

Attach Participant ID label

Visit Date:

Unscheduled
 First line EOT + week
 Retreatment EOT + week

Please complete or tick boxes as appropriate. Return completed CRFs to mrctu.stophcv1@ucl.ac.uk by secure email or by fax 0207 670 4817.

A. CLINICAL INFORMATION

Required at: First line: EOT+4 weeks, EOT+12 weeks, EOT+24 weeks
Retreatment: EOT+4 weeks, EOT+12 weeks, EOT+24 weeks

1. Weight: • kg

B. ADVERSE EVENTS

1. Since the last study visit, has the participant had a serious adverse event? Yes No

If yes, please record on Form 10 - Serious Adverse Event and submit if not already sent

2. Since the last study visit, has the participant had a non-serious but grade 3 or 4 adverse event or reaction? (Please ensure lab test results have been checked) Yes No

If yes, please record on Form 11 - Non-Serious Adverse Event and submit if not already sent

C. QUESTIONNAIRES:

Required at: First-line: EOT+12 weeks
Retreatment: EOT+12 weeks

Please ensure Form 05 - EQ-5D, Form 06 - MOSCOG and Form 07 - SF-12 are completed by the participant.

D. PREGNANCY

Required at: First line: EOT+12 weeks, EOT+24 weeks
Retreatment: EOT+12 weeks, EOT+24 weeks

1. Is the participant a woman of childbearing potential? Yes No **If no, go to question 4**
 2a. If yes, was a pregnancy test done? Yes No b. If 2a. is no, reason: _____

3. If 2a. is yes, record the result of the urine pregnancy test: a. b. Positive
 Negative

If positive, please record on Form 10 - Serious Adverse Event and submit if not already sent

4. Is the participant male and has their partner become pregnant since the last visit? Yes No

If yes, please provide the participant with the Pregnancy PIS and please record on Form 10 - Serious Adverse Event and submit if not already sent

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E. ROUTINE BLOODS

- Please ensure the required bloods are taken at the visits listed below and complete Form 02 - Laboratory Results.**
- Please ensure that any extra haematology, biochemistry and HCV VLs performed are also reported on Form 02 - Laboratory Results.**

Have the following laboratory results been taken?

- | | | |
|--|--|--|
| 1. EDTA Blood for Haematology | Required at: First line: EOT+12 weeks, EOT+24 weeks
Retreatment: EOT+12 weeks, EOT+24 weeks | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Clotted Blood for Biochemistry | Required at: First line: EOT+12 weeks, EOT+24 weeks
Retreatment: EOT+12 weeks, EOT+24 weeks | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Question 3. Coagulation Markers has been removed (Not required at any Follow-up post treatment visits) | | |
| 4. HCV Viral Load | Required at: First line: EOT+4 weeks, EOT+8 weeks, EOT+12 weeks, EOT+24 weeks
Retreatment: EOT+4 weeks, EOT+8 weeks, EOT+12 weeks, EOT+24 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. HIV Viral load (If HIV infected) | Required at: First line: EOT+24 weeks
Retreatment: EOT+24 weeks | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. Immunology (If HIV infected) | Required at: First line: EOT+24 weeks
Retreatment: EOT+24 weeks | <input type="checkbox"/> Yes <input type="checkbox"/> No |

F. CONCOMITANT MEDICATIONS

1. Since the last study visit, has the participant started or stopped taking any medications? Yes No

If yes, complete Form 08 - Concomitant Medication Log and submit

G. STORED SAMPLES

Required storage

1. EDTA plasma
- | | | |
|-----------------------------------|---|--------------------------|
| | 10ml Required | 20ml Required |
| Local/Imperial Processing: | First line: EOT+4 weeks, EOT+8 weeks, EOT+24 weeks
Retreatment: EOT+4 weeks, EOT+8 weeks, EOT+12 weeks, EOT+24 weeks | First line: EOT+12 weeks |
| DX to Glasgow: | First line: EOT+4 weeks,
Retreatment: EOT+12 weeks | First line: EOT+12 weeks |

Size of collection tubes	Number of tubes collected	Date specimen obtained	Time of collection (use 24 hour clock)
a. <input type="text" value=""/> <input type="text" value=""/> • <input type="text" value=""/> ml	b. <input type="text" value=""/> <input type="text" value=""/>	c. <input type="text" value="d"/> <input type="text" value="d"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/>	d. <input type="text" value=""/> <input type="text" value=""/> : <input type="text" value=""/> <input type="text" value=""/>

Optional storage

2. 20ml PBMC (Specific sites only) **If day 0 taken, up to a maximum of 4 other time points may be taken: First line: EOT+4 weeks**

a. <input type="text" value=""/> <input type="text" value=""/> • <input type="text" value=""/> ml	b. <input type="text" value=""/> <input type="text" value=""/>	c. <input type="text" value="d"/> <input type="text" value="d"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/>	d. <input type="text" value=""/> <input type="text" value=""/> : <input type="text" value=""/> <input type="text" value=""/>
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H. RESOURCE UTILISATION

1. Since the last study visit how many times has the participant :
- a. Visited the GP
 - b. Visited A&E
 - c. Been admitted to hospital

☞ If the participant has not been admitted to hospital please move on to question 3

2. If the patient has been admitted to hospital:

a. Date of admission	b. Date of discharge	c. Reason for admission:
<input type="text" value="d"/> <input type="text" value="d"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/>	<input type="text" value="d"/> <input type="text" value="d"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/>	
<input type="text" value="d"/> <input type="text" value="d"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/>	<input type="text" value="d"/> <input type="text" value="d"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="m"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/> <input type="text" value="y"/>	

3a. Since the last visit, how many blood transfusions has the participant had?

If any,

b. Date of transfusion: c. Total Units

d. Date of any second transfusion: e. Total Units

4a. Since the last visit has the participant had any scans or X-rays? Yes No

b. If yes, please provide details on the scan or X-ray: _____

Signature:

Printed Name:

Date Completed:

☞ Please return by secure email to: mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817

For office use only:

Date form received at CTU: dd - mmm - yyyy

Date form entered onto database : dd - mmm - yyyy

Initials of data enterer: