if "**Ongoing?**" is "**Yes**"*
Was there a change in this event since screening before pre-infusion?	Select **No** or **Yes**. A response is required.
CTCAE v5.0 Grade before pre-infusion:	Select the **severity** of the event/diagnosis changed since screening before pre-infusion from the drop-down list according to the CTCAE v5.0 Grade scale: • **GRADE 1 – MILD** • **GRADE 2 – MODERATE** • **GRADE 3 – SEVERE** • **GRADE 4 – LIFE THREATENING** • **UNKNOWN** Note: *This field is only enabled if "**Was there a change in this event since screening before pre-infusion?**" is "**Yes**"*
End date:	Record the **end date** of the event/diagnosis in the **DD/MMM/YYYY** format. Note: *This field is only enabled if "**Ongoing?**" is "**No**". A year is required for end date. "**Unknown**" is an available selection for Day and Month*

MEDICAL HISTORY – RHEUMATOID ARTHRITIS



Initial diagnosis date:

Record the **date of the initial diagnosis** in the **DD/MMM/YYYY** format.
Note: *"**Unknown**" is an available option for the day and month of the initial diagnosis, however a year is required*

Date of Rheumatoid factor (RF) test:

Record the **date of Rheumatoid factor (RF) test** in the **DD/MMM/YYYY** format. A complete date is required.
Note: *A year is required for start date. "**Unknown**" is an available selection for Day and Month*

Rheumatoid factor (RF) status at Screening

Indicate the **Rheumatoid factor (RF) status at screening** by selecting from the drop-down list:

- **Negative**
- **Positive**
- **Unknown**

Rheumatoid factor (RF) titer at Screening (IU/mL)

Record the **Rheumatoid factor (RF) titer at screening** in **IU/mL**.
Note: *This field is only enabled if "**Rheumatoid factor (RF) status at Screening**" is "**Positive**"*

Date of Anti-Citrullinated Protein Antibody (ACPA) test:

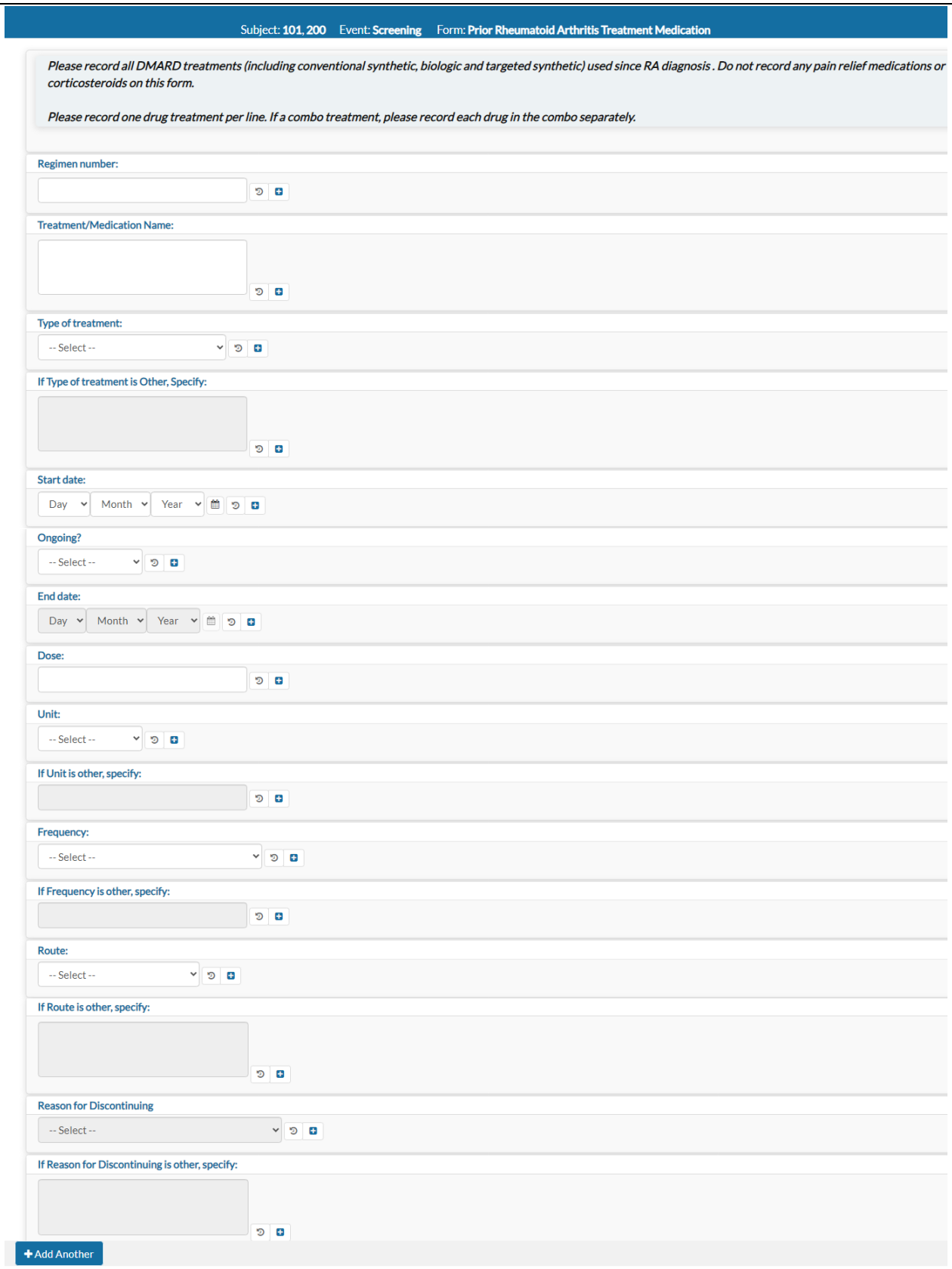
Record the **date of Anti-Citrullinated Protein Antibody (ACPA) test** in the **DD/MMM/YYYY** format. A complete date is required.
Note: *A year is required for start date. "**Unknown**" is an available selection for Day and Month*

Anti-Citrullinated Protein Antibody (ACPA) status at Screening

Indicate the **Anti-Citrullinated Protein Antibody (ACPA) status at screening** by selecting from the drop-down list:

- **Negative**
- **Positive**
- **Unknown**

PRIOR RHEUMATOID ARTHRITIS TREATMENT MEDICATION



Subject: **101, 200** Event: **Screening** Form: **Prior Rheumatoid Arthritis Treatment Medication**

Please record all DMARD treatments (including conventional synthetic, biologic and targeted synthetic) used since RA diagnosis . Do not record any pain relief medications or corticosteroids on this form.

Please record one drug treatment per line. If a combo treatment, please record each drug in the combo separately.

Regimen number:

Treatment/Medication Name:

Type of treatment:

-- Select --

If Type of treatment is Other, Specify:

Start date:

Day Month Year

Ongoing?

-- Select --

End date:

Day Month Year

Dose:

Unit:

-- Select --

If Unit is other, specify:

Frequency:

-- Select --

If Frequency is other, specify:

Route:

-- Select --

If Route is other, specify:

Reason for Discontinuing

-- Select --

If Reason for Discontinuing is other, specify:

+ Add Another

PRIOR RHEUMATOID ARTHRITIS TREATMENT MEDICATION (CONTINUED)

This is a repeating form (multiple records can be added).

Please record all DMARD treatments (including conventional synthetic, biologic and targeted synthetic) used since RA diagnosis. Do not record any pain relief medications or corticosteroids on this form.

Please record one drug treatment per line. If a combo treatment, please record each drug in the combo separately.

Regimen number:

Record the numerical **regimen number** associated with the Rheumatoid Arthritis treatment medication.
Note: ***For any given regimen with multiple treatment medications, record the same regimen number for each log line***

Treatment/Medication Name:

Enter one **treatment/medication** into the text box provided.
Note: ***If treatment/medication is a combination, record each drug separately***

Type of treatment:

Select the **type of treatment** from the drop-down list:

- **csDMARD (Methotrexate, Hydroxychloroquine)**
- **bDMARD or biosimilar (Adalimumab, Golimumab, Infliximab,...)**
- **tsDMARD (Baricitinib, Filgotinib, Tofacitinib, Upadacitinib)**
- **Steroids**
- **Investigational Agent**
- **Other**

Note: *If "**Other**" is selected, provide a response in the "**If Type of treatment is Other, Specify:**" field*

Start date:

Record the **start date** of the treatment/medication in the **DD/MMM/YYYY** format.
Note: *A year is required for start date. "**Unknown**" is an available selection for Day and Month*

Ongoing?

Select **No** or **Yes** to indicate if the treatment/medication is currently **ongoing**.
Note: ***If the treatment/medication changes/updates from ongoing to resolved during the study, update this field accordingly***

End date:

Record the **end date** of the treatment/medication in the **DD/MMM/YYYY** format.
Note: *This field is only enabled if "**Ongoing?**" is "**No**". A year is required for end date. "**Unknown**" is an available selection for Day and Month*

PRIOR RHEUMATOID ARTHRITIS TREATMENT MEDICATION (CONTINUED)

Dose: Record the numeric **dose** of the treatment/medication taken in the field provided.

Unit: Select the **unit** of the dose taken from the drop-down list:

- **mg**
- **mg/kg**
- **gram**
- **mg/m^2**
- **Other**

Note: *If "**Other"** is selected, provide a response in the "**If Unit is other, specify:**" field*

Frequency: Select the **frequency** of the treatment/medication from the drop-down list:

- **Once Daily QD**
- **Twice Daily BID**
- **Three Times Daily TID**
- **4 Times a Day QID**
- **Once weekly or Every Week**
- **As Needed PRN**
- **Once a Month**
- **Every 6 Months**
- **Other**

Note: *If "**Other**" is selected, provide a response in the "**If Frequency is other, specify:**" field*

Route: Select the **route** of the treatment/medication from the drop-down list:

- **Oral PO**
- **Intramuscular IM**
- **Intra-articular IA**
- **Intravenous IV**
- **Subcutaneous SC**
- **Other**

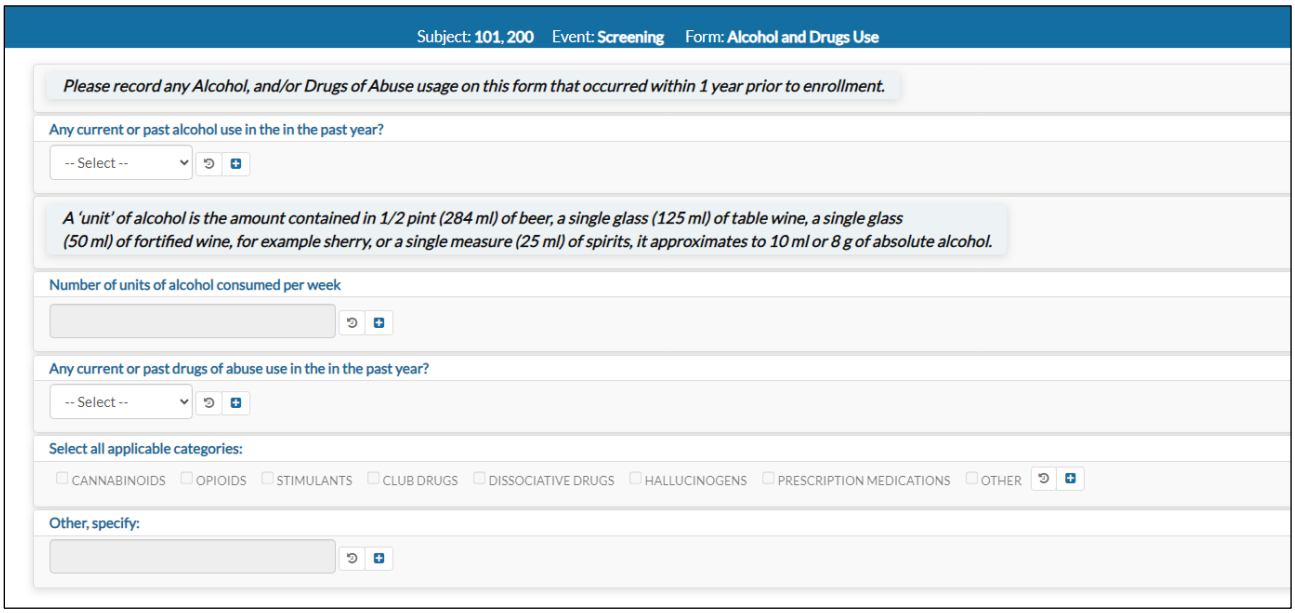
Note: *If "**Other**" is selected, provide a response in the "**If Route is other, specify:**" field*

Reason for Discontinuing Select the **reason for discontinuing** from the drop-down list:

- **Completed course of therapy**
- **Inadequate response**
- **Toxicity**
- **Other**

Note: *This field is only enabled if "**Ongoing?**" is "**No**"*
Note: *If "**Other**" is selected, provide a response in the "**If Reason for Discontinuing is other, specify:**" field*

ALCOHOL AND DRUG USE



Please record any Alcohol, and/or Drugs of Abuse usage on this form that occurred within 1 year prior to enrollment.

Any current or past alcohol use in the past year?

Select **No** or **Yes** to indicate **any current or past alcohol use in the past year**.

A 'unit' of alcohol is the amount contained in 1/2 pint (284 ml) of beer, a single glass (125 ml) of table wine, a single glass (50 ml) of fortified wine, for example sherry, or a single measure (25 ml) of spirits, it approximates to 10 ml or 8 g of absolute alcohol.

Number of units of alcohol consumed per week

Record the **number of units of alcohol consumed per week**.
Note: *This field is only enabled if "**Any current or past alcohol use in the past year?**" is "**Yes**"*

Any current or past drugs of abuse use in the past year?

Select **No** or **Yes** to indicate **any current or past drugs of abuse use in the past year**.

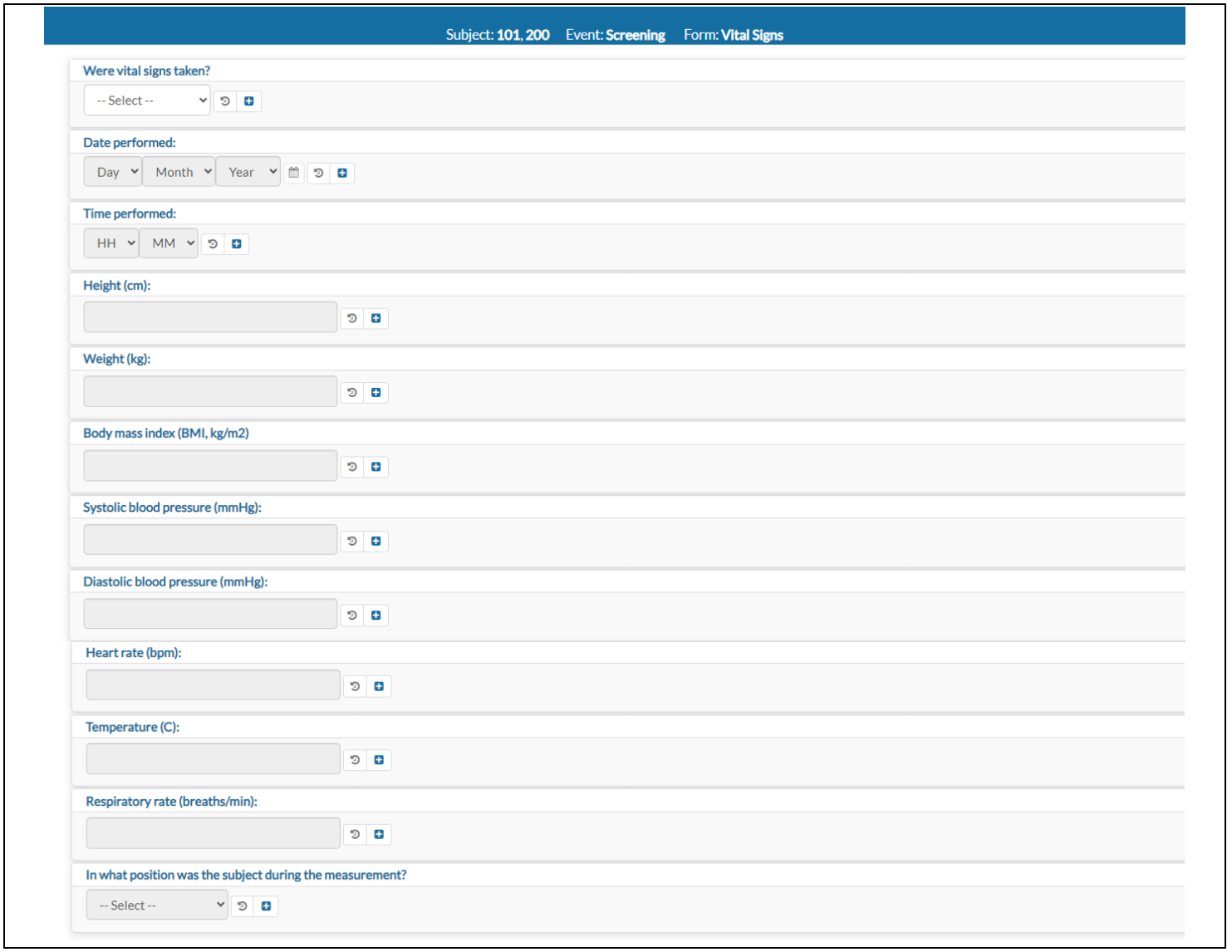
Select all applicable categories:

Select all applicable box(es) regarding **current or past drugs of abuse use in the past year** from the options provided:

- **Cannabinoids**
- **Opioids**
- **Stimulants**
- **Club Drugs**
- **Dissociative Drugs**
- **Hallucinogens**
- **Prescription Medications**
- **Other**

Note: *This field is only enabled if "**Any current or past drugs of abuse use in the past year?**" is "**Yes**"*
Note: *If "**Other**" is selected, provide a response in the "**Other, specify:**" field*

VITAL SIGNS



For the sake of brevity, the screenshot for this form only shows vital signs at Screening visit. Other visits and timepoints are comparable to the Screening image.

VITAL SIGNS (CONTINUED)

Were vital signs taken?	Indicate if **vital signs** were taken by selecting **No** or **Yes**.
Date performed:	Record the **date performed** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is enabled if vital signs were taken at **all** visits*
Time performed:	Record the **time performed** in the **HH:MM 24-hour clock** format. Note: *This field is enabled if vital signs were taken at **all** visits*
Height (cm):	Record the **height** of the subject in **centimeters** in the field provided. Note: *This field is only visible at **Screening** visit*
Weight (kg):	Record the **weight** of the subject in **kilograms (kg)** in the field provided. Note: *This field is only visible at the following visits:* • ***Screening*** • ***Pre-Treatment 2*** • ***W8D56*** • ***Early Termination*** • ***End of Study*** • ***Unscheduled***
Body mass index (BMI, kg/m^2)	This field is read only and is calculated automatically. Note: *This field is only visible at **Screening** visit*
Systolic blood pressure (mmHg):	Record the **systolic blood pressure** in **mmHg** in the field provided. Note: *This field is enabled if vital signs were taken at **all** visits*
Diastolic blood pressure (mmHg):	Record the **diastolic blood pressure** in **mmHg** in the field provided. Note: *This field is enabled if vital signs were taken at **all** visits*
Heart rate (bpm):	Record the **heart rate** in **beats per minute (bpm)** in the field provided. Note: *This field is enabled if vital signs were taken at **all** visits*
Temperature (C):	Record the **temperature** in **Celsius (C)** in the field provided. Note: *This field is enabled if vital signs were taken at **all** visits*
Respiratory rate (breaths/min):	Record the **respiratory rate** in **breaths/min** in the field provided. Note: *This field is enabled if vital signs were taken at **all** visits*
In what position was the subject during the measurement?	Select the **position** the subject was during the measurement from the drop-down list: • **SITTING** • **STANDING** • **SUPINE** • **SEMI-RECLINED** Note: *This field is enabled if vital signs were taken at **all** visits*

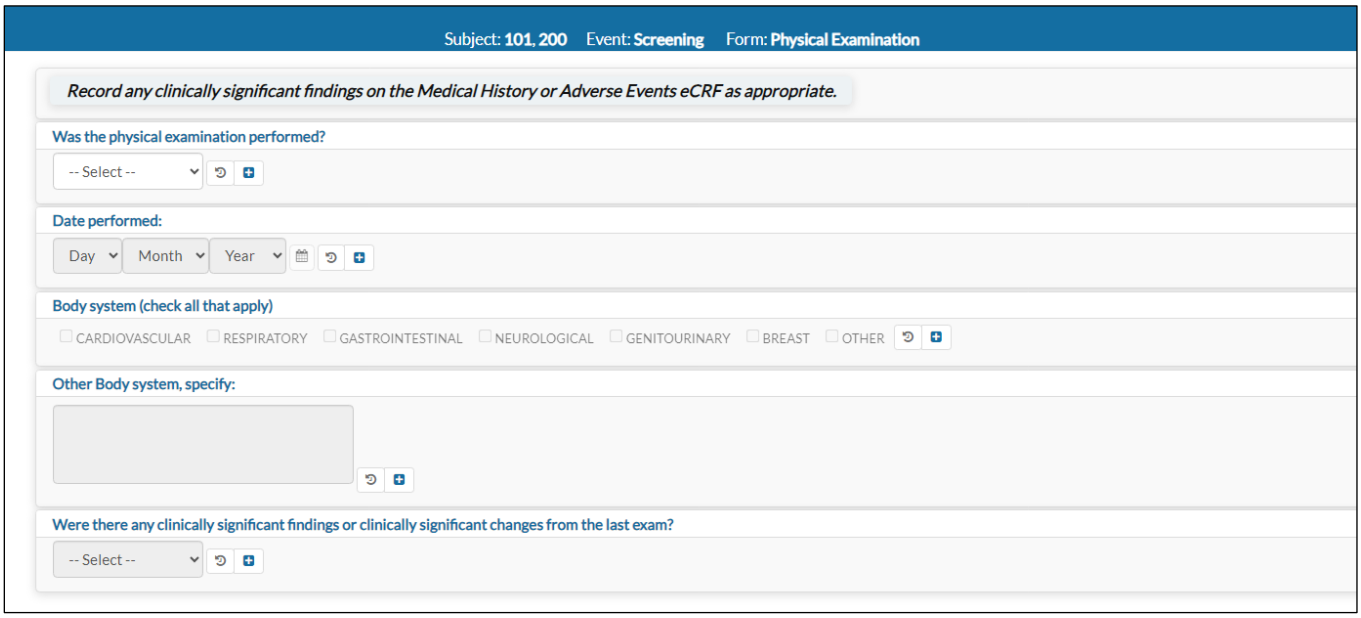
VITAL SIGNS (CONTINUED)

*The below are only visible at **W1D1** visit and will be enabled for completion if "**Yes**" is selected for the following fields:*

- ***Were vital signs 15 minutes post-infusion taken?***
- ***Were vital signs 30 minutes post-infusion taken?***
- ***Were vital signs 45 minutes post-infusion taken?***
- ***Were vital signs 60 minutes post-infusion taken?***
- ***Were vital signs 4 hours post-infusion taken?***
- ***Were vital signs 8 hours post-infusion taken?***
- ***Were vital signs 12 hours post-infusion taken?***
- ***Were vital signs 16 hours post-infusion signs taken?***
- ***Were vital signs 20 hours post-infusion taken?***
- ***Were vital signs 24 hours post-infusion taken?***

Date performed:	Record the **date performed** in the **DD/MMM/YYYY** format. A complete date is required. Note: *At **W1D1**, this field is enabled if vital signs were taken at the following timepoints:* • ***Pre-infusion*** • ***8 hours post-infusion*** • ***12 hours post-infusion*** • ***16 hours post-infusion*** • ***20 hours post-infusion*** • ***24 hours post-infusion***
Time performed:	Record the **time performed** in the **HH:MM 24-hour clock** format.
Systolic blood pressure (mmHg):	Record the **systolic blood pressure** in **mmHg** in the field provided.
Diastolic blood pressure (mmHg):	Record the **diastolic blood pressure** in **mmHg** in the field provided.
Heart rate (bpm):	Record the **heart rate** in **beats per min (bpm)** in the field provided.
Temperature (C):	Record the **temperature** in **Celsius (C)** in the field provided.
Respiratory rate (breaths/min):	Record the **respiratory rate** in **breaths/min** in the field provided.
In what position was the subject during the measurement?	Select the **position** the subject was during the measurement from the drop-down list: • **SITTING** • **STANDING** • **SUPINE** • **SEMI-RECLINED**

PHYSICAL EXAMINATION



Record any clinically significant findings on the Medical History or Adverse Events eCRF as appropriate.

Was the physical examination performed?

Select **No** or **Yes** to indicate if the **physical examination** was performed.

Date performed:

Record the **date performed** in the **DD/MMM/YYYY** format. A complete date is required.

Body system (check all that apply)

Select all applicable box(es) regarding **body system** from the options provided:

- **Cardiovascular**
- **Respiratory**
- **Gastrointestinal**
- **Neurological**
- **Genitourinary**
- **Breast**
- **Other**

Note: *If "**Other**" is selected, provide a response in the "**Other Body system, specify:**" field*

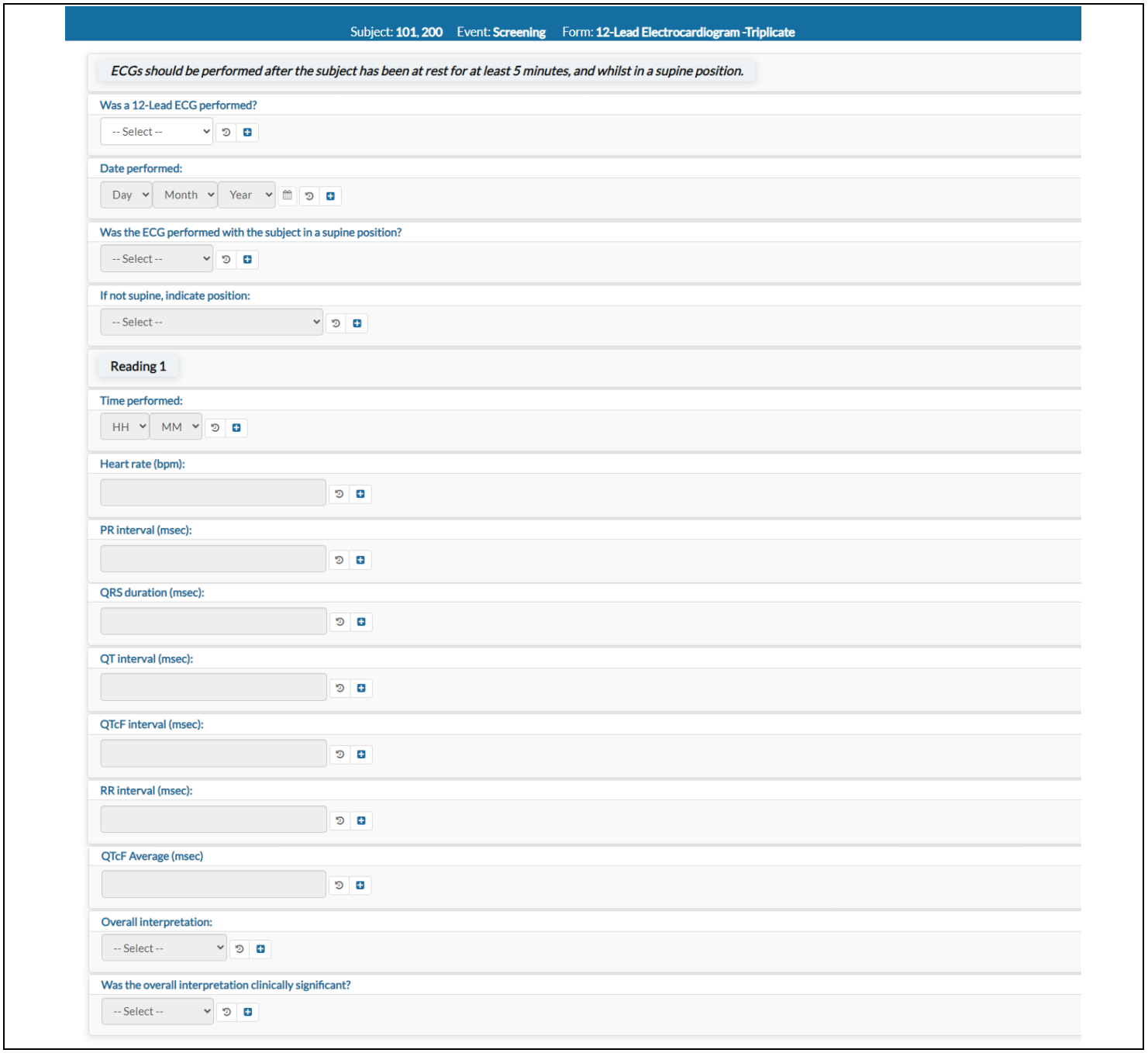
Note: *This field is only visible at the following visits:*

- ***Screening***
- ***W1D7***
- ***W4D28***
- ***W8D56***
- ***Early Termination***
- ***End of Study***
- ***Unscheduled***

Were there any clinically significant findings or clinically significant changes from the last exam?

Select **No** or **Yes** to indicate if there were **any clinically significant findings or clinically significant changes from the last exam**.

12-LEAD ELECTROCARDIOGRAM – TRIPLICATE



For the sake of brevity, the screenshot for this form only shows 12-Lead Electrocardiogram Reading 1. Reading 2 and Reading 3 fields are comparable to the Reading 1 image.

12-LEAD ELECTROCARDIOGRAM – TRIPLICATE (CONTINUED)

ECGs should be performed after the subject has been at rest for at least 5 minutes, and whilst in a supine position.

Was a 12-Lead ECG performed?	Select **No** or **Yes** to indicate if the **12-Lead ECG** was performed.
Date performed:	Record the **date performed** in the **DD/MMM/YYYY** format. A complete date is required.
Was the ECG performed with the subject in a supine position?	Select **No** or **Yes** to indicate if the **ECG was performed with the subject in a supine position**.
Position	Select the **position** the subject was during the measurement from the drop-down list: • **DECUBITUS** • **FOWLERS** • **LATERAL DECUBITUS** • **LEFT LATERAL DECUBITUS** • **PRONE** • **REVERSE TRENDELENBURG** • **RIGHT LATERAL DECUBITUS** • **SEMI-FOWLERS** • **SEMI-RECUMBENT** • **SITTING** • **SLING** • **STANDING** • **TRENDELENBURG** • **UNCONSTRAINED**

Reading 1

Time performed:	Record the ECG **time performed** in the **HH:MM 24-hour clock** format.
Heart rate (bpm):	Record the **heart rate** in **beats per minute (bpm)** in the field provided.
PR interval (msec):	Record the **PR interval** in **milliseconds (msec)** in the field provided.
QRS duration (msec):	Record the **QRS interval** in **milliseconds (msec)** in the field provided.
QT interval (msec):	Record the **QT interval** in **milliseconds (msec)** in the field provided.
QTcF interval (msec):	Record the **QTcF interval** in **milliseconds (msec)** in the field provided.
RR interval (msec):	Record the **RR interval** in **milliseconds (msec)** in the field provided.

12-LEAD ELECTROCARDIOGRAM – TRIPLICATE (CONTINUED)

Reading 2

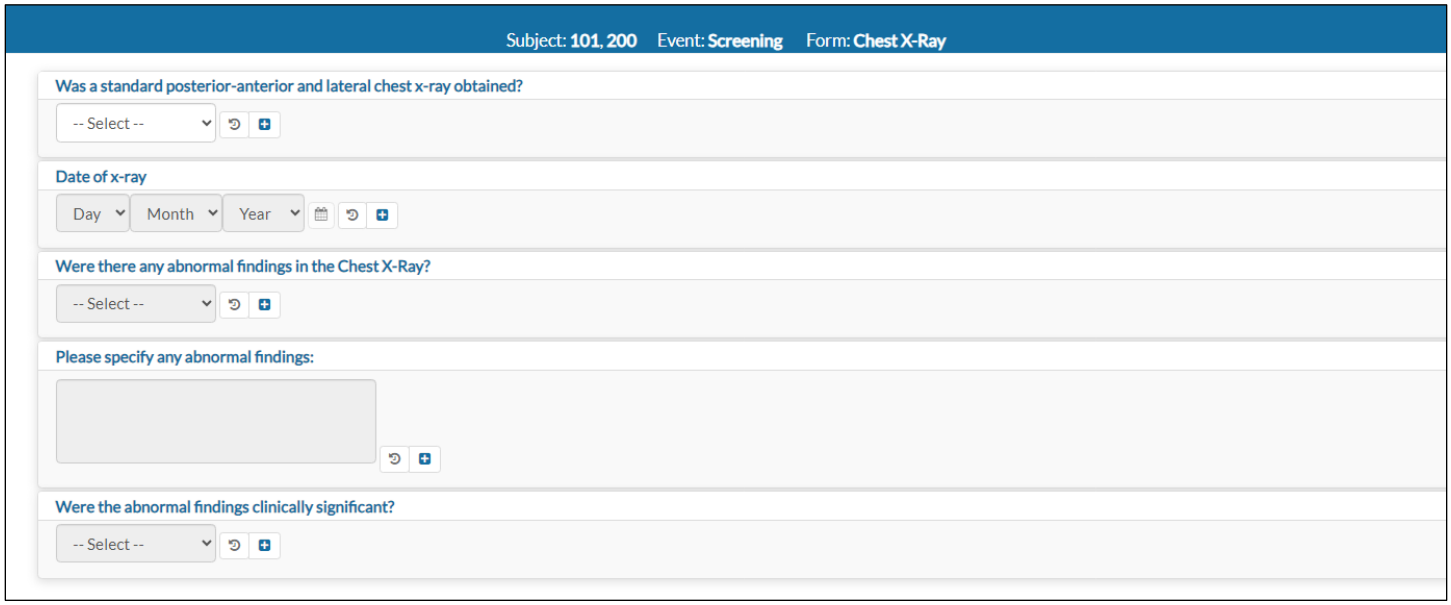
Time performed:	Record the ECG **time performed** in the **HH:MM 24-hour clock** format.
Heart rate (bpm):	Record the **heart rate** in **beats per minute (bpm)** in the field provided.
PR interval (msec):	Record the **PR interval** in **milliseconds (msec)** in the field provided.
QRS duration (msec):	Record the **QRS interval** in **milliseconds (msec)** in the field provided.
QT interval (msec):	Record the **QT interval** in **milliseconds (msec)** in the field provided.
QTcF interval (msec):	Record the **QTcF interval** in **milliseconds (msec)** in the field provided.
RR interval (msec):	Record the **RR interval** in **milliseconds (msec)** in the field provided.

