

Weeks 30, 35 Visits Visits 13.0, 14.0

Required forms

- 12-Lead Electrocardiogram (EGS-1, -2)**
- Follow-up Acceptability Questionnaire (FAQ-1~4)
- Follow-up Visit (FUV-1)
- HIV Test Results (HTR-1)
- Injection Site Reaction Evaluation (ISR-1, -2)
- Local Lab Results (LLR-1~4)
- Post-injection Exercise Assessment (PEA-1)*
- Specimen Storage (SS-1)
- Study Medication Satisfaction Questionnaire (SMS-1, -2)*

* *Completed only at Week 30 (Visit 13.0)*

** *Completed only at Week 35 (Visit 14.0)*

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12-Lead Electrocardiogram (EGS-1)

General Information/Instructions:

Record ECG test results on this form when results become available. If an ECG must be repeated, report the averaged values of the ECGs. You may report individual values in the comments.

Item-specific Instructions:

Items 1 and 2: Complete or update AE Log for results that meet AE Reporting Criteria and are not associated with a reported diagnosis. Refer to the protocol and the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events* for guidance on grading and AE reporting.

Item 3: If exam is "normal" end the form and do not fax page 2 to DataFax. The category "findings as noted in Specific ECG Findings" includes all ECGs with findings, including normal ECGs with findings, as well as abnormal ECGs.

12-Lead Electrocardiogram (EGS-2)
General Information/Instructions:
Record ECG test results on this form when results become available.

Follow-up Acceptability Questionnaire (FAQ-1)

Purpose: This questionnaire is used to assess attitudes and experiences about the injectable study product since joining the study.

General Information/Instructions:

- This is an interviewer-administered form.
- Complete this form at weeks 6, 18, and 30.
- Read each question exactly as it is written. Read response options only if indicated. In these cases, hand the participant a response card and read each response aloud to the participant as she reads silently.

Item-specific Instructions:

- Item 1:** Before reading the first item (1a), hand the response card to the participant.
- Explain that you will list some different characteristics of the injections.
 - You want to know how unimportant or important each characteristic was.
 - Before giving a response, he/she should first think about whether the reason was important or not important.
 - Then, he/she should think about HOW unimportant or important the characteristic was: "a little," "somewhat," or "a lot."
 - 1 means that he/she thinks the characteristic was UNACCEPTABLE A LOT and 6 means that he/she thinks that the characteristic was ACCEPTABLE A LOT.

Follow-up Acceptability Questionnaire (FAQ-2)

Item-specific Instructions:

- Item 2:** Before reading the first item (2a), hand the response card to the participant.
- Explain that you will read a set of statements meant to assess her/his level of interest in using a product like the one in the study.
 - You want to know how much he/she disagrees or agrees with the different statements.
 - Before giving a response, he/she should first think about whether he/she disagrees or agrees overall with the statement.
 - Then, he/she should think about HOW much he/she disagrees or agrees: "a little," "somewhat," or "a lot."
 - 1 means that he/she DISAGREES A LOT and 6 means that he/she AGREES A LOT with the statement.

Item 2a: Read the question as stated. Emphasize the word "**not**."

Item 2b: Read the question as stated. Emphasize the word "**think**."

Item 2c: Read the question as stated. Emphasize the words "**definitely use**" and "**for some time**." (Note: "for some time" means that she would think **about** using the injections for several rounds.)

Item 2e: Read the question as stated. Emphasize the word "**probably**."

Item 2f: Read the question as stated. Emphasize the word "**and**."

Follow-up Acceptability Questionnaire (FAQ-3)

Item-specific Instructions:

Item 3: Read the question as stated. Do not read the response options. Identify the option or options that most closely fit the participant's own words.

Item 3a: Mark "none" for item 3a if the participant says there are no changes she would recommend. Only mark "no response/decline to answer" if the participant refuses to answer the question.

Item 3g: If "other, specify" is marked, record the participant's response in English on the line provided.

Item 3h: Mark "no response/decline to answer" only if the participant refuses to answer the question.

Item 4: Read the question as stated. Hand the response card to participant. Read the options and the descriptions as stated. If the participant describes a different method (for example, condoms), mark "other, specify" and record the participant's response in English on the line provided.



Visit Code . **1**

Participant ID

- -
Site Number Participant Number Chk

Follow-up Acceptability Questionnaire

Item 5 is for male participants only. Female participants, end of form.

