

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 fields on Eligibility form per sponsor Updated <i>Adverse Event</i> 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 <i>Local Laboratory – Urinalysis</i> form
			<i>Dynamics</i> - Updated dynamics for which forms appear if subject meets all Screening Eligibility, Inclusion Not Met/Exclusion Criteria Met, Pre-Treatment Visits 2, Local Laboratory - Pregnancy, Local Laboratory - Post Menopause, Early Termination added dynamics for Infusion Related Reactions <i>Adverse Events</i> - 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?”
			<i>CRS Signs and Symptoms</i> - 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:” <i>Neurotoxicity/ICANS Signs and Symptoms</i> - 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:”,

VERSION DATE	VERSION NUMBER	AUTHOR	SUMMARY
			<p>"Associated Adverse Event #3:" and "ASTCT ICANS grade:"</p> <p><i>Apheresis Eligibility (Pre-Treatment)</i> - Added new fields "Date of Screen Failure at Apheresis:", "Primary Reason for Screen Failure at Apheresis:", and "Primary Reason for Screen Failure at Apheresis Other, Specify:"</p> <p><i>Pre-Treatment/Pre-Infusion Eligibility</i> - 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</p> <p><i>Eligibility</i> - 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:"</p> <p><i>Apheresis</i> - 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.</p> <p><i>Infusion Related Reactions</i> - New form added</p> <p><i>GATE form - Any AE/CM/PR</i> - Added new field "Were there any Infusion Related Reactions (IRR)?"</p> <p>General instructions – Updated section 2 #8 on SF limited casebooks, adding additional CRFs to SF casebook</p> <p><i>Vital Signs</i> – Changed BMI to note that it is a read-only field</p> <p><i>Adverse Events</i> – Added guidelines for AE changes in severity when an event is not a pre-existing condition</p> <p>Sponsor Approved Version 2.0</p>
03-Jul-2024	3.0	T.Nguyen, S.Hall	<p>Added note to section 2 to clarify subject ID is unique and cannot be reused</p> <p><i>Tobacco Use</i> – added new form and dynamics for form</p> <p><i>Any Medical History</i> – Added new field "Does the subject have any past and/or concomitant use of tobacco?", removed "abuse" language, and Updated "Does the subject have any past and/or concomitant" to match the SU screen note</p> <p><i>Alcohol and Drug Use</i> – updated field text, removed "abuse" language and updated screen note to "prior to signing informed consent"</p> <p><i>Apheresis Eligibility (Pre-Treatment)</i> and <i>Pre-Treatment/Pre-Infusion Eligibility</i> – renamed forms</p>

VERSION DATE	VERSION NUMBER	AUTHOR	SUMMARY
			<p>Added Prior Rheumatoid Arthritis Treatment Medication, Local Laboratory - HIV Screening, and Next Visit - Pre-Treatment</p> <p>Updated dynamics for various forms and added dynamics for new forms</p> <p>Physical Examination – Form was retired and replaced by Physical Examination 1 form</p> <p>Medical History - Rheumatoid Arthritis – Updated various field names</p> <p>Updated names for Apheresis Eligibility (Pre-Treatment) and Pre-Treatment/Pre-Infusion Eligibility forms</p> <p>Adverse Events – updated verbiage about SAE's and various other places to mirror changes in HS CCG's Prior & Concomitant Treatments/Medications – updated verbiage about medications and dosing to match HS CCG's</p> <p>Apheresis – removed second apheresis fields</p> <p>Sponsor Approved version 3.0</p>
09-Oct-2024	4.0	S.Hall	<p>Removed all COVID information from forms</p> <p><i>Dynamics</i> – Added PE1CS dynamics, updated dynamic for Next Visit – Pre-Treatment to appear for all subjects</p> <p><i>Adverse Events</i> – Added "Possibly" option to Is this event related to CRS and Neurotoxicity/ICANS? Fields</p> <p><i>12-Lead Electrocardiogram - Triplicate</i> – Updated QtcF Average field to be calculated and read only</p> <p><i>Synovitis Assessment</i> – Updated Was a Synovitis Assessment... field to "Was a Synovitis Assessment for the purpose of biopsy performed?" and Which Joints? field with "are potential sites for biopsy".</p> <p><i>Apheresis</i> – Added new fields re:Cell Manufacturing</p> <p><i>Health Assessment Questionnaire - Disability Index</i> – Removed highest score, highest adjusted score fields per sponsor request</p> <p><i>Medical History</i> – Removed CTCAE v5.0 to Severity</p> <p><i>Local Laboratories - Clinical Chemistry 1 and 2, Hematology 1 and 2, Lipid</i> – Removed some units from fields per sponsor request.</p> <p>Sponsor Approved version 4.0</p>
24-Apr-2025	5.0	S.Hall	<p><i>Medical History</i> – Updated "Was there a change in this event since screening before pre-infusion?" and "Severity Grade before Pre-Infusion" to clarify that it is the pre-infusion visit that is being referred to</p> <p><i>Vital Signs – Oxygen Saturation</i> – Added new form</p> <p><i>Immune Effector Cell-Associated Encephalopathy (ICE) Score</i> – updated ICE score fields to be read only and calculated fields</p> <p>Added Navigation Tree Icon Guide to general instructions</p>

VERSION DATE	VERSION NUMBER	AUTHOR	SUMMARY
			<p><i>Apheresis</i> – Added new field "Reason Cell Manufacturing Not Successful Other, Specify:"</p> <p><i>Health Assessment Questionnaire – Disability Index</i> – Updated AIDS DAEW/HRGA and HELP DAEW/HRGA fields to include "None" option</p> <p><i>Medical History – Rheumatoid Arthritis</i> – Added fields to capture ACPA titer/units</p> <p><i>C-Reactive Protein/Erythrocyte Sedimentation Rate</i> – Updated ESR field to remove decimal.</p> <p><i>Rheumatoid Arthritis Serology Testing (RA)</i> – Added new field</p> <p><i>Local Lab – Hematology 1 and 2</i> – Added additional lab units for certain analytes</p> <p><i>Joint Count Assessments</i> – Removed visible visit dynamics from (66) fields.</p> <p><i>Adverse Event</i> – Added note for action taken. Added note about post infusions event actions being “Not applicable”. Added note to IRR field.</p>
			<p><i>Synovitis Assessment</i> – Update gate field to “Was Synovitis Assessment performed using ultrasound?” and removed "How was the assessment...", "If Other assessment...", "Was synovitis confirmed?", "Which joints...", and "other" fields. Added grading fields</p> <p><i>Medical History</i> – Removed severity grade fields per sponsor request</p> <p><i>Adverse Event</i> – Added CRS and ICANs grade fields. Updated DLT field to remove " (Dose Escalation only, first 28 days of treatment)?".</p> <p><i>CRS Signs and Symptoms and Neurotoxicity/ICANS Signs and Symptoms</i> – Removed grade field</p>
			<p><i>MRI Assessment</i> – Added new repeating form and dynamics</p> <p><i>12-Lead Electrocardiogram</i> – Triplicate – Added “or sitting” to the position fields</p> <p><i>Inclusion Not Met/Exclusion Not Met</i> – Added options 28-31 for “What was the identifier...”. Updated visible dynamics for “What was the identifier...” field.</p> <p><i>Adverse Events</i> – Added new field “Is this event an AESI?”</p>
			Sponsor Approved Version 5.0

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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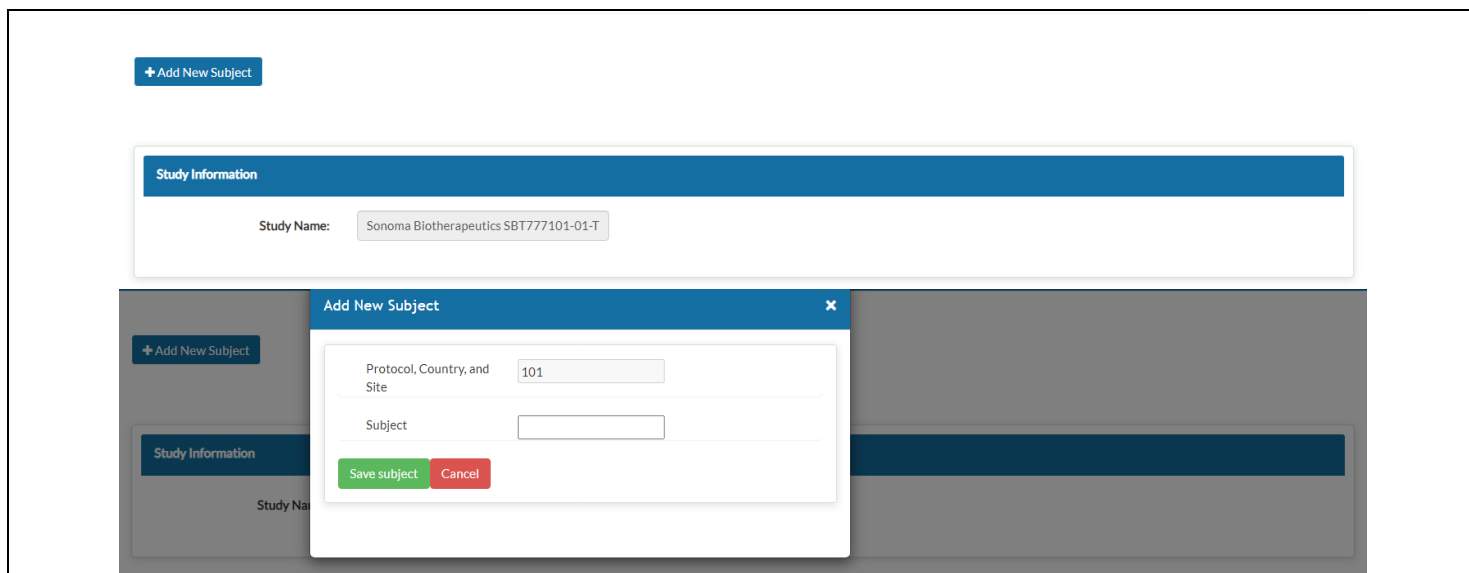
GENERAL INSTRUCTIONS

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-XXX, 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.

GENERAL INSTRUCTIONS (CONTINUED)

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.

Note: Each subject ID is unique and cannot be reused. If a subject is a re-screen, the subject will receive a new subject ID.

Subject: 101.001

Print CRFs

Subject Header

Protocol, Country, and Site: 101

Subject: 001

Edit Subject Key

Subject Header

Protocol, Country, and Site: 101

Subject: 001

Reason: Enter Reason

Save Cancel

- 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
 - 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.

GENERAL INSTRUCTIONS (CONTINUED)

3. Navigating EDC and Completing eCRFs

The screenshot displays the EDC interface. On the left is the 'Navigation Tree' for 'Subject 101.001'. It lists various forms under categories like 'Screening', 'Eligibility', 'Medical History', 'Vital Signs', 'Physical Examination', 'Laboratory', 'Summary', and 'Pre-Treatment'. The 'Eligibility' form is selected. On the right, the 'Eligibility' form is displayed for 'Subject: 101.001', 'Event: Screening', and 'Form: Eligibility'. The form contains several questions with dropdown menus and checkboxes, such as 'Did the subject meet all eligibility criteria?', 'Was subject enrolled into study?', 'Protocol version subject enrolled under:', 'Cohort', 'Cohort, Other Specify', 'Is this subject a rescreen?', and 'If yes, specify subject's previous Subject ID:'. A 'Reset Form' button is located at the bottom left of the form area.

- 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.
- For reference, below is the navigation tree icon guide

NAVIGATION TREE ICONS	
⌵	Option to filter Events/Forms displayed in the tree.
↺	Reset tree back to original view.
↔	Expand/Shrink width of navigation tree.
✕	Close the navigation tree.
📄	All required forms initially appear in this state.
📄	Entry is complete without issue.
📄	Form has been deleted pending CRA's Source Data Re-Verification.
📄	Source Data Verification is complete.
📄	Initial review by Data Management is complete.
📄	Data is missing or requires clarification via a query.
📄	Deleted form.
📄	Form is 'frozen' to prevent additional data changes. Contact your CRA or Data Coordinator if a change is required.
📄	Form is 'locked'. No further data changes can be made.
📄	Signature applied to form(s)/casebook.


GENERAL INSTRUCTIONS (CONTINUED)

Adding Repeating Forms

1. Locate the Gate 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 the corresponding CRF will be made available for data entry.
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.

Status Documents Data Entry	
Study Documents	
File Type	Document
 Protocol Version 5	
Page 1	Show All




- 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.

GENERAL INSTRUCTIONS (CONTINUED)

4. Data Entry and Query Guidelines

The screenshot displays the 'Data Entry' tab in the ClinTrak EDC system. At the top, there are tabs for 'Status', 'Documents', and 'Data Entry'. Below these, there are sub-tabs for 'Queries', 'Forms', and 'Signatures'. The main area contains filters for 'Site' (set to 'All Sites') and 'Status' (set to 'Open'), with 'Refresh' and 'Clear' buttons. An 'Apply Filters' button is on the left. On the right, there are 'Export' icons for PDF, Excel, and CSV. Below the filters is a table with the following columns: Site, Subject, Visit, Form, Field, Value, Query text(original), State, Created On, Last Modified, and Created By. The table contains three rows of data, all with a status of 'Open'.

