SHARP-C SOURCE DATA PROFORMA – POST TREATMENT RECURRENCE OF VIREMIA

Purpose of This Document:
This proforma is an optional tool you may use to assist in recording SHARP-C study source data. It may be used, in full or part, to record source data or adapted to suit the needs and preferences of your site. If you choose to use this it can form part of the source documentation for an enrolled patient.

What is Source Data and why is it needed?
All sites participating in this study must maintain source data for all study patients. All of the data entered into the study database (eCRF) need to be verifiable from source – this "Source Data Verification" will be performed during on-site monitoring visits throughout the study.

Source data is defined in (ICH) GCP (1.51) as "all information in original records (and certified copies of original records) of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial". In other words, it is the *first place that data are recorded* and provides evidence for data entered into the database.

Source data are documented in source documents which may be both electronic and paper. Examples of source documents where source data may be located include:

- medical records
- laboratory reports
- nurses', doctors' and allied health progress notes
- dispensing logs
- study questionnaires
- electrocardiogram (ECG) print-outs, etc

How to Use This Proforma:
All of the data entered into the database and listed in this proforma **must** be recorded in source documents. If you wish, you may use this document to record source data for SHARP-C patients. Once completed it will form part of the source documentation for that patient, along with the patient file or medical record, laboratory reports, and other types of source documents such as the examples listed above.

Proforma Document Instructions:
1. Record the patient initials and subject ID at the top of each page.
2. Each visit includes a checklist of the assessments to be completed at that visit. You can use this to tick off the assessments when they are completed.
3. Record the date of each visit.
4. Record the data for each section. Null statements should also be recorded – for example "Nil adverse events observed" if the patient has experienced no events.
5. All data recorded should match the data entered into the study database.
6. All corrections and additions must be initialled and dated.

Study number 1605-□□□□□-□□	Patient initials □□□□ E.g. <u>Smith</u> John SMJO	

RE-VIREMIA BASELINE VISIT CHECKLIST

Assessment	Complete
1. Local laboratory tests: – HCV RNA (to confirm finger-stick point of care) – HCV sequencing (on research sample collected at baseline)	☐

BASELINE VISIT (week 0)

Date of visit: □□-□□□-□□□□ (DD – MMM – YYYY)

LOCAL LABORATORY TESTS
HCV RNA *Specimen for HCV RNA collected:* ☐ Yes ☐ No *HCV RNA quantitative result:* ☐ *Non-quantifiable and undetected* ☐ *Non-quantifiable and detected* ☐ *Quantifiable* *HCV RNA quantitative result:* _____ *IU/mL* *HCV sequencing performed:* ☐ Yes ☐ No

Study number 1605-☐☐☐☐☐-☐☐	Patient initials ☐☐☐☐ E.g. <u>Smith</u> John SMJO	SHARP-C

RE-VIREMIA FOLLOW UP 1 (RFU1) - CHECKLIST

Assessment	Complete
1. Hepatitis C testing – EDTA plasma (10mL) – Finger-stick Xpert HCV RNA point-of-care test	☐
2. Research specimen collection – EDTA plasma (10mL)	☐

RE-VIREMIA FOLLOW UP 1 (RFU1) – 2 WEEKS AFTER RE-VIREMIA BSL

Date of visit: ☐☐-☐☐☐-☐☐☐☐ (DD – MMM – YYYY)

HEPATITIS C TESTING

Finger-stick GeneXpert HCV RNA point of care test

Sample collected: ☐ Yes   ☐ No

If yes, result: ☐ Detected   Viral load: _____ IU/mL ☐ Not detected

☐ Invalid   ☐ Error   Error code: _____

If no result, specify:_____

RESEARCH SPECIMEN COLLECTION

*Date of collection and sample(s) stored. **Make sure to complete the research specimen collection log.***

Date of collection (dd-mmm-yyyy), if different from visit date: _____

EDTA plasma (10ml) collected: ☐ Yes   ☐ No

If no result, specify: _____

Study number	Patient initials	
1605-☐☐☐☐☐-☐☐	☐☐☐☐ E.g. <u>Smith</u> John SMJO	SHARP-C

RE-VIREMIA FOLLOW UP 2 (RFU2) - CHECKLIST

Assessment	Complete
1. Hepatitis C testing – EDTA plasma (10mL) – Finger-stick Xpert HCV RNA point-of-care test	☐
2. Research specimen collection – EDTA plasma (10mL)	☐

RE-VIREMIA FOLLOW UP 2 (RFU2) – 4 WEEKS AFTER RE-VIREMIA BSL

Date of visit: ☐☐-☐☐☐-☐☐☐☐ (DD – MMM – YYYY)

HEPATITIS C TESTING

Finger-stick GeneXpert HCV RNA point of care test

Sample collected: ☐ *Yes*   ☐ *No*

If yes, result: ☐ *Detected Viral load:* _____ *IU/mL*   ☐ *Not detected*

☐ *invalid*   ☐ *Error Error code:* _____

*If no result, specify:*_____

RESEARCH SPECIMEN COLLECTION

Date of collection and sample(s) stored. ***Make sure to complete the research specimen collection log.***

Date of collection (dd-mmm-yyyy), if different from visit date: _____

EDTA plasma (10ml) collected: ☐ *Yes*   ☐ *No*

If no result, specify: _____

Study number	Patient initials	
1605-☐☐☐☐☐-☐☐	☐☐☐☐ E.g. <u>Smith</u> John SMJO	SHARP-C

RE-VIREMIA FOLLOW UP3 (RFU3) - CHECKLIST

Assessment	Complete
1. Hepatitis C testing – EDTA plasma (10mL) – Finger-stick Xpert HCV RNA point-of-care test	☐
2. Research specimen collection – EDTA plasma (10mL)	☐

RE-VIREMIA FOLLOW UP 3 (RFU3) – 8 WEEKS AFTER RE-VIREMIA BSL

Date of visit: ☐☐-☐☐☐-☐☐☐☐ (DD – MMM – YYYY)

HEPATITIS C TESTING

Finger-stick GeneXpert HCV RNA point of care test

Sample collected: ☐ *Yes*   ☐ *No*

If yes, result: ☐ *Detected Viral load: _____ IU/mL*   ☐ *Not detected*

☐ *invalid*   ☐ *Error Error code: _____*

RESEARCH SPECIMEN COLLECTION

Date of collection and sample(s) stored. ***Make sure to complete the research specimen collection log.***

Date of collection (dd-mmm-yyyy), if different from visit date: _____

EDTA plasma (10ml) collected: ☐ *Yes*   ☐ *No*

If no result, specify: _____