Reading 3

Time performed:	Record the ECG **time performed** in the **HH:MM 24-hour clock** format.
Heart rate (bpm):	Record the **heart rate** in **beats per minute (bpm)** in the field provided.
PR interval (msec):	Record the **PR interval** in **milliseconds (msec)** in the field provided.
QRS duration (msec):	Record the **QRS interval** in **milliseconds (msec)** in the field provided.
QT interval (msec):	Record the **QT interval** in **milliseconds (msec)** in the field provided.
QTcF interval (msec):	Record the **QTcF interval** in **milliseconds (msec)** in the field provided.
RR interval (msec):	Record the **RR interval** in **milliseconds (msec)** in the field provided.
QTcF Average (msec)	Record the **QTcF average** in **milliseconds (msec)** in the field provided.
Overall interpretation:	Select the **overall interpretation** of this 12-lead ECG from the drop-down list: • **ABNORMAL** • **INDETERMINATE** • **NORMAL** • **NOT EVALUABLE** • **UNKNOWN**
Was the overall interpretation clinically significant?	Select **No** or **Yes** to indicate if the **overall interpretation was clinically significant**.

CHEST X-RAY

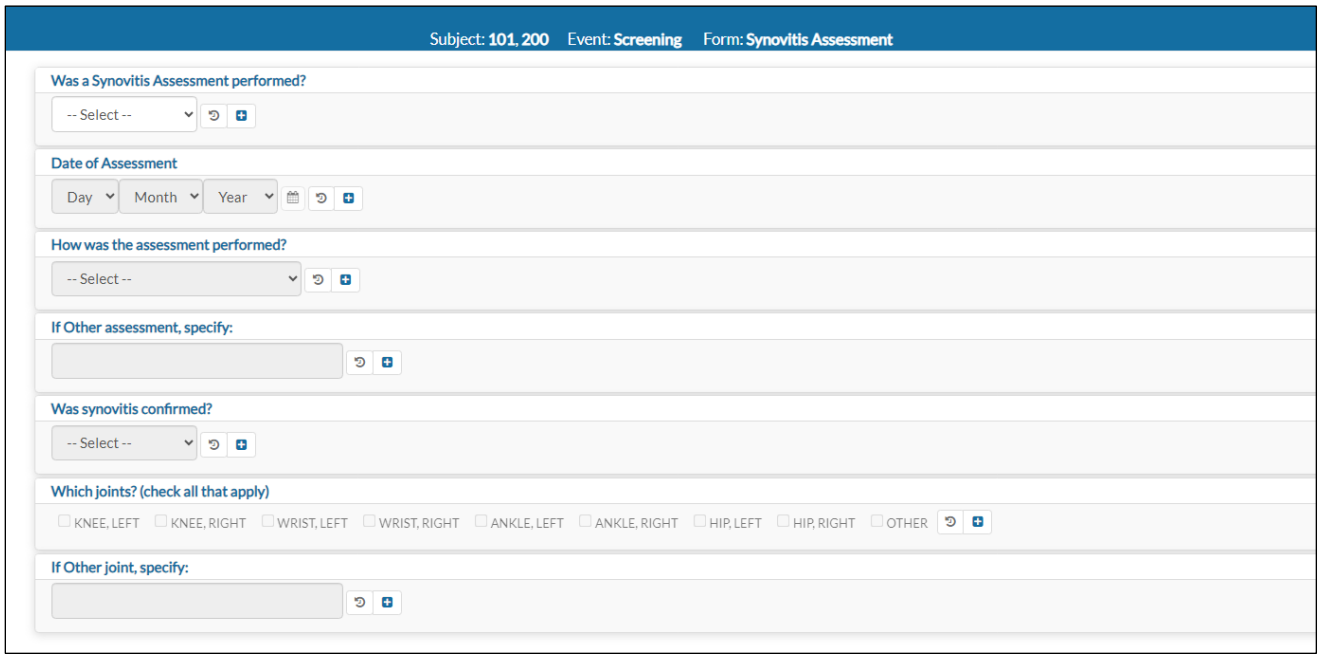
*Chest X-Ray eCRF is only available for completion at **Screening** visit.*



Was a standard posterior-anterior and lateral chest x-ray obtained?	Indicate if a **standard posterior-anterior and lateral chest x-ray** was obtained by selecting **No** or **Yes**.
Date of x-ray	Record the **date of X-Ray** in the **DD/MMM/YYYY** format. A complete date is required.
Were there any abnormal findings in the Chest X-Ray?	Indicate if there were **any abnormal findings in the Chest X-Ray** by selecting **No** or **Yes**.
Please specify any abnormal findings:	Record **any abnormal findings from X-Ray** in the text box provided. Note: *This field is only enabled if "**Were there any abnormal findings in the Chest X-Ray?**" is "**Yes**"*
Were the abnormal findings clinically significant?	Indicate if the **abnormal findings were clinically significant** by selecting **No** or **Yes**. Note: *This field is only enabled if "**Were there any abnormal findings in the Chest X-Ray?**" is "**Yes**"*

SYNOVITIS ASSESSMENT

*Synovitis Assessment eCRF is available for completion at **Screening**, **Pre-Treatment Visit 2**, and **Pre-Treatment Reassessment X Visit 2 (where X = 1, 2, 3,…)** visits.*



Was a Synovitis Assessment performed?

Indicate if a **synovitis assessment** was performed by selecting **No** or **Yes**.

Date of Assessment

Record the **date of assessment** in the **DD/MMM/YYYY** format. A complete date is required.

How was the assessment performed?

Indicate **how the assessment was performed** by selecting from the drop-down list:

- **Physical Examination**
- **Ultrasound**
- **Both**
- **Other**

Note: *If "**Other**" is selected, provide a response in the "**If Other assessment, specify:**" field*

Was synovitis confirmed?

Indicate if **synovitis was confirmed** by selecting **No** or **Yes**.

Which joints? (check all that apply)

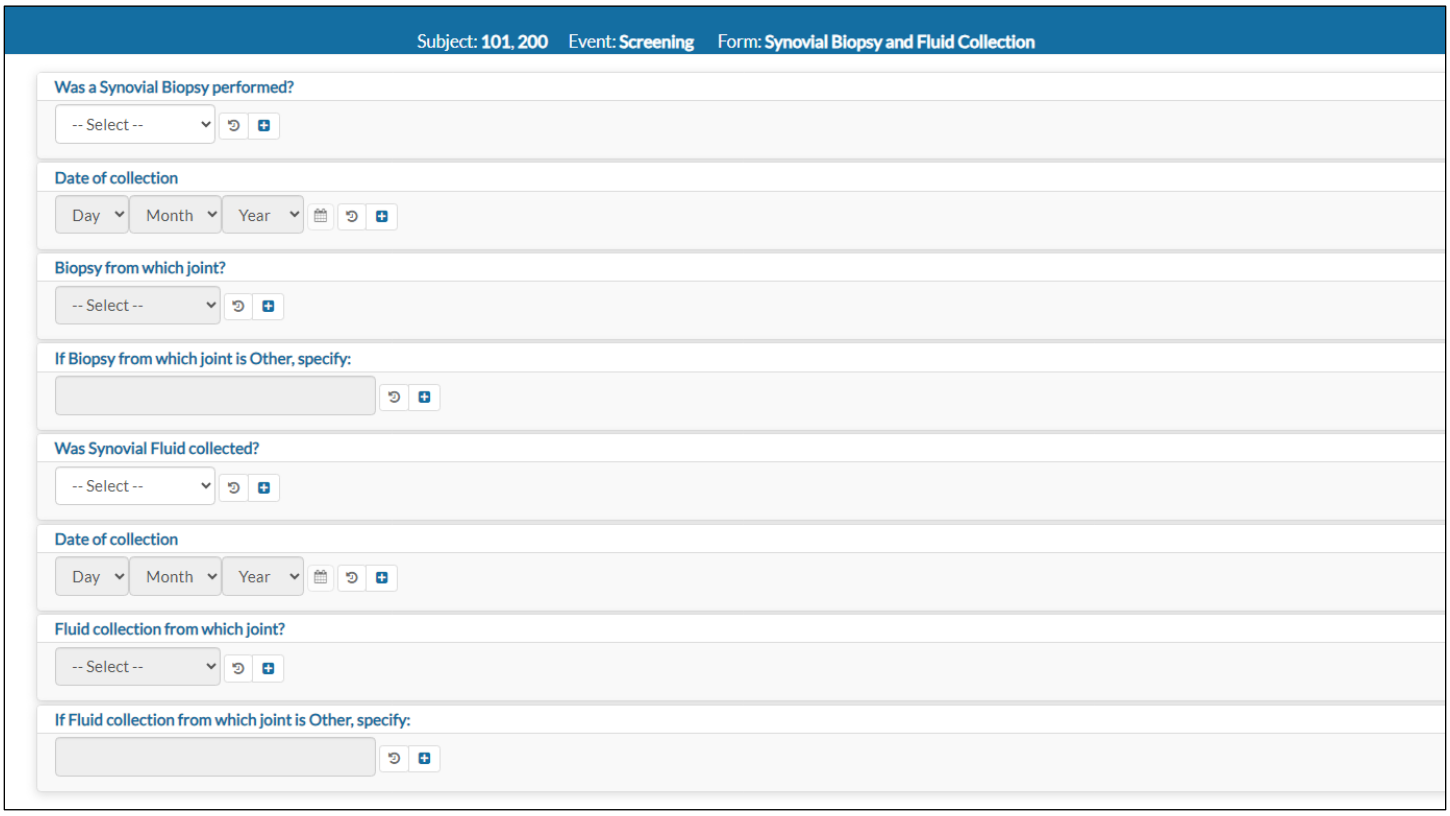
Select all applicable box(es) regarding the **location** of joint from the options provided:

- **Knee, Left**
- **Knee, Right**
- **Wrist, Left**
- **Wrist, Right**
- **Ankle, Left**
- **Ankle, Right**
- **Hip, Left**
- **Hip, Right**
- **Other**

Note: *If "**Other**" is selected, provide a response in the "**If Other joint, specify:**" field*

SYNOVIAL BIOPSY AND FLUID COLLECTION

*Synovial Biopsy and Fluid Collection eCRF is available for completion at **Screening**, **W4D28**, **W12D84**, **Early Termination**, and **Unscheduled** visits.*



Was a Synovial Biopsy performed?

Indicate if a **synovial biopsy** was performed by selecting **No** or **Yes**.
Note: *This field is NOT visible at **W12D84** visit*

Date of collection

Record the **date of collection** in the **DD/MMM/YYYY** format. A complete date is required.
Note: *This field is NOT visible at **W12D84** visit*

Biopsy from which joint?

Select the **location** of joint from the drop-down list:

- **Wrist, Left**
- **Wrist, Right**
- **Knee, Left**
- **Knee, Right**
- **Ankle, Left**
- **Ankle, Right**
- **Other**

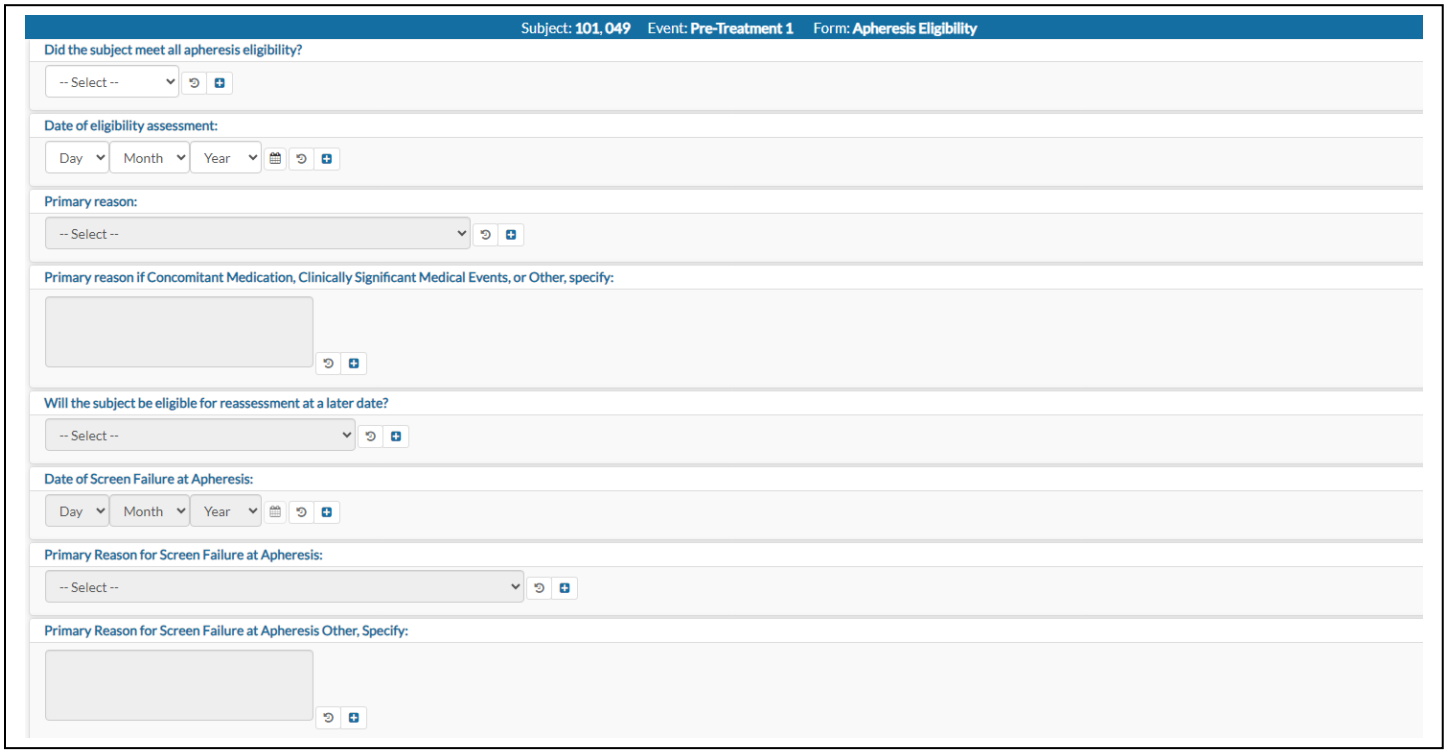
Note: *If "**Other**" is selected, provide a response in the "**If Biopsy from which joint is Other, specify:**" field*
Note: *This field is NOT visible at **W12D84** visit*

SYNOVIAL BIOPSY AND FLUID COLLECTION (CONTINUED)

Was Synovial Fluid collected?	Indicate if a **synovial fluid** was collected by selecting **No** or **Yes**.
Date of collection	Record the **date of collection** in the **DD/MMM/YYYY** format. A complete date is required.
Fluid collection from which joint?	Select the **location** of joint from the drop-down list: • **Wrist, Left** • **Wrist, Right** • **Knee, Left** • **Knee, Right** • **Ankle, Left** • **Ankle, Right** • **Other** Note: *If "**Other**" is selected, provide a response in the "**If Fluid collection from which joint is Other, specify:**" field*

APHERESIS ELIGIBILITY

*Apheresis Eligibility eCRF is available for completion at **Pre-Treatment Visit 1**, and **Pre-Treatment Reassessment X Visit 1 (where X = 1, 2, 3,…)** visits.*



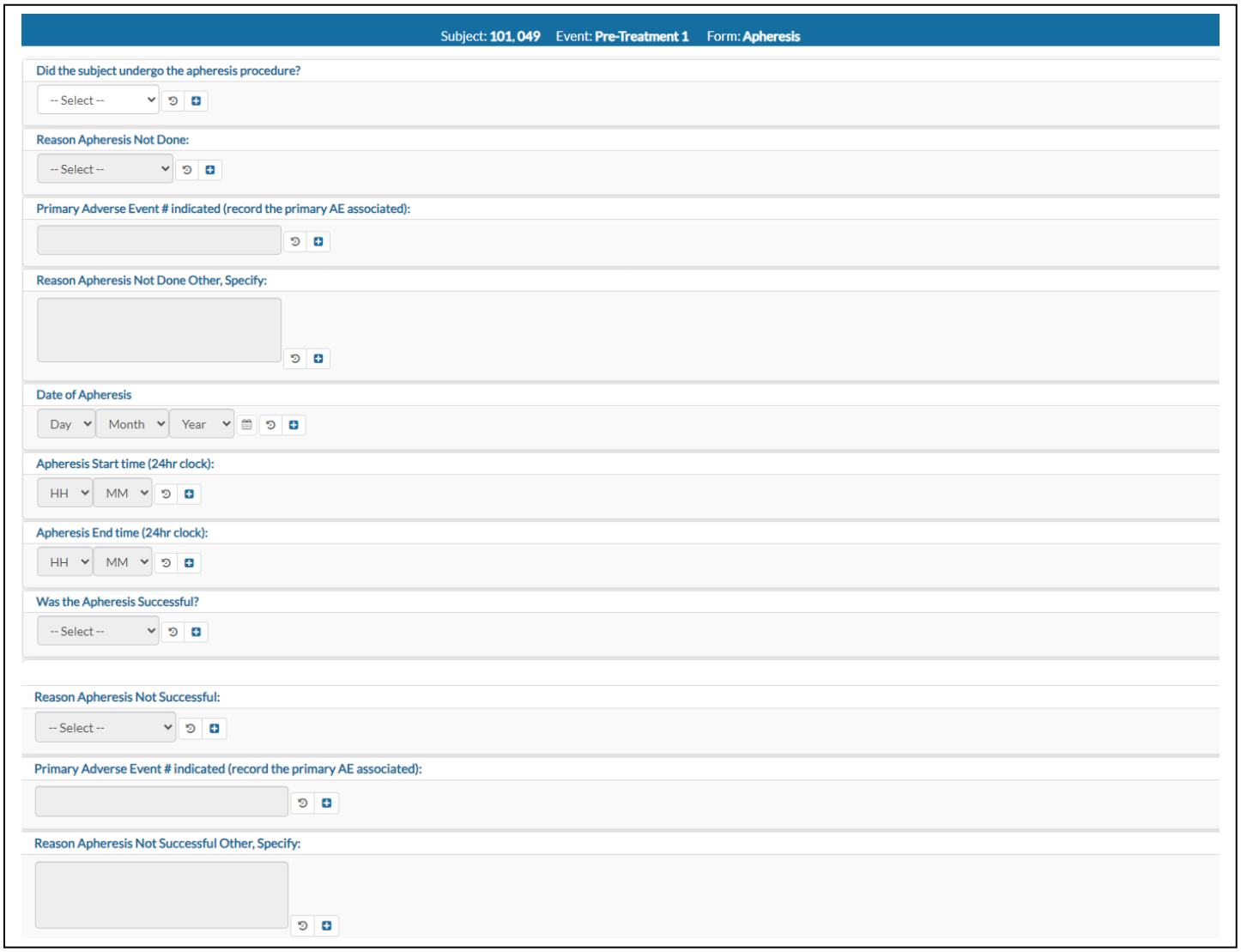
Did the subject meet all apheresis eligibility?	Select **No** or **Yes** to indicate if the **subject met all apheresis eligibility**.
Date of eligibility assessment:	Record the **date of eligibility assessment** in the **DD/MMM/YYYY** format. A complete date is required.
Primary reason:	Select the **primary reason** from the drop-down list: • **CONCOMITANT MEDICATION** • **CLINICALLY SIGNIFICANT MEDICAL EVENTS** • **OTHER** Note: *This field is only enabled if "**Did the subject meet all apheresis eligibility?**" is "**No**"*
Primary reason if Concomitant Medication, Clinically Significant Medical Events, or Other, specify:	Specify the **primary reason** in the text box provided. Note: *This field is only enabled if "**Primary reason:**" is "**Concomitant Medication**", "**Clinically Significant Medical Events**", or "**Other**"*

APHERESIS ELIGIBITY (CONTINUED)

Will the subject be eligible for reassessment at a later date?	Indicate if the **subject will be eligible for reassessment at a later date** by selecting from the drop-down list: • **No** • **Yes** • **Not applicable at this time** Note: *This field is only enabled if "**Did the subject meet all apheresis eligibility?**" is "**No**"*
Date of Screen Failure at Apheresis:	Record the **date of Screen Failure at Apheresis phase** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Will the subject be eligible for reassessment at a later date?**" is "**No**"*
Primary Reason for Screen Failure at Apheresis:	Select the **primary reason** from the drop-down list: • **ADVERSE EVENT** • **FAILURE TO MEET APHERESIS ELIGIBILITY REQUIREMENTS** • **STUDY TERMINATED BY SPONSOR** • **WITHDRAWAL BY SUBJECT** • **OTHER** Note: *This field is only enabled if "**Will the subject be eligible for reassessment at a later date?**" is "**No**"* Note: *If "**Other**" is selected, provide a response in the corresponding "***Primary Reason for Screen Failure at Apheresis Other, Specify:"** *field*

APHERESIS

*Apheresis eCRF is available for completion at **Pre-Treatment Visit 1**, and **Pre-Treatment Reassessment X Visit 1 (where X = 1, 2, 3,…)** visits.*



Did the subject undergo the apheresis procedure?

Select **No** or **Yes** to indicate if **subject underwent initial apheresis procedure**.

Reason Apheresis Not Done:

Select the **reason Apheresis not done** from the drop down-list:

- **ADVERSE EVENT**
- **OTHER**

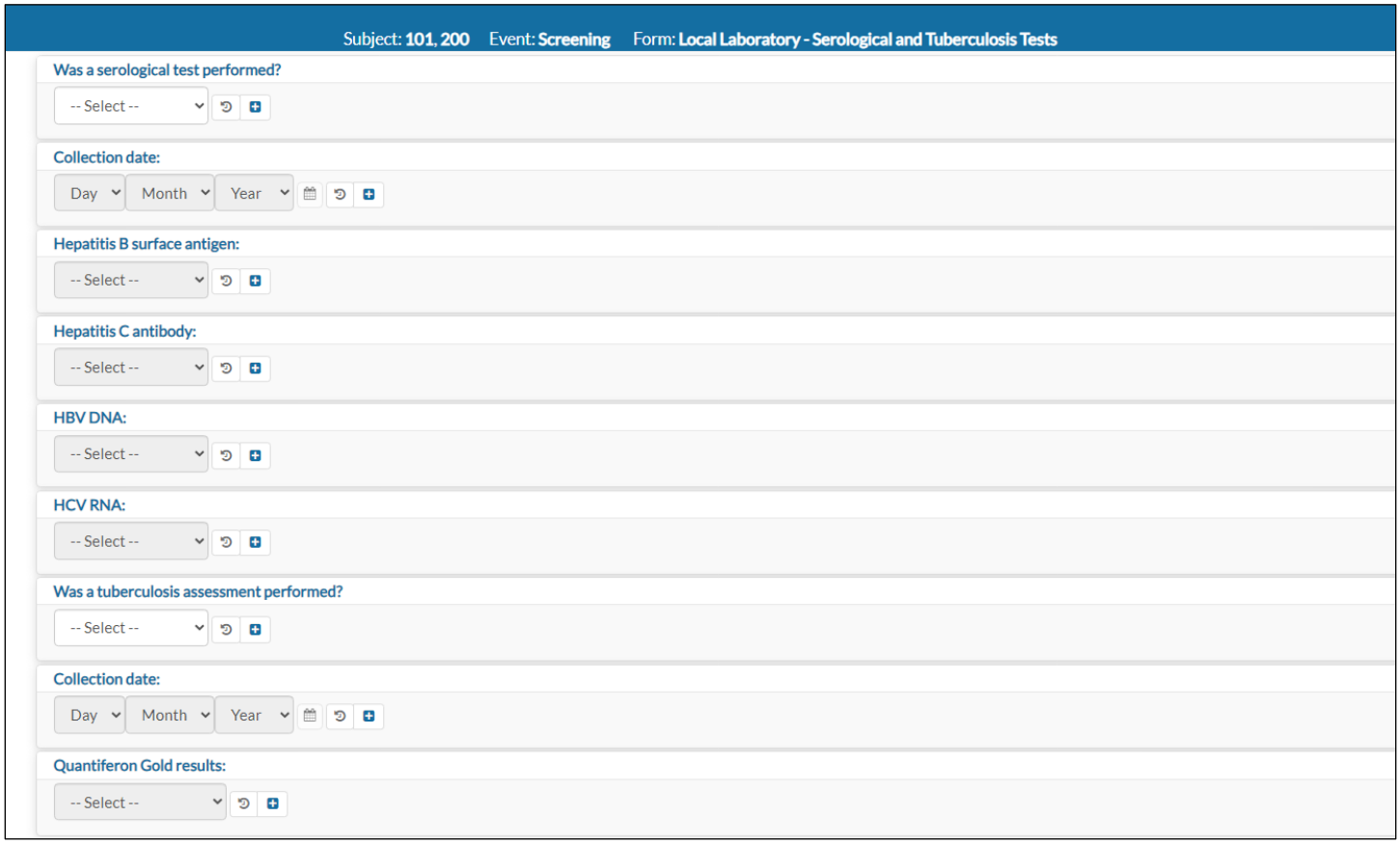
Note: *If "**Adverse Event**" is selected, record the* corresponding primary adverse event number *in the "**Specify Primary Adverse Event sequence number**" field*
Note: *If "**Other**" is selected, specify the primary cause of death in the "**If Other, specify**" field*

APHERESIS ELIGIBITY (CONTINUED)

Date of Apheresis	Record the **date of initial apheresis** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Did the subject undergo initial apheresis procedure?**" is "**Yes**"*
Apheresis Start time (24hr clock):	Record the **Apheresis start time** in the **HH:MM 24-hour clock** format.
Apheresis End time (24hr clock):	Record the **Apheresis end time** in the **HH:MM 24-hour clock** format.
Was Apheresis Successful?	Select **No** or **Yes** to indicate if **initial apheresis was successful**. Note: *This field is only enabled if "**Did the subject undergo initial apheresis procedure?**" is "**Yes**"*
Reason Apheresis Not Successful:	Select the **reason Apheresis not done** from the drop down-list: • **ADVERSE EVENT** • **OTHER** Note: *If "**Adverse Event**" is selected, record the* corresponding primary adverse event number *in the "**Specify Primary Adverse Event sequence number**" field* Note: *If "**Other**" is selected, specify the primary cause of death in the "**If Other, specify**" field*
Was Second Apheresis Successful?	Select **No** or **Yes** to indicate if **second apheresis was successful**. Note: *This field is only enabled if "**Did the subject undergo a second apheresis procedure?**" is "**Yes**"*
Did the subject undergo any other apheresis procedure?	Select **No** or **Yes** to indicate if **subject underwent any other apheresis procedure**. Note: *This field is only enabled if "**Did the subject undergo a second apheresis procedure?**" is "**Yes**"*
Date of Other Apheresis	Record the **date of other apheresis** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Did the subject undergo any other apheresis procedure?**" is "**Yes**"*
Was Other Apheresis Successful?	Select **No** or **Yes** to indicate if **other apheresis was successful**. Note: *This field is only enabled if "**Did the subject undergo any other apheresis procedure?**" is "**Yes**"*

LOCAL LABORATORY – SEROLOGICAL AND TUBERCULOSIS TESTS

*Local Laboratory – Serological and Tuberculosis Tests eCRF is only available for completion at **Screening** visit.*



Was a serological test performed?

Select **No** or **Yes** to indicate if a **serological test** was performed.

Collection date:

Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.

Note: *This field is only enabled if "**Was a serological test performed?**" is "**Yes**"*

Hepatitis B surface antigen:

Select the result of **Hepatitis B surface antigen** from the drop-down list:

- **Positive**
- **Negative**
- **Not Done**

Note: *This field is only enabled if "**Was a serological test performed?**" is "**Yes**"*

Hepatitis C antibody:

Select the result of **Hepatitis C antibody** from the drop-down list:

- **Positive**
- **Negative**
- **Not Done**

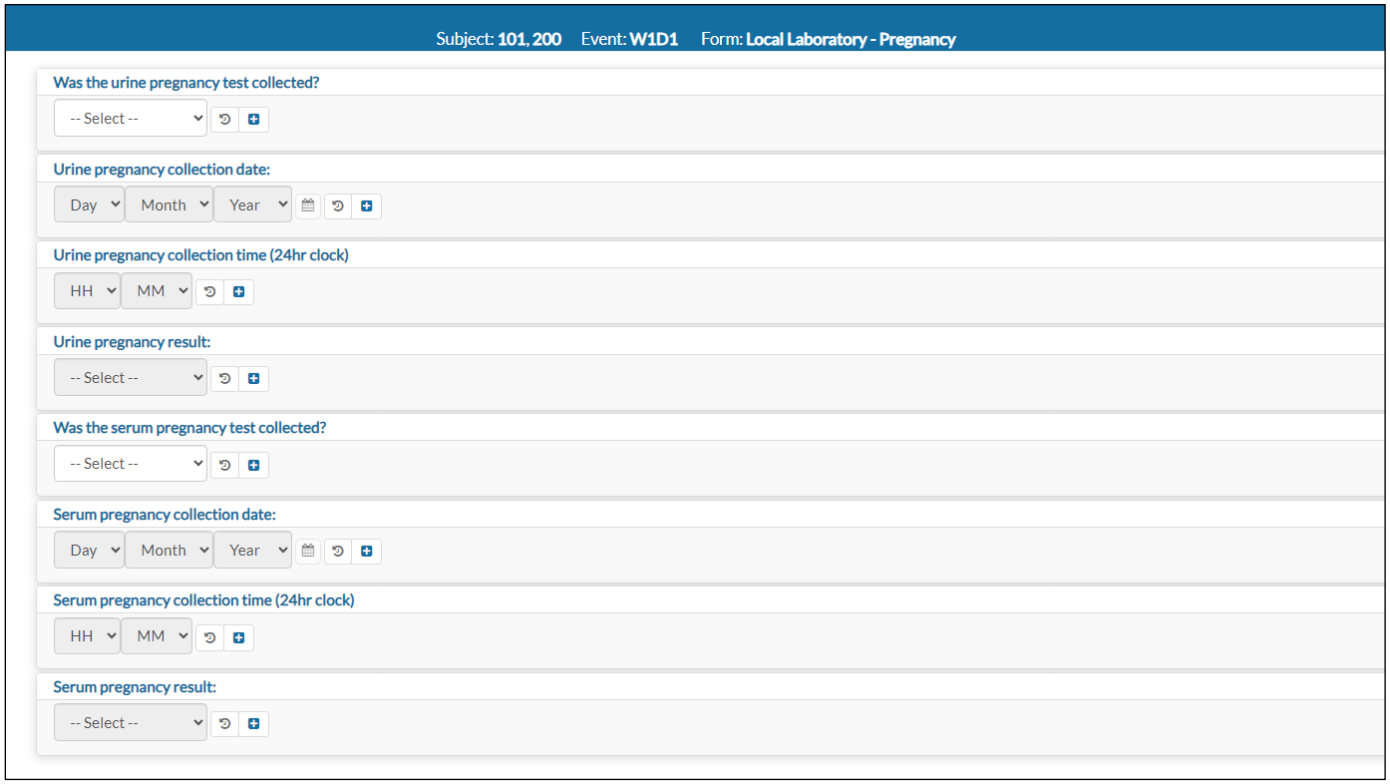
Note: *This field is only enabled if "**Was a serological test performed?**" is "**Yes**"*

LOCAL LABORATORY – SEROLOGICAL AND TUBERCULOSIS (CONTINUED)

HBV DNA:	Select the result of **HBV DNA** from the drop-down list: • **Positive** • **Negative** • **Not Done** Note: *This field is only enabled if "**Hepatitis B surface antigen:**" is "**Positive**"*
HCV RNA:	Select the result of **HCV RNA** from the drop-down list: • **Positive** • **Negative** • **Not Done** Note: *This field is only enabled if "**Hepatitis C antibody:**" is "**Positive**"*
Was a tuberculosis assessment performed?	Select **No** or **Yes** to indicate if a tuberculosis assessment was performed.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Was a tuberculosis assessment performed?**" is "**Yes**"*
Quantiferon Gold results:	Select the **Quantiferon Gold results** from the drop-down list: • **Positive** • **Negative** • **Indeterminate** Note: *This field is only enabled if "**Was a tuberculosis assessment performed?**" is "**Yes**"*

LOCAL LABORATORY – PREGNANCY

*Serum pregnancy fields are available for completion at **Screening**, **Pre-Treatment Visit 2**, **Pre-Treatment Reassessment X Visit 2 (where X = 1, 2, 3,…)**, **W1D1**, **W12D84**, **W18D126**, **W24D168**, **Early Termination**, **End of Study**, and **Unscheduled** visits. Urine pregnancy fields are only available for completion at **W1D1**, **W12D84**, **W18D126**, **W24D168**, **Early Termination**, **End of Study**, and **Unscheduled** visits.*



For the sake of brevity, the screenshot for this form only shows pregnancy lab at W1D1 visit. Other visits are comparable to the W1D1 image.