Site	Subject	Visit	Form	Field	Value	Query text(original)	State	Created On	Last Modified	Created By
UAT Medpace Site	101, 001	Screening	Local Laboratory - Hematology 1	Platelet count:		Please provide a response.	Open	03/Jan/2023 11:5:12	03/Jan/2023 11:5:12	system
UAT Medpace Site	101, 001	Screening	Local Laboratory - Hematology 1	Red blood count (RBC):		Please provide a response.	Open	03/Jan/2023 11:5:12	03/Jan/2023 11:5:12	system
UAT Medpace Site	101, 001	Screening	Local Laboratory - Hematology 1	% Reticulocytes:		Please provide a response.	Open	03/Jan/2023 11:5:12	03/Jan/2023 11:5:12	system

- 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.

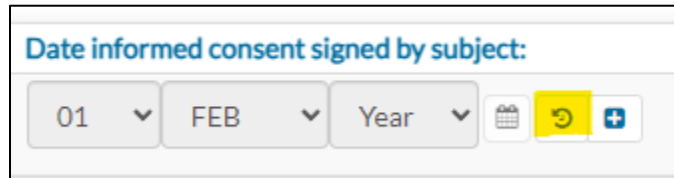
7. Principal Investigator Signature and Serious Adverse Event Reporting

- 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 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.

GENERAL INSTRUCTIONS (CONTINUED)

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.



Date informed consent signed by subject:

01 ▼ FEB ▼ Year ▼

Calendar icon, History icon (yellow square with circular arrow), Plus icon

Note: History Icon highlighted above

- 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

Note: Form availability shown is for Enrollment through Week 4 (Safety Follow-Up).

	Screening Period	Pre-Treatment Period		Pre-Treatment Reassessment X Period (X = 1, and each new period adds 1)†		Safety Follow-Up Period							
† Indicates Repeating Visit or Form	Screening Visit	Pre-Treatment 1	Pre-Treatment 2	Pre-Treatment 1	Pre-Treatment 2	Week 1				Week 2		Week 3	Week 4
Visit: Day	Screening Visit	Pre-Treatment 1	Pre-Treatment 2	Pre-Treatment 1	Pre-Treatment 2	1	2	4/5	7	11	14	21	28
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	W1D2	W1D4/5	W1D7	W2D11	W2D14	W3D21	W4D28
Visit Name in EDC Extract	SCR	PRT1	PRT2	Pre-Treatment Reassessment X Visit 1	Pre-Treatment Reassessment X Visit 2	W1D1	W1D2	W1D4/5	W1D7	W2D11	W2D14	W3D21	W4D28
Visit Window (Days)	-56 to -42	-41 to -11	-10 to -4	-41 to -11	-10 to -4				±1	±1	±2	±2	±2
Sheet Form*													
Date of Visit	X	X	X	X	X	X	X	X	X	X	X	X	X
Informed Consent/Demographics	X												
Eligibility	X												
Inclusion Not Met/Exclusion Criteria Met†	X												
Any Medical History	X												
Medical History†	X												
Alcohol and Drug Use	X												
Tobacco Use†	X												
Medical History - Rheumatoid Arthritis	X												
Prior Rheumatoid Arthritis Treatment Medication†	X												
Prior Rheumatoid Arthritis Treatment Medication 1†	X												
Vital Signs	X		X		X	X	X	X	X	X	X	X	X
Vital Signs - Oxygen Saturation	X		X		X	X							
Physical Examination 1	X		X		X	X	X	X	X	X	X	X	X
Physical Examination 1 - Clinical Findings†	X		X		X	X	X	X	X	X	X	X	X
12 Lead Electrocardiogram - Triplicate	X		X		X				X		X		
Chest X-Ray			X		X								
Synovitis Assessment			X		X								X
Synovial Biopsy and Fluid Collection			X		X								X
Apheresis Eligibility (Pre-Treatment)	X	X		X									
Apheresis		X		X									
Local Laboratory - HIV Screening	X												
Local Laboratory - Serological and Tuberculosis Tests	X												
Local Laboratory - Pregnancy	X		X		X	X							
Local Laboratory - Post Menopause	X												
Local Laboratory - Coagulation	X		X		X								
Local Laboratory - Hematology 1	X		X		X		X	X	X	X	X	X	X
Local Laboratory - Hematology 2	X		X		X		X	X	X	X	X	X	X
Local Laboratory - Clinical Chemistry 1	X		X		X		X	X	X	X	X	X	X
Local Laboratory - Clinical Chemistry 2	X		X		X		X	X	X	X	X	X	X
Local Laboratory - Creatinine Clearance/eGFR	X												
Local Laboratory - Urinalysis	X		X		X								

SCHEDULE OF ASSESSMENTS (CONTINUED)

Note: Form availability shown is for Enrollment through Week 4 (Safety Follow-Up)

	Screening Period	Pre-Treatment Period		Pre-Treatment Reassessment X Period (X = 1, and each new period adds 1)†		Safety Follow-Up							
† Indicates Repeating Visit or Form	Screening Visit	Pre-Treatment 1	Pre-Treatment 2	Pre-Treatment 1	Pre-Treatment 2	Week 1				Week 2		Week 3	Week 4
Day						1	2	4/5	7	11	14	21	28
Visit Name (How visits will appear ins EDC)	Screening	Pre-Treatment Visit 1	Pre-Treatment Visit 2	Pre-Treatment Reassessment	Pre-Treatment Reassessment	W1D1	W1D2	W1D4/5	W1D7	W2D11	W2D14	W3D21	W4D28
Visit Name in EDC Extract	SCR	PRT1	PRT2	Pre-Treatment Reassessment	Pre-Treatment Reassessment	W1D1	W1D2	W1D4/5	W1D7	W2D11	W2D14	W3D21	W4D28
Visit Window (Days)	-56 to -42	-41 to -11	-10 to -4	-41 to -11	-10 to -4				±1	±1	±2	±2	±2
Sheet Form*													
Local Laboratory - Lipid Tests			X		X								
C-Reactive Protein/Erythrocyte Sedimentation Rate	X		X		X		X		X		X	X	X
Rheumatoid Arthritis Serology Testing (RA)													
Joint Count Assessments	X		X		X						X		X
Visual Analog Scale (VAS)	X		X		X						X		X
Immune Effector Cell-Associated Encephalopathy (ICE) Score†			X		X	X	X	X	X	X	X	X	X
Health Assessment Questionnaire - Disability Index	X		X		X						X		X
Functional Assessment of Chronic Illness Therapy - Fatigue			X		X								
Pharmacokinetic Blood Samples			X		X		X	X	X	X	X	X	X
PBMC Immunogenicity			X		X								X
Serum Anti-drug Antibody			X		X								X
Plasma/Serum Exploratory Biomarkers	X		X		X		X		X		X	X	X
PBMC Exploratory Biomarkers	X		X		X		X	X	X	X	X	X	X
Replication Competent Lentivirus			X		X								
Pre-Treatment/Pre-Infusion Eligibility			X		X								
SBT777101 Administration						X							
Next Visit						X	X	X	X	X	X	X	X
Next Visit - Pre-Treatment		X		X									
GATE form - Any AE/CM/PR													
Adverse Events†													
CRS Signs and Symptoms†													
Neurotoxicity/ICANS Signs and Symptoms†													
Infusion Related Reactions†													
Prior & Concomitant Treatments/Medications†													
Prior & Concomitant Procedures†													
MRI Assessments†													
GATE - Markers													
Markers of Inflammation†													
Early Termination/End of Study													
Death Details													
Reconsent†													

SCHEDULE OF ASSESSMENTS (CONTINUED)

Note: Form availability shown is for Week 6 (Safety Follow-Up) through Early Termination/End of Study visits including Unscheduled visits.

	Follow-Up								Early Termination			
† Indicates Repeating Visit or Form	Week 6	Week 8	Week 10	Week 12	Week 18	Week 24	Week 36	Week 48/End of Study	Early Termination	Summary	Markers of Inflammation	Unscheduled†
Visit: Day	42	56	70	84	126	168	252	336				
Visit Name (How visits will appear in EDC)	W6D42	W8D56	W10D70	W12D84	W18D126	W24D168	W36D252	End of Study	Early Termination	Summary	Markers of Inflammation	Unscheduled Visits X
Visit Name in EDC Extract	W6D42	W8D56	W10D70	W12D84	W18D126	W24D168	W36D252	EOS	ET	N/A	N/A	Unscheduled Visits X
Visit Window (Days)	±2	±2	±2	±3	±7	±7	±7	±7				
Sheet Form*												
Date of Visit	X	X	X	X	X	X	X	X	X			X
Informed Consent/Demographics												
Eligibility												
Inclusion Not Met/Exclusion Criteria Met†												
Any Medical History												
Medical History†												
Alcohol and Drug Use												
Tobacco Use†												
Medical History - Rheumatoid Arthritis												
Prior Rheumatoid Arthritis Treatment Medication†												
Prior Rheumatoid Arthritis Treatment Medication 1†												
Vital Signs	X	X	X	X	X	X	X	X	X			X
Vital Signs - Oxygen Saturation												X
Physical Examination 1	X	X	X	X	X	X	X	X	X			X
Physical Examination 1 - Clinical Findings†	X	X	X	X	X	X	X	X	X			X
12-Lead Electrocardiogram -Triplicate								X	X			X
Chest X-Ray												
Synovitis Assessment				X					X			
Synovial Biopsy and Fluid Collection				X					X			X
Apheresis Eligibility (Pre-Treatment)												
Apheresis												
Local Laboratory - HIV Screening												X
Local Laboratory - Serological and Tuberculosis Tests												
Local Laboratory - Pregnancy				X	X	X		X	X			X
Local Laboratory - Post Menopause												
Local Laboratory - Coagulation					X	X		X				
Local Laboratory - Hematology 1	X	X	X	X	X	X	X	X	X			X
Local Laboratory - Hematology 2	X	X	X	X	X	X	X	X	X			X
Local Laboratory - Clinical Chemistry 1	X	X	X	X	X	X	X	X	X			X
Local Laboratory - Clinical Chemistry 2	X	X	X	X	X	X	X	X	X			X
Local Laboratory - Creatinine Clearance/eGFR												
Local Laboratory - Urinalysis		X					X	X	X			

SCHEDULE OF ASSESSMENTS (CONTINUED)

Note: Form availability shown is for Week 6 (Safety Follow-Up) through Early Termination/End of Study visits including Unscheduled visits.

	Follow-Up								Early Termination			
<i>† Indicates Repeating Visit or Form</i>	Week 6	Week 8	Week 10	Week 12	Week 18	Week 24	Week 36	Week 48/End of Study	Early Termination	Summary	Markers of Inflammation	Unscheduled [†]
Visit: Day	42	56	70	84	126	168	252	336				
Visit Name (How visits will appear in EDC)	W6D42	W8D56	W10D70	W12D84	W18D126	W24D168	W36D252	End of Study	Early Termination	Summary	Markers of Inflammation	Unscheduled Visits X
Visit Name in EDC Extract	W6D42	W8D56	W10D70	W12D84	W18D126	W24D168	W36D252	EOS	ET	N/A	N/A	Unscheduled Visits X
Visit Window (Days)	±2	±2	±2	±3	±7	±7	±7	±7				
Sheet Form*												
Local Laboratory – Lipid Tests								X				
C-Reactive Protein/Erythrocyte Sedimentation Rate	X	X	X	X	X	X	X	X	X			X
Rheumatoid Arthritis Serology Testing (RA)												X
Joint Count Assessments		X		X	X	X		X	X			X
Visual Analog Scale (VAS)		X		X	X	X		X	X			
Immune Effector Cell-Associated Encephalopathy (ICE) Score†	X	X	X	X	X	X	X	X	X			X
Health Assessment Questionnaire – Disability Index		X		X	X	X		X	X			
Functional Assessment of Chronic Illness Therapy – Fatigue					X	X		X	X			
Pharmacokinetic Blood Samples	X	X	X	X	X	X	X	X	X			X
PBMC Immunogenicity		X		X				X	X			X
Serum Anti-drug Antibody		X		X				X	X			X
Plasma/Serum Exploratory Biomarkers	X	X	X	X	X	X	X	X	X			X
PBMC Exploratory Biomarkers	X	X	X	X	X	X	X	X	X			X
Replication Competent Lentivirus				X		X		X				X
Pre-Treatment/Pre-Infusion Eligibility												
SBT777101 Administration												
Next Visit	X	X	X	X	X	X	X					
Next Visit – Pre-Treatment												
GATE form – Any AE/CM/PR										X		
Adverse Events†										X		
CRS Signs and Symptoms†										X		
Neurotoxicity/ICANS Signs and Symptoms†										X		
Infusion Related Reactions†										X		
Prior & Concomitant Treatments/Medications†										X		
Prior & Concomitant Procedures†										X		
MRI Assessments†										X		
GATE – Markers											X	
Markers of Inflammation†											X	
Early Termination/End of Study										X		
Death Details										X		
Reconsent†										X		

DYNAMICS AND TRIGGERS

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.