5. If you could receive the same level of protection (from pregnancy or disease) by taking one of the following products, which one would you prefer? **Interview card #8.**

- oral pill taken every day
Why? _____
- injection received once every 3 months
Why? _____
- rectal gel
Why? _____
- other, specify: _____
- doesn't matter

Follow-up Acceptability Questionnaire (FAQ-4)

Item 5: Read the question as stated. Hand the response card to participant. Read the options and the descriptions as stated. If the participant describes a different method (for example, condoms), mark "other, specify" and record the participant's response in English on the line provided.

Follow-up Visit (FUV-1)

Purpose: This form is used to summarize information from each participant follow-up study visit (including interim visits).

Item-specific Instructions:

Item 1b: Mark the newly completed forms (in addition to this form) that are being submitted for the interim visit/contact. If "other, specify" is marked, record the form acronym(s) in the space provided.

HIV Test Results (HTR-1)	
Purpose:	The HIV Test Results CRF documents the results of HIV testing performed at the site at scheduled and interim visits.
General Information/Instructions:	
	<ul style="list-style-type: none"> Record test results on this form as they become available from the local lab. Fax this form to DataFax when the final test results are available and recorded. If HIV infection is suspected or confirmed during follow-up, complete a Product Hold/Discontinuation Log.
Specimen Collection Date:	Record the date that the specimen(s) was collected (NOT the date results were reported or recorded on the form) for this visit. Complete date is required.
Item-specific Instructions:	
Not done:	For each test, mark either the "Not done" box or enter a test result. If the "Not done" box is marked at a visit where that test is required by the protocol, record the reason in Comments.
Kit codes:	<ul style="list-style-type: none"> Refer to Atlas for kit codes. If a test kit being used at your site is not listed, contact the SCHARP Project Manager for a new code. Rapid tests on oral transudate are not allowed per protocol.
Items 1b and 2b:	A second Rapid Test is performed if required per site's standard operating procedures.

Injection Site Reaction Evaluation (ISR-1)
Purpose: This form is used to document clinician- and participant-assessed injection site reactions at required safety visits as well as any injection site reactions assessed at other visits.
General Information/Instructions:
Complete this form at weeks 6, 9, 13, 18, 23, 30, and 35 and any other visit where an injection site reaction is noted.

Injection Site Reaction Evaluation (ISR-2)

No additional instructions.

Local Laboratory Results (LLR-1)	
Purpose:	This form is used to collect results from tests performed by site's local laboratory at follow-up visits.
General Information/Instructions:	
	At the Enrollment Visit, report gradable lab results on the Pre-existing Conditions form; do not complete an AE for abnormal lab results found at enrollment.
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Results Reporting:	<ul style="list-style-type: none"> • If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. <ul style="list-style-type: none"> - If the site lab does not produce test results in the units used on this form, <i>first</i> perform the conversion, then round the converted result if necessary.
AE Severity Grade:	<ul style="list-style-type: none"> • If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i>, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. <ul style="list-style-type: none"> - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
AE Log Page #:	Record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not reportable as an AE:	Only mark this response if the lab value is gradable according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i> , but is not reportable as an AE. This includes pre-existing conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Not done/Not collected:	For every test, mark either "Not done/Not collected" or enter a test result. If "Not done/Not collected" is marked, provide an explanation in Comments.
Repeat Local Laboratory Tests:	<p>Sometimes it is necessary to repeat a local lab test.</p> <ul style="list-style-type: none"> • For a repeat test of the same sample, record only the results considered the most accurate. If a first result was already recorded and faxed to DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and re fax the amended form to DataFax. • For a repeat test using a different sample (e.g., a blood re-draw for a repeat CBC), record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax new form to DataFax.

Local Laboratory Results (LLR-2)	
General Information/Instructions:	
	At the Enrollment Visit, report gradable lab results on the Pre-existing Conditions form; do not complete an AE for abnormal lab results found at enrollment.
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Results Reporting:	<ul style="list-style-type: none"> • If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. <ul style="list-style-type: none"> - If the site lab does not produce test results in the units used on this form, <i>first</i> perform the conversion, then round the converted result if necessary.
AE Severity Grade:	<ul style="list-style-type: none"> • If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i>, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. <ul style="list-style-type: none"> - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
AE Log Page #:	Record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not reportable as an AE:	Only mark this response if the lab value is gradable according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i> , but is not reportable as an AE. This includes pre-existing conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Not done/Not collected:	For every test, mark either "Not done/Not collected" or enter a test result. If "Not done/Not collected" is marked, provide an explanation in Comments on page 3.
Repeat Local Laboratory Tests:	<p>Sometimes it is necessary to repeat a local lab test.</p> <ul style="list-style-type: none"> • For a repeat test of the same sample, record only the results considered the most accurate. If a first result was already recorded and faxed to DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to DataFax. • For a repeat test using a different sample (e.g., a blood re-draw for a repeat CBC), record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax new form to DataFax.
Item-specific Instructions:	
Items 5b and 5c:	Either BUN or Urea are required, not both.