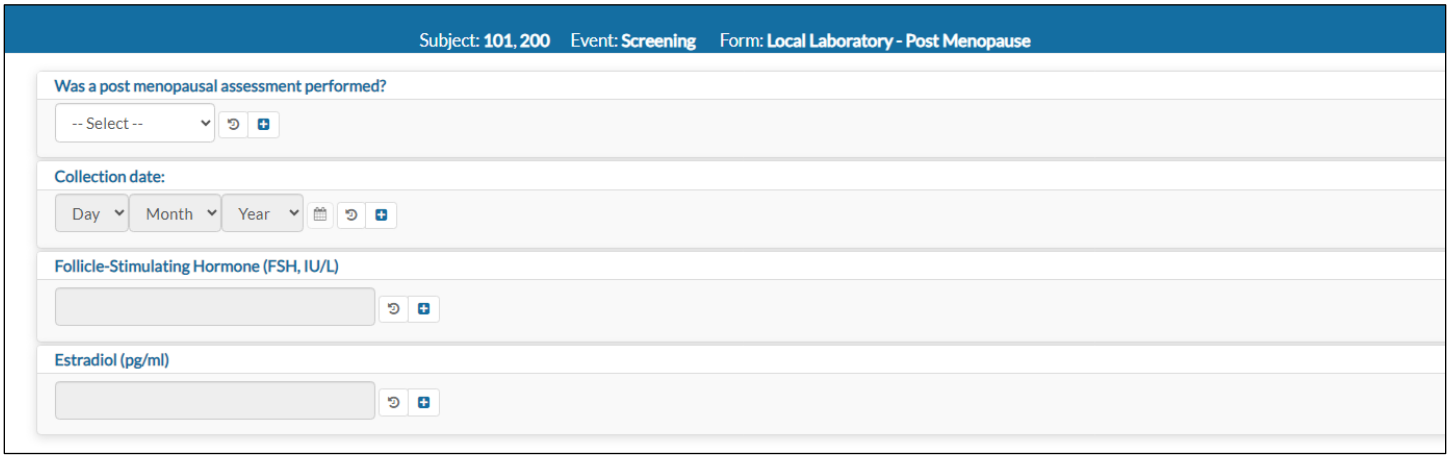
Was the urine pregnancy test collected?	Select **No** or **Yes** to indicate if a **urine pregnancy** test was collected. Note: *This field is only visible at **W1D1**, **W12D84**, **W18D126**, **W24D168**, **Early Termination**, **End of Study**, and **Unscheduled** visits*
Urine pregnancy collection date:	Record the **urine pregnancy collection date** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Was the urine pregnancy test collected?**" is "**Yes**"* Note: *This field is only visible at **W1D1**, **W12D84**, **W18D126**, **W24D168**, **Early Termination**, **End of Study**, and **Unscheduled** visits*
Urine pregnancy collection time (24hr clock)	Record the **urine pregnancy collection time** performed in the **HH:MM 24-hour clock** format. Note: *This field is only enabled if "**Was the urine pregnancy test collected?**" is "**Yes**"* Note: *This field is only visible at **W1D1** visit*

LOCAL LABORATORY – PREGNANCY (CONTINUED)

Urine pregnancy result:	Select the **urine pregnancy result** from the drop-down list: • **Positive** • **Negative** Note: *This field is only enabled if "**Was the urine pregnancy test collected?**" is "**Yes**"* Note: *This field is only visible at **W1D1**, **W12D84**, **W18D126**, **W24D168**, **Early Termination**, **End of Study**, and **Unscheduled** visits*
Was the serum pregnancy test collected?	Select **No** or **Yes** to indicate if a **serum pregnancy test** was collected.
Serum pregnancy collection date:	Record the **serum pregnancy collection date** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Was the serum pregnancy test collected?**" is "**Yes**"*
Serum pregnancy collection time (24hr clock)	Record the **serum pregnancy collection time** performed in the **HH:MM 24-hour clock** format. Note: *This field is only enabled if "**Was the serum pregnancy test collected?**" is "**Yes**"* Note: *This field is only visible at **W1D1** visit*
Serum pregnancy result:	Select the **serum pregnancy result** from the drop-down list: • **Positive** • **Negative** Note: *This field is only enabled if "**Was the serum pregnancy test collected?**" is "**Yes**"*

LOCAL LABORATORY – POST MENOPAUSE

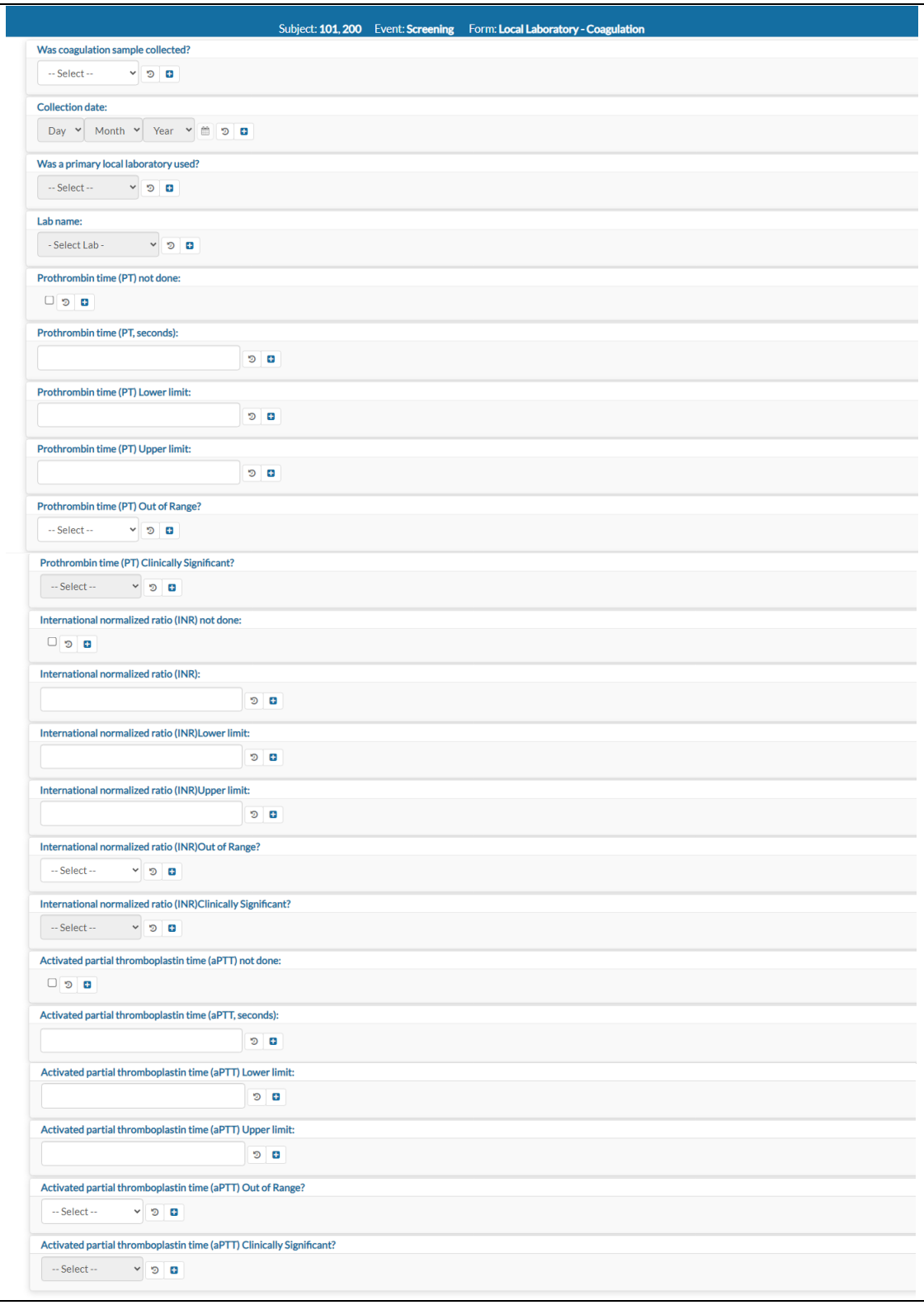
*Local Laboratory - Post Menopause eCRF is only available for completion at **Screening** visit.*



Was a post menopausal assessment performed?	Select **No** or **Yes** to indicate if a **post menopausal assessment** was performed.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Follicle-Stimulating Hormone (FSH, IU/L)	Record the **Follicle-Stimulating Hormone (FSH)** (round to the nearest tenth) in **IU/L** in the field provided.
Estradiol (pg/ml)	Record the **Estradiol** in **pg/ml** in the field provided.

LOCAL LABORATORY – COAGULATION

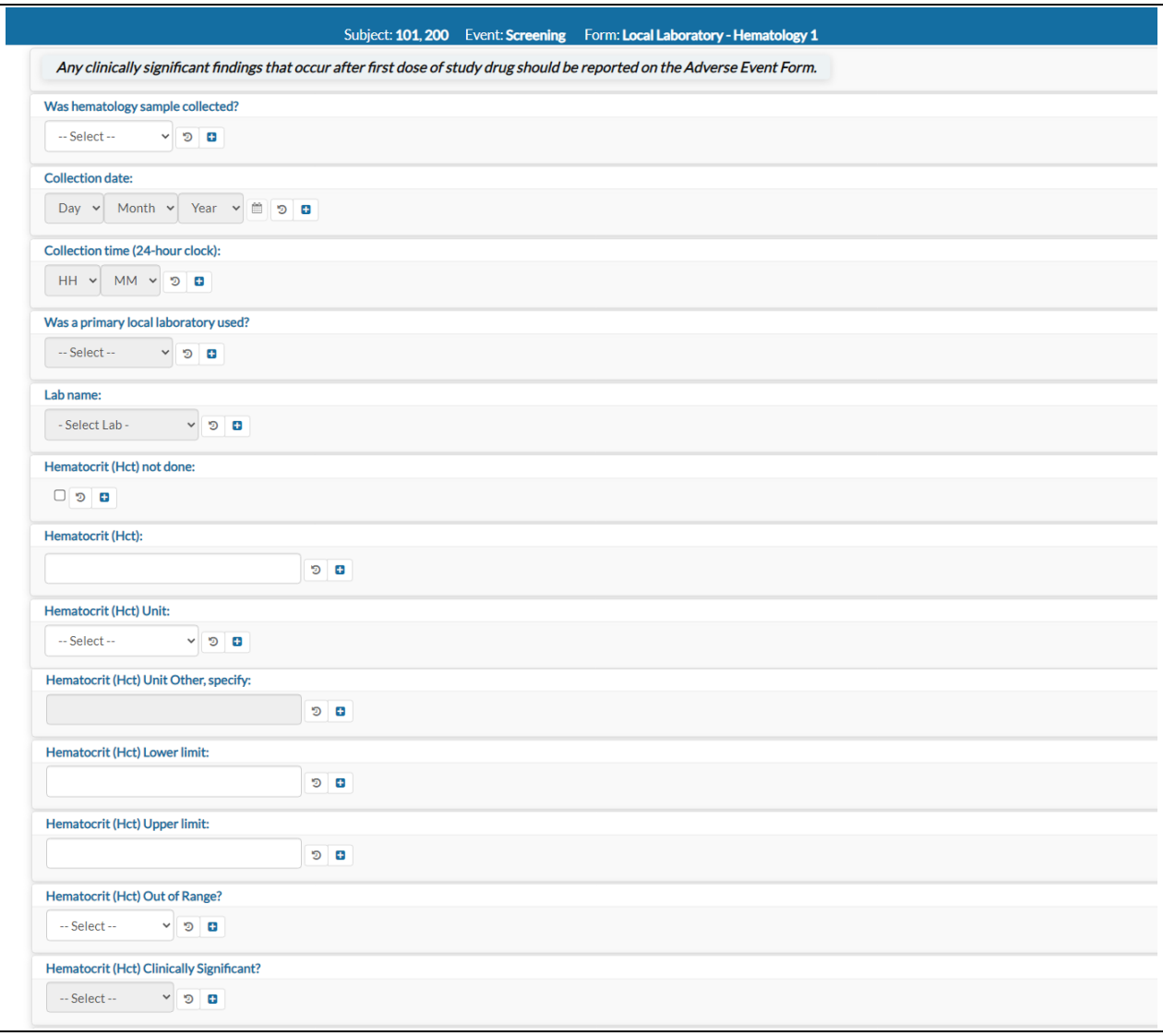
*Local Laboratory – Coagulation eCRF is available for completion at **Screening**, **Pre-Treatment Visit 2**, **Pre-Treatment Reassessment X Visit 2 (where X = 1, 2, 3,…)**, **W18D126**, **W24D168**, and **End of Study** visits.*



LOCAL LABORATORY – COAGULATION (CONTINUED)

Was coagulation sample collected?	Select **No** or **Yes** to indicate if a **coagulation sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Was a primary local laboratory used?	Select **No** or **Yes** to indicate if a **a primary local laboratory** was used. *Note: If "**No**" is selected, enter the range in the lower and upper limit fields for the indicated parameters*
Lab name:	Select the corresponding **lab name** from the drop-down list. Note: *If a lab name is selected, the lower and upper limit fields are not required for data entry* Note: *If the required lab name is unavailable, please contact your CRA and Medpace Data Management*
Results:	Record the **test results** for the following parameters. If the parameter was not collected, select the '**Not Done**' checkbox. • **Prothrombin time (PT, seconds)** • **International normalized ratio (INR)** • **Activated partial thromboplastin time (aPTT, seconds)**
Out of Range?	Select **No** or **Yes** to indicate if the test result was **out of range**.
Clinically Significant?	Select **No** or **Yes** to indicate if the out of range test result was **clinically significant**. Note: *This field is only enabled if "**Out of Range?**" is "**Yes**"*

LOCAL LABORATORY – HEMATOLOGY 1



For the sake of brevity, not all the available analytes are shown in the above image.

LOCAL LABORATORY – HEMATOLOGY 1 (CONTINUED)

Any clinically significant findings that occur after first dose of study drug should be reported on the Adverse Event Form.

Was hematology sample collected?	Select **No** or **Yes** to indicate if the **hematology sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.
Was a primary local laboratory used?	Select **No** or **Yes** to indicate if a **primary local laboratory** was used. *Note: If "**No**" is selected, enter the range in the lower and upper limit fields for the indicated parameters*
Lab name:	Select the corresponding **lab name** from the drop-down list. Note: *If a lab name is selected, the lower and upper limit fields are not required for data entry* Note: *If the required lab name is unavailable, please contact your CRA and Medpace Data Management*

Complete the following fields for each parameter listed if available.

Results:	Record the **test results** for the following parameters. If the parameter was not collected, select the '**Not Done**' checkbox. • **Hematocrit (Hct)** • **Hemoglobin (Hb)** • **Platelet count** • **Red blood count (RBC)** • **% Reticulocytes** • **Mean corpuscular volume (MCV)** • **Mean corpuscular hemoglobin (MCH)**

LOCAL LABORATORY – HEMATOLOGY 1 (CONTINUED)

Unit:

Select the corresponding **unit** for the parameter from the drop down-list:

- **%**
- **/hpf**
- **/lpf**
- **cc/min**
- **cells/mcL**
- **cells/uL**
- **E.U./dL**
- **Ehr U**
- **Ehr U/dL**
- **Eq/L**
- **fL**
- **g/dL**
- **g/L**
- **IU/L**
- **IU/mL**
- **K/mm^3**
- **K/mcL**
- **L/L**
- **M/mcL**
- **mcg/dL**
- **mcIU**
- **mcIU/mL**
- **mcm^3**
- **mcmol/L**
- **mEq/L**
- **mg/dL**
- **mg/L**
- **mIU/mL**
- **mL/min**
- **mL/min/1.73m^2**
- **mmol/L**
- **mU/L**
- **ng/dL**
- **ng/mL**
- **nmol/L**
- **pg**
- **pg/mL**
- **pmol/L**
- **seconds**
- **U/L**
- **U/mL**
- **uIU/mL**
- **x 10^3/mm^3**
- **x 10^3/mcL**
- **x 10^6/mm^3**
- **x 10^6/mcL**
- **x 10^9/L**
- **x 10^12/L**
- **No Unit**
- **Other**

Note: *If "**Other**" is selected, provide a response in the corresponding "**Unit Other, specify:**" field*

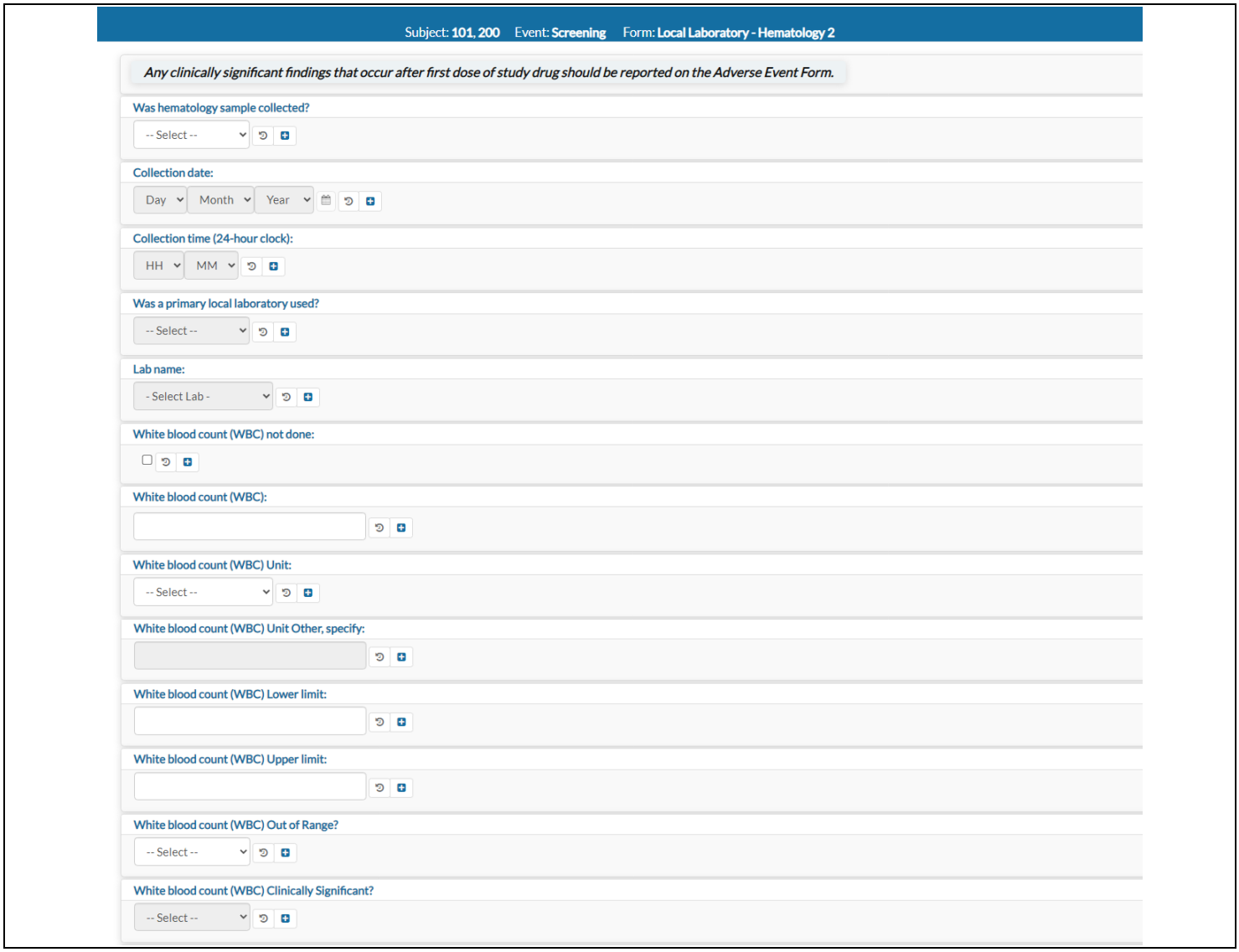
Out of Range?

Select **No** or **Yes** to indicate if the test result was **out of range**.

Clinically Significant?

Select **No** or **Yes** to indicate if the out of range test result was **clinically significant**.
Note: *This field is only enabled if "**Out of Range?**" is "**Yes**"*

LOCAL LABORATORY – HEMATOLOGY 2



For the sake of brevity, not all the available analytes are shown in the above image.

LOCAL LABORATORY – HEMATOLOGY 2 (CONTINUED)

Any clinically significant findings that occur after first dose of study drug should be reported on the Adverse Event Form.

Was hematology sample collected?	Select **No** or **Yes** to indicate if the **hematology sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.
Was a primary local laboratory used?	Select **No** or **Yes** to indicate if a **primary local laboratory** was used. *Note: If "**No**" is selected, enter the range in the lower and upper limit fields for the indicated parameters*
Lab name:	Select the corresponding **lab name** from the drop-down list. Note: *If a lab name is selected, the lower and upper limit fields are not required for data entry* Note: *If the required lab name is unavailable, please contact your CRA and Medpace Data Management*

Complete the following fields for each parameter listed if available.

Results:

Record the **test results** for the following parameters. If the parameter was not collected, select the '**Not Done**' checkbox.

- **White blood count (WBC)**
- **Absolute Neutrophil count**
- **Absolute Lymphocyte count**
- **Absolute Monocyte count**
- **Absolute Eosinophil count**
- **Absolute Basophil count**
- **Neutrophils (Differential, %)**
- **Lymphocytes (Differential, %)**
- **Monocytes (Differential, %)**
- **Eosinophils (Differential, %)**
- **Basophils (Differential, %)**

LOCAL LABORATORY – HEMATOLOGY 2 (CONTINUED)

Unit:

Select the corresponding **unit** for the parameter from the drop down-list (if applicable):

- **%**
- **/hpf**
- **/lpf**
- **cc/min**
- **cells/mcL**
- **cells/uL**
- **E.U./dL**
- **Ehr U**
- **Ehr U/dL**
- **Eq/L**
- **fL**
- **g/dL**
- **g/L**
- **IU/L**
- **IU/mL**
- **K/mm^3**
- **K/mcL**
- **L/L**
- **M/mcL**
- **mcg/dL**
- **mcIU**
- **mcIU/mL**
- **mcm^3**
- **mcmol/L**
- **mEq/L**
- **mg/dL**
- **mg/L**
- **mIU/mL**
- **mL/min**
- **mL/min/1.73m^2**
- **mmol/L**
- **mU/L**
- **ng/dL**
- **ng/mL**
- **nmol/L**
- **pg**
- **pg/mL**
- **pmol/L**
- **seconds**
- **U/L**
- **U/mL**
- **uIU/mL**
- **x 10^3/mm^3**
- **x 10^3/mcL**
- **x 10^6/mm^3**
- **x 10^6/mcL**
- **x 10^9/L**
- **x 10^12/L**
- **No Unit**
- **Other**

Note: *If "**Other**" is selected, provide a response in the corresponding "**Unit Other, specify:**" field*

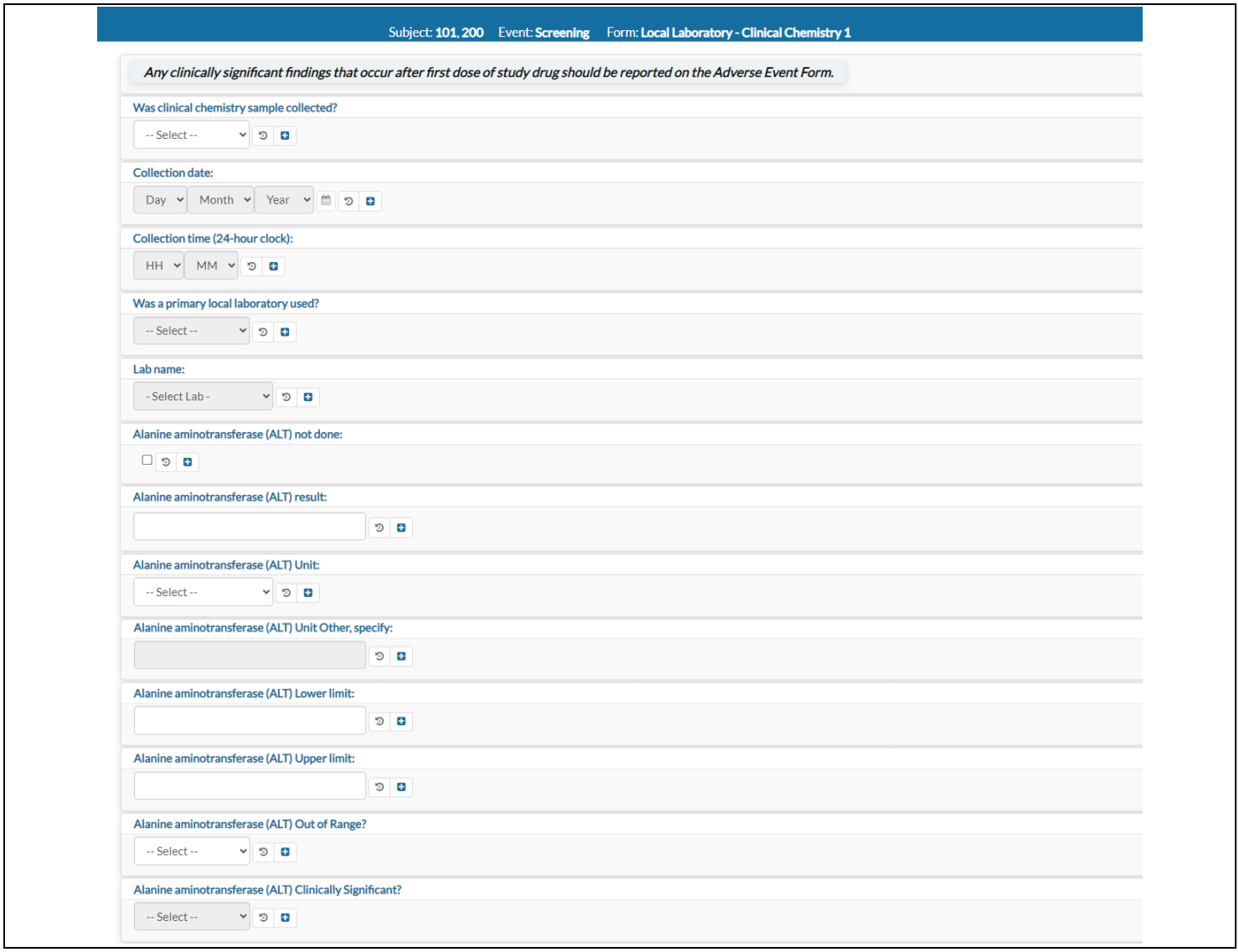
Out of Range?

Select **No** or **Yes** to indicate if the test result was **out of range**.

Clinically Significant?

Select **No** or **Yes** to indicate if the out of range test result was **clinically significant**.
Note: *This field is only enabled if "**Out of Range?**" is "**Yes**"*

LOCAL LABORATORY – CLINICAL CHEMISTRY 1



For the sake of brevity, not all the available analytes are shown in the above image.

LOCAL LABORATORY – CLINICAL CHEMISTRY 1 (CONTINUED)

Any clinically significant findings that occur after first dose of study drug should be reported on the Adverse Event Form.

Was clinical chemistry sample collected?	Select **No** or **Yes** to indicate if the **chemistry sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.
Was a primary local laboratory used?	Select **No** or **Yes** to indicate if a **primary local laboratory** was used. *Note: If "**No**" is selected, enter the range in the lower and upper limit fields for the indicated parameters*
Lab name:	Select the corresponding **lab name** from the drop-down list. Note: *If a lab name is selected, the lower and upper limit fields are not required for data entry* Note: *If the required lab name is unavailable, please contact your CRA and Medpace Data Management*

Complete the following fields for each parameter listed if available.

Results: Record the **test results** for the following parameters. If the parameter was not collected, select the '**Not Done**' checkbox.

- **Alanine aminotransferase (ALT)**
- **Albumin**
- **Alkaline phosphatase**
- **Aspartate aminotransferase (AST)**
- **Bicarbonate**
- **Blood urea nitrogen (BUN)**
- **Calcium**
- **Chloride**
- **Creatinine**

LOCAL LABORATORY – CLINICAL CHEMISTRY 1 (CONTINUED)

Unit:

Select the corresponding **unit** for the parameter from the drop down-list (if applicable):

- **%**
- **/hpf**
- **/lpf**
- **cc/min**
- **cells/mcL**
- **cells/uL**
- **E.U./dL**
- **Ehr U**
- **Ehr U/dL**
- **Eq/L**
- **fL**
- **g/dL**
- **g/L**
- **IU/L**
- **IU/mL**
- **K/mm^3**
- **K/mcL**
- **L/L**
- **M/mcL**
- **mcg/dL**
- **mcIU**
- **mcIU/mL**
- **mcm^3**
- **mcmol/L**
- **mEq/L**
- **mg/dL**
- **mg/L**
- **mIU/mL**
- **mL/min**
- **mL/min/1.73m^2**
- **mmol/L**
- **mU/L**
- **ng/dL**
- **ng/mL**
- **nmol/L**
- **pg**
- **pg/mL**
- **pmol/L**
- **seconds**
- **U/L**
- **U/mL**
- **uIU/mL**
- **x 10^3/mm^3**
- **x 10^3/mcL**
- **x 10^6/mm^3**
- **x 10^6/mcL**
- **x 10^9/L**
- **x 10^12/L**
- **No Unit**
- **Other**

Note: *If "**Other**" is selected, provide a response in the corresponding "**Unit Other, specify:**" field*

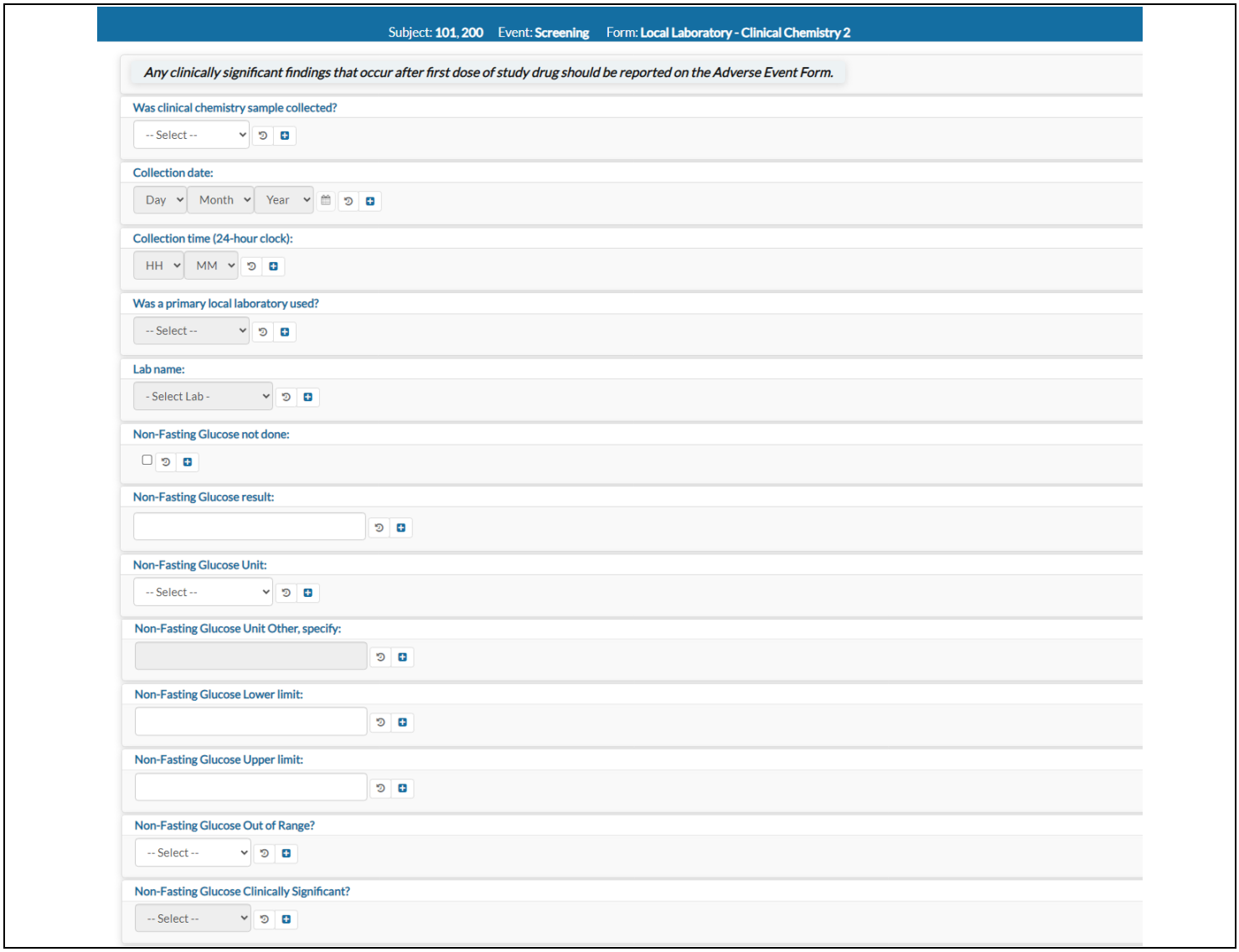
Out of Range?

Select **No** or **Yes** to indicate if the test result was **out of range**.

Clinically Significant?

Select **No** or **Yes** to indicate if the out of range test result was **clinically significant**.
Note: *This field is only enabled if "**Out of Range?**" is "**Yes**"*

LOCAL LABORATORY – CLINICAL CHEMISTRY 2



For the sake of brevity, not all the available analytes are shown in the above image.

LOCAL LABORATORY – CLINICAL CHEMISTRY 2 (CONTINUED)

Any clinically significant findings that occur after first dose of study drug should be reported on the Adverse Event Form.

Was clinical chemistry sample collected?	Select **No** or **Yes** to indicate if the **chemistry sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.
Was a primary local laboratory used?	Select **No** or **Yes** to indicate if a **primary local laboratory** was used. *Note: If "**No**" is selected, enter the range in the lower and upper limit fields for the indicated parameters*
Lab name:	Select the corresponding **lab name** from the drop-down list. Note: *If a lab name is selected, the lower and upper limit fields are not required for data entry* Note: *If the required lab name is unavailable, please contact your CRA and Medpace Data Management*

Complete the following fields for each parameter listed if available.