<u>Trigger Form</u>	<u>Trigger Form Question</u>	<u>Target Form</u>
Eligibility	Did the subject meet all screening eligibility? [YES]	<p><u>Screening folder</u>: Any Medical History, Vital Signs, Vital Signs – Oxygen Saturation, Physical Examination 1, 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, Medical History - Rheumatoid Arthritis, Synovitis Assessment, C-Reactive Protein/Erythrocyte Sedimentation Rate, Joint Count Assessments, Visual Analog Scale (VAS)</p> <p><u>Summary folder</u>: Early Termination/End of Study, Death Details, Reconsent</p> <p><u>Markers of Inflammation folder</u>: GATE - Markers</p> <p>Unscheduled Visits</p>
Eligibility	Primary Reason for Screen Failure at Screening phase: [FAILURE TO MEET TREATMENT ELIGIBILITY REQUIREMENTS]	Inclusion Not Met/Exclusion Criteria Met

DYNAMICS (CONTINUED)

<u>Trigger Form</u>	<u>Trigger Form Question</u>	<u>Target Form/Visit</u>
Eligibility AND Apheresis Eligibility (Pre-Treatment)	Did the subject meet all screening eligibility? [YES] AND Protocol version subject consented to [5.0] OR Did the subject meet all screening eligibility? [YES] AND Protocol version subject consented to [6.0 or above] AND Did the subject meet all apheresis eligibility? [YES] at Screening	Pre-Treatment Visits 1
Next Visit - Pre-Treatment	Is the subject continuing to the Pre-Treatment/Pre-Infusion visit OR will the subject be reassessed for apheresis at a later date?" [Pre-Treatment/Pre-Infusion] @ Pre-Treatment 1 OR Pre-Treatment Reassessment X Visit 1 where X = 1, 2, 3...	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 within the previous year? [YES]	Alcohol and Drugs Use
Any Medical History	Does the subject have any past and/or concomitant use of tobacco? [YES]	Tobacco 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

DYNAMICS (CONTINUED)

<u>Trigger Form</u>	<u>Trigger Form Question</u>	<u>Target Form/Visit</u>
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/Pre-Infusion 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)
Next Visit – Pre-Treatment	Is the subject continuing to the Pre-Treatment/Pre-Infusion visit OR will the subject be reassessed for apheresis at a later date? [Apheresis reassessment]	Pre-Treatment Reassessment X Visit 1 where X = 1, 2, 3...
Pre-Treatment/Pre-Infusion Eligibility	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 X 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/Pre-Infusion Eligibility	Will the subject be eligible for reassessment at a later date? [NO] at Pre-treatment 2 or any Pre-Treatment Reassessment X Visit 2 where X = 1, 2, 3,...	Early Termination visit
Eligibility	Did the subject meet all screening eligibility? [Yes] AND Protocol version subject consented to [5.0]	Synovial Biopsy and Fluid Collection @Screening
Eligibility	Protocol version subject consented to [6.0 or above]	Synovial Biopsy and Fluid Collection @Pre-Treatment 2 or any Pre-Treatment Reassessment X Visit 2 where X = 1, 2, 3...
Eligibility	Did the subject meet all screening eligibility? [Yes] AND Protocol version subject consented to [6.0 or above]	Apheresis Eligibility (Pre-Treatment) @Screening
Eligibility	Protocol version subject consented to [5.0 or above]	Apheresis Eligibility (Pre-Treatment) @Pre-Treatment 1
Eligibility	Did the subject meet all screening eligibility? [Yes] AND Protocol version subject consented to [6.0 or above]	Local Laboratory - HIV Screening @SCR

DYNAMICS (CONTINUED)

<u>Trigger Form</u>	<u>Trigger Form Question</u>	<u>Target Form/Visit</u>
Eligibility	Did the subject meet all screening eligibility? [Yes] AND Protocol version subject consented to [5.0]	Prior Rheumatoid Arthritis Treatment Medication
Eligibility	Did the subject meet all screening eligibility? [Yes] AND Protocol version subject consented to [6.0 or above]	Prior Rheumatoid Arthritis Treatment Medication 1
Physical Examination 1	Were there any abnormal and clinically significant findings or changes since the last exam? [Yes]	Physical Examination 1 – Clinical Findings
Eligibility AND Reconsent	Did the subject meet all screening eligibility? [Yes] AND Protocol version subject consented to [7.0 or above] OR Did the subject meet all screening eligibility? [Yes] AND Protocol version subject which subject reconsented under [7.0 or above]	MRI

DATE OF VISIT

Subject: 101.222Event: ScreeningForm: Date of Visit

Did the visit occur?

-- Select --

Reason visit did not occur:

Date of visit:

DayMonthYear

How was the visit conducted?

-- Select --

- 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.
- 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

INFORMED CONSENT/DEMOGRAPHICS

Subject: 101, 200 Event: Screening Form: Informed Consent/Demographics		
Date informed consent signed by subject:		
Day ▾	Month ▾	Year ▾   
Did the subject consent to future research of Blood, CAR Treg Cells, Synovial Tissue, and Synovial Fluid samples?		
-- Select -- ▾  		
Date of birth:		
Day ▾	Month ▾	Year ▾   
Sex at birth:		
-- Select -- ▾  		
Subject child bearing potential:		
-- Select -- ▾  		
Ethnicity:		
-- Select -- ▾  		
Race (Select all that apply):		
<input type="checkbox"/> AMERICAN INDIAN OR ALASKA NATIVE <input type="checkbox"/> ASIAN <input type="checkbox"/> BLACK OR AFRICAN AMERICAN <input type="checkbox"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER <input type="checkbox"/> WHITE <input type="checkbox"/> OTHER  		
If Other, specify:		
<div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>  		

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 childbearing 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

Subject: 101.049Event: ScreeningForm: Eligibility

Did the subject meet all screening eligibility?

-- Select --

Protocol version subject consented to:

-- Select --

Cohort

-- Select --

Cohort, Other Specify

Date of Screen Failure at Screening:

Day

Month

Year

Primary Reason for Screen Failure at Screening:

-- Select --

Primary Reason for Screen Failure at Screening Other, Specify:

Is this subject a rescreen?

-- Select --

If yes, specify subject's previous Subject ID:

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.

ELIGIBILITY (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-XXY, 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

Subject: 101, 200Event: ScreeningForm: Inclusion Not Met/Exclusion Criteria Met

Please enter a record for each criterion not met.

What was the category of the criterion?

-- Select --

What was the identifier of the criterion?

-- Select --

+ Add Another

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:		
	<div>1</div>	<div>11</div>	<div>21</div>
	<div>2</div>	<div>12</div>	<div>22</div>
	<div>3</div>	<div>13</div>	<div>23</div>
	<div>4</div>	<div>14</div>	<div>24</div>
	<div>5</div>	<div>15</div>	<div>25</div>
	<div>6</div>	<div>16</div>	<div>26</div>
	<div>7</div>	<div>17</div>	<div>27</div>
	<div>8</div>	<div>18</div>	<div>28</div>
	<div>9</div>	<div>19</div>	<div>29</div>
	<div>10</div>	<div>20</div>	<div>30</div>
			<div>31</div>

Note: Values 1-19 will only be available if the category is **Inclusion**, and values 1-31 will be available if the category is **Exclusion**

PRE-TREATMENT AND PRE-INFUSION ELIGIBILITY

An 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**.

Subject: 101, 109 Event: Pre-Treatment 2 Form: Pre-Treatment/Pre-Infusion Eligibility

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

-- Select --

Date of eligibility assessment:

Day Month Year

Primary reason:

-- Select --

Primary Adverse Event

Primary reason, Other specify:

Will the subject be eligible for reassessment at a later date?

-- Select --

Date of failure of Pre-Treatment eligibility:

Day Month Year

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 AND PRE-INFUSION ELIGIBILITY (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 eligibility failure:

Record the **date of eligibility failure** 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

Subject: 101. 115 Event: Screening Form: Any Medical History

Has the subject experienced any past and/or concomitant diseases?

-- Select --

Does the subject have any past and/or concomitant use of alcohol and/or drugs within 1 year prior to signing informed consent?

-- Select --

Does the subject have any past and/or concomitant use of tobacco?

-- Select --

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 within 1 year prior to signing informed consent?

Select **No** or **Yes**. A response is required.
Note: If **Yes** is selected, an **Alcohol and Drugs Use** eCRF will appear for completion

Does the subject have any past and/or concomitant use of tobacco?

Select **No** or **Yes**. A response is required.
Note: If **Yes** is selected, a **Tobacco Use** eCRF will appear for completion

MEDICAL HISTORY

Subject: 101,020 Event: Screening Form: Medical History

Event/diagnosis:

Start date:
Day Month Year

Ongoing?
-- Select --

End date:
Day Month Year

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

Medical history will include but is not limited to clinically significant diseases, surgeries, cancer history (including prior cancer therapies and procedures), inflammatory/autoimmune disease.

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.).

Note: Please do not record Rheumatoid Arthritis as a medical history event since it is the disease under study.

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

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

Subject: 101.055 Event: Screening Form: Medical History - Rheumatoid Arthritis		
Initial diagnosis date:		
Day	Month	Year
Date of Rheumatoid factor (RF) test:		
Day	Month	Year
Rheumatoid factor (RF) status		
-- Select --		
Rheumatoid factor (RF) titer (IU/mL)		
Date of Anti-Citrullinated Protein Antibody (ACPA) test:		
Day	Month	Year
Anti-Citrullinated Protein Antibody (ACPA) status		
-- Select --		
Anti-Citrullinated Protein Antibody (ACPA) titer at Screening		
ACPA Unit		
-- Select --		
ACPA Unit Other, Specify		

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

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

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

Rheumatoid factor (RF) titer (IU/mL)

Record the **Rheumatoid factor (RF) titer at screening** in **IU/mL**.

Note: This field is only enabled if **“Rheumatoid factor (RF) status”** 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

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

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

MEDICAL HISTORY– RHEUMATOID ARTHRITIS (CONTINUED)

Anti-Citrullinated Protein Antibody (ACPA) titer at Screening

Record the **Anti-Citrullinated Protein Antibody (ACPA)** titer at screening.

Note: *This field is only enabled if “Anti-Citrullinated Protein Antibody (ACPA) status” is “Positive”*

ACPA Unit

Select the **unit** for ACPA from the drop-down list:

- **Units/U**
CU
- **EU/mL**
- **Other**

Note: *This field is only enabled if “Anti-Citrullinated Protein Antibody (ACPA) status” is “Positive”*

Note: *If “Other” is selected, provide a response in the “ACPA Unit Other, Specify:” field*

PRIOR RHEUMATOID ARTHRITIS TREATMENT MEDICATION

Only populates for subjects enrolled in protocol version 5.0

Subject: 101,222	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.

Treatment/Medication Name:
<input type="text"/>
Type of treatment:
-- Select --
If Type of treatment is Other, Specify:
<input type="text"/>
Start date:
Day Month Year
Ongoing?
-- Select --
End date:
Day Month Year
Dose:
<input type="text"/>
Unit:
-- Select --
If Unit is other, specify:
<input type="text"/>
Frequency:
-- Select --
If Frequency is other, specify:
<input type="text"/>
Route:
-- Select --
If Route is other, specify:
<input type="text"/>
Reason for Discontinuing
-- Select --
If Reason for Discontinuing is other, specify:
<input type="text"/>

+ 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.

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 or at the end of the study, update this field accordingly to avoid overlapping records.

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. If dose of an ongoing medication changes, add and end date to prior record and add a new record for the new dosage.

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

- mg
- mg/kg
- gram
- mg/m²
- 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. For injections, start date and stop date are usually the same.

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

RHEUMATOID ARTHRITIS SEROLOGY TESTING (RA)

Subject: 101.055 Event: Unscheduled Visits 1 Form: Rheumatoid Arthritis Serology Testing (RA)	
Date of Rheumatoid factor (RF) test:	
Day	Month Year
Rheumatoid factor (RF) status	
-- Select --	
Rheumatoid factor (RF) titer (IU/mL)	
Date of Anti-Citrullinated Protein Antibody (ACPA) test:	
Day	Month Year
Anti-Citrullinated Protein Antibody (ACPA) status	
-- Select --	
Anti-Citrullinated Protein Antibody (ACPA) titer	
ACPA Unit	
-- Select --	
ACPA Unit Other, Specify	

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

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

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

Rheumatoid factor (RF) titer (IU/mL)

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

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

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

Anti-Citrullinated Protein Antibody (ACPA) titer

Record the **Anti-Citrullinated Protein Antibody (ACPA) titer**.
Note: This field is only enabled if **“Anti-Citrullinated Protein Antibody (ACPA) status”** is **“Positive”**

RHEUMATOID ARTHRITIS SEROLOGY TESTING (RA) (CONTINUED)

ACPA Unit

Select the **unit** for ACPA from the drop-down list:

- Units/U
CU
- EU/mL
- Other

Note: This field is only enabled if “Anti-Citrullinated Protein Antibody (ACPA) **status**” is “**Positive**”

Note: If “**Other**” is selected, provide a response in the “**ACPA Unit Other, Specify:**” field

PRIOR RHEUMATOID ARTHRITIS TREATMENT MEDICATION 1

Only populates for subjects enrolled in protocol version 6.0 and above

Subject: 101, 222 Event: Screening Form: Prior Rheumatoid Arthritis Treatment Medication 1		
<p>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.</p> <p>Please record one drug treatment per line. If a combo treatment, please record each drug in the combo separately.</p>		
Treatment/Medication Name:		
<input type="text"/>		
Type of treatment:		
<div>-- Select --</div>		
If Type of treatment is Other, Specify:		
<input type="text"/>		
Start date:		
<div>Day Month Year</div>		
Ongoing?		
<div>-- Select --</div>		
End date:		
<div>Day Month Year</div>		
Reason for Discontinuing		
<div>-- Select --</div>		
If Reason for Discontinuing is other, specify:		
<input type="text"/>		
+ Add Another		

If a medication is stopped for a period of time and started up again, it should be as two separate instances of the medication and so on.