Local Laboratory Results (LLR-3)	
General Information/Instructions:	
	At the Enrollment Visit, report gradable lab results on the Pre-existing Conditions form; do not complete an AE for abnormal lab results found at enrollment.
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Results Reporting:	<ul style="list-style-type: none"> • If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. <ul style="list-style-type: none"> - If the site lab does not produce test results in the units used on this form, <i>first</i> perform the conversion, then round the converted result if necessary.
AE Severity Grade:	<ul style="list-style-type: none"> • If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i>, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. <ul style="list-style-type: none"> - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
AE Log Page #:	Record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not reportable as an AE:	Only mark this response if the lab value is gradable according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i> , but is not reportable as an AE. This includes pre-existing conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Not done/Not collected:	For every test, mark either "Not done/Not collected" or enter a test result. If "Not done/Not collected" is marked, provide an explanation in Comments.
Repeat Local Laboratory Tests:	<p>Sometimes it is necessary to repeat a local lab test.</p> <ul style="list-style-type: none"> • For a repeat test of the same sample, record only the results considered the most accurate. If a first result was already recorded and faxed to DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and refax the amended form to DataFax. • For a repeat test using a different sample (e.g., a blood re-draw for a repeat CBC), record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax new form to DataFax.

Local Laboratory Results (LLR-4)	
General Information/Instructions:	
	At the Enrollment Visit, report gradable lab results on the Pre-existing Conditions form; do not complete an AE for abnormal lab results found at enrollment.
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Results Reporting:	<ul style="list-style-type: none"> • If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. <ul style="list-style-type: none"> - If the site lab does not produce test results in the units used on this form, <i>first</i> perform the conversion, then round the converted result if necessary.
AE Severity Grade:	<ul style="list-style-type: none"> • If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i>, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. <ul style="list-style-type: none"> - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
AE Log Page #:	Record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not reportable as an AE:	Only mark this response if the lab value is gradable according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i> , but is not reportable as an AE. This includes pre-existing conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Not done/Not collected:	For every test, mark either "Not done/Not collected" or enter a test result. If "Not done/Not collected" is marked, provide an explanation in Comments.
Repeat Local Laboratory Tests:	<p>Sometimes it is necessary to repeat a local lab test.</p> <ul style="list-style-type: none"> • For a repeat test of the same sample, record only the results considered the most accurate. If a first result was already recorded and faxed to DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and re fax the amended form to DataFax. • For a repeat test using a different sample (e.g., a blood re-draw for a repeat CBC), record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax new form to DataFax.
Item-specific Instructions:	
Item 8d:	Either direct or calculated LDL is acceptable.

Post-injection Exercise Assessment (PEA-1)

General Information/Instructions:

- Complete this form at weeks 6, 18, and 30.
- This information should be obtained as part of the participant's targeted history and medical exam.

Item-specific Instructions:

Item 1a: Vigorous exercise makes you breathe much harder than normal and may include activities such as sports, like soccer, bicycling, or running; also weight training or lifting heavy objects; and various job-related activities or chores such as field work, cutting and fetching firewood, or walking long distances to get and carry water.

Item 1b: Record the participant's response in English on the lines provided.

Specimen Storage (SS-1)	
Purpose:	This form is used to document the storage of specimens that will be tested at a lab other than the site local laboratory.
General Information/Instructions:	
Initial Specimen Collection Date:	Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
Item-specific Instructions:	
Item 1:	Samples collected will also be used for PK and pharmacogenomics testing.
Items 1-2:	<ul style="list-style-type: none"> • Mark "not stored" if the specimen was collected as required at this visit but was not stored. • Mark "not collected" if the specimen is required to be collected and stored at this visit but was not collected. • Mark "not required" if a specimen is not required and was not collected and stored at this visit.

Study Medication Satisfaction Questionnaire (SMS-1)

Study Medication Satisfaction Questionnaire (SMS-2)