Results:	Record the **test results** for the following parameters. If the parameter was not collected, select the '**Not Done**' checkbox. • **Non-Fasting Glucose** • **Fasting Glucose** • **Direct bilirubin** • **Total bilirubin** • **Total protein** • **Potassium** • **Sodium** • **HbA1c**

LOCAL LABORATORY – CLINICAL CHEMISTRY 2 (CONTINUED)

Unit:

Select the corresponding **unit** for the parameter from the drop down-list (if applicable):

- **%**
- **/hpf**
- **/lpf**
- **cc/min**
- **cells/mcL**
- **cells/uL**
- **E.U./dL**
- **Ehr U**
- **Ehr U/dL**
- **Eq/L**
- **fL**
- **g/dL**
- **g/L**
- **IU/L**
- **IU/mL**
- **K/mm^3**
- **K/mcL**
- **L/L**
- **M/mcL**
- **mcg/dL**
- **mcIU**
- **mcIU/mL**
- **mcm^3**
- **mcmol/L**
- **mEq/L**
- **mg/dL**
- **mg/L**
- **mIU/mL**
- **mL/min**
- **mL/min/1.73m^2**
- **mmol/L**
- **mU/L**
- **ng/dL**
- **ng/mL**
- **nmol/L**
- **pg**
- **pg/mL**
- **pmol/L**
- **seconds**
- **U/L**
- **U/mL**
- **uIU/mL**
- **x 10^3/mm^3**
- **x 10^3/mcL**
- **x 10^6/mm^3**
- **x 10^6/mcL**
- **x 10^9/L**
- **x 10^12/L**
- **No Unit**
- **Other**

Note: *If "**Other**" is selected, provide a response in the corresponding "**Unit Other, specify:**" field*

Out of Range?

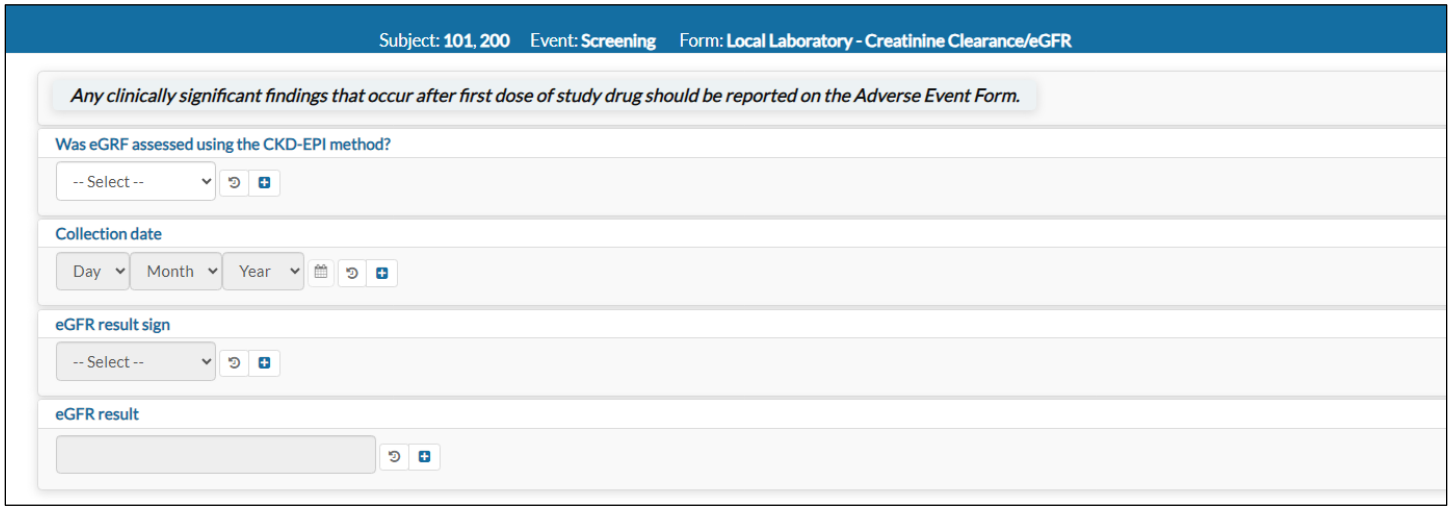
Select **No** or **Yes** to indicate if the test result was **out of range**.

Clinically Significant?

Select **No** or **Yes** to indicate if the out of range test result was **clinically significant**.
Note: *This field is only enabled if "**Out of Range?**" is "**Yes**"*

LOCAL LABORATORY – CREATININE CLEARANCE/EGFR

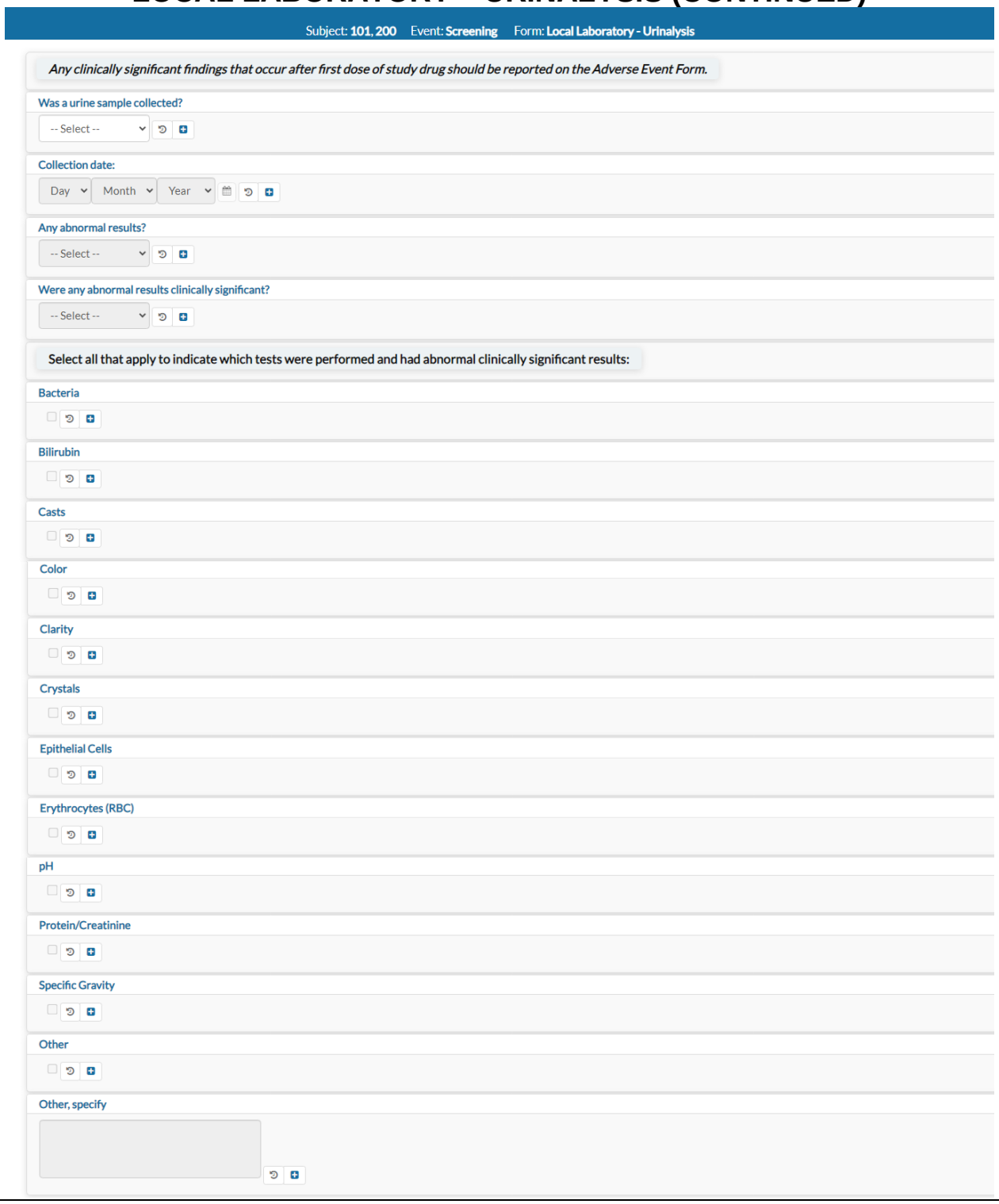
*Local Laboratory - Creatinine Clearance/eGFR eCRF is only available for completion at **Screening** visit.*



Any clinically significant findings that occur after first dose of study drug should be reported on the Adverse Event Form.

Was eGRF assessed using the CKD-EPI method?	Select **No** or **Yes** to indicate if the **eGRF was assessed using the CKD-EPI method**.
Collection date	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
eGFR result sign	Select the **eGFR result sign** from the drop-down list: • **<** • **<=** • **=** • **>=** • **>**
eGFR result	Record the **eGFR result** in the field provided.

LOCAL LABORATORY – URINALYSIS (CONTINUED)



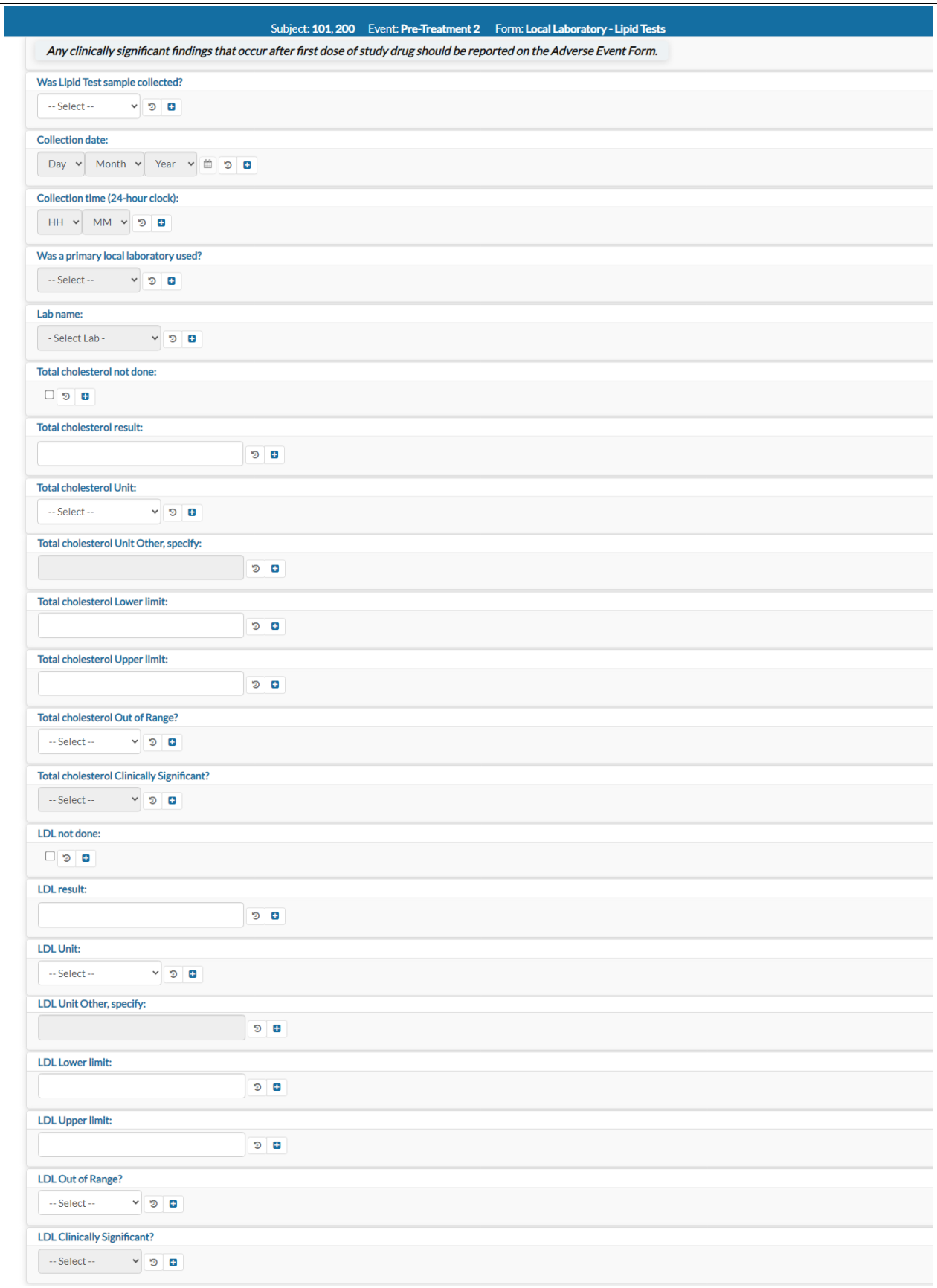
For the sake of brevity, not all the available analytes are shown in the above image.

LOCAL LABORATORY – URINALYSIS (CONTINUED)

Any clinically significant findings that occur after first dose of study drug should be reported on the Adverse Event Form.

Was a urine sample collected?	Select **No** or **Yes** to indicate if the **urine sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Any abnormal results?	Select **No** or **Yes** to indicate if there are **any abnormal results**.
Were any abnormal results clinically significant?	Select **No** or **Yes** to indicate if there are **any abnormal clinically significant results**. Note: *This field is only visible if "**Any abnormal results?**" is "**Yes**"*
Select all that apply to indicate which tests were performed and had abnormal clinically significant results:	Select all applicable box(es) regarding **abnormal clinically significant results** from the drop-down list: • **Bacteria** • **Bilirubin** • **Casts** • **Color** • **Clarity** • **Crystals** • **Epithelial Cells** • **Erythrocytes (RBC)** • **Fat Droplet** • **Glucose** • **Ketones** • **Ketone Bodies** • **Hyaline Casts** • **Leukocyte Esterase** • **Leukocytes (WBC)** • **Nitrite** • **Occult Blood** • **Protein** • **Sediment Examination / Microscopic Sediment Analysis** • **Specimen Appearance** • **Spermatozoa** • **Trichomonas** • **Urobilinogen** • **Yeast Cells** • **pH** • **Protein/Creatinine** • **Specific Gravity** • **Other** Note: *If "**Other**" is selected, provide a response in the "**Other, specify**" field* Note: *This field is only visible if "**Were any abnormal results clinically significant?"** is "**Yes**"*

LOCAL LABORATORY – LIPID TESTS



LOCAL LABORATORY – LIPID TESTS (CONTINUED)

Any clinically significant findings that occur after first dose of study drug should be reported on the Adverse Event Form.

Was Lipid Test sample collected?	Select **No** or **Yes** to indicate if the **lipid test sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.
Was a primary local laboratory used?	Select **No** or **Yes** to indicate if a **primary local laboratory** was used. *Note: If "**No**" is selected, enter the range in the lower and upper limit fields for the indicated parameters*
Lab name:	Select the corresponding **lab name** from the drop-down list. Note: *If a lab name is selected, the lower and upper limit fields are not required for data entry* Note: *If the required lab name is unavailable, please contact your CRA and Medpace Data Management*

Complete the following fields for each parameter listed if available.

Results:	Record the **test results** for the following parameters. If the parameter was not collected, select the '**Not Done**' checkbox. • **Total cholesterol** • **LDL**

LOCAL LABORATORY – LIPID TESTS (CONTINUED)

Unit:

Select the corresponding **unit** for the parameter from the drop down-list (if applicable):

- **%**
- **/hpf**
- **/lpf**
- **cc/min**
- **cells/mcL**
- **cells/uL**
- **E.U./dL**
- **Ehr U**
- **Ehr U/dL**
- **Eq/L**
- **fL**
- **g/dL**
- **g/L**
- **IU/L**
- **IU/mL**
- **K/mm^3**
- **K/mcL**
- **L/L**
- **M/mcL**
- **mcg/dL**
- **mcIU**
- **mcIU/mL**
- **mcm^3**
- **mcmol/L**
- **mEq/L**
- **mg/dL**
- **mg/L**
- **mIU/mL**
- **mL/min**
- **mL/min/1.73m^2**
- **mmol/L**
- **mU/L**
- **ng/dL**
- **ng/mL**
- **nmol/L**
- **pg**
- **pg/mL**
- **pmol/L**
- **seconds**
- **U/L**
- **U/mL**
- **uIU/mL**
- **x 10^3/mm^3**
- **x 10^3/mcL**
- **x 10^6/mm^3**
- **x 10^6/mcL**
- **x 10^9/L**
- **x 10^12/L**
- **No Unit**
- **Other**

Note: *If "**Other**" is selected, provide a response in the corresponding "**Unit Other, specify:**" field*

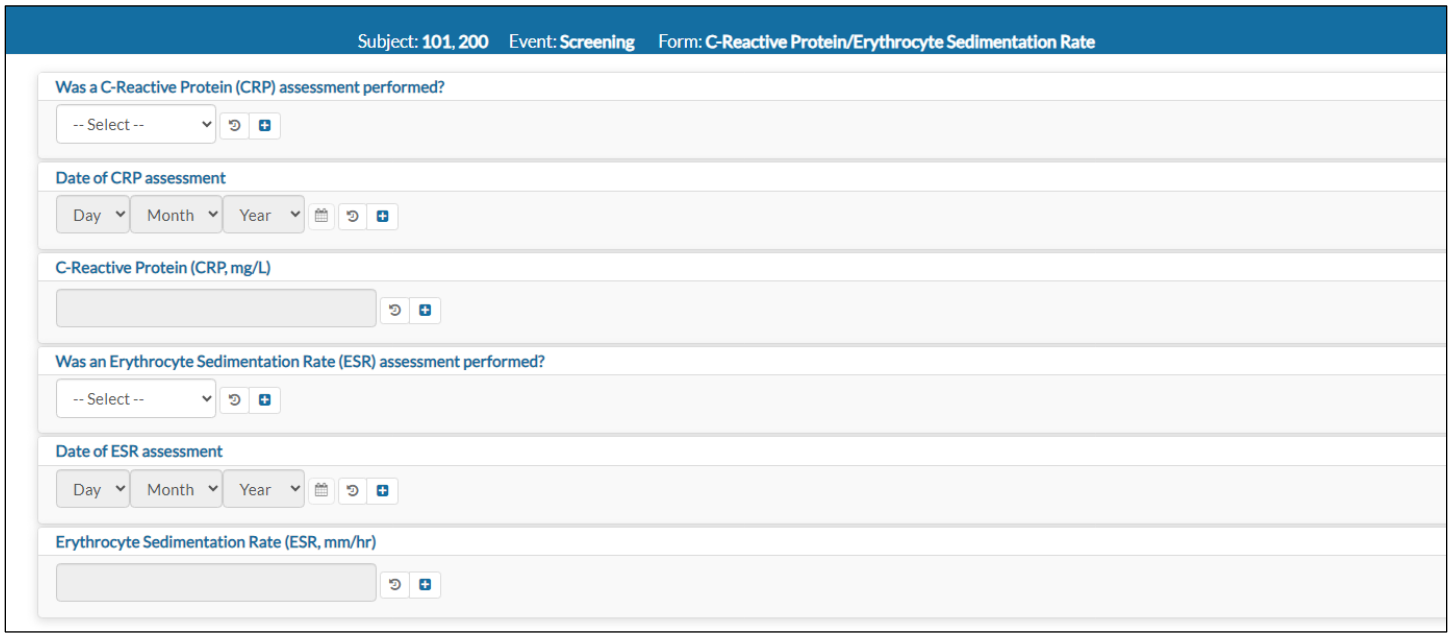
Out of Range?

Select **No** or **Yes** to indicate if the test result was **out of range**.

Clinically Significant?

Select **No** or **Yes** to indicate if the out of range test result was **clinically significant**.
Note: *This field is only enabled if "**Out of Range?**" is "**Yes**"*

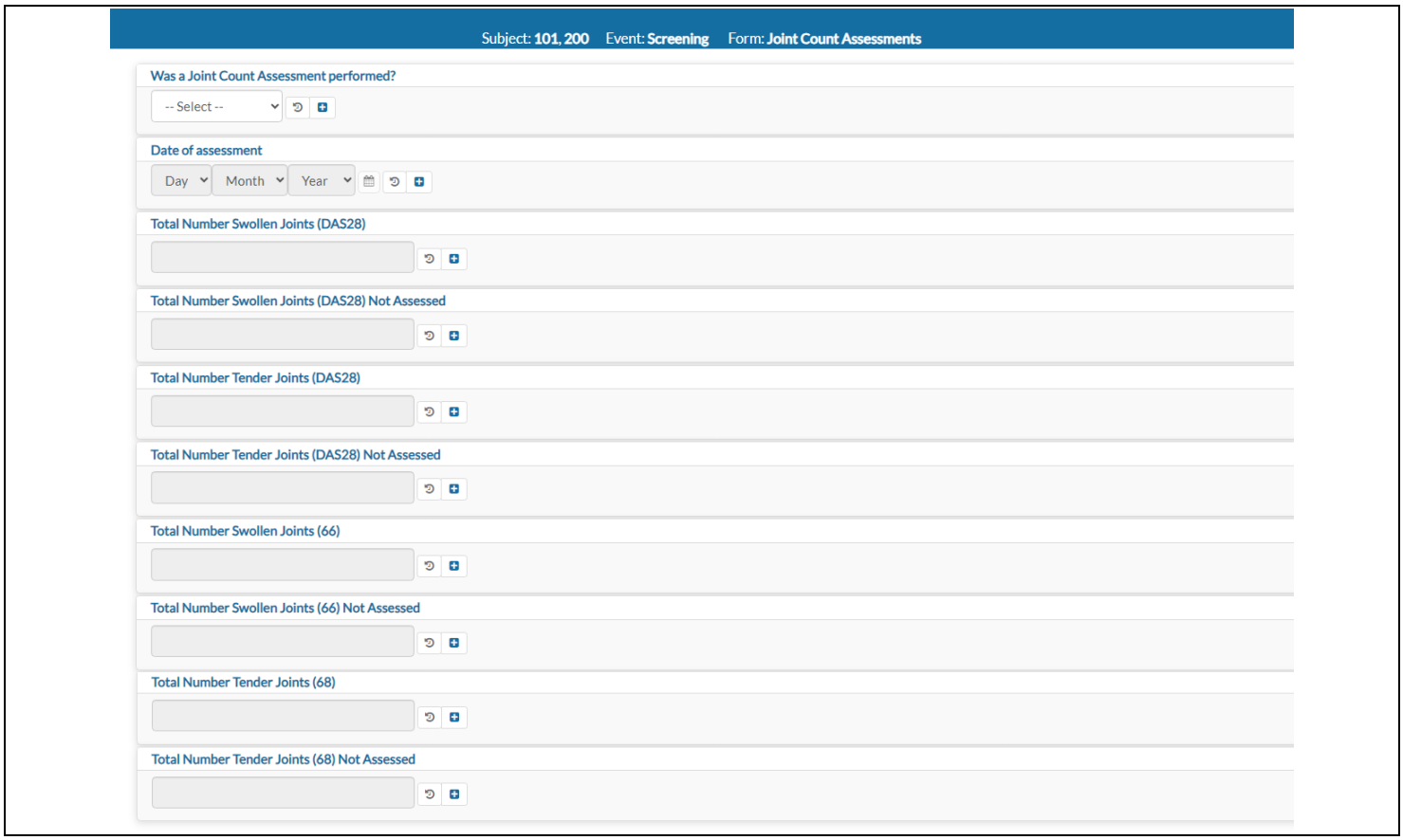
C-REACTIVE PROTEIN/ERYTHROCYTE SEDIMENTATION RATE



Was a C-Reactive Protein (CRP) assessment performed?	Select **No** or **Yes** to indicate if the **C-Reactive Protein (CRP) assessment** was performed.
Date of CRP assessment	Record the **date of CRP assessment** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Was a C-Reactive Protein (CRP) assessment performed?**" is "**Yes**"*
C-Reactive Protein (CRP, mg/L)	Record the **C-Reactive Protein (CRP)** in **mg/L** (round to the nearest tenth) in the field provided. Note: *This field is only enabled if "**Was a C-Reactive Protein (CRP) assessment performed?**" is "**Yes**"*
Was an Erythrocyte Sedimentation Rate (ESR) assessment performed?	Select **No** or **Yes** to indicate if the **Erythrocyte Sedimentation Rate (ESR) assessment** was performed.
Date of ESR assessment	Record the **date of ESR assessment** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Was an Erythrocyte Sedimentation Rate (ESR) assessment performed?**" is "**Yes**"*
Erythrocyte Sedimentation Rate (ESR, mm/hr)	Record the **Erythrocyte Sedimentation Rate (ESR)** in **mm/hr** (round to the nearest tenth) in the field provided. Note: *This field is only enabled if "**Was an Erythrocyte Sedimentation Rate (ESR) assessment performed?**" is "**Yes**"*

JOINT COUNT ASSESSMENTS

The information regarding Joint Count Assessments can be found on the Homunculus worksheet provided to the site.

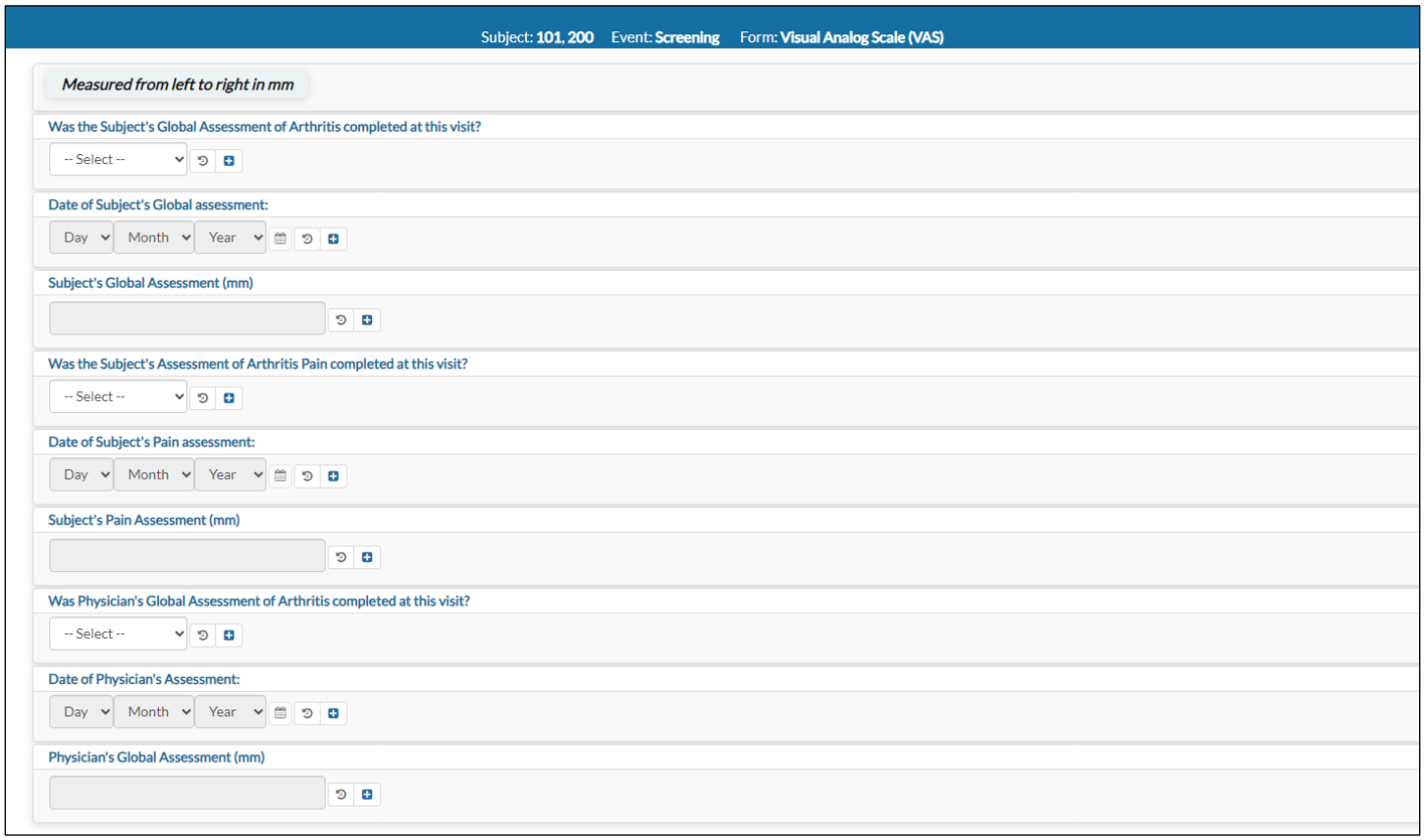


Was a Joint Count Assessment performed?	Select **No** or **Yes** to indicate if the **joint count assessment** was performed.
Date of assessment	Record the **date of assessment** in the **DD/MMM/YYYY** format. A complete date is required.
Total Number Swollen Joints (DAS28)	Record the **Total Number Swollen Joints (DAS28)** in the field provided.
Total Number Swollen Joints (DAS28) Not Assessed	Record the **Total Number Swollen Joints (DAS28) was not assessed** in the field provided.
Total Number Tender Joints (DAS28)	Record the **Total Number Tender Joints (DAS28)** in the field provided.
Total Number Tender Joints (DAS28) Not Assessed	Record the **Total Number Tender Joints (DAS28) was not assessed** in the field provided.

JOINT COUNT ASSESSMENTS (CONTINUED)

Total Number Swollen Joints (66)	Record the **Total Number Swollen Joints (66)** in the field provided. Note: *This field is only visible at **Screening**, **W12D84**, and **Unscheduled** visits*
Total Number Swollen Joints (66) Not Assessed	Record the **Total Number Swollen Joints (66) was not assessed** in the field provided. Note: *This field is only visible at **Screening**, **W12D84**, and **Unscheduled** visits*
Total Number Tender Joints (68)	Record the **Total Number Tender Joints (68)** in the field provided. Note: *This field is only visible at **Screening**, **W12D84**, and **Unscheduled** visits*
Total Number Tender Joints (68) Not Assessed	Record the **Total Number Tender Joints (68) was not assessed** in the field provided. Note: *This field is only visible at **Screening**, **W12D84**, and **Unscheduled** visits*

VISUAL ANALOG SCALE (VAS)



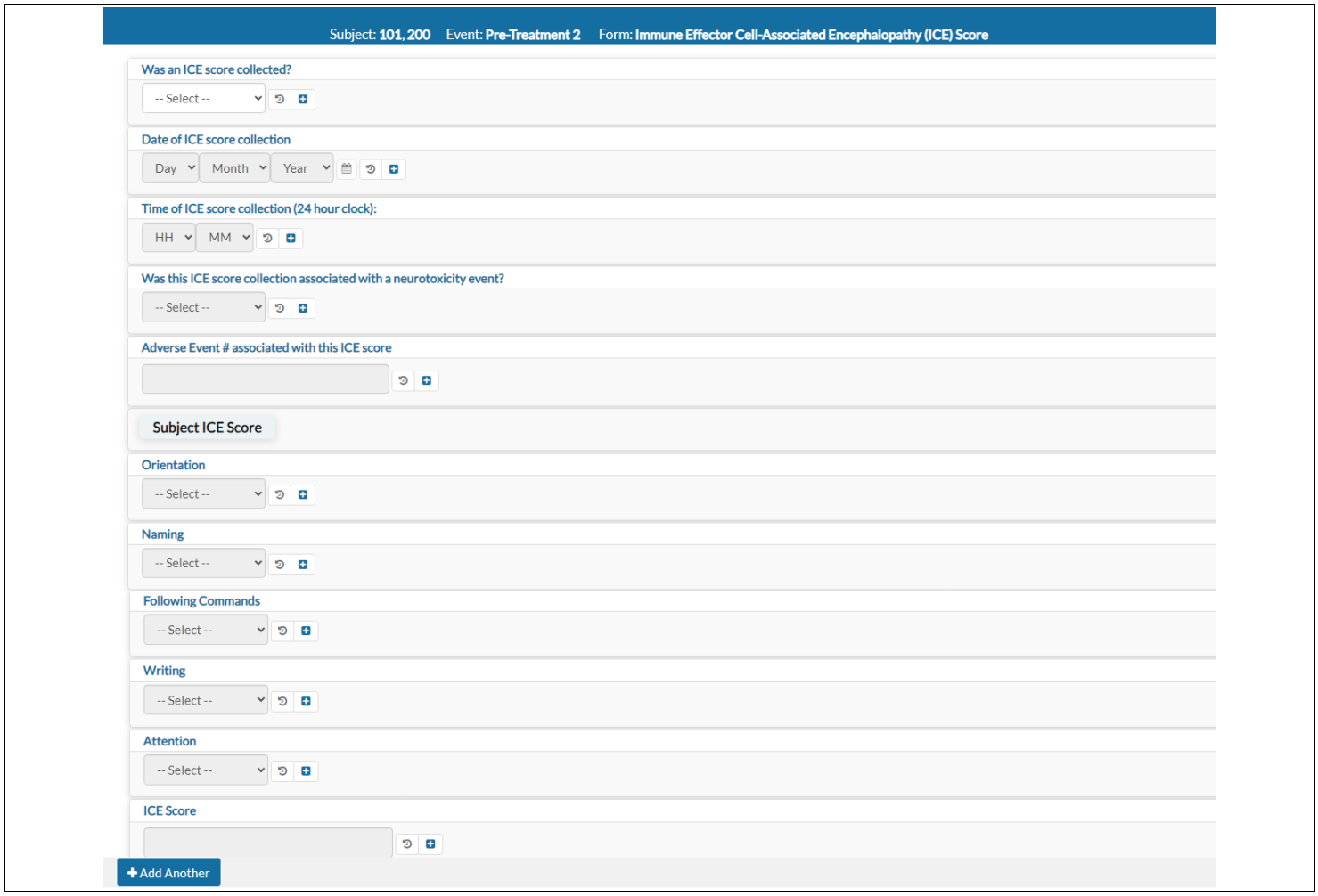
Measured from left to right in mm

Was the Subject's Global Assessment of Arthritis completed at this visit?	Select **No** or **Yes** to indicate if the **Subject's Global Assessment of Arthritis** was completed.
Date of Subject's Global assessment:	Record the **date of Subject's Global assessment** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Was the Subject's Global Assessment of Arthritis completed at this visit?**" is "**Yes**"*
Subject's Global Assessment (mm)	Record the **Subject's Global Assessment** in **millimeter (mm)** in the field provided. Note: *This field is only enabled if "**Was the Subject's Global Assessment of Arthritis completed at this visit?**" is "**Yes**"*

VISUAL ANALOG SCALE (VAS) (CONTINUED)

Was the Subject's Assessment of Arthritis Pain completed at this visit?	Select **No** or **Yes** to indicate if the **Subject's Assessment of Arthritis Pain** was completed.
Date of Subject's Pain assessment:	Record the **date of Subject's Pain assessment** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Was the Subject's Assessment of Arthritis Pain completed at this visit?**" is "**Yes**"*
Subject's Pain Assessment (mm)	Record the **Subject's Pain Assessment** in **millimeter (mm)** in the field provided. Note: *This field is only enabled if "**Was the Subject's Assessment of Arthritis Pain completed at this visit?**" is "**Yes**"*
Was Physician's Global Assessment of Arthritis completed at this visit?	Select **No** or **Yes** to indicate if the **Physician's Global Assessment of Arthritis** was completed.
Date of Physician's Assessment:	Record the **date of Physician's Assessment** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Was Physician's Global Assessment of Arthritis completed at this visit?**" is "**Yes**"*
Physician's Global Assessment (mm)	Record the **Physician's Global Assessment** in **millimeter (mm)** in the field provided. Note: *This field is only enabled if "**Was Physician's Global Assessment of Arthritis completed at this visit?**" is "**Yes**"*

IMMUNE EFFECTOR CELL-ASSOCIATED ENCEPHALOPATHY (ICE) SCORE



Was an ICE score collected?	Select **No** or **Yes** to indicate if the **ICE score** was collected.
Date of ICE score collection	Record the **date of ICE score collection** in the **DD/MMM/YYYY** format. A complete date is required.
Time of ICE score collection (24 hour clock):	Record the **time of ICE score collection** performed in the **HH:MM 24-hour clock** format.
Was this ICE score collection associated with a neurotoxicity event?	Select **No** or **Yes** to indicate if this **ICE score collection was associated with a neurotoxicity event**.
Adverse Event # associated with this ICE score	Record the **Adverse Event # associated with this ICE score** in the field provided.