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.

Treatment/Medication Name: Enter one **treatment/medication** into the text box provided.

Note: If treatment/medication is a combination, record each drug separately

PRIOR RHEUMATOID ARTHRITIS TREATMENT MEDICATION 1 (CONTINUED)

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

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

Subject: 101, 115 Event: Screening Form: Alcohol and Drugs Use	
Please record any Alcohol, and/or Drugs usage on this form that occurred within 1 year prior to signing informed consent.	
Any current or past alcohol use in the in the past year?	
<div>-- Select --</div>	
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	
<div></div>	
Any current or past drugs use in the in the past year?	
<div>-- Select --</div>	
Select all applicable categories:	
<div><input type="checkbox"/> CANNABINOIDS <input type="checkbox"/> OPIOIDS <input type="checkbox"/> STIMULANTS <input type="checkbox"/> CLUB DRUGS <input type="checkbox"/> DISSOCIATIVE DRUGS <input type="checkbox"/> HALLUCINOGENS <input type="checkbox"/> PRESCRIPTION MEDICATIONS <input type="checkbox"/> OTHER</div>	
Other, specify:	
<div></div>	

Please record any Alcohol, and/or Drugs usage on this form that occurred within 1 year prior to signing informed consent.

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 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

TOBACCO USE

Subject: **101.115** Event: **Screening** Form: **Tobacco Use**
Register

Please record any Tobacco usage on this log form. Each log should record 1 type of Tobacco use.

Is the subject a Current or Former user of tobacco?

-- Select --

Type of Tobacco

-- Select --

Other type of Tobacco, Specify:

Amount used:

Unit:

-- Select --

Other Unit, Specify:

Frequency

-- Select --

Start date of tobacco use:

Day Month Year

End date of tobacco use:

Day Month Year

+ Add Another

Please record any Tobacco usage on this log form. Each log should record 1 type of Tobacco use.

Is the subject a Current or Former user of tobacco?

Indicate if the subject is a **current or former user of tobacco** by selecting from the drop-down list:

- Current
- Former

Type of Tobacco

Indicate the **type of tobacco** by selecting from the drop-down list:

- Cigarettes
- e-Cigarettes
- Cigars
- Pipe
- Smokeless Tobacco
- Other

Note: If **“Other”** is selected, provide a response in the **“Other type of Tobacco, Specify:”** field

Amount used:

Record the **amount of tobacco used**

TOBACCO USE (CONTINUED)

Unit:

Select the **unit** of the tobacco used from the drop-down list:

- **Pack**
- **Cigarette**
- **Cigar**
- **Milliliter**
- **Ounces**
- **Pipe**
- **Cartridge**
- **Pouch**
- **Other**

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

Frequency

Select the **frequency** of the tobacco used from the drop-down list:

- **Per day**
- **Per week**
- **Per month**
- **Per year**
- **Occasionally**

Start date of tobacco use:

Record the **start date of tobacco use** 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

End date of tobacco use:

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

Note: This field is only visible if "**Is the subject a Current or Former user of tobacco?**" is "**Former**"

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

VITAL SIGNS

Subject: 101,200 Event: Screening Form: Vital Signs		
Were vital signs taken?		
<div>-- Select --</div>		
Date performed:		
<div>Day</div>	<div>Month</div>	<div>Year</div>
Time performed:		
<div>HH</div>	<div>MM</div>	
Height (cm):		
Weight (kg):		
Body mass index (BMI, kg/m2)		
Systolic blood pressure (mmHg):		
Diastolic blood pressure (mmHg):		
Heart rate (bpm):		
Temperature (C):		
Respiratory rate (breaths/min):		
In what position was the subject during the measurement?		
<div>-- Select --</div>		

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. <u>Note:</u> <i>This field is enabled if vital signs were taken at all visits</i>
Time performed:	Record the time performed in the HH:MM 24-hour clock format. <u>Note:</u> <i>This field is enabled if vital signs were taken at all visits</i>
Height (cm):	Record the height of the subject in centimeters in the field provided. <u>Note:</u> <i>This field is only visible at Screening visit</i>
Weight (kg):	Record the weight of the subject in kilograms (kg) in the field provided. <u>Note:</u> <i>This field is only visible at the following visits:</i> <ul style="list-style-type: none">• Screening• Pre-Treatment 2• W8D56• Early Termination• End of Study• Unscheduled
Body mass index (BMI, kg/m²)	This field is read only and is calculated automatically. <u>Note:</u> <i>This field is only visible at Screening visit</i>
Systolic blood pressure (mmHg):	Record the systolic blood pressure in mmHg in the field provided. <u>Note:</u> <i>This field is enabled if vital signs were taken at all visits</i>
Diastolic blood pressure (mmHg):	Record the diastolic blood pressure in mmHg in the field provided. <u>Note:</u> <i>This field is enabled if vital signs were taken at all visits</i>
Heart rate (bpm):	Record the heart rate in beats per minute (bpm) in the field provided. <u>Note:</u> <i>This field is enabled if vital signs were taken at all visits</i>
Temperature (C):	Record the temperature in Celsius (C) in the field provided. <u>Note:</u> <i>This field is enabled if vital signs were taken at all visits</i>
Respiratory rate (breaths/min):	Record the respiratory rate in breaths/min in the field provided. <u>Note:</u> <i>This field is enabled if vital signs were taken at all visits</i>
In what position was the subject during the measurement?	Select the position the subject was during the measurement from the drop-down list: <ul style="list-style-type: none">• SITTING• STANDING• SUPINE• SEMI-RECLINED <u>Note:</u> <i>This field is enabled if vital signs were taken at all visits</i>

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 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**

VITAL SIGNS – OXYGEN SATURATION

Subject: 101.062 Event: Screening Form: Vital Signs - Oxygen Saturation

Were oxygen saturation readings taken?

-- Select --

Date performed:

Day Month Year

Oxygen Saturation (%)

Were oxygen saturation readings taken?

Indicate if **oxygen saturation readings** 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

Oxygen Saturation (%)

Record the **oxygen saturation** of the subject in **percentage** in the field provided.

Note: This field is only visible at **Screening, Pre-Treatment 2, Pre-Treatment Reassessment X Visit 2, W1D1, and Unscheduled** visit

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

- **Were oxygen saturation readings 15 minutes post-infusion taken?**
- **Were oxygen saturation readings 30 minutes post-infusion taken?**
- **Were oxygen saturation readings 45 minutes post-infusion taken?**
- **Were oxygen saturation readings 60 minutes post-infusion taken?**
- **Were oxygen saturation readings 4 hours post-infusion taken?**
- **Were oxygen saturation readings 8 hours post-infusion taken?**
- **Were oxygen saturation readings 12 hours post-infusion taken?**
- **Were oxygen saturation readings 16 hours post-infusion taken?**
- **Were oxygen saturation readings 20 hours post-infusion taken?**
- **Were oxygen saturation readings 24 hours post-infusion taken?**

X minutes/hours post-infusion Oxygen Saturation (%)

Record the **oxygen saturation** of the subject in **percentage** in the field provided.

PHYSICAL EXAMINATION 1

Subject: 101, 222 Event: Screening Form: Physical Examination 1

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

Was the physical examination performed?

-- Select --

Type of physical examination

-- Select --

Date performed:

Day Month Year

Were there any abnormal and clinically significant findings or changes since the last exam?

-- Select --

Indicate below which body systems had any abnormal and clinically significant findings since the last exam with a "Yes" response. If no findings or not assessed, then a "No" or "Not Done" response is expected. Then record the indication and brief description of each finding on a corresponding Physical Examination 1 - Clinical Significance log.

Cardiovascular

-- Select --

Respiratory

-- Select --

Gastrointestinal

-- Select --

Neurological

-- Select --

Musculoskeletal

-- Select --

Dermatological

-- Select --

Other

-- Select --

Other Body system, specify:

Record any **abnormal** and clinically significant findings on the Medical History or Adverse Events eCRF as appropriate. Indicate any clinically significant findings of the physical exam related to Medical History, Adverse Events, or Rheumatoid Arthritis on this form.

Was the physical examination performed?

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

Type of physical examination

Select **type of physical examination** from the drop down list:

- **Complete**
- **Symptom Directed**

Date performed:

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

Were there any abnormal and clinically significant findings or changes since the last exam?

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

PHYSICAL EXAMINATION 1 (CONTINUED)

*Indicate below which body systems had any **abnormal and clinically significant findings** since the last exam with a "Yes" response. If no findings or not assessed, then a "No" or "Not Done" response is expected. Then record the indication and brief description of each finding on a corresponding Physical Examination 1 - Clinical Findings log.*

Select **Not Done** to indicate if the physical exam was not done for that body system.











Select **No** to indicate there were no clinically significant findings or clinically significant changes in the body systems from last exam for the following fields.

Select **Yes** to indicate if there were any clinically significant findings or clinically significant changes in the body systems from last exam for the following fields:

- **Cardiovascular**
- **Respiratory**
- **Gastrointestinal**
- **Neurological**
- **Musculoskeletal**
- **Dermatological**
- **Other**

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

PHYSICAL EXAMINATION 1 – CLINICAL FINDINGS

Subject: 101, 222 Event: Screening Form: Physical Examination 1 - Clinical Findings	
Indicate Body System	
<input type="text" value="-- Select --"/>	 
Other Body system, specify:	
<input type="text"/>	 
Primary Indication	
<input type="text" value="-- Select --"/>	 
Primary Indication # in EDC	
<input type="text"/>	 
Description of finding:	
<input type="text"/>	 

Indicate Body System

Indicate **body system** from the drop down list:

- **Cardiovascular**
- **Respiratory**
- **Gastrointestinal**
- **Neurological**
- **Dermatologic**
- **Musculoskeletal**
- **Other**

Note: If **Yes** is selected for “**Other**”, provide a response in the “**Other Body system, specify:**” field

Primary Indication

Select the **primary indication** from the drop down list:

- **Adverse Event**
- **Medical History**
- **Rheumatoid Arthritis**

Note: If “**Adverse Event**” or “**Medical History**” are selected, record the corresponding primary adverse event/medical history number in the “**Primary Indication # in EDC**” field

Description of finding:

Record **description of findings** in the text box provided.

Note: Only visible if “**Adverse Event**” or “**Medical History**” are selected for **Primary Indication**

Note – Physical exam findings should only be noted for clinical finding during the actual physical exam, e.g. rash, etc. Any medical history during the screening visit should be recorded as such unless it is newly identified during the physical exam.

12-LEAD ELECTROCARDIOGRAM – TRIPLICATE

Subject: 101, 123	Event: Pre-Treatment 2	Form: 12-Lead Electrocardiogram -TriPLICATE
-------------------	------------------------	---

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

Was a 12-Lead ECG performed?

-- Select --

Date performed:

Day Month Year

Was the ECG performed with the subject in a supine or sitting position?

-- Select --

If not supine or sitting, indicate position:

-- Select --

Reading 1

Time performed:

HH MM

Heart rate (bpm):

PR interval (msec):

QRS duration (msec):

QT interval (msec):

QTcF interval (msec):

RR interval (msec):

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 or sitting 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 or sitting position?	Select No or Yes to indicate if the ECG was performed with the subject in a supine or sitting position.
If not supine or sitting, indicate position	Select the position the subject was during the measurement from the drop-down list: <ul style="list-style-type: none">• DECUBITUS• FOWLERS• LATERAL DECUBITUS• LEFT LATERAL DECUBITUS• PRONE• REVERSE TRENDELENBURG• RIGHT LATERAL DECUBITUS• SEMI-FOWLERS• SEMI-RECUMBENT• 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)	This field is read only and is calculated automatically.
Overall interpretation:	Select the overall interpretation of this 12-lead ECG from the drop-down list: <ul style="list-style-type: none">• 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.

Subject: 101, 200Event: ScreeningForm: Chest X-Ray

Was a standard posterior-anterior and lateral chest x-ray obtained?

-- Select --

Date of x-ray

DayMonthYear

Were there any abnormal findings in the Chest X-Ray?

-- Select --

Please specify any abnormal findings:

Were the abnormal findings clinically significant?

-- Select --

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. <i>Note: This field is only enabled if “Were there any abnormal findings in the Chest X-Ray?” is “Yes”</i>
Were the abnormal findings clinically significant?	Indicate if the abnormal findings were clinically significant by selecting No or Yes . <i>Note: This field is only enabled if “Were there any abnormal findings in the Chest X-Ray?” is “Yes”</i>

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.**

For the sake of brevity, the screenshot for this form does not show ALL of the joint fields visible on this form.

Was a Synovitis Assessment performed using ultrasound?

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

Date of Assessment

If **Yes**, record the **date of assessment** in the **DD/MMM/YYYY** format. A complete date is required.

