MRC Clinical Trials Unit | UCL

STOP-HCV
Stratified Medicine for HepC

Attach Participant ID label

Visit Date: ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

Unscheduled ☐

First line	Day ☐☐	EOT ☑
Retreatment	Week ☐☐	EOT ☑

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

A. TRIAL DRUG

1. Since the last study visit, has the participant stopped, re-started or changed dose or frequency of any trial drugs? ☐ Yes ☐ No

☞ **If yes, please record on Form 09 - Trial Drug Log and submit**

2. Since the last study visit, has the participant missed any doses of trial drug ? ☐ Yes ☐ No **If no, go to question 6**

If yes, since the last visit, how many doses of each prescribed trial drug has the participant missed over the last 7 days?

3. Drug Code   **4. Number of Missed Doses**   **5. Number of Prescribed Doses over the last 7 Days**

☐☐ missed ☐☐•☐ doses out of ☐☐ prescribed doses

☐☐ missed ☐☐•☐ doses out of ☐☐ prescribed doses

☐☐ missed ☐☐•☐ doses out of ☐☐ prescribed doses

Drug Codes
EXV Exviera (Dasabuvir) 14 doses in 7 days
VIK Viekirax (Ombitasvir Paritaprevir/ritonavir) 7 doses in 7 days
MVT Maviret (Glecaprevir/Pibrentasvir) 7 doses in 7 days (3 pills per dose)
RBV Ribavirin 14 doses in 7 days
HAR Harvoni (Sofosbuvir/Ledipasvir) 7 doses in 7 days

☞ **If the participant missed doses for 2 consecutive days or more, please record on Form 09 - Trial Drug Log and submit**

6. Record date and time the participant took their last pills:

a. Last once daily pill: ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y   b. Time: ☐h ☐h : ☐m ☐m (use 24 hour clock)

c. Last twice daily pill: ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y   d. Time: ☐h ☐h : ☐m ☐m (use 24 hour clock)

7. Prior to this visit, how often did the participant take their VIK +/- EXV or MVT doses with food?

☐ Not taking VIK +/- EXV or MVT ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ None of the time

8. Prior to this visit, how often did the participant take their RBV doses with food?

☐ Not taking RBV ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ None of the time

B. CLINICAL INFORMATION

Required at: First line: day 28, EOT
Retreatment: week 0, 4, 8, 12(EOT)

1. Weight: ☐☐☐•☐ kg

C. ADVERSE EVENTS

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

☞ **If yes, please record on Form 10a- 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, or an adverse event of any grade leading to modification of any trial drug? (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**

D. QUESTIONNAIRES:

Required at: First-line: EOT
Retreatment: week 0, 12(EOT)

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

	Clinical Trials Unit	UCL

STOP-HCV
Stratified Medicine for HepC

Attach Participant ID label

Visit Date: ☐d ☐d ☐m ☐m ☐y ☐y ☐y ☐y

E. PREGNANCY

Required at: First line: day 28, EOT
            Retreatment: week 0, 4, 12(EOT)

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: _____

	Date specimen obtained	**Result**

3. If 2a. is yes, record the result of the urine pregnancy test: a. ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y   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

F. 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: day 14, 28, EOT Retreatment: week 0, 2, 4, 8, 12(EOT)	☐ Yes ☐ No
2. Clotted Blood for Biochemistry	Required at: First line: day 14, 28, EOT Retreatment: week 0, 2, 4, 8, 12(EOT)	☐ Yes ☐ No
3. Coagulation Markers	Required at: Retreatment: week 0	☐ Yes ☐ No
4. HCV Viral Load	Required at: First line: day 3, 7, 14, 28, EOT Retreatment: week 0, 2, 4, 8, 12(EOT)	☐ Yes ☐ No
5. HIV Viral load (If HIV infected)	Required at: First line: EOT Retreatment: week 0, 12(EOT)	☐ Yes ☐ No
6. Immunology (If HIV infected)	Required at: First line: EOT Retreatment: week 0, 12(EOT)	☐ Yes ☐ No

G. CONCOMITANT MEDICATIONS

1. Since the last study visit, has the participant started or stopped taking any medications other than trial drugs? ☐ Yes ☐ No

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

H. STORED SAMPLES

Required storage

1. EDTA plasma

	10ml Required	**20ml Required**
Local/Imperial Processing:	First line: day 3, 7, 14, 28 Retreatment: week 0, 2, 4, 8, 12 (EOT)	First line: EOT
DX to Glasgow:	First line: day 3, 7, 14 Retreatment: week 0	

Size of collection tubes	**Number of tubes collected**	**Date specimen obtained**	**Time of collection** (use 24 hour clock)
a. ☐☐ • ☐ ml	b. ☐☐	c. ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y	d. ☐☐ : ☐☐

MRC Clinical Trials Unit | UCL

STOP-HCV
Stratified Medicine for HepC

Attach Participant ID label

Visit Date: | d | d | m | m | m | y | y | y | y |

H. STORED SAMPLES cont.

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: Day 03, Day 07, EOT**

Size of collection tubes	**Number of tubes collected**	**Date specimen obtained**	**Time of collection** (use 24 hour clock)
a. ☐☐ • ☐ ml	b. ☐☐	c. d d m m m y y y y	d. ☐☐ : ☐☐

I. 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:
d d m m m y y y y	d d m m m y y y y	
d d m m m y y y y	d d m m m y y y y	

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

If any, b. Date of transfusion: d d m m m y y y y   c. Total Units ☐☐

d. Date of any second transfusion: d d m m m y y y y   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: _____

J. STUDY TREATMENT

1. If this is the day 28 visit, please ensure the participant is prescribed the correct number of pills as per their randomisation allocation and record the number of days treatment prescribed here: ☐☐

☞ **If this is the participant's EOT visit add 'stop' record to Form 09 - Trial Drug Log. If they are HIV-infected on a Ritonavir boosted ART regimen, please ensure the participant restarts Ritonavir today and update Form 08 - Concomitant Medication Log.**

K. NEXT VISIT

1. Date of next visit: d d m m m y y y y

Signature:	Printed Name:	Date Completed:
		d d m m m y y y y

For office use only:

Date form received at CTU: dd - mmm - yyyy   Date form entered _____ dd - mmm - yyyy   Initials of ☐☐☐☐