IMMUNE EFFECTOR CELL-ASSOCIATED ENCEPHALOPATHY (ICE) SCORE (CONTINUED)

Subject ICE Score

Orientation

Select the score for **orientation** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **4**

Note: *This field is visible at **all** visits including **Unscheduled** visits **except W1D1** visit*

Naming

Select the score for **naming** from the drop-down list:

- **0**
- **1**
- **2**
- **3**

Note: *This field is visible at **all** visits including **Unscheduled** visits **except W1D1** visit*

Following Commands

Select the score for **following commands** from the drop-down list:

- **0**
- **1**

Note: *This field is visible at **all** visits including **Unscheduled** visits **except W1D1** visit*

Writing

Select the score for **writing** from the drop-down list:

- **0**
- **1**

Note: *This field is visible at **all** visits including **Unscheduled** visits **except W1D1** visit*

Attention

Select the score for **attention** from the drop-down list:

- **0**
- **1**

Note: *This field is visible at **all** visits including **Unscheduled** visits **except W1D1** visit*

ICE Score

Record the numeric **ICE score** in the field provided.

Note: *This field is visible at **all** visits including **Unscheduled** visits **except W1D1** visit*

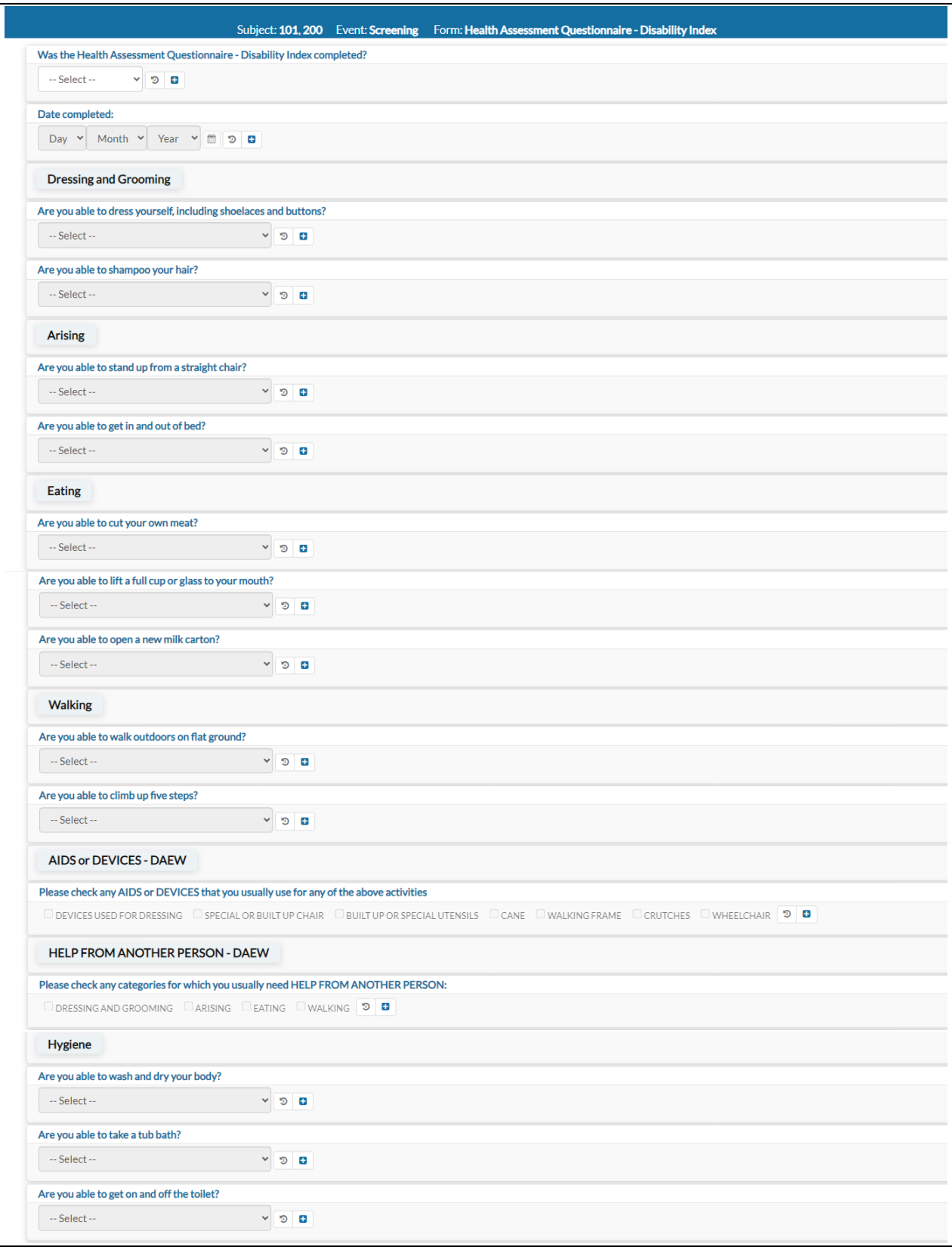
IMMUNE EFFECTOR CELL-ASSOCIATED ENCEPHALOPATHY (ICE) SCORE (CONTINUED)

*The below are only visible at **W1D1** visit and will be enabled for completion if "**Timepoint not done**" field is NOT selected for the following timepoints:*

- ***Pre-dose***
- ***4 hours post-infusion***
- ***8 hours post-infusion***
- ***12 hours post-infusion***
- ***16 hours post-infusion***
- ***20 hours post-infusion***
- ***24 hours post-infusion***

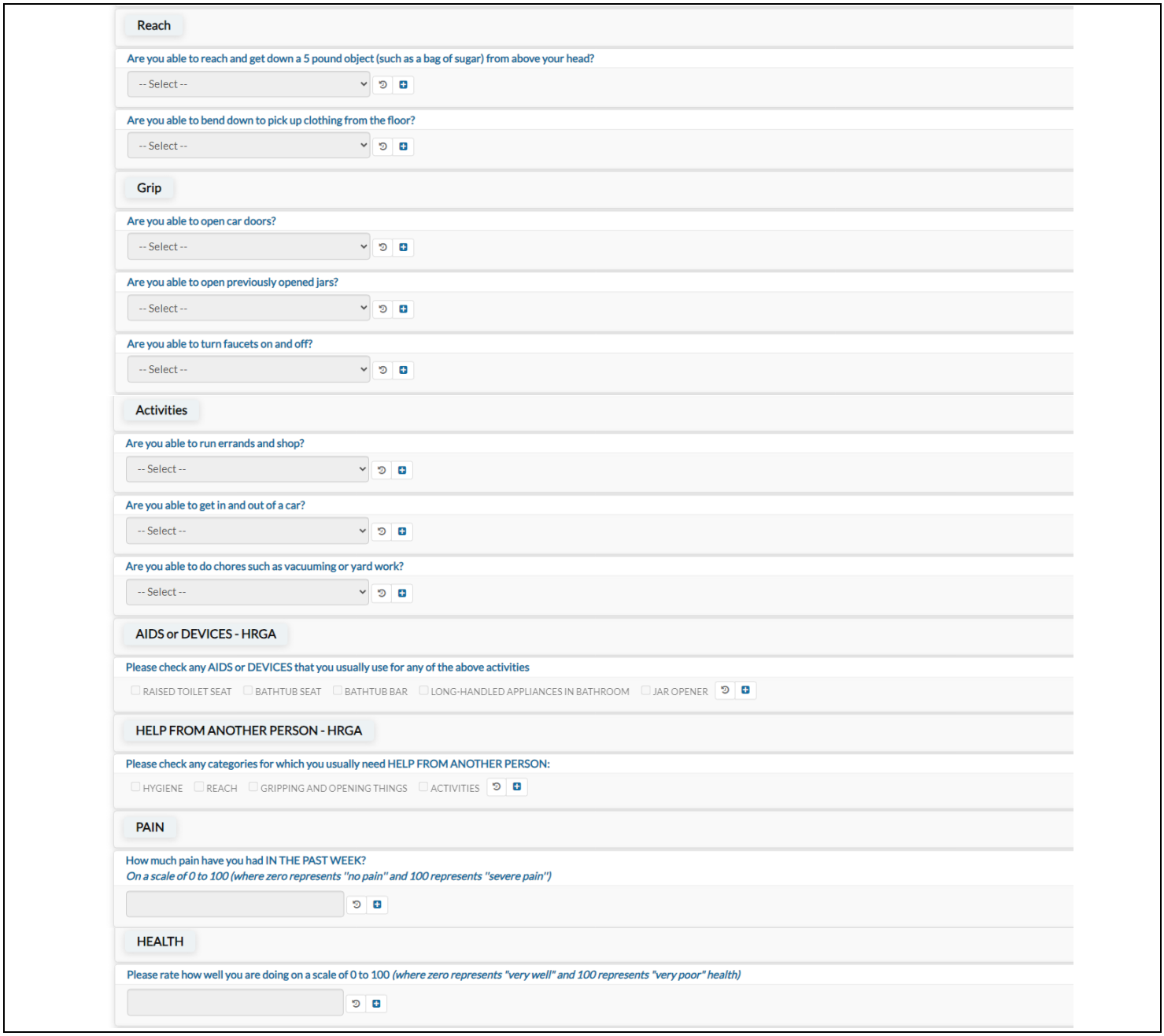
Date of ICE score collection	Record the **date of ICE score collection** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only visible at the following timepoints: **8 hours post-infusion**, **12 hours post-infusion**, **16 hours post-infusion**, **20 hours post-infusion**, **24 hours post-infusion***
Time of ICE score collection (24 hour clock):	Record the **time of ICE score collection** performed in the **HH:MM 24-hour clock** format. Note: *This field is visible at **all** timepoints **except Pre-dose** timepoint*
Orientation	Select the score for **orientation** from the drop-down list: • **0** • **1** • **2** • **3** • **4**
Naming	Select the score for **naming** from the drop-down list: • **0** • **1** • **2** • **3**
Following Commands	Select the score for **following commands** from the drop-down list: • **0** • **1**
Writing	Select the score for **writing** from the drop-down list: • **0** • **1**
Attention	Select the score for **attention** from the drop-down list: • **0** • **1**
ICE Score	Record the numeric **ICE score** in the field provided.

HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX

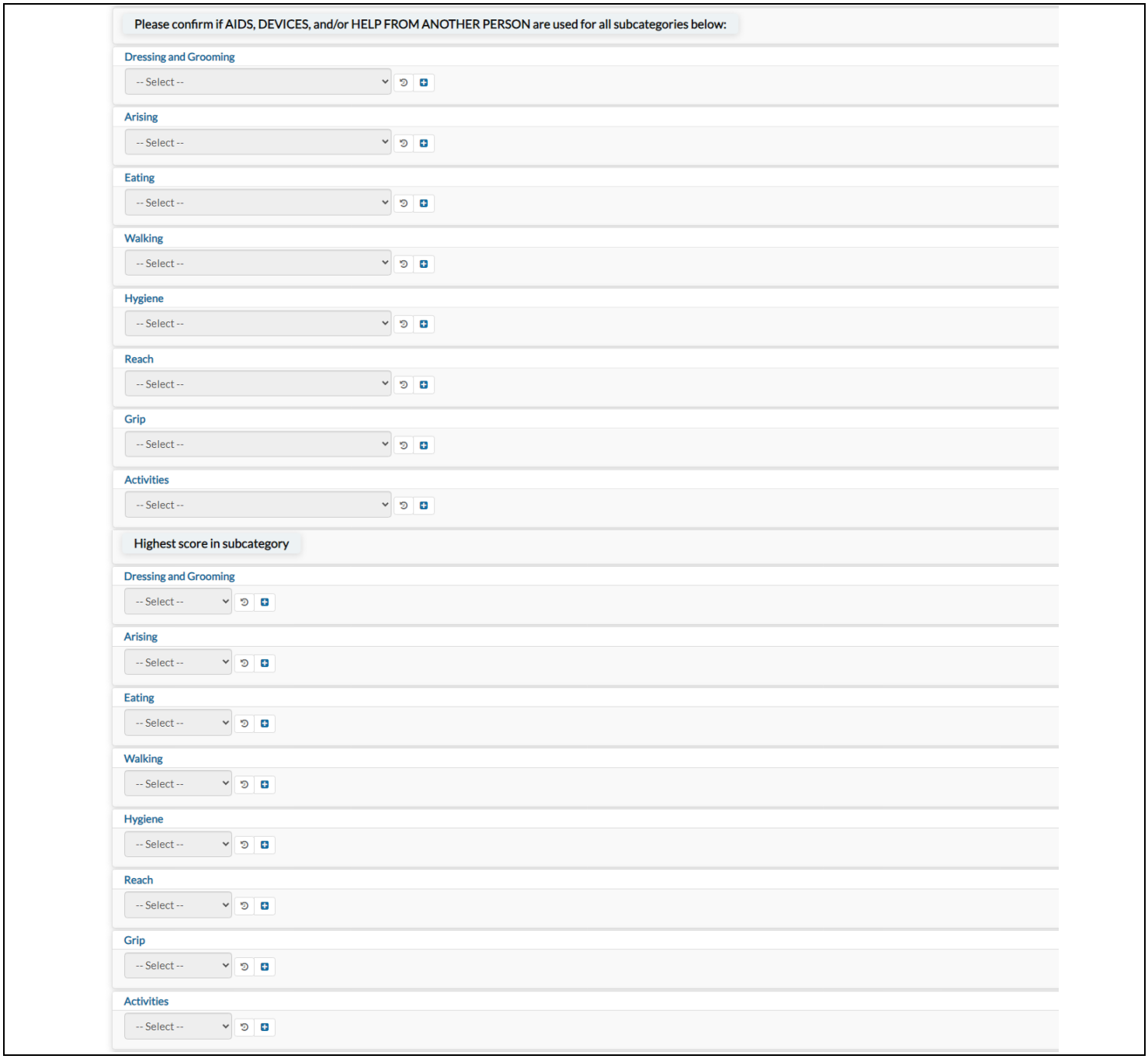


The first portion of the Health Assessment Questionnaire – Disability Index eCRF is shown here. See subsequent parts on the following page(s).

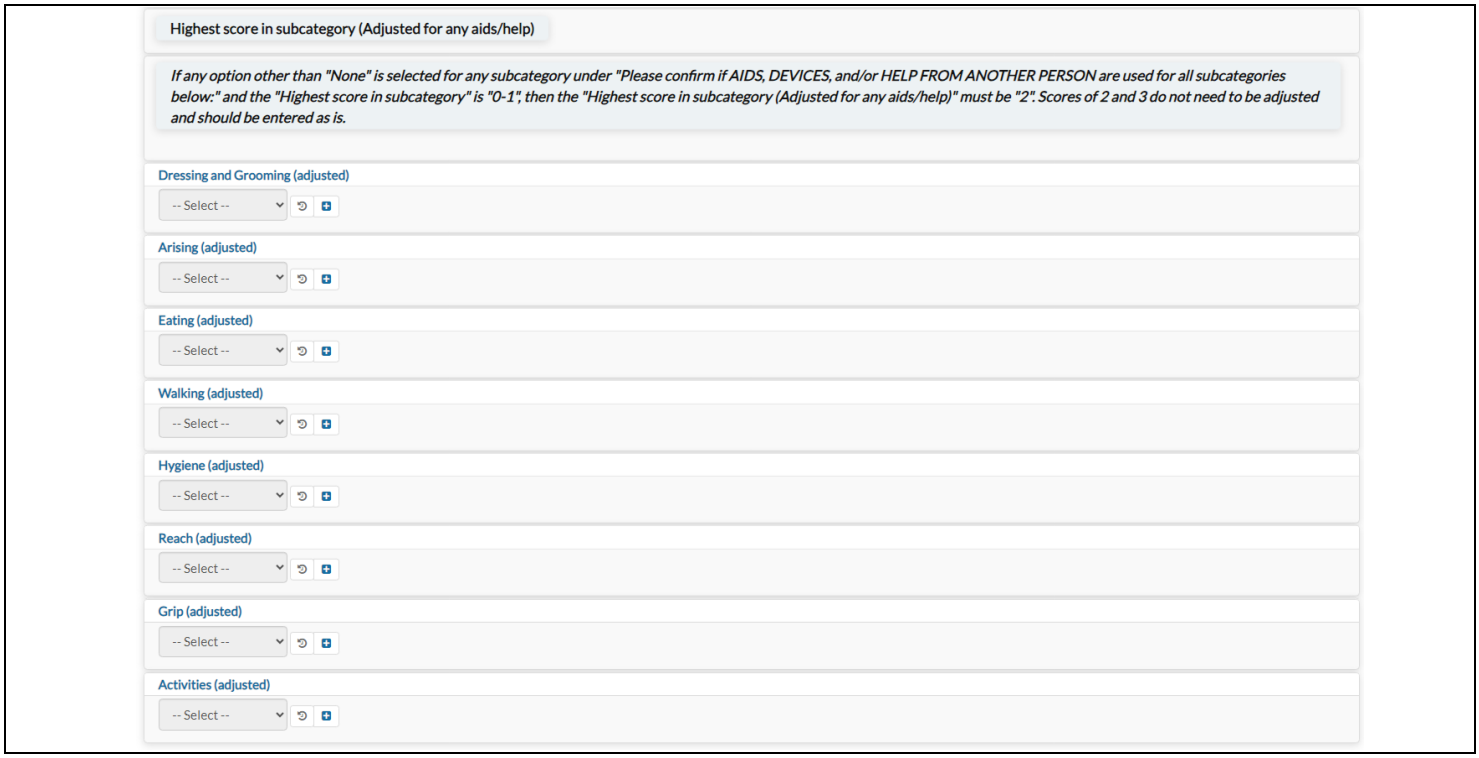
HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)



HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)



HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)



HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)

Was the Health Assessment Questionnaire - Disability Index completed?	Select **No** or **Yes** to indicate if the **Health Assessment Questionnaire - Disability Index** was completed.
Date completed:	Record the **date completed** in the **DD/MMM/YYYY** format. A complete date is required.
	Dressing and Grooming
Are you able to dress yourself, including shoelaces and buttons?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
Are you able to shampoo your hair?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
	Arising
Are you able to stand up from a straight chair?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
Are you able to get in and out of bed?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
	Eating
Are you able to cut your own meat?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
Are you able to lift a full cup or glass to your mouth?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
Are you able to open a new milk carton?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**

HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)

Walking

Are you able to walk outdoors on flat ground?

Select the **score** from the drop-down list:

- **Without Any Difficulty – 0**
- **With Some Difficulty – 1**
- **With Much Difficulty – 2**
- **Unable to Do – 3**

Are you able to climb up five steps?

Select the **score** from the drop-down list:

- **Without Any Difficulty – 0**
- **With Some Difficulty – 1**
- **With Much Difficulty – 2**
- **Unable to Do – 3**

AIDS or DEVICES - DAEW

Please check any AIDS or DEVICES that you usually use for any of the above activities

Select all applicable box(es) regarding **AIDS or DEVICES that are usually used for any of the above activities** from the drop-down list:

- **Devices used for dressing**
- **Special or built up chair**
- **Built up or special utensils**
- **Cane**
- **Walking Frame**
- **Crutches**
- **Wheelchair**

HELP FROM ANOTHER PERSON - DAEW

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

Select all applicable box(es) regarding **help from another person** from the drop-down list:

- **Dressing and grooming**
- **Arising**
- **Eating**
- **Walking**

Hygiene

Are you able to wash and dry your body?

Select the **score** from the drop-down list:

- **Without Any Difficulty – 0**
- **With Some Difficulty – 1**
- **With Much Difficulty – 2**
- **Unable to Do – 3**

Are you able to take a tub bath?

Select the **score** from the drop-down list:

- **Without Any Difficulty – 0**
- **With Some Difficulty – 1**
- **With Much Difficulty – 2**
- **Unable to Do – 3**

Are you able to get on and off the toilet?

Select the **score** from the drop-down list:

- **Without Any Difficulty – 0**
- **With Some Difficulty – 1**
- **With Much Difficulty – 2**
- **Unable to Do – 3**

HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)

Reach

Are you able to reach and get down a 5 pound object (such as a bag of sugar) from above your head?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
Are you able to bend down to pick up clothing from the floor?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**

Grip

Are you able to open car doors?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
Are you able to open previously opened jars?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
Are you able to turn faucets on and off?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**

Activities

Are you able to run errands and shop?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
Are you able to get in and out of a car?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**
Are you able to do chores such as vacuuming or yard work?	Select the **score** from the drop-down list: • **Without Any Difficulty – 0** • **With Some Difficulty – 1** • **With Much Difficulty – 2** • **Unable to Do – 3**

HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)

AIDS or DEVICES - HRGA

Please check any AIDS or DEVICES that you usually use for any of the above activities	Select all applicable box(es) regarding **AIDS or DEVICES that are usually used for any of the above activities** from the drop-down list: • **Raised toilet seat** • **Bathtub seat** • **Bathtub bar** • **Long-handled appliances in bathroom** • **Jar opener**

HELP FROM ANOTHER PERSON - HRGA

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:	Select all applicable box(es) regarding **help from another person** from the drop-down list: • **Hygiene** • **Reach** • **Gripping and opening things** • **Activities**

PAIN

How much pain have you had IN THE PAST WEEK? ***On a scale of 0 to 100 (where zero represents "no pain" and 100 represents "severe pain")***	Record the numeric **score regarding how much pain the subject had in the past week**.

HEALTH

Please rate how well you are doing on a scale of 0 to 100 (where zero represents "very well" and 100 represents "very poor" health)	Record the numeric **score regarding how well the subject is doing**.

HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)

Please confirm if AIDS, DEVICES, and/or HELP FROM ANOTHER PERSON are used for all subcategories below:

Dressing and Grooming

Select the **option** from the drop-down list:

- **None**
- **Aids or Devices only**
- **Help from another person only**
- **Both**

Arising

Select the **option** from the drop-down list:

- **None**
- **Aids or Devices only**
- **Help from another person only**
- **Both**

Eating

Select the **option** from the drop-down list:

- **None**
- **Aids or Devices only**
- **Help from another person only**
- **Both**

Walking

Select the **option** from the drop-down list:

- **None**
- **Aids or Devices only**
- **Help from another person only**
- **Both**

Hygiene

Select the **option** from the drop-down list:

- **None**
- **Aids or Devices only**
- **Help from another person only**
- **Both**

Reach

Select the **option** from the drop-down list:

- **None**
- **Aids or Devices only**
- **Help from another person only**
- **Both**

Grip

Select the **option** from the drop-down list:

- **None**
- **Aids or Devices only**
- **Help from another person only**
- **Both**

Activities

Select the **option** from the drop-down list:

- **None**
- **Aids or Devices only**
- **Help from another person only**
- **Both**

HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)

Highest score in subcategory

Dressing and Grooming

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Arising

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Eating

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Walking

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Hygiene

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Reach

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Grip

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Activities

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX (CONTINUED)

Highest score in subcategory (Adjusted for any aids/help)

If any option other than "None" is selected for any subcategory under "Please confirm if AIDS, DEVICES, and/or HELP FROM ANOTHER PERSON are used for all subcategories below:" and the "Highest score in subcategory" is "0-1", then the "Highest score in subcategory (Adjusted for any aids/help)" must be "2". Scores of 2 and 3 do not need to be adjusted and should be entered as is.

Dressing and Grooming (adjusted)

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Arising (adjusted)

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Eating (adjusted)

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Walking (adjusted)

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Hygiene (adjusted)

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Reach (adjusted)

Select the **option** from the drop-down list:

- **0**
- **1**
- **2**
- **3**
- **Not Done**

Grip (adjusted)

Select the **option** from the drop-down list:

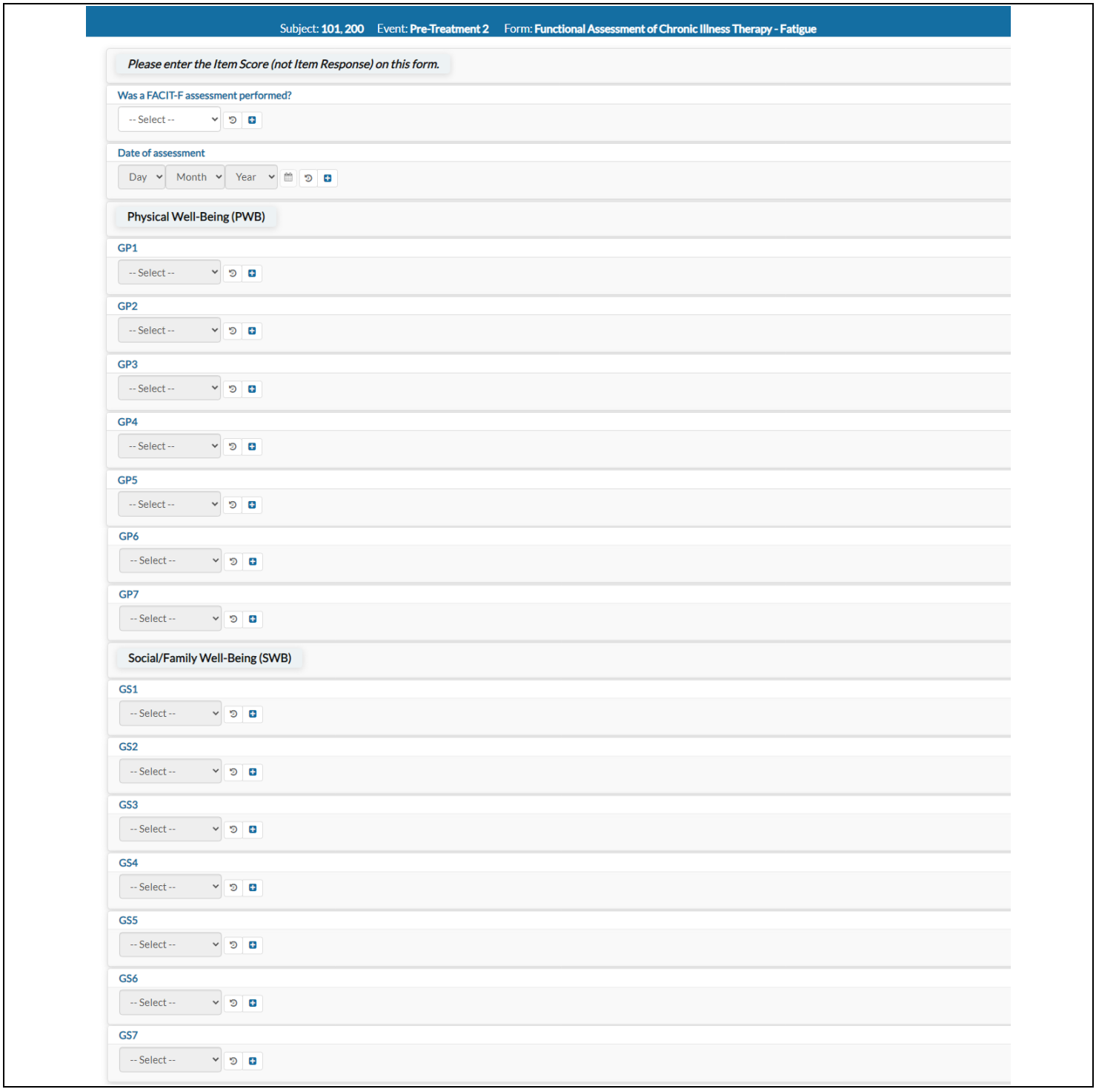
- **0**
- **1**
- **2**
- **3**
- **Not Done**

Activities (adjusted)

Select the **option** from the drop-down list:

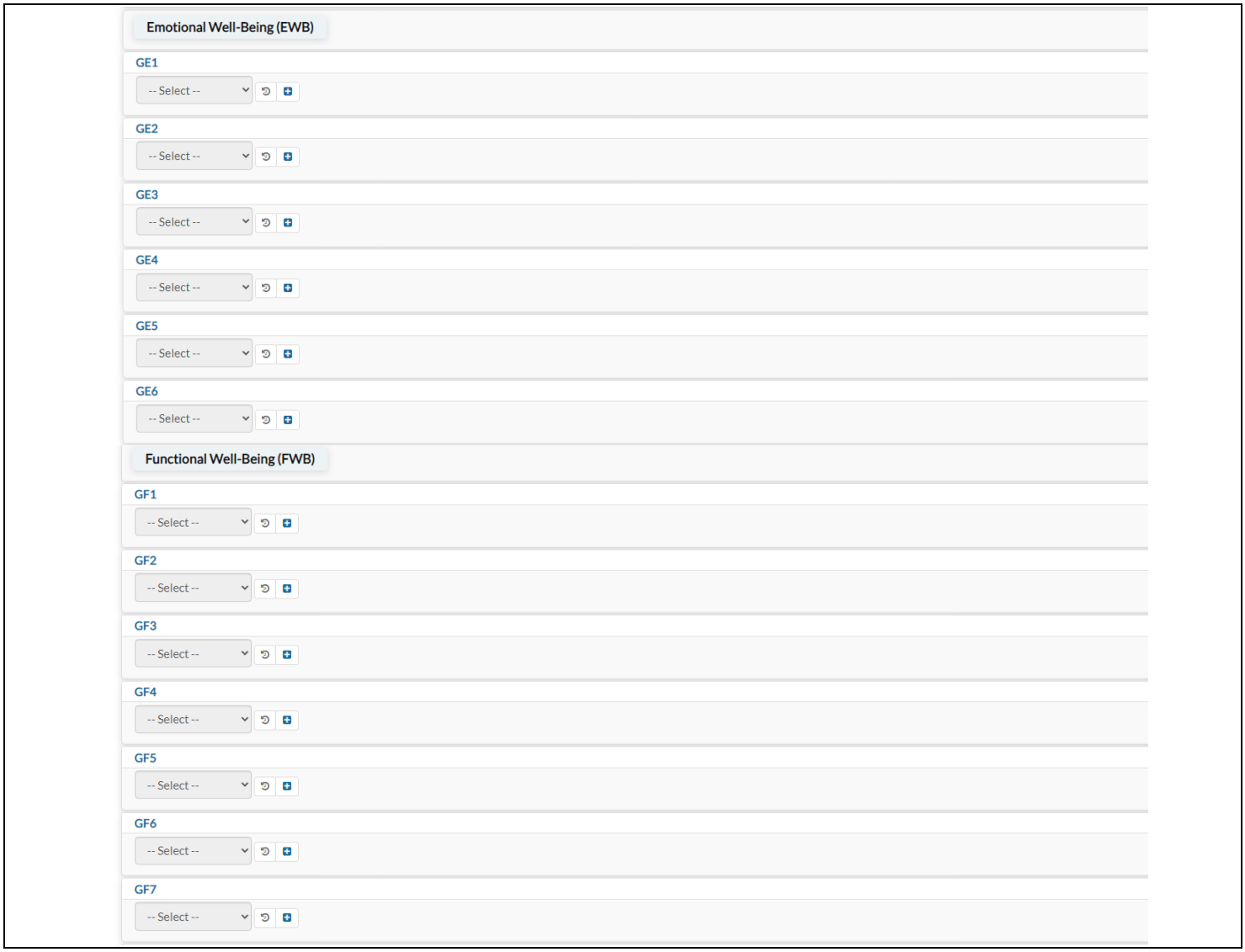
- **0**
- **1**
- **2**
- **3**
- **Not Done**

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE

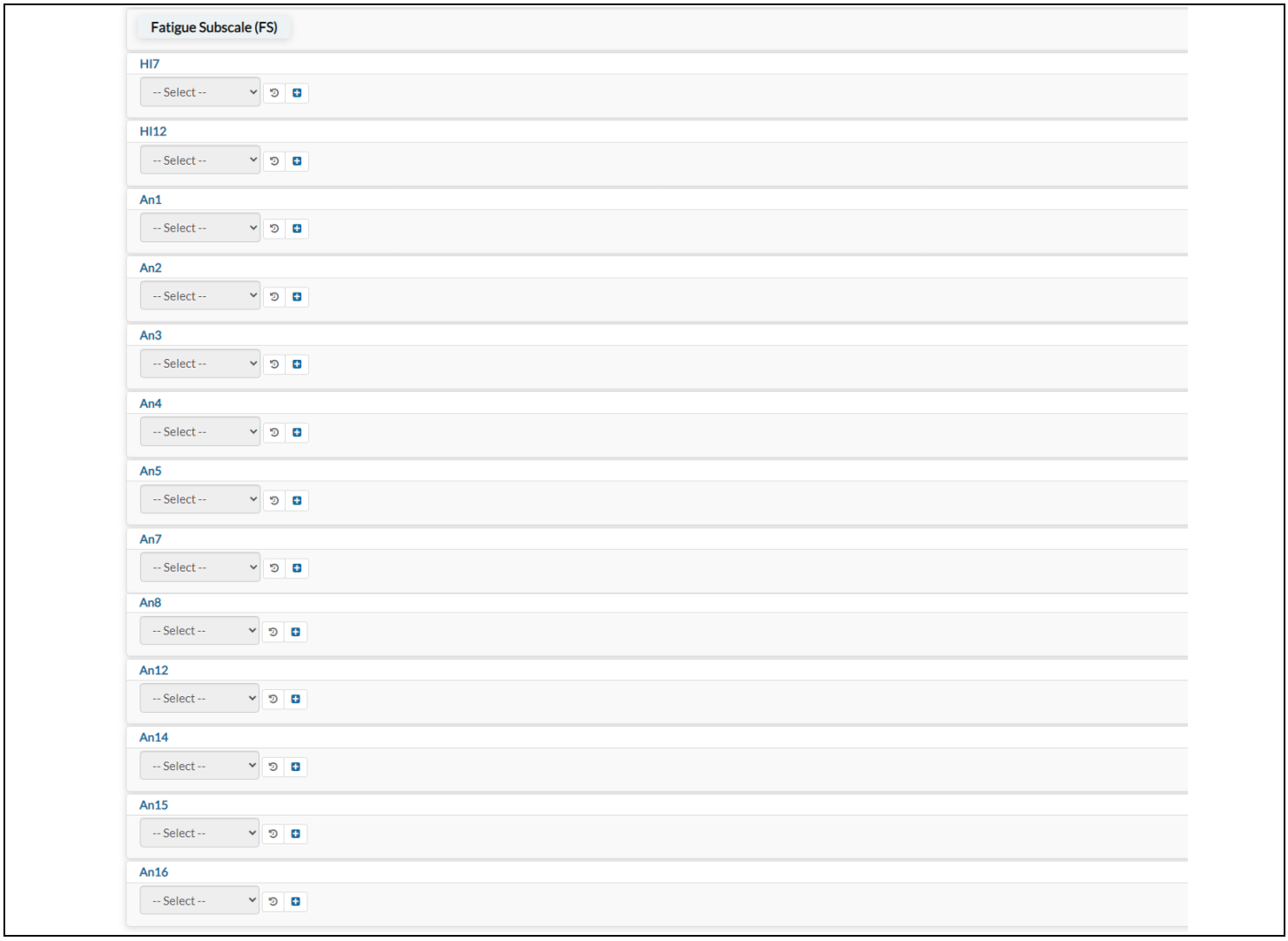


The first portion of the Functional Assessment of Chronic Illness Therapy – Fatigue eCRF is shown here. See subsequent parts on the following page(s).