Left and Right Joints fields for the following sites will be enabled for completion if “**Yes**” is selected for “**Was a Synovitis Assessment performed using ultrasound?**”:

- | | | | |
|------------------------------|------------------------------|------------------------------|------------------------------|
| • Wrist | • 1 st MCP (hand) | • Tibiotalar | • 2 nd MTP (foot) |
| • Elbow | • 2 nd MCP (hand) | • Talonavicular | • 3 rd MTP (foot) |
| • Shoulder | • 3 rd MCP (hand) | • 1 st PIP (foot) | • 4 th MTP (foot) |
| • 1 st PIP (hand) | • 4 th MCP (hand) | • 2 nd PIP (foot) | • 5 th MTP (foot) |
| • 2 nd PIP (hand) | • 5 th MCP (hand) | • 3 rd PIP (foot) | • IP (foot) |
| • 3 rd PIP (hand) | • IP (hand) | • 4 th PIP (foot) | • Other |
| • 4 th PIP (hand) | • Knee | • 1 st MTP (foot) | |

Indicate the scoring/grading for each site by selecting “**0, 1, 2, or 3**” from the drop down list.

Note: If “**Other**” is selected, provide a response in the “**If L/R-Other, 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.**

Subject: 101, 200 Event: Screening Form: Synovial Biopsy and Fluid Collection

Was a Synovial Biopsy performed?

-- Select --

Date of collection

Day Month Year

Biopsy from which joint?

-- Select --

If Biopsy from which joint is Other, specify:

Was Synovial Fluid collected?

-- Select --

Date of collection

Day Month Year

Fluid collection from which joint?

-- Select --

If Fluid collection from which joint is Other, specify:

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 (PRE-TREATMENT)

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

Subject: 101, 115
Event: Screening
Form: Apheresis Eligibility (Pre-Treatment)

Did the subject meet all apheresis eligibility?

-- Select --

Date of eligibility assessment:

Day
Month
Year

Primary reason:

-- Select --

Primary reason if Concomitant Medication, Clinically Significant Medical Events, or Other, specify:

Will the subject be eligible for reassessment at a later date?

-- Select --

Date of Screen Failure at Apheresis:

Day
Month
Year

Primary Reason for Screen Failure at Apheresis:

-- Select --

Primary Reason for Screen Failure at Apheresis Other, Specify:

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 ELIGIBILITY (Pre-Treatment) (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

Subject: 101.055 Event: Pre-Treatment 1 Form: Apheresis	
Did the subject undergo the apheresis procedure?	
<div style="border: 1px solid #ccc; padding: 2px;"> -- Select -- </div>	
Reason Apheresis Not Done:	
<div style="border: 1px solid #ccc; padding: 2px;"> -- Select -- </div>	
Primary Adverse Event # Indicated (record the primary AE associated):	
<div style="border: 1px solid #ccc; padding: 2px;"> </div>	
Reason Apheresis Not Done Other, Specify:	
<div style="border: 1px solid #ccc; padding: 2px;"> </div>	
Date of Apheresis	
<div style="display: flex; align-items: center;"> <div style="margin-right: 5px;">Day</div> <div style="margin-right: 5px;">Month</div> <div style="margin-right: 5px;">Year</div> <div style="margin-right: 5px;"> <input type="text"/> </div> <div style="margin-right: 5px;"> <input type="text"/> </div> <div> <input type="text"/> </div> </div>	
Apheresis Start time (24hr clock):	
<div style="display: flex; align-items: center;"> <div style="margin-right: 5px;">HH</div> <div style="margin-right: 5px;">MM</div> <div> <input type="text"/> </div> </div>	
Apheresis End time (24hr clock):	
<div style="display: flex; align-items: center;"> <div style="margin-right: 5px;">HH</div> <div style="margin-right: 5px;">MM</div> <div> <input type="text"/> </div> </div>	
Was the Apheresis Successful?	
<div style="border: 1px solid #ccc; padding: 2px;"> -- Select -- </div>	
Reason Apheresis Not Successful:	
<div style="border: 1px solid #ccc; padding: 2px;"> -- Select -- </div>	
Primary Adverse Event # Indicated (record the primary AE associated):	
<div style="border: 1px solid #ccc; padding: 2px;"> </div>	
Reason Apheresis Not Successful Other, Specify:	
<div style="border: 1px solid #ccc; padding: 2px;"> </div>	
Was Cell Manufacturing Successful?	
<div style="border: 1px solid #ccc; padding: 2px;"> -- Select -- </div>	
Reason Cell Manufacturing Not Successful:	
<div style="border: 1px solid #ccc; padding: 2px;"> -- Select -- </div>	
Reason Cell Manufacturing Not Successful Other, Specify:	
<div style="border: 1px solid #ccc; padding: 2px;"> </div>	

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 (CONTINUED)

Date of Apheresis	Record the date of initial apheresis in the DD/MMM/YYYY format. A complete date is required. <u>Note:</u> 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 . <u>Note:</u> 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: <ul style="list-style-type: none"> • ADVERSE EVENT • OTHER <u>Note:</u> If “ Adverse Event ” is selected, record the corresponding primary adverse event number in the “ Specify Primary Adverse Event sequence number ” field <u>Note:</u> If “ Other ” is selected, specify the primary cause of death in the “ If Other, specify ” field
Was Cell Manufacturing Successful?	Select No or Yes to indicate if cell manufacturing was successful . <u>Note:</u> This field is only enabled if “ Was Apheresis Successful? ” is “ Yes ”
Reason Cell Manufacturing Not Successful:	Select the reason cell manufacturing was not successful from the drop down-list: <ul style="list-style-type: none"> • ADVERSE EVENT • OTHER <u>Note:</u> If “ Adverse Event ” is selected, record the corresponding primary adverse event number in the “ Specify Primary Adverse Event sequence number ” field <u>Note:</u> If “ Other ” is selected, specify the reason cell manufacturing was not successful in the “ Reason Cell Manufacturing Not Successful Other, specify ” field

LOCAL LABORATORY – SEROLOGICAL AND TUBERCULOSIS TESTS

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

Subject: 101, 200 Event: Screening Form: Local Laboratory - Serological and Tuberculosis Tests

Was a serological test performed?

-- Select --

Collection date:

Day Month Year

Hepatitis B surface antigen:

-- Select --

Hepatitis C antibody:

-- Select --

HBV DNA:

-- Select --

HCV RNA:

-- Select --

Was a tuberculosis assessment performed?

-- Select --

Collection date:

Day Month Year

Quantiferon Gold results:

-- Select --

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.

Subject: 101.200 Event: W1D1 Form: Local Laboratory - Pregnancy

Was the urine pregnancy test collected?

-- Select --

Urine pregnancy collection date:

Day Month Year

Urine pregnancy collection time (24hr clock)

HH MM

Urine pregnancy result:

-- Select --

Was the serum pregnancy test collected?

-- Select --

Serum pregnancy collection date:

Day Month Year

Serum pregnancy collection time (24hr clock)

HH MM

Serum pregnancy result:

-- Select --

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.

Subject: 101, 200Event: ScreeningForm: Local Laboratory - Post Menopause

Was a post menopausal assessment performed?

-- Select --

Collection date:

DayMonthYear

Follicle-Stimulating Hormone (FSH, IU/L)

Estradiol (pg/ml)

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.

Subject: 101,200	Event: Screening	Form: Local Laboratory - Coagulation
------------------	------------------	--------------------------------------

Was coagulation sample collected?

-- Select --

Collection date:

Day Month Year

Was a primary local laboratory used?

-- Select --

Lab name:

- Select Lab -

Prothrombin time (PT) not done:

☐

Prothrombin time (PT, seconds):

Prothrombin time (PT) Lower limit:

Prothrombin time (PT) Upper limit:

Prothrombin time (PT) Out of Range?

-- Select --

Prothrombin time (PT) Clinically Significant?

-- Select --

International normalized ratio (INR) not done:

☐

International normalized ratio (INR):

International normalized ratio (INR) Lower limit:

International normalized ratio (INR) Upper limit:

International normalized ratio (INR) Out of Range?

-- Select --

International normalized ratio (INR) Clinically Significant?

-- Select --

Activated partial thromboplastin time (aPTT) not done:

☐

Activated partial thromboplastin time (aPTT, seconds):

Activated partial thromboplastin time (aPTT) Lower limit:

Activated partial thromboplastin time (aPTT) Upper limit:

Activated partial thromboplastin time (aPTT) Out of Range?

-- Select --

Activated partial thromboplastin time (aPTT) Clinically Significant?

-- Select --

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 primary local laboratory was used. <i><u>Note:</u> If “No” is selected, enter the range in the lower and upper limit fields for the indicated parameters</i>
Lab name:	Select the corresponding lab name from the drop-down list. <i><u>Note:</u> If a lab name is selected, the lower and upper limit fields are not required for data entry</i> <i><u>Note:</u> If the required lab name is unavailable, please contact your CRA and Medpace Data Management</i>
Results:	Record the test results for the following parameters. If the parameter was not collected, select the ‘ Not Done ’ checkbox. <ul style="list-style-type: none">• 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 . <i><u>Note:</u> This field is only enabled if “Out of Range?” is “Yes”</i> <i><u>Note:</u> If this field is “Yes”, please record any clinically significant findings on the Medical History or Adverse Events eCRF as appropriate.</i>

LOCAL LABORATORY – HEMATOLOGY 1

Subject: 101, 200	Event: Screening	Form: Local Laboratory - Hematology 1
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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 --

Collection date:

Day Month Year

Collection time (24-hour clock):

HH MM

Was a primary local laboratory used?

-- Select --

Lab name:

- Select Lab -

Hematocrit (Hct) not done:

☐

Hematocrit (Hct):

Hematocrit (Hct) Unit:

-- Select --

Hematocrit (Hct) Unit Other, specify:

Hematocrit (Hct) Lower limit:

Hematocrit (Hct) Upper limit:

Hematocrit (Hct) Out of Range?

-- Select --

Hematocrit (Hct) Clinically Significant?

-- Select --

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 (if applicable):

- %
- fL
- g/dL
- mcm³
- pg
- x 10³/mcL
- x 10⁶/mcL
- x 10⁹/L
- x 10¹²/L
- K/mm³
- M/mcL
- 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**”

Note: If this field is “**Yes**”, please record any clinically significant findings on the Medical History or Adverse Events eCRF as appropriate.

LOCAL LABORATORY – HEMATOLOGY 2

Subject: 101, 200	Event: Screening	Form: Local Laboratory - Hematology 2
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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 --

Collection date:

Day Month Year

Collection time (24-hour clock):

HH MM

Was a primary local laboratory used?

-- Select --

Lab name:

- Select Lab -

White blood count (WBC) not done:

☐

White blood count (WBC):

White blood count (WBC) Unit:

-- Select --

White blood count (WBC) Unit Other, specify:

White blood count (WBC) Lower limit:

White blood count (WBC) Upper limit:

White blood count (WBC) Out of Range?

-- Select --

White blood count (WBC) Clinically Significant?

-- Select --

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):

- $\times 10^3/\text{mcL}$
- $\times 10^9/\text{L}$
- K/mm^3
- **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**”

Note: If this field is “**Yes**”, please record any clinically significant findings on the Medical History or Adverse Events eCRF as appropriate.

LOCAL LABORATORY – HIV SCREENING

Subject: 101, 115Event: ScreeningForm: Local Laboratory - HIV Screening

Was HIV testing completed?

-- Select --

Collection date:

Day

Month

Year

HIV testing results:

-- Select --

Was HIV testing completed?

Select **No** or **Yes** to indicate if **HIV testing** was completed

Collection date:

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

HIV testing results:

Select **Positive** or **Negative** to indicate if **HIV testing results**

LOCAL LABORATORY – CLINICAL CHEMISTRY 1

Subject: 101, 200	Event: Screening	Form: Local Laboratory - Clinical Chemistry 1
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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 --

Collection date:

Day

Month

Year

Collection time (24-hour clock):

HH

MM

Was a primary local laboratory used?

-- Select --

Lab name:

- Select Lab -

Alanine aminotransferase (ALT) not done:

Alanine aminotransferase (ALT) result:

Alanine aminotransferase (ALT) Unit:

-- Select --

Alanine aminotransferase (ALT) Unit Other, specify:

Alanine aminotransferase (ALT) Lower limit:

Alanine aminotransferase (ALT) Upper limit:

Alanine aminotransferase (ALT) Out of Range?

-- Select --

Alanine aminotransferase (ALT) Clinically Significant?

-- Select --

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):

- g/dL
- mEq/L
- mg/dL
- mmol/L
- U/L
- 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**”

Note: If this field is “**Yes**”, please record any clinically significant findings on the Medical History or Adverse Events eCRF as appropriate.

LOCAL LABORATORY – CLINICAL CHEMISTRY 2

Subject: 101, 200	Event: Screening	Form: Local Laboratory - Clinical Chemistry 2
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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 --

Collection date:

Day

Month

Year

Collection time (24-hour clock):

HH

MM

Was a primary local laboratory used?

-- Select --

Lab name:

- Select Lab -

Non-Fasting Glucose not done:

Non-Fasting Glucose result:

Non-Fasting Glucose Unit:

-- Select --

Non-Fasting Glucose Unit Other, specify:

Non-Fasting Glucose Lower limit:

Non-Fasting Glucose Upper limit:

Non-Fasting Glucose Out of Range?

-- Select --

Non-Fasting Glucose Clinically Significant?

-- Select --

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):

- %
- g/dL
- g/L
- mg/dL
- mEq/L
- mmol/L
- 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**”

Note: If this field is “**Yes**”, please record any clinically significant findings on the Medical History or Adverse Events eCRF as appropriate.