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)



FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)



FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)

Please enter the Item Score (not Item Response) on this form.

Was a FACIT-F assessment performed?	Select **No** or **Yes** to indicate if the **FACIT-F assessment** was performed.
Date of assessment	Record the **date of assessment** in the **DD/MMM/YYYY** format. A complete date is required.

Physical Well-Being (PWB)

GP1	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GP2	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GP3	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GP4	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GP5	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GP6	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GP7	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)

Social/Family Well-Being (SWB)

GS1	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GS2	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GS3	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GS4	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GS5	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GS6	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GS7	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)

Emotional Well-Being (EWB)

GE1	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GE2	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GE3	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GE4	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GE5	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GE6	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)

Functional Well-Being (FWB)

GF1	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GF2	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GF3	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GF4	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GF5	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GF6	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
GF7	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)

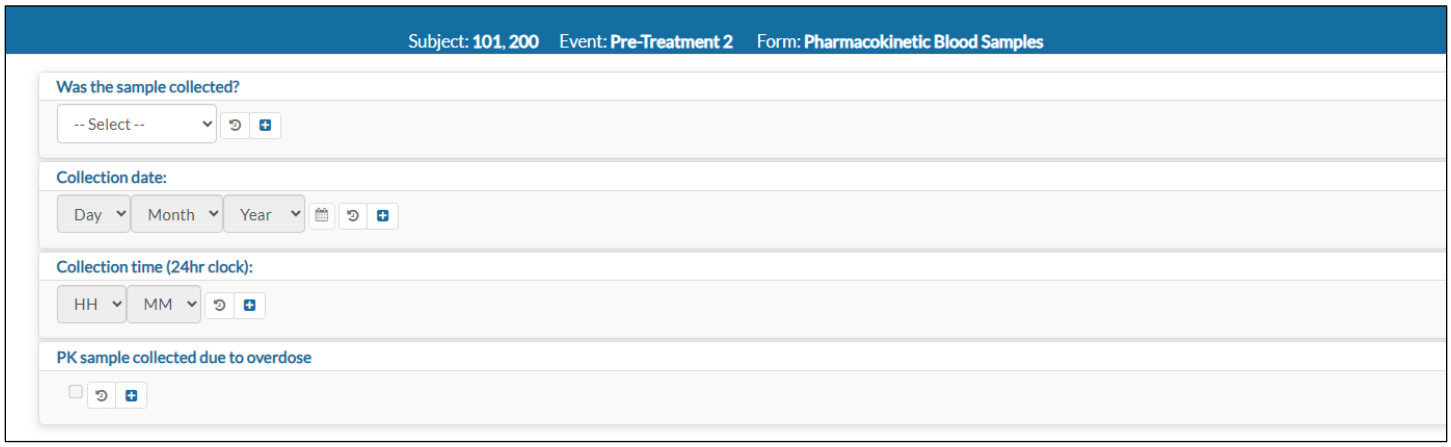
Fatigue Subscale (FS)

HI7	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
HI12	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An1	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An2	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An3	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An4	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An5	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An7	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An8	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)

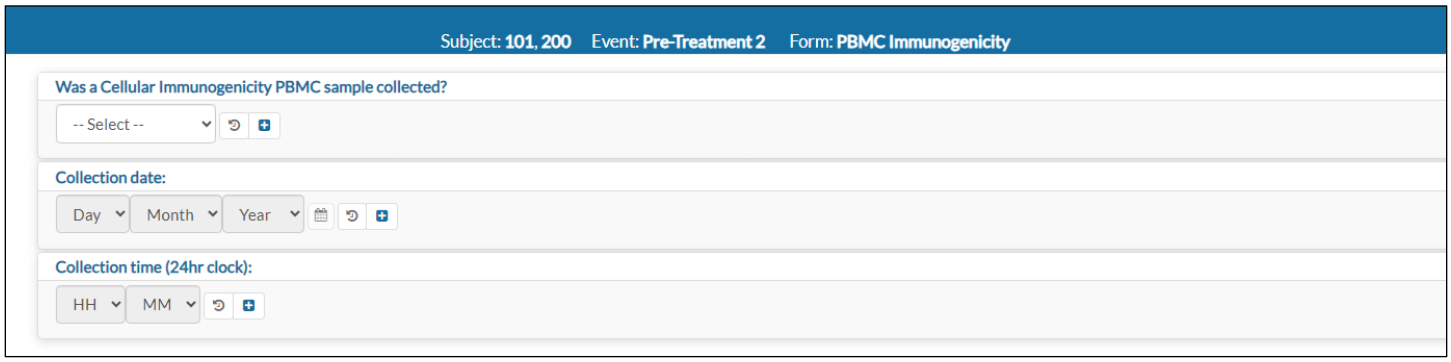
An12	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An14	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An15	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**
An16	Select the **option** from the drop-down list: • **0** • **2** • **4** • **1** • **3** • **Not Done**

PHARMACOKINETIC BLOOD SAMPLES



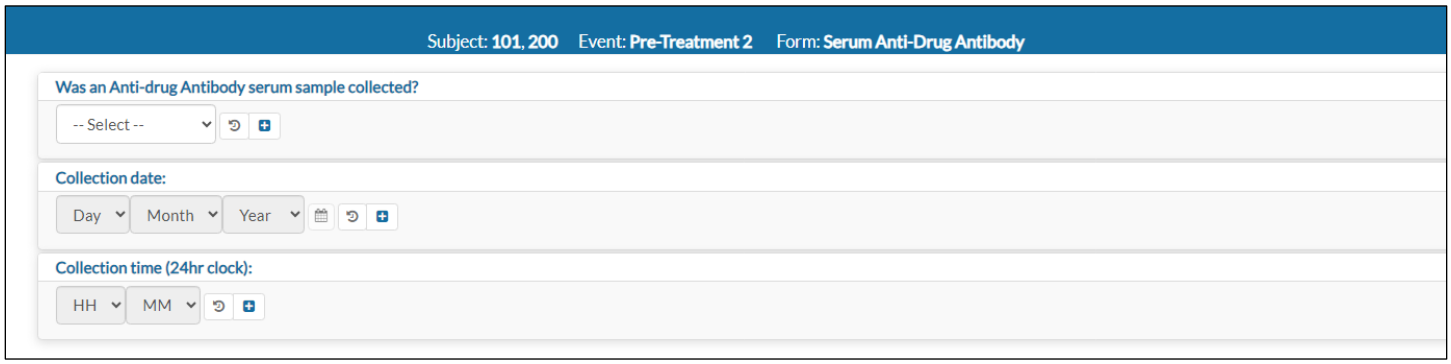
Was the sample collected?	Select **No** or **Yes** to indicate if the **sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.
PK sample collected due to overdose	Check the box if the **PK sample collected due to overdose**.

PBMC IMMUNOGENICITY



Was a Cellular Immunogenicity PBMC sample collected?	Select **No** or **Yes** to indicate if the **Cellular Immunogenicity PBMC sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.

SERUM ANTI-DRUG ANTIBODY



Was an Anti-drug Antibody serum sample collected?	Select **No** or **Yes** to indicate if the **Anti-drug Antibody serum sample** was collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.

PLASMA/SERUM EXPLORATORY BIOMARKERS

Was an Exploratory Biomarkers plasma sample collected?

Select **No** or **Yes** to indicate if the **Exploratory Biomarkers plasma sample** was collected.

Collection date:

Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Note: *This field is only enabled if "**Was an Exploratory Biomarkers plasma sample collected?**" is "**Yes**"*

Collection time (24-hour clock):

Record the **collection time** performed in the **HH:MM 24-hour clock** format.
Note: *This field is only enabled if "**Was an Exploratory Biomarkers plasma sample collected?**" is "**Yes**"*

Was an Exploratory Biomarkers serum sample collected?

Select **No** or **Yes** to indicate if the **Exploratory Biomarkers serum sample** was collected.
Note: *This field is visible at **all** visits **except Screening** visit*

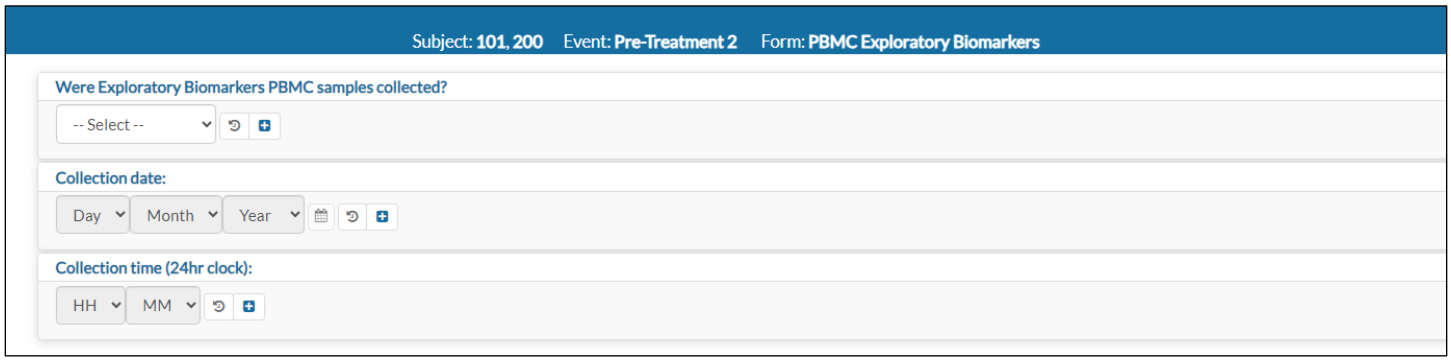
Collection date:

Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Note: *This field is visible at **all** visits **except Screening** visit*
Note: *This field is only enabled if "**Was an Exploratory Biomarkers serum sample collected?**" is "**Yes**"*

Collection time (24-hour clock):

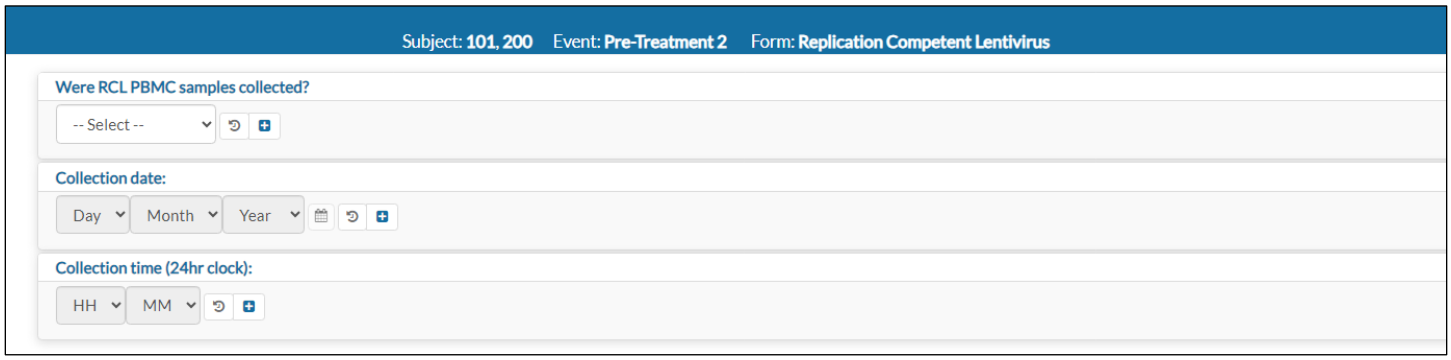
Record the **collection time** performed in the **HH:MM 24-hour clock** format.
Note: *This field is visible at **all** visits **except Screening** visit*
Note: *This field is only enabled if "**Was an Exploratory Biomarkers serum sample collected?**" is "**Yes**"*

PBMC EXPLORATORY BIOMARKERS



Were Exploratory Biomarkers PBMC samples collected?	Select **No** or **Yes** to indicate if the **Exploratory Biomarkers PBMC samples** were collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.

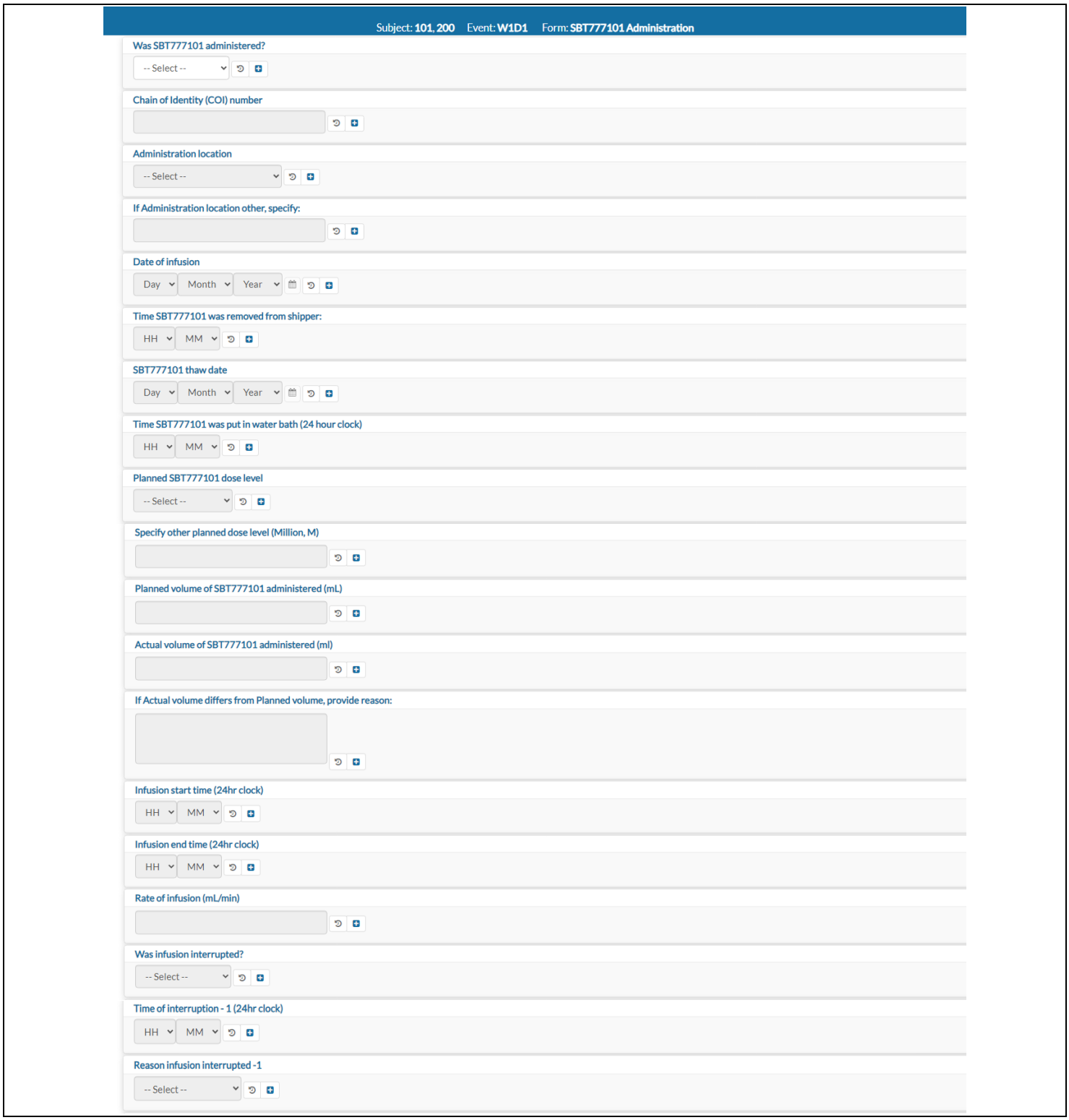
REPLICATION COMPETENT LENTIVIRUS



Were RCL PBMC samples collected?	Select **No** or **Yes** to indicate if the **RCL PBMC samples** were collected.
Collection date:	Record the **collection date** in the **DD/MMM/YYYY** format. A complete date is required.
Collection time (24-hour clock):	Record the **collection time** performed in the **HH:MM 24-hour clock** format.

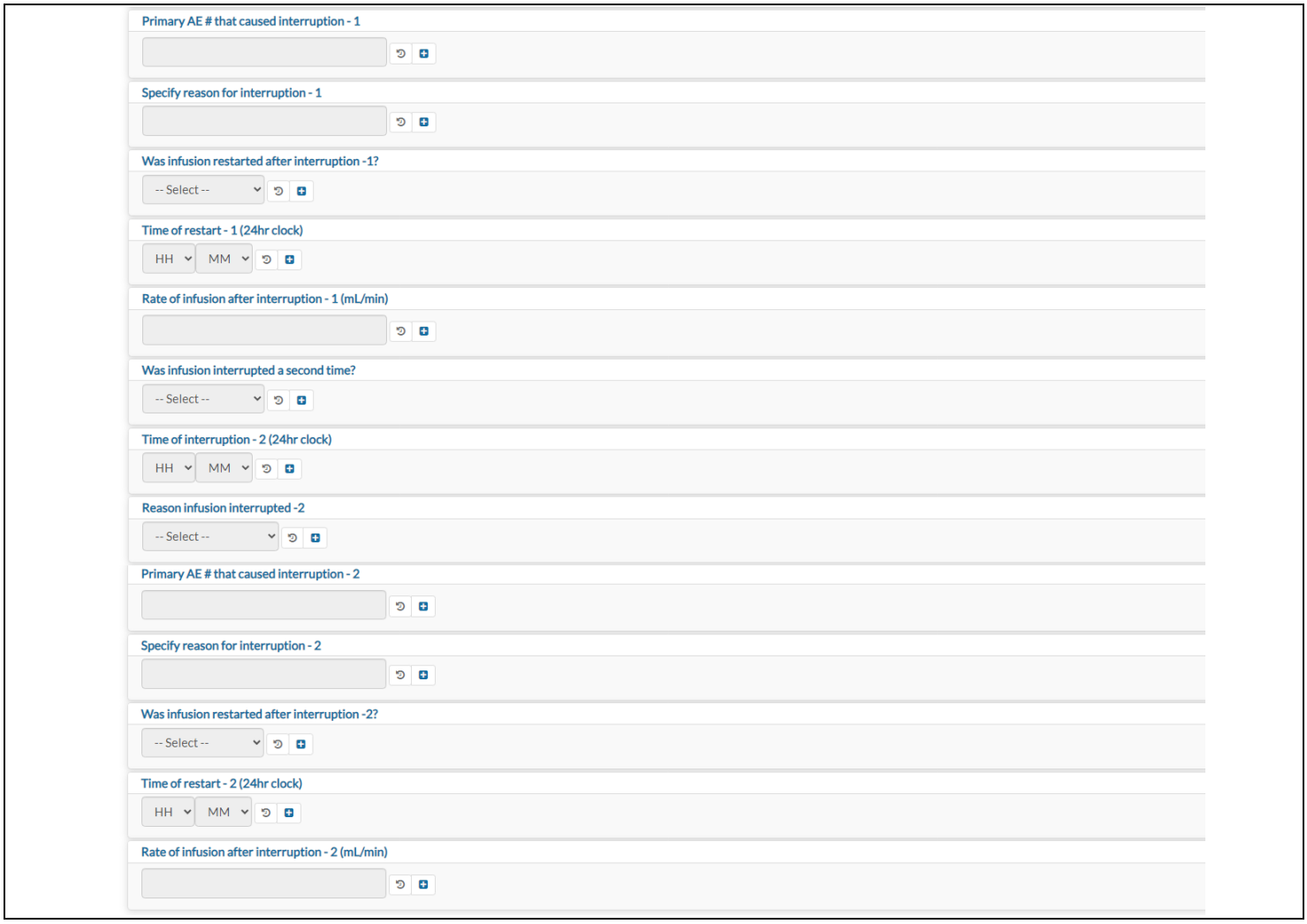
SBT777101 ADMINISTRATION

*SBT777101 Administration eCRF is only available for completion at **W1D1** visit.*



The first portion of the SBT777101 Administration eCRF is shown here. See subsequent parts on the following page(s).

SBT777101 ADMINISTRATION (CONTINUED)



SBT777101 ADMINISTRATION (CONTINUED)

Was SBT777101 administered?	Select **No** or **Yes** to indicate if the **SBT777101** was administered.
Chain of Identity (COI) number	Record the **Chain of Identity (COI) number** in the field provided.
Administration location	Select the **location** of administration from the drop-down list: • **Hand** • **Wrist** • **Antecubital** • **Leg** • **Other** Note: *If "**Other**" is selected, provide a response in the "**If Administration location other, specify:**" field*
Date of infusion	Record the **date of infusion** in the **DD/MMM/YYYY** format. A complete date is required.
Time SBT777101 was removed from shipper:	Record the **time SBT777101 was removed from shipper** in the **HH:MM 24-hour clock** format.
SBT777101 thaw date	Record the **SBT777101 thaw date** in the **DD/MMM/YYYY** format. A complete date is required.
Time SBT777101 was put in water bath (24 hour clock)	Record the **time SBT777101 was put in water bath** in the **HH:MM 24-hour clock** format.
Planned SBT777101 dose level	Select the **planned SBT777101 dose level** in from the drop-down list: • **Dose Level 1** • **Dose Level 2** • **Dose Level 3** • **Other** Note: *If "**Other**" is selected, provide a response in the "**Specify other planned dose level (Million, M)**" field*
Planned volume of SBT777101 administered (mL)	Record the **planned volume of SBT777101 administered** in **milliliter (mL)** in the field provided.
Actual volume of SBT777101 administered (ml)	Record the **actual volume of SBT777101 administered** in **milliliter (mL)** in the field provided.

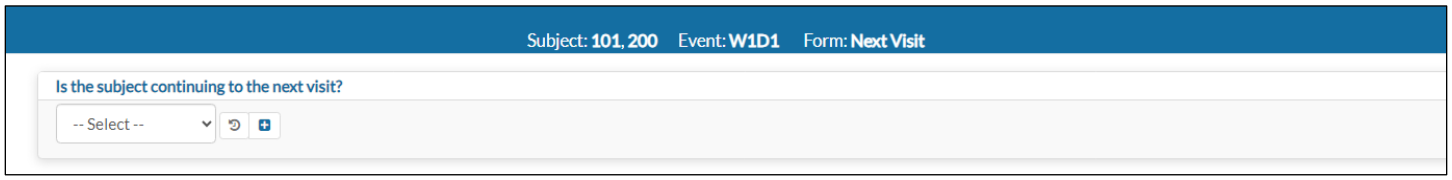
SBT777101 ADMINISTRATION (CONTINUED)

If Actual volume differs from Planned volume, provide reason:	Provide the **reason** actual volume differs from planned volume in the field provided.
Infusion start time (24hr clock)	Record the **infusion start time** in the **HH:MM 24-hour clock** format.
Infusion end time (24hr clock)	Record the **infusion end time** in the **HH:MM 24-hour clock** format.
Rate of infusion (mL/min)	Record the **rate of infusion** in **mL/min** in the field provided.
Was infusion interrupted?	Select **No** or **Yes** to indicate if the **infusion** was interrupted.
Time of interruption - 1 (24hr clock)	Record the **time of interruption - 1** in the **HH:MM 24-hour clock** format. Note: *This field is only enabled if "**Was infusion interrupted?**" is "**Yes**"*
Reason infusion interrupted -1	Select the **reason infusion interrupted -1** from the dropdown list: • **ADVERSE EVENT** • **OTHER** Note: *This field is only enabled if "**Was infusion interrupted?**" is "**Yes**"* Note: *If "**Adverse Event**" is selected, provide an Adverse Event number in the "**Primary AE # that caused interruption - 1**" field* Note: *If "**Other**" is selected, specify the reason in the "**Specify reason for interruption - 1**" field*
Was infusion restarted after interruption -1?	Select **No** or **Yes** to indicate if the **infusion** was restarted after interruption -1. Note: *This field is only enabled if "**Was infusion interrupted?**" is "**Yes**"*
Time of restart - 1 (24hr clock)	Record the **time of restart - 1** in the **HH:MM 24-hour clock** format. Note: *This field is only enabled if "**Was infusion restarted after interruption -1?**" is "**Yes**"*
Rate of infusion after interruption - 1 (mL/min)	Record the **rate of infusion after interruption - 1** in **mL/min** in the field provided. Note: *This field is only enabled if "**Was infusion restarted after interruption -1?**" is "**Yes**"*

SBT777101 ADMINISTRATION (CONTINUED)

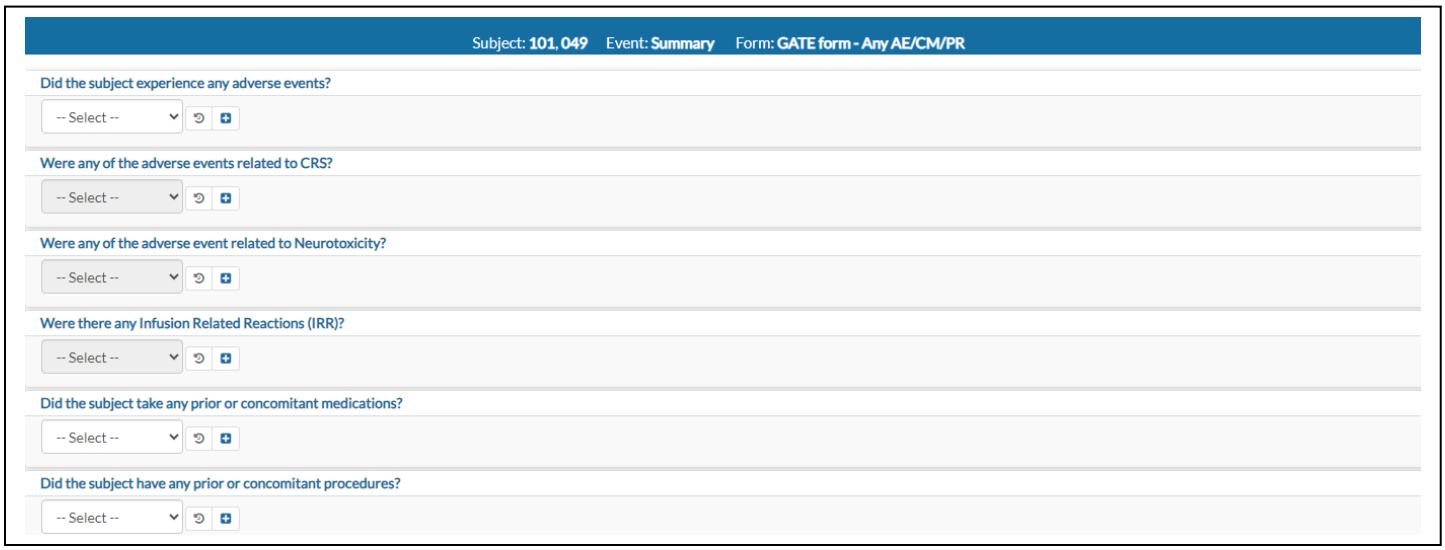
Was infusion interrupted a second time?	Select **No** or **Yes** to indicate if the **infusion** was interrupted a second time.
Time of interruption - 2 (24hr clock)	Record the **time of interruption - 2** in the **HH:MM 24-hour clock** format. Note: *This field is only enabled if "**Was infusion interrupted a second time?**" is "**Yes**"*
Reason infusion interrupted -2	Select the **reason infusion interrupted -2** from the dropdown list: • **ADVERSE EVENT** • **OTHER** Note: *This field is only enabled if "**Was infusion interrupted a second time?**" is "**Yes**"* Note: *If "**Adverse Event**" is selected, provide an Adverse Event number in the "**Primary AE # that caused interruption - 2**" field* Note: *If "**Other**" is selected, specify the reason in the "**Specify reason for interruption - 2**" field*
Was infusion restarted after interruption -2?	Select **No** or **Yes** to indicate if the **infusion** was restarted after interruption -2. Note: *This field is only enabled if "**Was infusion interrupted a second time?**" is "**Yes**"*
Time of restart - 2 (24hr clock)	Record the **time of restart - 2** in the **HH:MM 24-hour clock** format. Note: *This field is only enabled if "**Was infusion restarted after interruption -2?**" is "**Yes**"*
Rate of infusion after interruption - 2 (mL/min)	Record the **rate of infusion after interruption - 2** in **mL/min** in the field provided. Note: *This field is only enabled if "**Was infusion restarted after interruption -2?**" is "**Yes**"*

NEXT VISIT



Is the subject continuing to the next visit?	Select **No** or **Yes** to indicate if the **subject is continuing to the next visit**.

GATE FORM – ANY AE/CM/PR



Did the subject experience any adverse events?

Select **No** or **Yes**.

- If "**Yes**" is selected, an **Adverse Events** eCRF will appear for completion.

Were any of the adverse events related to CRS?

Select **No** or **Yes**.

- If "**Yes**" is selected, a **CRS Signs and Symptoms** eCRF will appear for completion.

Note: *This field is only enabled if "**Did the subject experience any adverse events?**" is "**Yes**"*

Were any of the adverse event related to Neurotoxicity?

Select **No** or **Yes**.

- If "**Yes**" is selected, a **Neurotoxicity Signs and Symptoms** eCRF will appear for completion.

Note: *This field is only enabled if "**Did the subject experience any adverse events?**" is "**Yes**"*

Were there any Infusion Related Reactions (IRR)?

Select **No** or **Yes**.

- If "**Yes**" is selected, a **Infusion Related Reactions** eCRF will appear for completion.

Note: *This field is only enabled if "**Did the subject experience any adverse events?**" is "**Yes**"*

Did the subject take any prior or concomitant medications?

Select **No** or **Yes**.