LOCAL LABORATORY – CREATININE CLEARANCE/EGFR

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

Subject: 101, 200 Event: Screening Form: Local Laboratory - Creatinine Clearance/eGFR

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 --

Collection date

Day

Month

Year

eGFR result sign

-- Select --

eGFR result

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

Subject: 101, 200 Event: Screening Form: Local Laboratory - Urinalysis
--

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 --

Collection date:

Day Month Year

Any abnormal results?

-- Select --

Were any abnormal results clinically significant?

-- Select --

Select all that apply to indicate which tests were performed and had abnormal clinically significant results:

Bacteria

Bilirubin

Casts

Color

Clarity

Crystals

Epithelial Cells

Erythrocytes (RBC)

pH

Protein/Creatinine

Specific Gravity

Other

Other, specify

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**”

Note: If this field is “**Yes**”, please record any clinically significant findings on the Medical History or Adverse Events eCRF as appropriate.

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

Subject: 101, 200 Event: Pre-Treatment 2 Form: Local Laboratory - Lipid Tests

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 --

Collection date:

Day Month Year

Collection time (24-hour clock):

HH MM

Was a primary local laboratory used?

-- Select --

Lab name:

- Select Lab -

Total cholesterol not done:

☐

Total cholesterol result:

Total cholesterol Unit:

-- Select --

Total cholesterol Unit Other, specify:

Total cholesterol Lower limit:

Total cholesterol Upper limit:

Total cholesterol Out of Range?

-- Select --

Total cholesterol Clinically Significant?

-- Select --

LDL not done:

☐

LDL result:

LDL Unit:

-- Select --

LDL Unit Other, specify:

LDL Lower limit:

LDL Upper limit:

LDL Out of Range?

-- Select --

LDL Clinically Significant?

-- Select --

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):
- **mg/dL**
 - **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"**
Note: If this field is **"Yes"**, please record any clinically significant findings on the Medical History or Adverse Events eCRF as appropriate.

C-REACTIVE PROTEIN/ERYTHROCYTE SEDIMENTATION RATE

Subject: **101, 200**
Event: **Screening**
Form: **C-Reactive Protein/Erythrocyte Sedimentation Rate**

Was a C-Reactive Protein (CRP) assessment performed?

-- Select --

Date of CRP assessment

Day
Month
Year

C-Reactive Protein (CRP, mg/L)

Was an Erythrocyte Sedimentation Rate (ESR) assessment performed?

-- Select --

Date of ESR assessment

Day
Month
Year

Erythrocyte Sedimentation Rate (ESR, mm/hr)

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** 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.

Subject: 101.200 Event: Screening Form: Joint Count Assessments	
Was a Joint Count Assessment performed?	
<div>-- Select --</div>	
Date of assessment	
<div>Day Month Year</div>	
Total Number Swollen Joints (DAS28)	
<div></div>	
Total Number Swollen Joints (DAS28) Not Assessed	
<div></div>	
Total Number Tender Joints (DAS28)	
<div></div>	
Total Number Tender Joints (DAS28) Not Assessed	
<div></div>	
Total Number Swollen Joints (66)	
<div></div>	
Total Number Swollen Joints (66) Not Assessed	
<div></div>	
Total Number Tender Joints (68)	
<div></div>	
Total Number Tender Joints (68) Not Assessed	
<div></div>	

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.
Total Number Swollen Joints (66) Not Assessed	Record the Total Number Swollen Joints (66) was not assessed in the field provided.
Total Number Tender Joints (68)	Record the Total Number Tender Joints (68) in the field provided.
Total Number Tender Joints (68) Not Assessed	Record the Total Number Tender Joints (68) was not assessed in the field provided.

VISUAL ANALOG SCALE (VAS)

Subject: 101,200 Event: Screening Form: Visual Analog Scale (VAS)

Measured from left to right in mm

Was the Subject's Global Assessment of Arthritis completed at this visit?

-- Select --

Date of Subject's Global assessment:

Day Month Year

Subject's Global Assessment (mm)

Was the Subject's Assessment of Arthritis Pain completed at this visit?

-- Select --

Date of Subject's Pain assessment:

Day Month Year

Subject's Pain Assessment (mm)

Was Physician's Global Assessment of Arthritis completed at this visit?

-- Select --

Date of Physician's Assessment:

Day Month Year

Physician's Global Assessment (mm)

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

Subject: 101_062 Event: Pre-Treatment 2 Form: Immune Effector Cell-Associated Encephalopathy (ICE) Score	
Was an ICE score collected?	
-- Select --	
Date of ICE score collection	
Day	Month Year
Time of ICE score collection (24 hour clock):	
HH	MM
Was this ICE score collection associated with a neurotoxicity event?	
-- Select --	
Adverse Event # associated with this ICE score	
Subject ICE Score	
Orientation	
-- Select --	
Naming	
-- Select --	
Following Commands	
-- Select --	
Writing	
-- Select --	
Attention	
-- Select --	
ICE Score	
--	
+ Add Another	

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

This field is read only and is calculated automatically.

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. <u>Note:</u> 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. <u>Note:</u> This field is visible at all timepoints except Pre-dose timepoint
Orientation	Select the score for orientation from the drop-down list: <ul style="list-style-type: none">• 0• 1• 2• 3• 4
Naming	Select the score for naming from the drop-down list: <ul style="list-style-type: none">• 0• 1• 2• 3
Following Commands	Select the score for following commands from the drop-down list: <ul style="list-style-type: none">• 0• 1
Writing	Select the score for writing from the drop-down list: <ul style="list-style-type: none">• 0• 1
Attention	Select the score for attention from the drop-down list: <ul style="list-style-type: none">• 0• 1
ICE Score	This field is read only and is calculated automatically.

HEALTH ASSESSMENT QUESTIONNAIRE – DISABILITY INDEX

Subject: 101,200 Event: Screening Form: Health Assessment Questionnaire - Disability Index	
Was the Health Assessment Questionnaire - Disability Index completed?	
<div>-- Select --</div>	
Date completed:	
<div>Day</div> <div>Month</div> <div>Year</div> <div></div> <div></div> <div></div>	
Dressing and Grooming	
Are you able to dress yourself, including shoelaces and buttons?	
<div>-- Select --</div>	
Are you able to shampoo your hair?	
<div>-- Select --</div>	
Arising	
Are you able to stand up from a straight chair?	
<div>-- Select --</div>	
Are you able to get in and out of bed?	
<div>-- Select --</div>	
Eating	
Are you able to cut your own meat?	
<div>-- Select --</div>	
Are you able to lift a full cup or glass to your mouth?	
<div>-- Select --</div>	
Are you able to open a new milk carton?	
<div>-- Select --</div>	
Walking	
Are you able to walk outdoors on flat ground?	
<div>-- Select --</div>	
Are you able to climb up five steps?	
<div>-- Select --</div>	
AIDS or DEVICES - DAEW	
Please check any AIDS or DEVICES that you usually use for any of the above activities	
<div><input type="checkbox"/> DEVICES USED FOR DRESSING</div> <div><input type="checkbox"/> SPECIAL OR BUILT UP CHAIR</div> <div><input type="checkbox"/> BUILT UP OR SPECIAL UTENSILS</div> <div><input type="checkbox"/> CANE</div> <div><input type="checkbox"/> WALKING FRAME</div> <div><input type="checkbox"/> CRUTCHES</div> <div><input type="checkbox"/> WHEELCHAIR</div> <div></div> <div></div>	
HELP FROM ANOTHER PERSON - DAEW	
Please check any categories for which you usually need HELP FROM ANOTHER PERSON:	
<div><input type="checkbox"/> DRESSING AND GROOMING</div> <div><input type="checkbox"/> ARISING</div> <div><input type="checkbox"/> EATING</div> <div><input type="checkbox"/> WALKING</div> <div></div> <div></div>	
Hygiene	
Are you able to wash and dry your body?	
<div>-- Select --</div>	
Are you able to take a tub bath?	
<div>-- Select --</div>	
Are you able to get on and off the toilet?	
<div>-- Select --</div>	

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)

Reach

Are you able to reach and get down a 5 pound object (such as a bag of sugar) from above your head?

-- Select --

Are you able to bend down to pick up clothing from the floor?

-- Select --

Grip

Are you able to open car doors?

-- Select --

Are you able to open previously opened jars?

-- Select --

Are you able to turn faucets on and off?

-- Select --

Activities

Are you able to run errands and shop?

-- Select --

Are you able to get in and out of a car?

-- Select --

Are you able to do chores such as vacuuming or yard work?

-- Select --

AIDS or DEVICES - HRGA

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

☐ 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:

☐ 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")

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)

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 --

Arising

-- Select --

Eating

-- Select --

Walking

-- Select --

Hygiene

-- Select --

Reach

-- Select --

Grip

-- Select --

Activities

-- Select --

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**
- **None**

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**
- **None**

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**
- **None**

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**
- **None**

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**

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE

Subject: 101.200 Event: Pre-Treatment 2 Form: Functional Assessment of Chronic Illness Therapy - Fatigue		
Please enter the Item Score (not Item Response) on this form.		
Was a FACIT-F assessment performed?		
<div>-- Select --</div>		
Date of assessment		
<div>Day</div> <div>Month</div> <div>Year</div> <div></div> <div></div> <div></div>		
Physical Well-Being (PWB)		
GP1		
<div>-- Select --</div>		
GP2		
<div>-- Select --</div>		
GP3		
<div>-- Select --</div>		
GP4		
<div>-- Select --</div>		
GP5		
<div>-- Select --</div>		
GP6		
<div>-- Select --</div>		
GP7		
<div>-- Select --</div>		
Social/Family Well-Being (SWB)		
GS1		
<div>-- Select --</div>		
GS2		
<div>-- Select --</div>		
GS3		
<div>-- Select --</div>		
GS4		
<div>-- Select --</div>		
GS5		
<div>-- Select --</div>		
GS6		
<div>-- Select --</div>		
GS7		
<div>-- Select --</div>		

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)

Emotional Well-Being (EWB)

GE1

-- Select --

GE2

-- Select --

GE3

-- Select --

GE4

-- Select --

GE5

-- Select --

GE6

-- Select --

Functional Well-Being (FWB)

GF1

-- Select --

GF2

-- Select --

GF3

-- Select --

GF4

-- Select --

GF5

-- Select --

GF6

-- Select --

GF7

-- Select --

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE
(CONTINUED)

Fatigue Subscale (FS)

HI7

-- Select --

HI12

-- Select --

An1

-- Select --

An2

-- Select --

An3

-- Select --

An4

-- Select --

An5

-- Select --

An7

-- Select --

An8

-- Select --

An12

-- Select --

An14

-- Select --

An15

-- Select --

An16

-- Select --

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
- 1
- 2
- 3
- 4
- Not Done

GP2 Select the **option** from the drop-down list:

- 0
- 1
- 2
- 3
- 4
- Not Done

GP3 Select the **option** from the drop-down list:

- 0
- 1
- 2
- 3
- 4
- Not Done

GP4 Select the **option** from the drop-down list:

- 0
- 1
- 2
- 3
- 4
- Not Done

GP5 Select the **option** from the drop-down list:

- 0
- 1
- 2
- 3
- 4
- Not Done

GP6 Select the **option** from the drop-down list:

- 0
- 1
- 2
- 3
- 4
- Not Done

GP7 Select the **option** from the drop-down list:

- 0
- 1
- 2
- 3
- 4
- Not Done

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)

Social/Family Well-Being (SWB)

GS1	Select the option from the drop-down list: <ul style="list-style-type: none">• 0• 1	<ul style="list-style-type: none">• 2• 3	<ul style="list-style-type: none">• 4• Not Done
GS2	Select the option from the drop-down list: <ul style="list-style-type: none">• 0• 1	<ul style="list-style-type: none">• 2• 3	<ul style="list-style-type: none">• 4• Not Done
GS3	Select the option from the drop-down list: <ul style="list-style-type: none">• 0• 1	<ul style="list-style-type: none">• 2• 3	<ul style="list-style-type: none">• 4• Not Done
GS4	Select the option from the drop-down list: <ul style="list-style-type: none">• 0• 1	<ul style="list-style-type: none">• 2• 3	<ul style="list-style-type: none">• 4• Not Done
GS5	Select the option from the drop-down list: <ul style="list-style-type: none">• 0• 1	<ul style="list-style-type: none">• 2• 3	<ul style="list-style-type: none">• 4• Not Done
GS6	Select the option from the drop-down list: <ul style="list-style-type: none">• 0• 1	<ul style="list-style-type: none">• 2• 3	<ul style="list-style-type: none">• 4• Not Done
GS7	Select the option from the drop-down list: <ul style="list-style-type: none">• 0• 1	<ul style="list-style-type: none">• 2• 3	<ul style="list-style-type: none">• 4• Not Done

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)

Emotional Well-Being (EWB)

GE1	Select the option from the drop-down list:	<ul style="list-style-type: none">• 0• 1• 2• 3• 4• Not Done
GE2	Select the option from the drop-down list:	<ul style="list-style-type: none">• 0• 1• 2• 3• 4• Not Done
GE3	Select the option from the drop-down list:	<ul style="list-style-type: none">• 0• 1• 2• 3• 4• Not Done
GE4	Select the option from the drop-down list:	<ul style="list-style-type: none">• 0• 1• 2• 3• 4• Not Done
GE5	Select the option from the drop-down list:	<ul style="list-style-type: none">• 0• 1• 2• 3• 4• Not Done
GE6	Select the option from the drop-down list:	<ul style="list-style-type: none">• 0• 1• 2• 3• 4• 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
- 1
- 2
- 3
- 4
- Not Done

HI12

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An1

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An2

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An3

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An4

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An5

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An7

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An8

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

- 0
- 1
- 2
- 3
- 4
- Not Done

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY – FATIGUE (CONTINUED)

An12

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An14

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An15

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

- 0
- 1
- 2
- 3
- 4
- Not Done

An16

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

- 0
- 1
- 2
- 3
- 4
- Not Done

PHARMACOKINETIC BLOOD SAMPLES

Subject: 101, 200Event: Pre-Treatment 2Form: Pharmacokinetic Blood Samples

Was the sample collected?