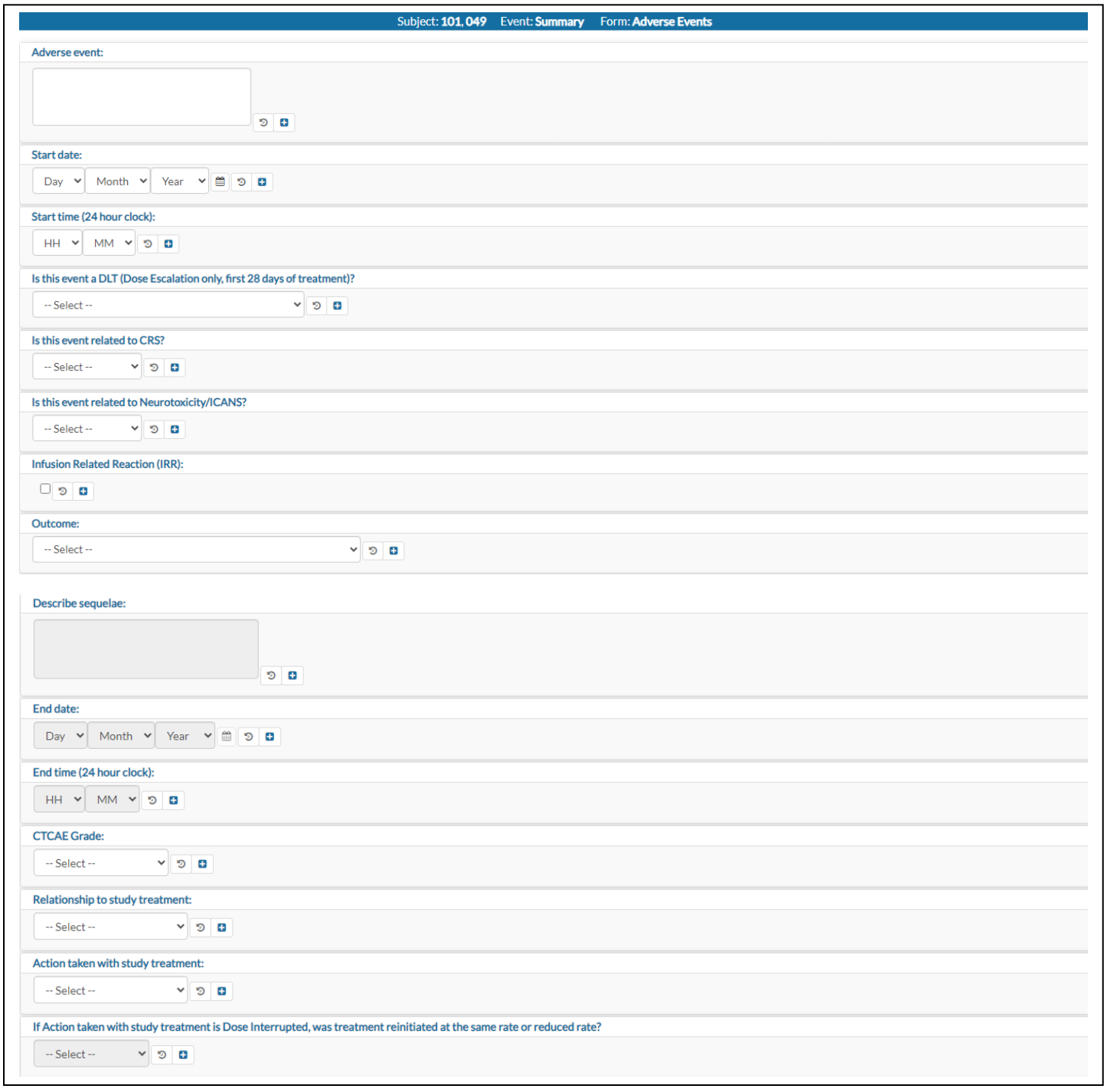
- If "**Yes**" is selected, a **Prior & Concomitant Treatments/Medications** eCRF will appear for completion.

Did the subject have any prior or concomitant procedures?

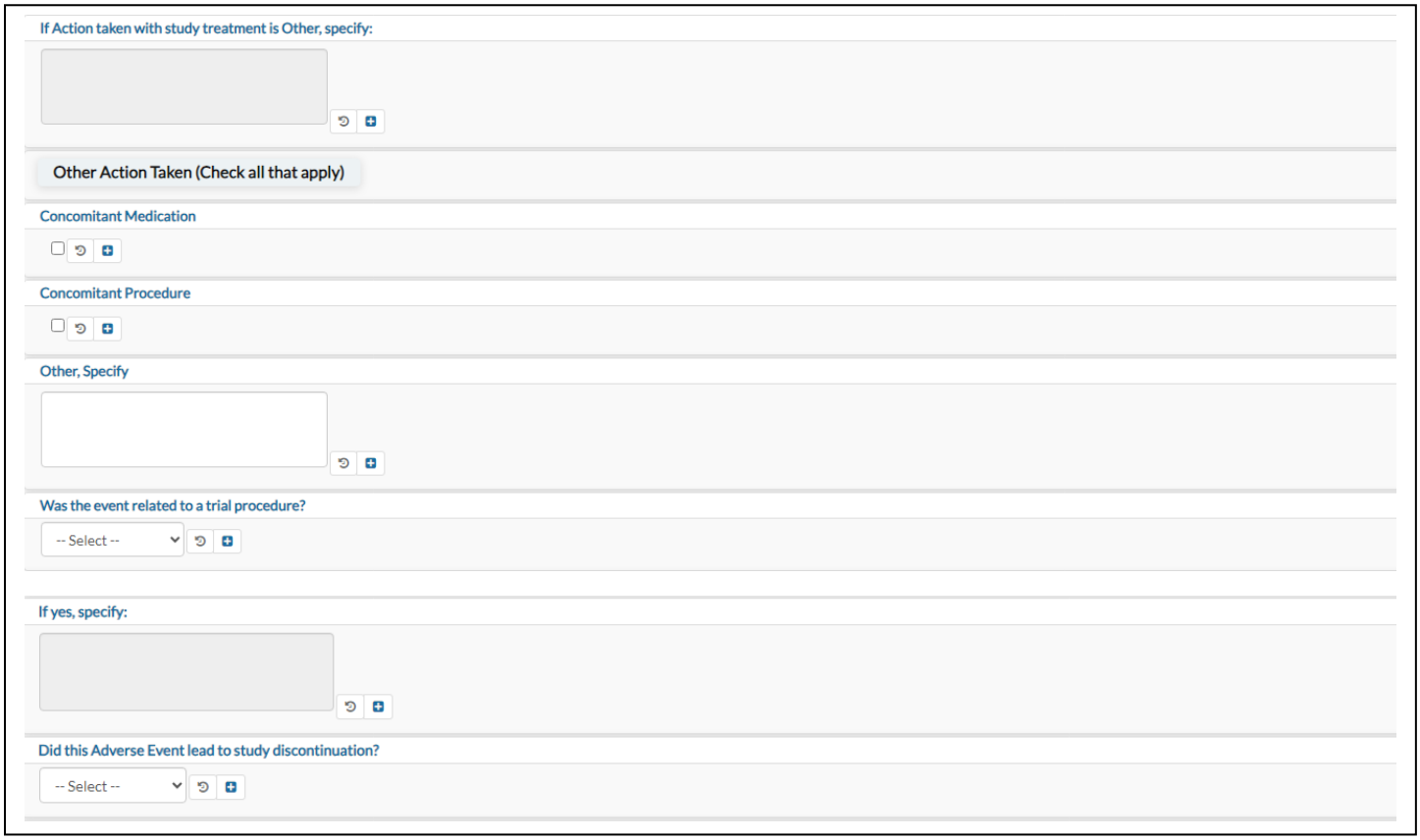
Select **No** or **Yes**.

- If "**Yes**" is selected, a **Prior & Concomitant Procedures** eCRF will appear for completion.

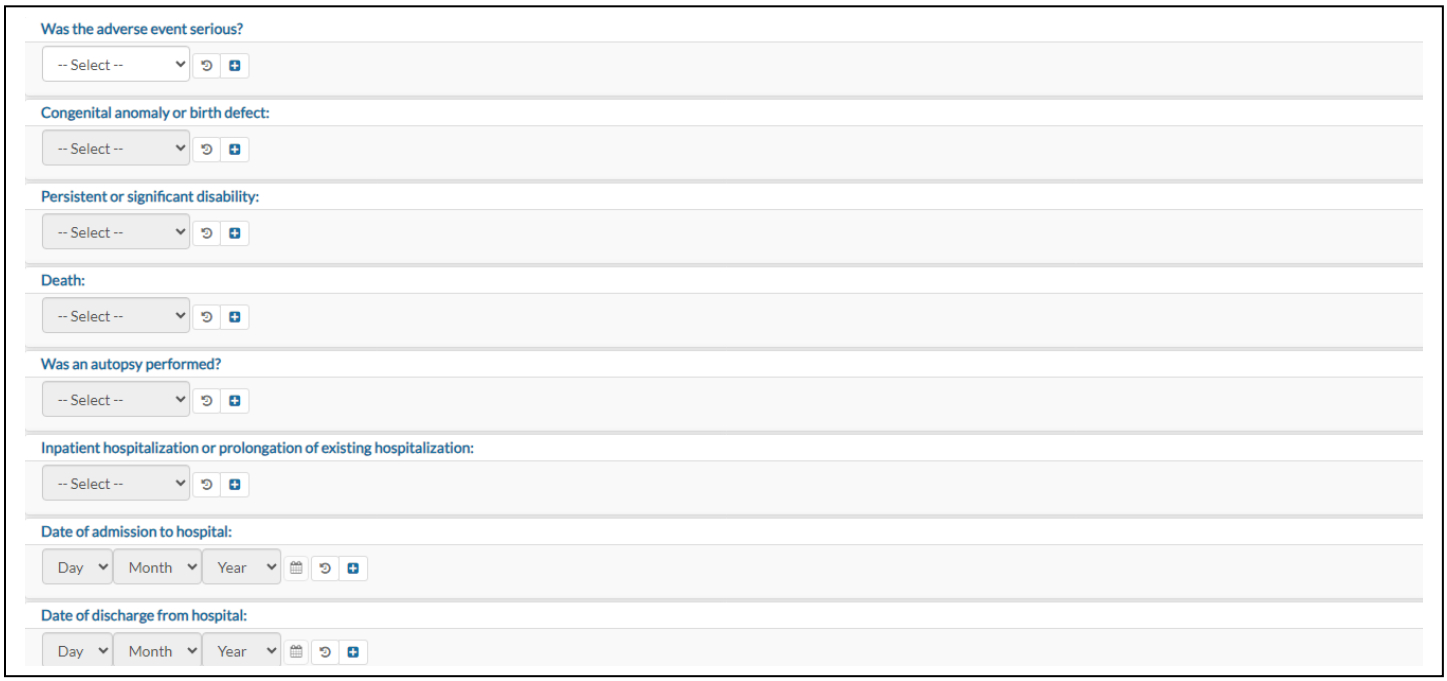
ADVERSE EVENTS



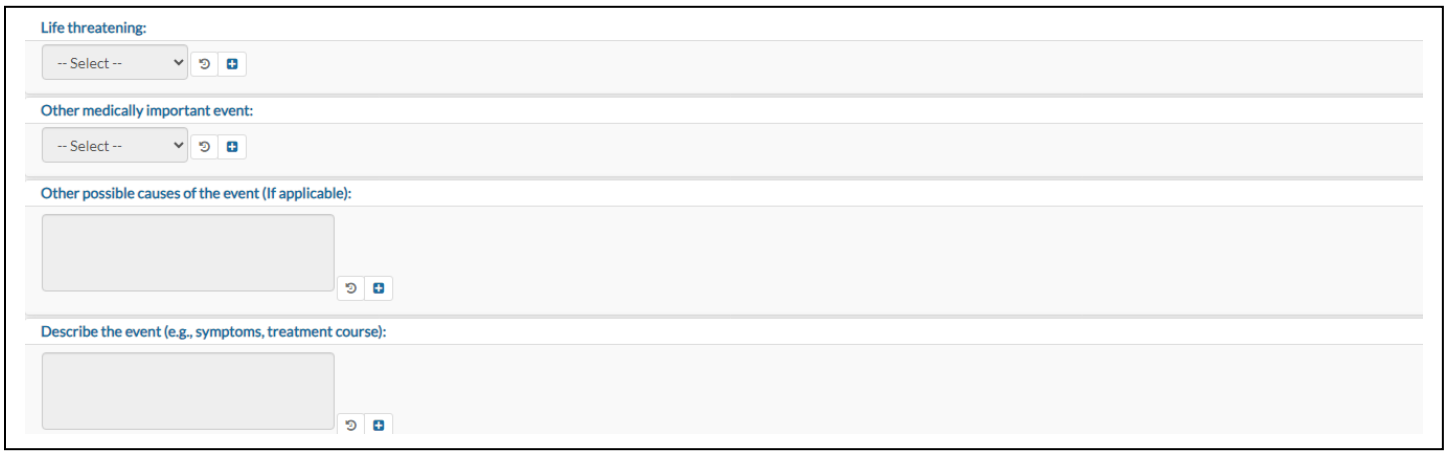
ADVERSE EVENTS (CONTINUED)



Additional fields are required if the Adverse Event is Serious ("Was the adverse event serious?" is "Yes"), shown here.



ADVERSE EVENTS (CONTINUED)



ADVERSE EVENTS (CONTINUED)

All Adverse Events (AEs), regardless of seriousness or relationship to Investigational Product or study intervention, occurring from the time of first study drug administration until the final safety follow-up visit are to be recorded on the Adverse Events eCRF. This is a repeating form (multiple records can be added).

Medical occurrences that begin before study drug administration but after obtaining informed consent will be recorded as medical history/current medical conditions, not as AEs.

Serious Adverse Events plus any AE that is the result of a protocol specified procedure or intervention, including death due to any cause, that occurred from the signing of Informed Consent until study drug administration, regardless of relationship to the study drug, must be reported immediately (no later than 24 hours) on the Adverse Events eCRF. The Investigator will submit any updated SAE data to the Sponsor within 24 hours of it being available. Planned hospitalizations or procedures will not be considered as SAEs.

Adverse Event:

Provide the **verbatim term of the adverse event**.

- Record only one condition per record.
- The overall diagnosis should be reported rather than individual associated symptoms.
- If a specific diagnosis cannot be made, symptoms should be recorded as separate records.
- For intermittent or periodic events with the same CTCAE Grade, report the event only once with a qualifier that indicates that it is intermittent (e.g., 'intermittent headache') and select start and stop dates that show the overall duration of the event.
- If an event is an exacerbation of a pre-existing condition, report the event with a qualifier that indicates that it is worsening (e.g., 'worsening headache'), and ensure that a corresponding Medical History record is completed for the pre-existing condition.
- If an event is not a pre-existing condition that is recorded in Medical History eCRF, all changes in severity should be recorded as separate records. Examples include:
    - **Day 5** – Develops Grade 1 AE
        - → AE #1 is recorded in EDC
    - **Day 12** – Develops Grade 3 AE
        - → Grade 1 AE #1 ends with outcome of recovered, New Grade 3 AE #2 is recorded in EDC
    - **Day 17** – The event drops to Grade 2 AE
        - → Grade 3 AE #2 ends with outcome of recovered, New Grade 2 AE #3 recorded in EDC
    - **Day 25** – The event drops to Grade 1 AE and continues to the end of study
        - → Grade 2 AE #3 ends with outcome of recovered, New Grade 1 AE #4 recorded in EDC. Please note, AE #4 might have the same grade as AE #1. This is because the subject had no Medical History baseline to return to, so it is considered as a "new" AE.

- Medical/surgical procedures are not considered adverse events. If a surgical procedure occurs, ensure the associated indication is added as an adverse event or is a medical history condition.
- Death is an outcome and is not considered an adverse event. The cause of death should be recorded.
- Any condition that could have various locations or types should be specified. Examples include:
    - Anemia – provide the type of anemia
    - Pain – specify the location (e.g., left shoulder pain)
- Any condition which is ambiguous must include additional information. Example include:
    - Aches in hands - Provide more detail (e.g., muscle aches, or Joint aches, or general)
    - Weakness - Provide location or more detail (e.g., general weakness, or muscle weakness)
- Full stops, periods, and commas in the event term should be avoided.
- If CRS or Neurotoxicity is confirmed, record "**CRS**" or "**Neurotoxicity**" in the "**Adverse event:**" field. Then record the signs/symptoms of CRS or Neurotoxicity on the CRS or Neurotoxicity Signs and Symptoms eCRFs.

ADVERSE EVENTS (CONTINUED)

Start date:	Record the **start date** of the AE in the **DD/MMM/YYYY** format. Start date should be recorded as the date of first symptom onset. A complete date is required.
Start Time:	Record the start time of the AE in the **HH:MM 24-hour clock** format.
Is this event a DLT (Dose Escalation only, first 28 days of treatment)?	Indicate if the **event is a DLT (only for Dose Escalation subjects during their first 28 days of treatment)** from the drop-down list: • **No** • **Yes, confirmed at SMC meeting** • **Possibly, pending SMC meeting**
Is this event related to CRS?	Check the box if the AE is related to **CRS**.
Is this event related to Neurotoxicity/ICANS?	Check the box if the AE is related to **Neurotoxicity/ICANS**.
Infusion Related Reaction (IRR)	Check the box if the AE is **Infusion Related Reaction**.
Outcome:	Select the **outcome** of the AE from the drop-down list: • **Fatal** • **Not Recovered or Not Resolved** • **Recovered or Resolved** • **Recovered or Resolved with Sequelae** • **Recovering or Resolving** • **Unknown** Note: *If "**Recovered or Resolved with Sequelae**" is selected, describe sequelae in the "**Describe sequelae:**" field*
End Date:	Record the **end date** of the AE in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Outcome**" is "**Recovered or Resolved**", "**Recovered or Resolved with Sequelae**", or "**Fatal"***
End Time:	Record the end time of the AE in the **HH:MM 24-hour clock** format. Note: Note: *This field is only enabled if "**Outcome**" is "**Recovered or Resolved**", "**Recovered or Resolved with Sequelae**", or "**Fatal"***
CTCAE Grade:	Select the **CTCAE Grade** of the AE from the drop-down list: • **Grade 1** • **Grade 2** • **Grade 3** • **Grade 4** • **Grade 5** • **Not Applicable**

ADVERSE EVENTS (CONTINUED)

Relationship to study treatment:

Select the **relationship to study treatment** from the drop-down list:

- **Related**
- **Possibly Related**
- **Not Related**

Action taken with study treatment:

Select the **action taken with study treatment** from the drop-down list:

- **DOSE NOT CHANGED**
- **DOSE REDUCED**
- **DOSE INTERRUPTED**
- **DRUG WITHDRAWN**
- **NOT APPLICABLE**
- **UNKNOWN**
- **OTHER**

Note: *If "**Other**" is selected, specify in the "**If Action taken with study treatment is Other, specify:**" field*

If Action taken with study treatment is Dose Interrupted, was treatment reinitiated at the same rate or reduced rate?

Select the **rate the study treatment reinitiated** from the drop-down list:

- **Same Rate**
- **Reduced Rate**

Note: *This field is only enabled if "**Action taken with study treatment:**" is "**DOSE INTERRUPTED**"*

Other Action Taken (Check all that apply)

Check the applicable box(es) for **other action taken** from the options provided:

- **Concomitant Medication**
- **Concomitant Procedure**
- **Other, Specify**

Note: *If "**Concomitant Medication**" is selected, record the medication taken for this adverse event on the **Prior & Concomitant Treatments/Medications** eCRF*
Note: *If "**Concomitant Procedure**" is selected, record the procedure performed for this adverse event on the **Prior & Concomitant Procedures** eCRF*
Note: *If none of the provided options is applicable, specify in the "**Other, Specify**" field*

Was the event related to a trial procedure?

Indicate if the AE was **related to a trial procedure** by selecting from the drop-down list: **No** or **Yes**.
Note: *If "**Yes**" is selected, specify in the "**If yes, specify**" field*

Did this Adverse Event lead to study discontinuation?

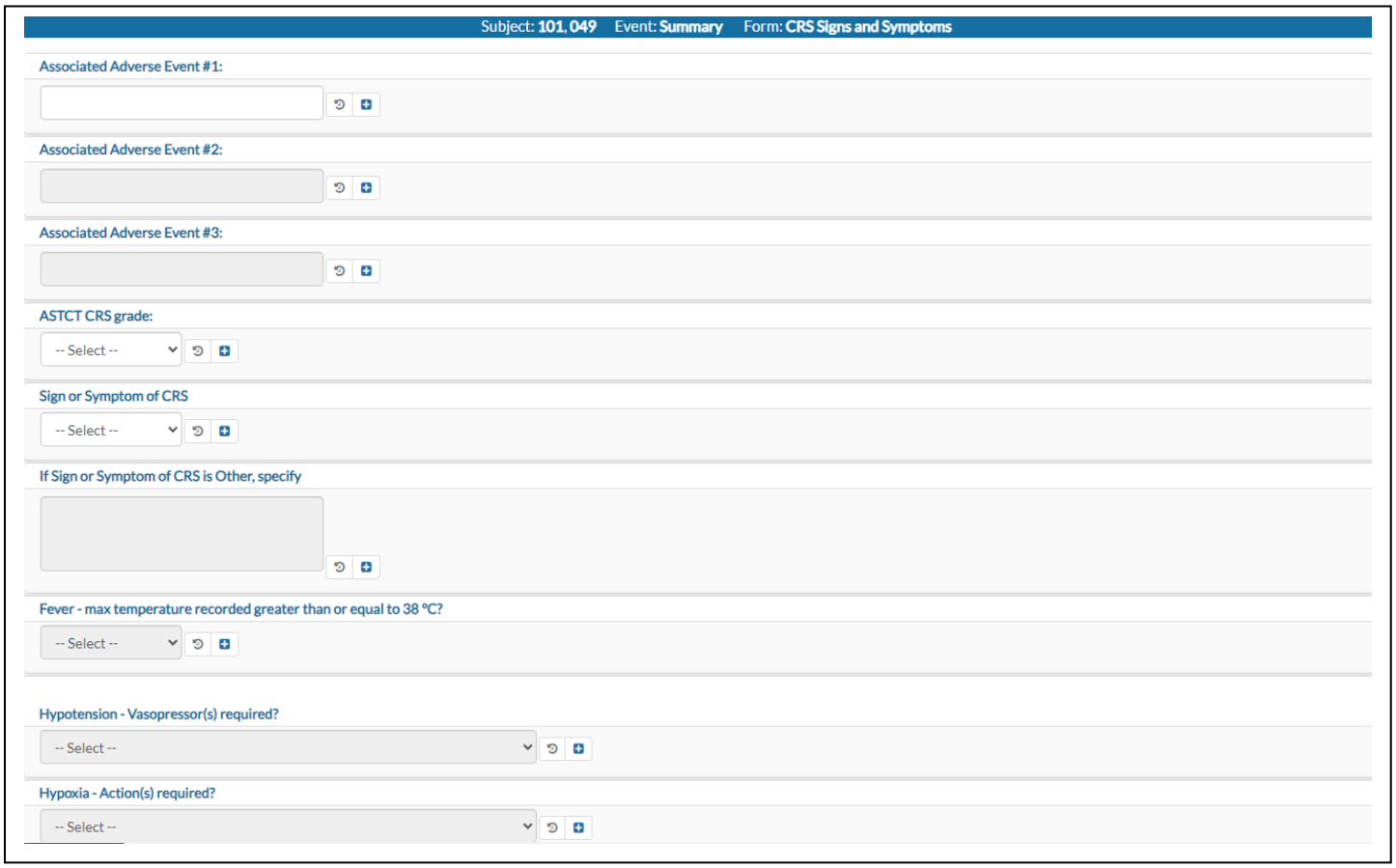
Indicate if the **Adverse Event led to study discontinuation** by selecting from the drop-down list: **No** or **Yes**.
Note: *This field is required for all AEs*
Note: *If "**Yes**" is selected, complete the **Early Termination/End of Study** eCRF*

ADVERSE EVENTS (CONTINUED)

Was the adverse event serious?	Select **No** or **Yes**. Note: *If "**Yes**" is selected, the serious criteria fields below will be enabled for completion for the serious adverse event*
Congenital anomaly or birth defect:	Indicate if the serious AE is a **congenital anomaly or birth defect** by selecting from the drop-down list: **No** or **Yes**.
Persistent or significant disability:	Indicate if the serious AE results in **persistent or significant disability** by selecting from the drop-down list: **No** or **Yes**.
Death:	Indicate if the serious AE results in **death** by selecting from the drop-down list: **No** or **Yes**. Note: *If "**Yes**" is selected, complete the **Death Details** CRF*
Was an autopsy performed?	Indicate if an **autopsy was performed** by selecting from the drop-down list: **No** or **Yes**. Note: *This field is only enabled if "**Death:**" is "**Yes**"*
Inpatient hospitalization or prolongation of existing hospitalization:	Indicate if the serious AE results in **inpatient hospitalization or prolongs the existing hospitalization** by selecting from the drop-down list: **No** or **Yes**.
Date of admission to hospital:	Record the **date of hospital admission** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Inpatient hospitalization or prolongation of existing hospitalization:**" is "**Yes**"*
Date of discharge from hospital:	Record the **date of hospital discharge** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Inpatient hospitalization or prolongation of existing hospitalization:**" is "**Yes**"*
Life threatening:	Indicate if the serious AE is a **life-threatening** event by selecting from the drop-down list: **No** or **Yes**.
Other medically important event:	Indicate if the serious AE is other **medically important** event by selecting from the drop-down list: **No** or **Yes**.
Other possible causes of the event (If applicable):	If applicable, record any **other possible causes** of the serious AE in the text box provided.
Describe the event (e.g., symptoms, treatment course):	**Describe the serious AE (symptoms, treatment, course, etc.)** in the text box provided.

CRS SIGNS AND SYMPTOMS

This is a repeating form (multiple records can be added).

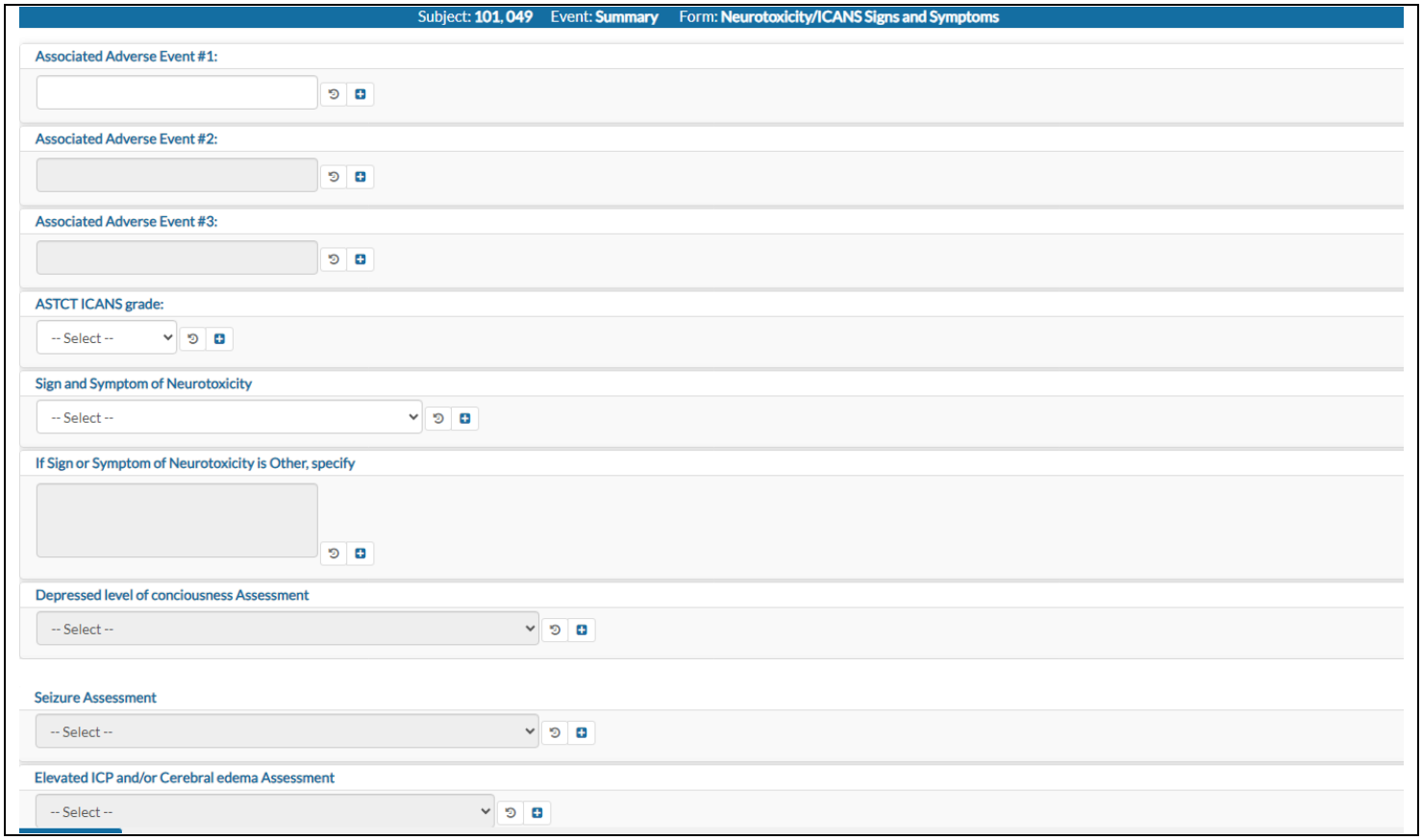


CRS SIGNS AND SYMPTOMS (CONTINUED)

Associated Adverse Event #1:	Record the **associated adverse event #1 number** in field provided
Associated Adverse Event #2:	Record the **associated adverse event #2 number** in field provided
Associated Adverse Event #3:	Record the **associated adverse event #3 number** in field provided
ASTCT CRS grade:	Select the **ASTCT CRS grade** of the AE from the drop-down list: • **GRADE 1** • **GRADE 2** • **GRADE 3** • **GRADE 4**
Sign or Symptom of CRS	Select the **sign or symptom of CRS** from the drop-down list: • **Fever** • **Hypotension** • **Hypoxia** • **Other** Note: *If "**Other**" is selected, provide a response in the "**If Sign or Symptom of CRS is Other, specify**" field*
Fever - max temperature recorded greater than or equal to 38 °C?	Select **No** or **Yes** to indicate if the **max temperature recorded greater than or equal to 38 °C**. Note: *This field is only enabled if "**Sign or Symptom of CRS**" is "**Fever**"*
Hypotension - Vasopressor(s) required?	Select the **option** regarding vasopressor(s) required from the drop-down list: • **None** • **Yes, a vasopressor with or without vasopressin** • **Yes, multiple vasopressors (excluding vasopressin)** Note: *This field is only enabled if "**Sign or Symptom of CRS**" is "**Hypotension**"*
Hypoxia - Action(s) required?	Select the **option** regarding action(s) required from the drop-down list: • **None** • **Low-flow nasal cannula or blow-by** • **High-flow nasal cannula, facemask, nonrebreather mask, or Venturi mask** • **Positive pressure** Note: *This field is only enabled if "**Sign or Symptom of CRS**" is "**Hypoxia**"*

NEUROTOXICITY/ICANS SIGNS AND SYMPTOMS

This is a repeating form (multiple records can be added).



Associated Adverse Event #1:	Record the **associated adverse event #1 number** in field provided
Associated Adverse Event #2:	Record the **associated adverse event #2 number** in field provided
Associated Adverse Event #3:	Record the **associated adverse event #3 number** in field provided
ASTCT CRS grade:	Select the **ASTCT CRS grade** of the AE from the drop-down list: • **GRADE 1** • **GRADE 2** • **GRADE 3** • **GRADE 4**

NEUROTOXICITY/ICANS SIGNS AND SYMPTOMS (CONTINUED)

Sign and Symptom of Neurotoxicity

Select the **sign or symptom of Neurotoxicity** from the drop-down list:

- **Seizures**
- **Tremor**
- **Elevated ICP - Cerebral edema**
- **Depressed level of consciousness**
- **Myoclonus**
- **Hemi or Paraparesis**
- **Other**

Note: *If "**Other**" is selected, provide a response in the "**If Sign or Symptom of Neurotoxicity is Other, specify**" field*

Depressed level of consciousness Assessment

Select the **option** regarding depressed level of consciousness assessment from the drop-down list:

- **Awakens spontaneously**
- **Awakens to voice**
- **Awakens only to tactile stimulus**
- **Unarousable or requires vigorous or repetitive tactile stimuli to around**
- **Stupor or Coma**

Note: *This field is only enabled if "**Sign and Symptom of Neurotoxicity**" is "**Depressed level of consciousness**"*

Seizure Assessment

Select the **option** regarding seizure assessment from the drop-down list:

- **Clinical seizure that resolved rapidly**
- **Nonconvulsive seizures on EEG that resolve with intervention**
- **Life-threatening prolonged seizure>5 min**
- **Repetitive clinical or electrical seizures without return to baseline in between**

Note: *This field is only enabled if "**Sign and Symptom of Neurotoxicity**" is "**Seizures**"*

Elevated ICP and/or Cerebral edema Assessment

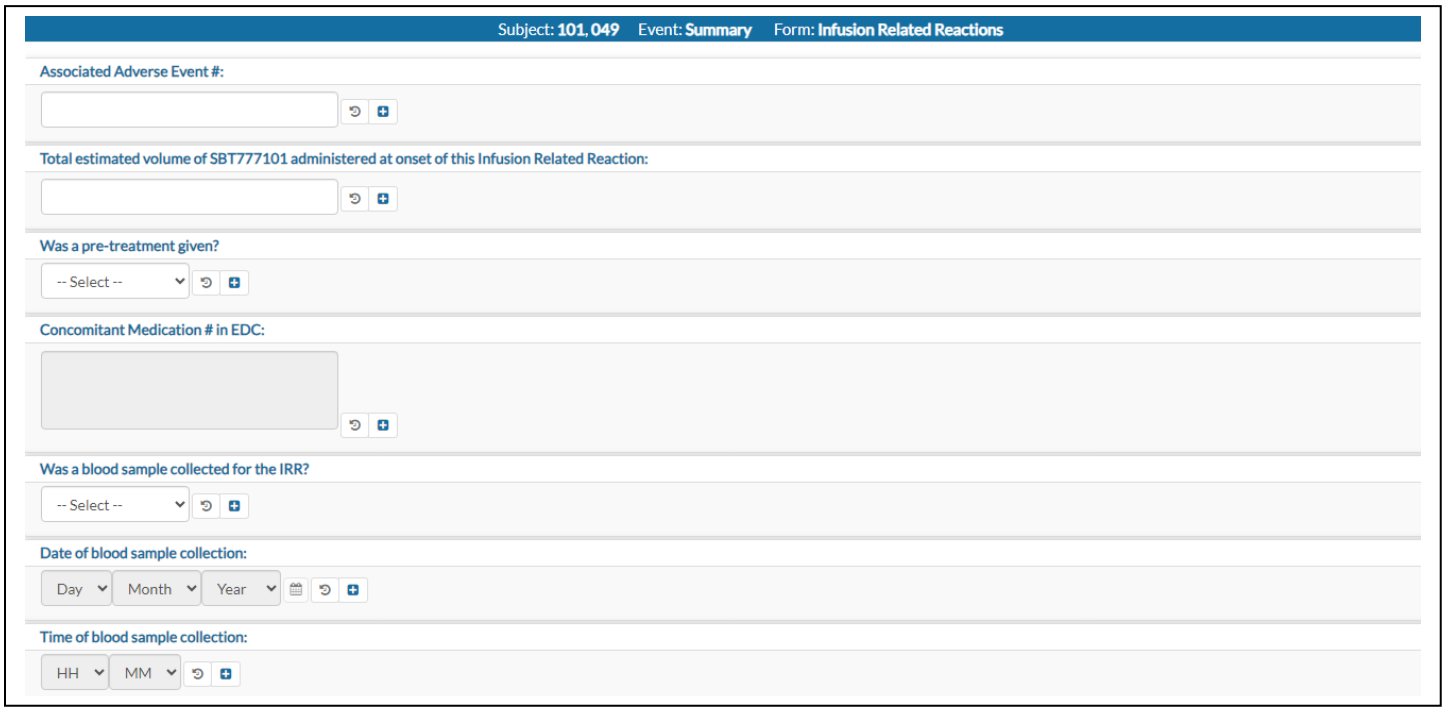
Select the **option** regarding elevated ICP and/or cerebral edema assessment from the drop-down list:

- **Focal-Local edema on neuroimaging**
- **Diffuse cerebral edema on neuroimaging**
- **Decerebrate or decorticate posturing**
- **Cranial nerve VI palsy**
- **Papilledema**
- **Cushing's triad**

Note: *This field is only enabled if "**Sign and Symptom of Neurotoxicity**" is "**Elevated ICP - Cerebral edema**"*

INFUSION RELATED REACTIONS

This is a repeating form (multiple records can be added).