-- Select --

Collection date:

DayMonthYear

Collection time (24hr clock):

HHMM

PK sample collected due to overdose

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 .

Subject: 101, 200Event: Pre-Treatment 2Form: PBMC Immunogenicity

Was a Cellular Immunogenicity PBMC sample collected?

-- Select --

Collection date:

DayMonthYear

Collection time (24hr clock):

HHMM

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

Subject: 101, 200Event: Pre-Treatment 2Form: Serum Anti-Drug Antibody

Was an Anti-drug Antibody serum sample collected?

-- Select --

Collection date:

DayMonthYear

Collection time (24hr clock):

HHMM

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.

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PLASMA/SERUM EXPLORATORY BIOMARKERS

Subject: 101, 200 Event: Pre-Treatment 2 Form: Plasma/Serum Exploratory Biomarkers		
Was an Exploratory Biomarkers plasma sample collected?		
<div>-- Select --</div> <div>↺</div> <div>+</div>		
Collection date:		
Day	Month	Year
Collection time (24hr clock):		
HH	MM	
Was an Exploratory Biomarkers serum sample collected?		
<div>-- Select --</div> <div>↺</div> <div>+</div>		
Collection date:		
Day	Month	Year
Collection time (24hr clock):		
HH	MM	

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

Subject: 101,200Event: Pre-Treatment 2Form: PBMC Exploratory Biomarkers

Were Exploratory Biomarkers PBMC samples collected?

-- Select --

Collection date:

DayMonthYear

Collection time (24hr clock):

HHMM

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

Subject: 101, 200 Event: Pre-Treatment 2 Form: Replication Competent Lentivirus

Were RCL PBMC samples collected?

-- Select --

Collection date:

Day Month Year

Collection time (24hr clock):

HH MM

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.

MRI ASSESSMENTS

Subject: 101, 123Event: SummaryForm: MRI Assessments

Was MRI assessed?

-- Select --

Timepoint

-- Select --

Date of MRI Assessment

Day

Month

Year

Was MRI assessed?

Select **No** or **Yes** to indicate if the **MRI** was assessed.

Timepoint

Select the **timepoint** from the dropdown menu.

• **Baseline**

• **3 to 6 Weeks Post-Infusion**

• **10 to 14 Weeks Post-Infusion**

• **24 to 48 Weeks Post-Infusion**

• **Unscheduled**

Collection date:

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

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NEXT VISIT – PRE-TREATMENT

Subject: 101, 115Event: Pre-Treatment 1Form: Next Visit - Pre-Treatment

Is the subject continuing to the Pre-Treatment/Pre-Infusion visit OR will the subject be reassessed for apheresis at a later date?

-- Select --

Is the subject continuing to the Pre-Treatment/Pre-Infusion visit OR will the subject be reassessed for apheresis at a later date?

Select **Pre-Treatment/Pre-Infusion** or **Apheresis reassessment** to indicate if the **Pre-Treatment/Pre-Infusion visit OR will the subject be reassessed for apheresis at a later date.**

































SBT777101 ADMINISTRATION

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

Subject: 101, 200 Event: W1D1 Form: SBT777101 Administration	
Was SBT777101 administered?	
<div>-- Select --</div>	
Chain of Identity (COI) number	
<div></div>	
Administration location	
<div>-- Select --</div>	
If Administration location other, specify:	
<div></div>	
Date of infusion	
<div>Day Month Year</div>	
Time SBT777101 was removed from shipper:	
<div>HH MM</div>	
SBT777101 thaw date	
<div>Day Month Year</div>	
Time SBT777101 was put in water bath (24 hour clock)	
<div>HH MM</div>	
Planned SBT777101 dose level	
<div>-- Select --</div>	
Specify other planned dose level (Million, M)	
<div></div>	
Planned volume of SBT777101 administered (mL)	
<div></div>	
Actual volume of SBT777101 administered (mL)	
<div></div>	
If Actual volume differs from Planned volume, provide reason:	
<div></div>	
Infusion start time (24hr clock)	
<div>HH MM</div>	
Infusion end time (24hr clock)	
<div>HH MM</div>	
Rate of infusion (mL/min)	
<div></div>	
Was infusion interrupted?	
<div>-- Select --</div>	
Time of interruption - 1 (24hr clock)	
<div>HH MM</div>	
Reason infusion interrupted -1	
<div>-- Select --</div>	

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

SBT777101 ADMINISTRATION (CONTINUED)

Primary AE # that caused interruption - 1
<input type="text"/>  
Specify reason for interruption - 1
<input type="text"/>  
Was infusion restarted after interruption -1?
-- Select --  
Time of restart - 1 (24hr clock)
HH  MM   
Rate of infusion after interruption - 1 (mL/min)
<input type="text"/>  
Was infusion interrupted a second time?
-- Select --  
Time of interruption - 2 (24hr clock)
HH  MM   
Reason infusion interrupted -2
-- Select --  
Primary AE # that caused interruption - 2
<input type="text"/>  
Specify reason for interruption - 2
<input type="text"/>  
Was infusion restarted after interruption -2?
-- Select --  
Time of restart - 2 (24hr clock)
HH  MM   
Rate of infusion after interruption - 2 (mL/min)
<input type="text"/>  

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	<p>Select the location of administration from the drop-down list:</p> <ul style="list-style-type: none">• Hand• Wrist• Antecubital• Leg• Other <p><u>Note:</u> If “Other” is selected, provide a response in the “If Administration location other, specify:” field</p>
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	<p>Select the planned SBT777101 dose level in from the drop-down list:</p> <ul style="list-style-type: none">• Dose Level 1• Dose Level 2• Dose Level 3• Other <p><u>Note:</u> If “Other” is selected, provide a response in the “Specify other planned dose level (Million, M)” field</p>
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. <u>Note:</u> 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: <ul style="list-style-type: none">• ADVERSE EVENT• OTHER <u>Note:</u> This field is only enabled if " Was infusion interrupted? " is " Yes " <u>Note:</u> If " Adverse Event " is selected, provide an Adverse Event number in the " Primary AE # that caused interruption - 1 " field <u>Note:</u> 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. <u>Note:</u> 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. <u>Note:</u> 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. <u>Note:</u> 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. <u>Note:</u> <i>This field is only enabled if “Was infusion interrupted a second time?” is “Yes”</i>
Reason infusion interrupted -2	Select the reason infusion interrupted -2 from the dropdown list: <ul style="list-style-type: none">• ADVERSE EVENT• OTHER <u>Note:</u> <i>This field is only enabled if “Was infusion interrupted a second time?” is “Yes”</i> <u>Note:</u> <i>If “Adverse Event” is selected, provide an Adverse Event number in the “Primary AE # that caused interruption - 2” field</i> <u>Note:</u> <i>If “Other” is selected, specify the reason in the “Specify reason for interruption - 2” field</i>
Was infusion restarted after interruption -2?	Select No or Yes to indicate if the infusion was restarted after interruption -2. <u>Note:</u> <i>This field is only enabled if “Was infusion interrupted a second time?” is “Yes”</i>
Time of restart - 2 (24hr clock)	Record the time of restart - 2 in the HH:MM 24-hour clock format. <u>Note:</u> <i>This field is only enabled if “Was infusion restarted after interruption -2?” is “Yes”</i>
Rate of infusion after interruption - 2 (mL/min)	Record the rate of infusion after interruption - 2 in mL/min in the field provided. <u>Note:</u> <i>This field is only enabled if “Was infusion restarted after interruption -2?” is “Yes”</i>

NEXT VISIT

Subject: 101, 200Event: W1D1Form: Next Visit

Is the subject continuing to the next visit?

-- Select --

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

Subject: 101,049 Event: Summary Form: GATE form - Any AE/CM/PR	
Did the subject experience any adverse events?	-- Select --
Were any of the adverse events related to CRS?	-- Select --
Were any of the adverse event related to Neurotoxicity?	-- Select --
Were there any Infusion Related Reactions (IRR)?	-- Select --
Did the subject take any prior or concomitant medications?	-- Select --
Did the subject have any prior or concomitant procedures?	-- Select --

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, an **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

Subject: 101,121 Event: Summary Form: Adverse Events

Adverse event:
<div><div></div><div><div></div><div></div></div></div>
Start date:
<div><div>Day</div><div>Month</div><div>Year</div><div><div></div><div></div></div><div></div></div>
Start time (24 hour clock):
<div><div>HH</div><div>MM</div><div><div></div><div></div></div><div></div></div>
Is this event a DLT?
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
Is this event related to CRS?
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
Is this event related to Neurotoxicity/ICANS?
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
Infusion Related Reaction (IRR):
<div><div><input type="checkbox"/></div><div><div></div><div></div></div><div></div></div>
Is this event an AESI?
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
Outcome:
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
Describe sequelae:
<div><div></div><div><div></div><div></div></div></div>
End date:
<div><div>Day</div><div>Month</div><div>Year</div><div><div></div><div></div></div><div></div></div>
End time (24 hour clock):
<div><div>HH</div><div>MM</div><div><div></div><div></div></div><div></div></div>
CTCAE Grade:
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
ASTCT CRS grade:
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
ASTCT ICANS grade:
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
Relationship to study treatment:
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
Action taken with study treatment:
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>
If Action taken with study treatment is Dose Interrupted, was treatment reinitiated at the same rate or reduced rate?
<div><div>-- Select --</div><div><div></div><div></div></div><div></div></div>

ADVERSE EVENTS (CONTINUED)

If Action taken with study treatment is Other, specify:		
<div></div>		
<div></div>		
Other Action Taken (Check all that apply)		
Concomitant Medication		
<div></div>		
Concomitant Procedure		
<div></div>		
Other, Specify		
<div></div>		
<div></div>		
Was the event related to a trial procedure?		
<div>-- Select --</div>		
If yes, specify:		
<div></div>		
<div></div>		
Did this Adverse Event lead to study discontinuation?		
<div>-- Select --</div>		

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

Was the adverse event serious?		
<div>-- Select --</div>		
Congenital anomaly or birth defect:		
<div>-- Select --</div>		
Persistent or significant disability:		
<div>-- Select --</div>		
Death:		
<div>-- Select --</div>		
Was an autopsy performed?		
<div>-- Select --</div>		
Inpatient hospitalization or prolongation of existing hospitalization:		
<div>-- Select --</div>		
Date of admission to hospital:		
<div>Day</div> <div>Month</div> <div>Year</div> <div></div> <div></div> <div></div>		
Date of discharge from hospital:		
<div>Day</div> <div>Month</div> <div>Year</div> <div></div> <div></div> <div></div>		

ADVERSE EVENTS (CONTINUED)

Life threatening:
<div>-- Select --</div>
Other medically important event:
<div>-- Select --</div>
Other possible causes of the event (If applicable):
<div></div>
Describe the event (e.g., symptoms, treatment course):
<div></div>

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).

All Serious Adverse Events (SAEs) plus any AE that is the result of a protocol-specified procedure or intervention will be collected from the signing of the ICF until study drug administration. SAEs 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.

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.

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 e.g. from physical examination, 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 a clinically significant abnormality is noted at a physical examination, report the event as an Adverse Event.
- 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.

ADVERSE EVENTS (CONTINUED)

- 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?	Indicate if the event is a DLT from the drop-down list: <ul style="list-style-type: none">• No• Yes, confirmed at SMC meeting• Possibly, pending SMC meeting
Is this event related to CRS?	Indicate if the event is related to CRS? from the drop-down list: <ul style="list-style-type: none">• No• Yes• Possibly
Is this event related to Neurotoxicity/ICANS?	Indicate if the event is related to Neurotoxicity/ICANS? from the drop-down list: <ul style="list-style-type: none">• No• Yes• Possibly <p><u>Note:</u> If an adverse event meets both CRS and Neurotoxicity/ICANS criteria, please enter as separate adverse events.</p>
Infusion Related Reaction (IRR)	Check the box if the AE is Infusion Related Reaction . <u>Note:</u> This applies to all AE's. If checked, please complete the Infusion Related Reactions form.
Is this event an AESI?	Indicate if the AE was an AESI by selecting from the drop-down list: No or Yes .
Outcome:	Select the outcome of the AE from the drop-down list: <ul style="list-style-type: none">• Fatal• Not Recovered or Not Resolved• Recovered or Resolved• Recovered or Resolved with Sequelae• Recovering or Resolving• Unknown <p><u>Note:</u> If "Recovered or Resolved with Sequelae" is selected, describe sequelae in the "Describe sequelae:" field</p>
End Date:	Record the end date of the AE in the DD/MMM/YYYY format. A complete date is required. <u>Note:</u> 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. <u>Note:</u> <u>Note:</u> This field is only enabled if " Outcome " is " Recovered or Resolved ", " Recovered or Resolved with Sequelae ", or " Fatal "

ADVERSE EVENTS (CONTINUED)

CTCAE Grade:

Select the **CTCAE Grade** of the AE from the drop-down list:

- **Grade 1**
- **Grade 2**
- **Grade 3**
- **Grade 4**
- **Grade 5**

Note: If **“Grade 5”** is selected, please complete **Death Details** form under the Summary folder.