Associated Adverse Event #:	Record the **associated adverse event number** in field provided
Total estimated volume of SBT777101 administered at onset of this Infusion Related Reaction:	Record the **total estimated volume of SBT777101 administered** at the onset of this IRR in the field provided.
Was a pre-treatment given?	Select **No** or **Yes** to indicate if a **pre-treatment** was given.
Concomitant Medication # in EDC:	Record the **associated concomitant medication number** in field provided Note: *This field is only enabled if "**Was a pre-treatment given?" = "Yes"***
Was a blood sample collected for the IRR?	Select **No** or **Yes** to indicate if a **blood sample** was collected for the IRR.
Date of blood sample collection:	Record the **date of collection** in the **DD/MMM/YYYY** format. A complete date is required. Note: *This field is only enabled if "**Was a blood sample collected?" = "Yes"***
Time of blood sample collection:	Record the **time of collection** in the **HH:MM 24-hour clock** format. Note: *This field is only enabled if "**Was a blood sample collected?**" is "**Yes**"*

PRIOR & CONCOMITANT TREATMENTS/MEDICATIONS

This is a repeating form (multiple records can be added).

PRIOR & CONCOMITANT TREATMENTS/MEDICATIONS (CONTINUED)

General medications taken by the subject within 4 weeks prior to screening to the end of the study/early termination visit should be recorded. Pain medications and corticosteroids used to manage signs and symptoms of RA are considered general medications.

Medication:

Provide the name of the **medication** in the field provided.

- Record only one medication per record.
- Confirm the recorded medication name is appropriate based on the dose provided.
- For combination medications:
  - Do not split into separate entries.
  - Record the brand name with the generic name in parentheses, if available. (E.g., Bactrim (sulfamethoxazole + trimethoprim))
- For multi-ingredient products, supplements, and store-brand medications:
  - Record active ingredients in parentheses next to product name. (E.g., Robitussin (guaifenesin/dextromethorphan HBr)
- Full stops, periods, and commas in the medication name should be avoided.

Indication:

Provide the **indication** in the field provided.

- Ensure the indication reflects the specific condition/diagnosis and not the type of drug.
- If medications are given to treat a medical history condition or adverse event, ensure the condition is recorded on the Medical History or Adverse Event eCRF.
- Medications taken as a preventative measure and not for general health or a pre-existing or current condition should include that information with the indication (e.g., 'infection prophylaxis').

Reason (select all that apply):

Select all applicable box(es) regarding the **reason for the treatment/medication** from the drop-down list:

- **Adverse Event**
- **Medical History**
- **Prophylaxis**
- **Procedure**
- **Rheumatoid Arthritis Treatment**
- **Other**

Note: *If "**Adverse Event**" is selected, record the* corresponding primary adverse event number *in the "**Primary Adverse Event # indicated (record the primary AE associated):**" field*

Note: *If "**Medical History**" is selected, record the* corresponding primary adverse event number *in the "**Primary Medical History # indicated (record the primary MH associated):**" field*

Note: *If "**Procedure**" is selected, record the* corresponding primary adverse event number *in the "**Primary Procedure # indicated (record the primary procedure associated):**" field*

Note: *If "**Other**" is selected, specify the reason in the "**Reason Other, specify:**" field*

PRIOR & CONCOMITANT TREATMENTS/MEDICATIONS (CONTINUED)

Dose:

Provide a numeric **dose** of the medication taken.

- For combination drugs, enter the number of tablets/capsules
  - If dose strength needed, record in medication field after medication name
- If the dose is a range (e.g., Insulin use of 2-10 units), the upper end of the range should be entered (e.g., 10 units).
- If a medication's dose changes, create a new record for each dose level.

Unit:

Select the **unit** of the dose taken from the drop-down list:

- **APPLICATION**
- **CAPSULE**
- **DROP**
- **g**
- **IU**
- **mEq**
- **mg**
- **mL**
- **mL/h**
- **mmol**
- **oz**
- **PUFF**
- **TABLET**
- **U**
- **U/kg**
- **U/kg/day**
- **ug**
- **OTHER**

Note: *If "**Other**" is selected, specify in the "**Unit specify:**" field*

Frequency:

Select the **frequency** of the treatment/medication from the drop-down list:

- **BID (twice per day)**
- **CONTINUOUS**
- **EVERY WEEK**
- **ONCE**
- **PRN (as needed)**
- **QD (once per day)**
- **QID (4 times per day)**
- **QOD (every other day)**
- **TID (three times a day)**
- **Unknown**
- **Other**

Note: *If "**Other**" is selected, provide a response in the "**Frequency specify:**" field*

Route:

Select the **route** of the treatment/medication from the drop-down list:

- **AURICULAR (OTIC)**
- **ENTERAL**
- **EPIDURAL**
- **INTRA-ARTICULAR**
- **INTRADERMAL**
- **INTRAMUSCULAR**
- **INTRAOCULAR**
- **INTRATHECAL**
- **INTRAVENOUS**
- **NASAL**
- **NASOGASTRIC**
- **OPHTHALMIC**
- **ORAL**
- **RECTAL**
- **RESPIRATORY (INHALATION)**
- **SUBCUTANEOUS**
- **TOPICAL**
- **TRANSDERMAL**
- **VAGINAL**
- **OTHER**

Note: *If "**Other**" is selected, provide a response in the "**Route specify:**" field*

Start date:

Record the **start date** of the treatment/medication in the **DD/MMM/YYYY** format.

Note: *A year is required for start date. "**Unknown**" is an available selection for Day and Month*

Ongoing?

Select **No** or **Yes** to indicate if the treatment/medication is currently **ongoing**.

Note: *If the treatment/medication changes/updates from ongoing to resolved during the study, update this field accordingly*

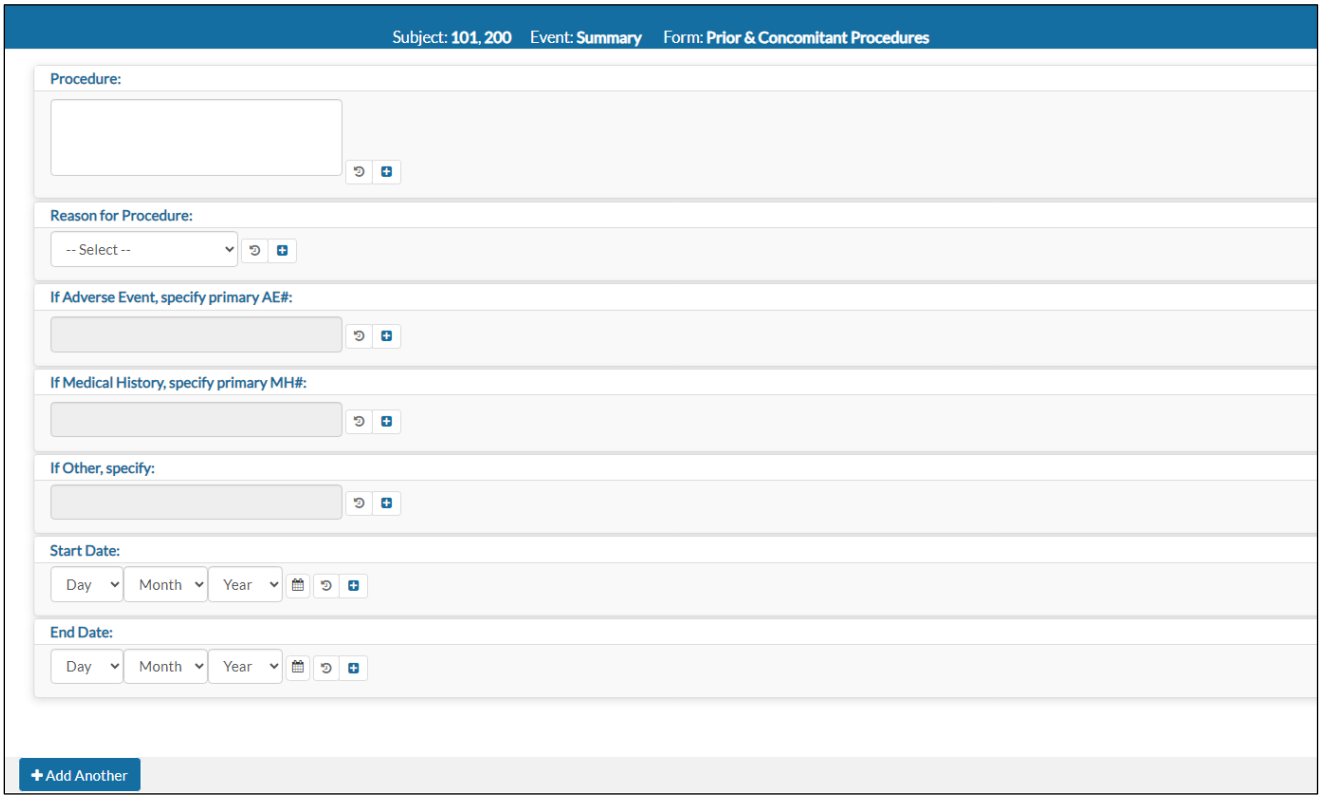
End date:

Record the **end date** of the treatment/medication in the **DD/MMM/YYYY** format.

Note: *This field is only enabled if "**Ongoing?**" is "**No**". A year is required for end date. "**Unknown**" is an available selection for Day and Month*

PRIOR & CONCOMITANT PROCEDURES

This is a repeating form (multiple records can be added).



Procedure: Record the **procedure** in the text box provided.

Reason for Procedure: Select the **reason for procedure** from the drop-down list:

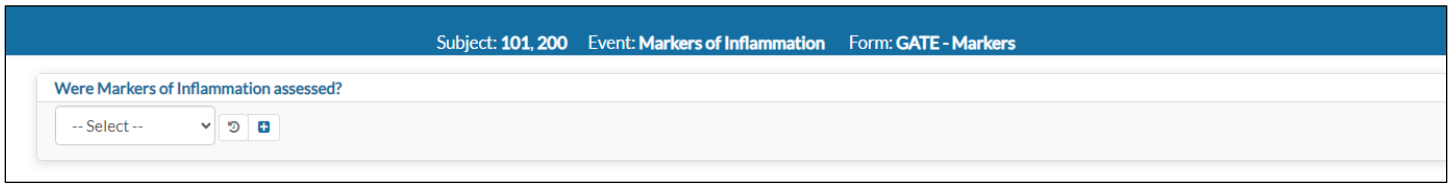
- **ADVERSE EVENT**
- **MEDICAL HISTORY**
- **TREATMENT OF RA**
- **OTHER**

Note: *If "**Adverse Event**" is selected, record the* corresponding primary adverse event number *in the "**If Adverse Event, specify primary AE#:**" field*
Note: *If "**Medical History**" is selected, record the* corresponding primary adverse event number *in the "**If Medical History, specify primary MH#:**" field*
Note: *If "**Other**" is selected, specify the reason in the "**If Other, specify:**" field*

Start date: Record the **start date** of the treatment/medication in the **DD/MMM/YYYY** format.
Note: *A year is required for start date. "**Unknown**" is an available selection for Day and Month*

End date: Record the **end date** of the treatment/medication in the **DD/MMM/YYYY** format.
Note: *A year is required for end date. "**Unknown**" is an available selection for Day and Month*

GATE – MARKERS



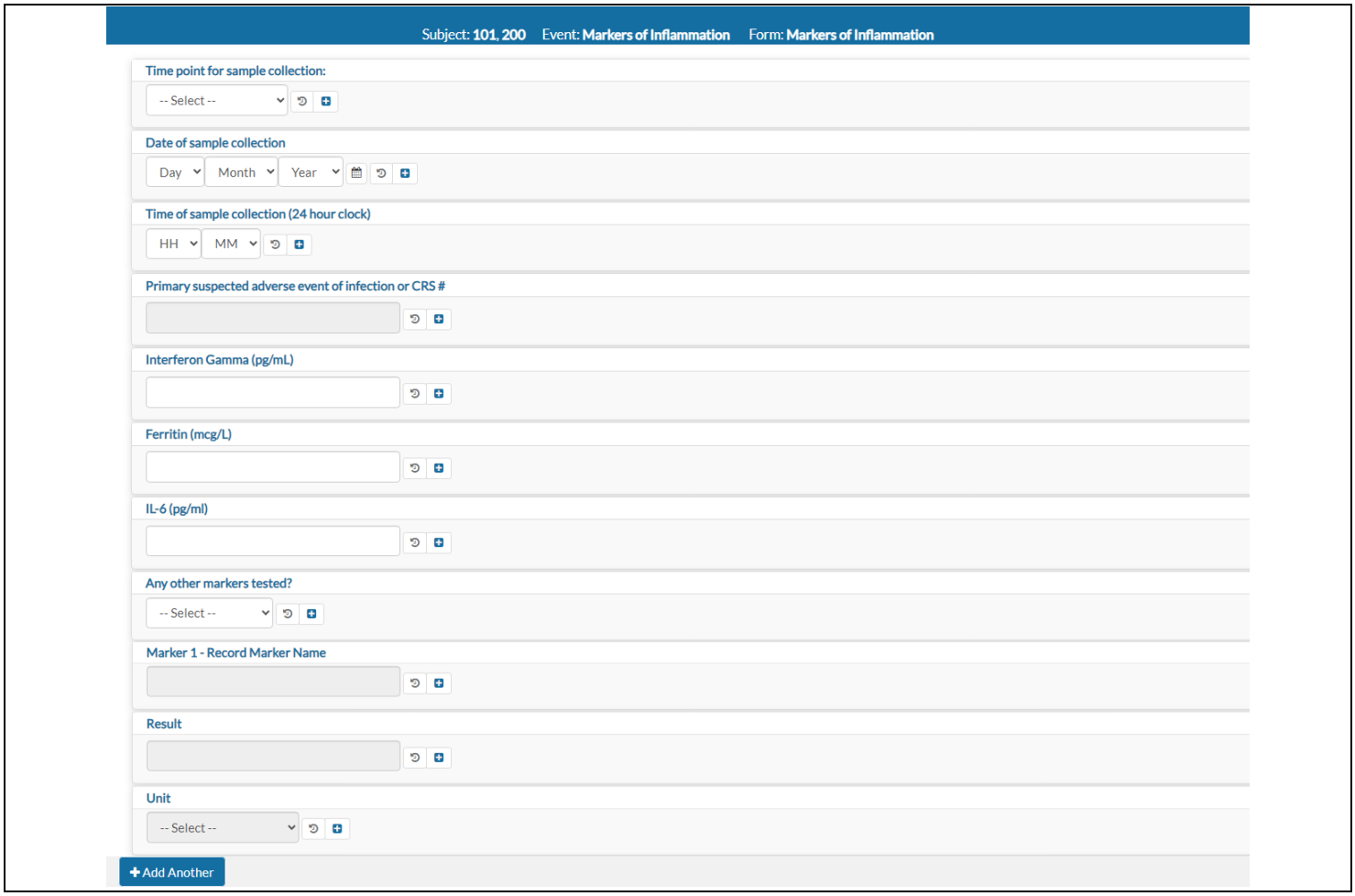
Were Markers of Inflammation assessed?

Select **No** or **Yes** to indicate if the **markers of inflammation** was assessed.

- *If "**Yes**" is selected, a **Markers of Inflammation** eCRF will appear for completion.*

MARKERS OF INFLAMMATION

This is a repeating form (multiple records can be added).



For the sake of brevity, the screenshot for this form only shows other markers tested – Marker 1. Other Marker #2-5 fields are comparable to the other Marker 1 image.

MARKERS OF INFLAMMATION (CONTINUED)

Time point for sample collection:	Select the **time point for sample collection** from the drop-down list: • **Pre-Treatment** • **Adverse Event**
Date of sample collection	Record the **date of sample collection** in the **DD/MMM/YYYY** format. A complete date is required.
Time of sample collection (24 hour clock)	Record the **time of sample collection** performed in the **HH:MM 24-hour clock** format.
Primary suspected adverse event of infection or CRS #	Record the **primary suspected adverse event of infection or CRS number** in the field provided.
Interferon Gamma (pg/mL)	Record the **Interferon Gamma** in **pg/mL** in the field provided.
Ferritin (mcg/L)	Record the **Ferritin** in **mcg/L** in the field provided.
IL-6 (pg/ml)	Record the **IL-6** in **pg/mL** in the field provided.

MARKERS OF INFLAMMATION (CONTINUED)

Any other markers tested?

Select **No** or **Yes** to indicate if **any other markers** was tested.
Note: *If "**No**" is selected, no additional fields to record other markers will appear. If "**Yes**" is selected, the "**Marker 1 - Record Marker Name**", "**Result**", and "**Unit**" fields will appear. Up to five (5) other markers can be recorded per Markers of Inflammation eCRF. Data may be recorded in the subsequent Other Marker #2-5 fields that appear. These subsequent Other Marker #2-5 fields should be completed in the same manner as the Other Marker #1 fields.*

Marker 1 - Record Marker Name

Record the **marker 1 name** in the field provided.
Note: *This field is only enabled if "**Any other markers tested?**" is "**Yes**"*

Result

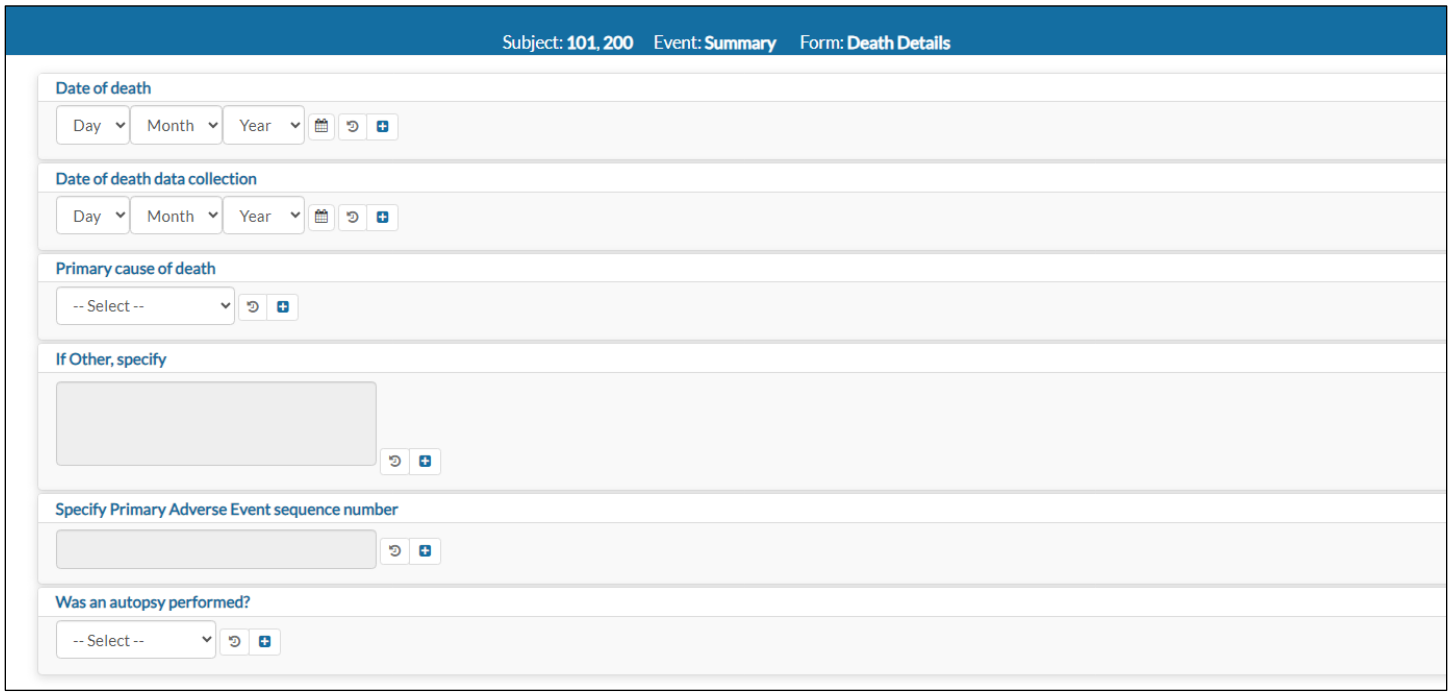
Record the **result of marker 1** in the field provided.
Note: *This field is only enabled if "**Any other markers tested?**" is "**Yes**"*

Unit:

Select the corresponding **unit** for the result from the drop down-list:

- **%**
- **/hpf**
- **/lpf**
- **cc/min**
- **cells/mcL**
- **cells/uL**
- **E.U./dL**
- **Ehr U**
- **Ehr U/dL**
- **Eq/L**
- **fL**
- **g/dL**
- **g/L**
- **IU/L**
- **IU/mL**
- **K/mm^3**
- **K/mcL**
- **L/L**
- **M/mcL**
- **mcg/dL**
- **mcIU**
- **mcIU/mL**
- **mcm^3**
- **mcmol/L**
- **mEq/L**
- **mg/dL**
- **mg/L**
- **mIU/mL**
- **mL/min**
- **mL/min/1.73m^2**
- **mmol/L**
- **mU/L**
- **ng/dL**
- **ng/mL**
- **nmol/L**
- **pg**
- **pg/mL**
- **pmol/L**
- **seconds**
- **U/L**
- **U/mL**
- **uIU/mL**
- **x 10^3/mm^3**
- **x 10^3/mcL**
- **x 10^6/mm^3**
- **x 10^6/mcL**
- **x 10^9/L**
- **x 10^12/L**
- **No Unit**

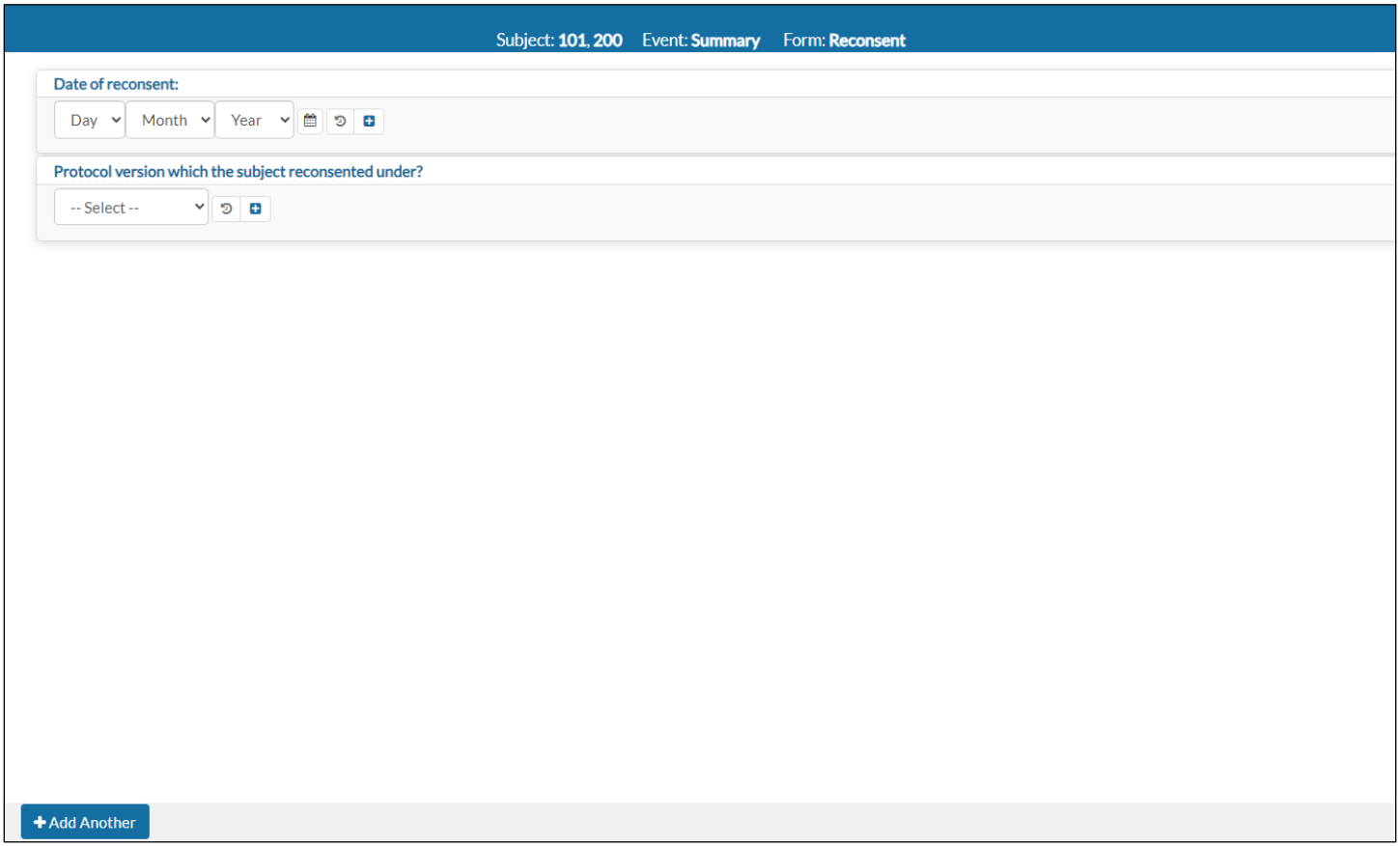
DEATH DETAILS



Date of death	Record the **date of death** in the **DD/MMM/YYYY** format. A complete date is required.
Date of death data collection	Record the **date of death data collection** in the **DD/MMM/YYYY** format. A complete date is required.
Primary cause of death	Select the **primary cause of death** from the drop-down list: • Adverse Event • Other Note: *If "**Adverse Event**" is selected, record the* corresponding primary adverse event number *in the "**Specify Primary Adverse Event sequence number**" field* Note: *If "**Other**" is selected, specify the primary cause of death in the "**If Other, specify**" field*
Was an autopsy performed?	Select **No** or **Yes** to indicate if **an autopsy was performed**.

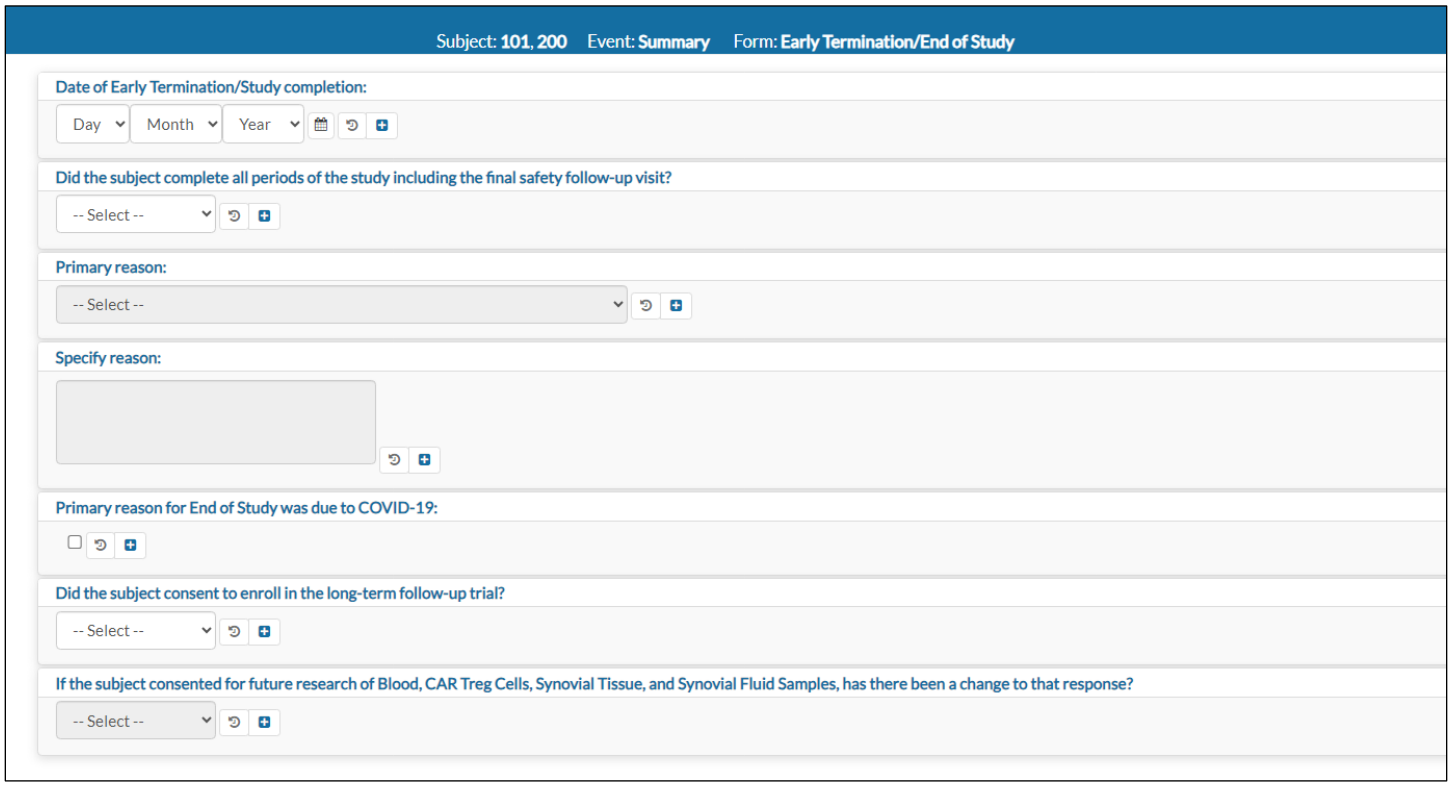
RECONSENT

This is a repeating form (multiple records can be added).



Date of reconsent:	Record the **date of reconsent** in the **DD/MMM/YYYY** format. A complete date is required.
Protocol version which the subject reconsented under?	Select the **protocol version** the subject the subject reconsented under from the drop-down list: • **5.0** • **6.0** • **7.0** • **8.0** • **9.0** • **10.0**

EARLY TERMINATION/END OF STUDY



Date of Early Termination/Study completion:	Record the **date of early termination/study completion** in the **DD/MMM/YYYY** format. A complete date is required.
Did the subject complete all periods of the study including the final safety follow-up visit?	Select **No** or **Yes** to indicate if the **subject completed all periods of the study including the final safety follow-up visit**.

EARLY TERMINATION/END OF STUDY (CONTINUED)

Primary reason:	Select the **primary reason** from the drop-down list: • **ADVERSE EVENT** • **DEATH** • **FAILURE TO MEET TREATMENT ELIGIBILITY REQUIREMENTS** • **LOST TO FOLLOW-UP** • **MANUFACTURING FAILURE** • **PHYSICIAN DECISION** • **PROTOCOL DEVIATION** • **STUDY TERMINATED BY SPONSOR** • **WITHDRAWAL BY SUBJECT** • **OTHER** Note: *This field is only enabled if "**Did the subject complete all periods of the study including the final safety follow-up visit?**" is "**No**"* Note: *If "**Other**" is selected, specify the reason in the "**Specify reason:**" field*
Primary reason for End of Study was due to COVID-19:	Check the box if the **primary reason for End of Study was due to COVID-19**.
Did the subject consent to enroll in the long-term follow-up trial?	Select **No** or **Yes** to indicate if the **subject consented to enroll in the long-term follow-up trial**.
If the subject consented for future research of Blood, CAR Treg Cells, Synovial Tissue, and Synovial Fluid Samples, has there been a change to that response?	Select **No** or **Yes** to indicate if **there has been a change to subject consented for future research of Blood, CAR Treg Cells, Synovial Tissue, and Synovial Fluid Samples**. Note: *This field is only enabled if "**Primary reason:**" is "**Withdrawal by Subject**"*