ASTCT CRS Grade:

Select the **ASTCT CRS Grade** of the AE from the drop-down list:

- **Grade 1**
- **Grade 2**
- **Grade 3**
- **Grade 4**

Note: This field is only applicable if **“Is this event related to CRS?”** is **“Yes”** or **“Possibly”**.

ASTCT ICANS Grade:

Select the **ASTCT ICANS Grade** of the AE from the drop-down list:

- **Grade 1**
- **Grade 2**
- **Grade 3**
- **Grade 4**

Note: This field is only applicable if **“Is this event related to Neurotoxicity/ICANS?”** is **“Yes”** or **“Possibly”**.

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: **“Dose not changed”** means no action is taken with study drug and is an applicable response only when the AE occurs during infusion on W1D1. For post infusion time events, action taken expected to be **“Not Applicable”**.

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”**

ADVERSE EVENTS (CONTINUED)

Other Action Taken (Check all that apply)	<p>Check the applicable box(es) for other action taken from the options provided:</p> <ul style="list-style-type: none"> • Concomitant Medication • Concomitant Procedure • Other, Specify <p><u>Note:</u> If “Concomitant Medication” is selected, record the medication taken for this adverse event on the Prior & Concomitant Treatments/Medications eCRF</p> <p><u>Note:</u> If “Concomitant Procedure” is selected, record the procedure performed for this adverse event on the Prior & Concomitant Procedures eCRF</p> <p><u>Note:</u> If none of the provided options is applicable, specify in the “Other, Specify” field</p>
Was the event related to a trial procedure?	<p>Indicate if the AE was related to a trial procedure by selecting from the drop-down list: No or Yes.</p> <p><u>Note:</u> If “Yes” is selected, specify in the “If yes, specify” field</p>
Did this Adverse Event lead to study discontinuation?	<p>Indicate if the Adverse Event led to study discontinuation by selecting from the drop-down list: No or Yes.</p> <p><u>Note:</u> This field is required for all AEs</p> <p><u>Note:</u> If “Yes” is selected, complete the Early Termination/End of Study eCRF</p>
Was the adverse event serious?	<p>Select No or Yes.</p> <p><u>Note:</u> If “Yes” is selected, the serious criteria fields below will be enabled for completion for the serious adverse event and an email alert will also be sent to the safety team when the form is saved.</p>
Congenital anomaly or birth defect:	<p>Indicate if the serious AE is a congenital anomaly or birth defect by selecting from the drop-down list: No or Yes.</p>
Persistent or significant disability:	<p>Indicate if the serious AE results in persistent or significant disability by selecting from the drop-down list: No or Yes.</p>
Death:	<p>Indicate if the serious AE results in death by selecting from the drop-down list: No or Yes.</p> <p><u>Note:</u> If “Yes” is selected, complete the Death Details CRF</p>
Was an autopsy performed?	<p>Indicate if an autopsy was performed by selecting from the drop-down list: No or Yes.</p> <p><u>Note:</u> This field is only enabled if “Death:” is “Yes”</p>
Inpatient hospitalization or prolongation of existing hospitalization:	<p>Indicate if the serious AE results in inpatient hospitalization or prolongs the existing hospitalization by selecting from the drop-down list: No or Yes.</p>
Date of admission to hospital:	<p>Record the date of hospital admission in the DD/MMM/YYYY format. A complete date is required.</p> <p><u>Note:</u> This field is only enabled if “Inpatient hospitalization or prolongation of existing hospitalization:” is “Yes”</p>

ADVERSE EVENTS (CONTINUED)

Date of discharge from hospital:	Record the date of hospital discharge in the DD/MMM/YYYY format. A complete date is required. <u>Note:</u> <i>This field is only enabled if “Inpatient hospitalization or prolongation of existing hospitalization:” is “Yes”</i>
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).

Subject: 101.020Event: SummaryForm: CRS Signs and Symptoms

Associated Adverse Event #1:

Associated Adverse Event #2:

Associated Adverse Event #3:

Sign or Symptom of CRS

-- Select --

If Sign or Symptom of CRS is Other, specify

Fever - max temperature recorded greater than or equal to 38 °C?

-- Select --

Hypotension - Vasopressor(s) required?

-- Select --

Hypoxia - Action(s) required?

-- Select --

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
Sign or Symptom of CRS	<p>Select the sign or symptom of CRS from the drop-down list:</p> <ul style="list-style-type: none">• Fever• Hypotension• Hypoxia• Other <p><u>Note:</u> If “Other” is selected, provide a response in the “If Sign or Symptom of CRS is Other, specify” field</p>
Fever - max temperature recorded greater than or equal to 38 °C?	<p>Select No or Yes to indicate if the max temperature recorded greater than or equal to 38 °C.</p> <p><u>Note:</u> This field is only enabled if “Sign or Symptom of CRS” is “Fever”</p>
Hypotension - Vasopressor(s) required?	<p>Select the option regarding vasopressor(s) required from the drop-down list:</p> <ul style="list-style-type: none">• None• Yes, a vasopressor with or without vasopressin• Yes, multiple vasopressors (excluding vasopressin) <p><u>Note:</u> This field is only enabled if “Sign or Symptom of CRS” is “Hypotension”</p>
Hypoxia - Action(s) required?	<p>Select the option regarding action(s) required from the drop-down list:</p> <ul style="list-style-type: none">• None• Low-flow nasal cannula or blow-by• High-flow nasal cannula, facemask, nonrebreather mask, or Venturi mask• Positive pressure <p><u>Note:</u> This field is only enabled if “Sign or Symptom of CRS” is “Hypoxia”</p>

NEUROTOXICITY/ICANS SIGNS AND SYMPTOMS

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

Subject: 101.020Event: SummaryForm: Neurotoxicity/ICANS Signs and Symptoms

Associated Adverse Event #1:

Associated Adverse Event #2:

Associated Adverse Event #3:

Sign and Symptom of Neurotoxicity

-- Select --

If Sign or Symptom of Neurotoxicity is Other, specify

Depressed level of consciousness Assessment

-- Select --

Seizure Assessment

-- Select --

Elevated ICP and/or Cerebral edema Assessment

-- Select --

- 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

NEUROTOXICITY/CANS 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 arouse
- 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).

Subject: 101,049 Event: Summary Form: Infusion Related Reactions	
Associated Adverse Event #:	
<input type="text"/>	 
Total estimated volume of SBT777101 administered at onset of this Infusion Related Reaction:	
<input type="text"/>	 
Was a pre-treatment given?	
<input type="text" value="-- Select --"/>	 
Concomitant Medication # in EDC:	
<input type="text"/>	 
Was a blood sample collected for the IRR?	
<input type="text" value="-- Select --"/>	 
Date of blood sample collection:	
<input type="text" value="Day"/> <input type="text" value="Month"/> <input type="text" value="Year"/>	  
Time of blood sample collection:	
<input type="text" value="HH"/> <input type="text" value="MM"/>	 

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 <u>Note:</u> <i>This field is only enabled if “Was a pre-treatment given?” = “Yes”</i>
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. <u>Note:</u> <i>This field is only enabled if “Was a blood sample collected?” = “Yes”</i>
Time of blood sample collection:	Record the time of collection in the HH:MM 24-hour clock format. <u>Note:</u> <i>This field is only enabled if “Was a blood sample collected?” is “Yes”</i>

PRIOR & CONCOMITANT TREATMENTS/MEDICATIONS

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

Subject: 101,200 Event: Summary Form: Prior & Concomitant Treatments/Medications Registered [1]	
<p>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.</p>	
<p>Medication:</p> <div></div>	
<p>Indication:</p> <div></div>	
<p>Reason (select all that apply):</p> <div><input type="checkbox"/> ADVERSE EVENT <input type="checkbox"/> MEDICAL HISTORY <input type="checkbox"/> PROPHYLAXIS <input type="checkbox"/> PROCEDURE <input type="checkbox"/> RHEUMATOID ARTHRITIS TREATMENT <input type="checkbox"/> OTHER</div>	
<p>Primary Adverse Event # indicated (record the primary AE associated):</p> <div></div>	
<p>Primary Medical History # indicated (record the primary MH associated):</p> <div></div>	
<p>Primary Procedure # indicated (record the primary procedure associated):</p> <div></div>	
<p>Reason Other, specify:</p> <div></div>	
<p>Dose:</p> <div></div>	
<p>Unit:</p> <div>-- Select --</div>	
<p>Unit specify:</p> <div></div>	
<p>Frequency:</p> <div>-- Select --</div>	
<p>Frequency specify:</p> <div></div>	
<p>Route:</p> <div>-- Select --</div>	
<p>Route specify:</p> <div></div>	
<p>Start date:</p> <div>Day Month Year   </div>	
<p>Ongoing?</p> <div>-- Select --</div>	
<p>End date:</p> <div>Day Month Year   </div>	
<div>+ Add Another</div>	

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.

- **Please do not record strength in the medication field**
- Record only one medication per record.
- If the same medication has multiple start/stop dates, please record each as its own record, e.g. prednisone either with multiple start/stop dates and/or changes in dose.
- Please record each administration of Rituximab as a unique entry for any administration completed after the subject signs consent and not as a single ongoing entry.
- Please list any RA medications initiated after signing consent as a conmed and not RA Med history.
- 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').

PRIOR & CONCOMITANT TREATMENTS/MEDICATIONS (CONTINUED)

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

Dose:

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

- For combination drugs, enter the number of tablets/capsules
- 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 | • mg | • TABLET |
| • CAPSULE | • mL | • U |
| • DROP | • mL/h | • U/kg |
| • g | • mmol | • U/kg/day |
| • IU | • oz | • ug |
| • mEq | • PUFF | • 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) | • QID (4 times per day) |
| • CONTINUOUS | • QOD (every other day) |
| • EVERY WEEK | • TID (three times a day) |
| • ONCE | • Unknown |
| • PRN (as needed) | • Other |
| • QD (once per day) | |

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

PRIOR & CONCOMITANT TREATMENTS/MEDICATIONS (CONTINUED)

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).

Subject: 101.200 Event: Summary Form: Prior & Concomitant Procedures

Procedure:

Reason for Procedure:

-- Select --

If Adverse Event, specify primary AE#:

If Medical History, specify primary MH#:

If Other, specify:

Start Date:

Day

Month

Year

End Date:

Day

Month

Year

+ Add Another

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: For RA medications, select “**Treatment of RA**” as the **Reason for Procedure**.

Do not select Medical History.

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

Subject: 101, 200 Event: Markers of Inflammation Form: GATE - Markers

Were Markers of Inflammation assessed?

-- Select --

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).

Subject: 101,200 Event: Markers of Inflammation Form: Markers of Inflammation		
Time point for sample collection:		
<div>-- Select --</div>		
Date of sample collection		
<div>Day</div>	<div>Month</div>	<div>Year</div>
Time of sample collection (24 hour clock)		
<div>HH</div>	<div>MM</div>	
Primary suspected adverse event of infection or CRS #		
<div></div>		
Interferon Gamma (pg/mL)		
<div></div>		
Ferritin (mcg/L)		
<div></div>		
IL-6 (pg/ml)		
<div></div>		
Any other markers tested?		
<div>-- Select --</div>		
Marker 1 - Record Marker Name		
<div></div>		
Result		
<div></div>		
Unit		
<div>-- Select --</div>		
<div>+ Add Another</div>		

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: <ul style="list-style-type: none">• 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:

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

DEATH DETAILS

Subject: 101, 200 Event: Summary Form: Death Details

Date of death

Day

Month

Year

Date of death data collection

Day

Month

Year

Primary cause of death

-- Select --

If Other, specify

Specify Primary Adverse Event sequence number

Was an autopsy performed?

-- Select --

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	<div>Select the primary cause of death from the drop-down list:</div> <div><ul style="list-style-type: none">Adverse EventOther</div> <div><u>Note:</u> If “Adverse Event” is selected, record the corresponding primary adverse event number in the “Specify Primary Adverse Event sequence number” field</div> <div><u>Note:</u> If “Other” is selected, specify the primary cause of death in the “If Other, specify” field</div>
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).

Subject: 101,200Event: SummaryForm: Reconsent

Date of reconsent:

Day

Month

Year

Protocol version which the subject reconsented under?

-- Select --

+ Add Another




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?	<div>Select the protocol version the subject the subject reconsented under from the drop-down list:<div><div><div>• 5.0</div><div>• 6.0</div><div>• 7.0</div></div><div><div>• 8.0</div><div>• 9.0</div><div>• 10.0</div></div></div></div>

EARLY TERMINATION/END OF STUDY



Early Termination/End of Study eCRF is found in **Summary** folder.

Subject: 101, 222 Event: Summary Form: Early Termination/End of Study



Date of Early Termination/Study completion:

Day Month Year   



Did the subject complete all periods of the study including the final safety follow-up visit?

-- Select --  



Primary reason:

-- Select --  



Specify reason:

Did the subject consent to enroll in the long-term follow-up trial?

-- Select --  

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 --  

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

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**”