MRC Clinical Trials Unit | UCL

STOP-HCV Stratified Medicine for HepC

Attach Participant ID label

Form 11a - Non-Serious Adverse Event
Version 4.0 01-Nov-2017

Date of onset: d d m m m y y y y

Event number on this date: ☐☐

- ☞ **Record only adverse events or reactions that are grade 3 or 4 or led to a modification of trial drugs (regardless of grade).**
- ☞ **These adverse events must be reported to mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817 within 7 days of site awareness.**
- ☞ **Update Form 09 – Trial Drug Log if events led to a change in trial drug (including dose).**
- ☞ **If an adverse event worsens, please complete a new form with the onset date of the new grade and status 'worsened'. Please make sure the same adverse event name is used.**
- ☞ **DO NOT RECORD Serious Adverse Events on this form - Use Form 10 - Serious Adverse Event**
- ☞ **Concomitant medications need to be listed on Form 08 - Concomitant Medication Log**

A. DETAILS OF ADVERSE EVENT

1. Date of site awareness d d m m m y y y y

2. Adverse Event (sign, symptom, syndrome or diagnosis)	3. Grade (1-4) Event grade should be determined using the GSI grading, see the protocol or MOOP for link.	4. Event Status 1= Resolved 2= Resolved with sequelae 3= Ongoing 4= Worsened
	☐	☐

Indicate below which study IMPs the participant is taking and whether it was expected as per SmPC.

5. Drug Code	6. Relatedness	7. Expectedness	8. Action taken (Ensure form 9 is updated)
☐☐☐	☐	☐	☐
☐☐☐	☐	☐	☐
☐☐☐	☐	☐	☐
☐☐☐	☐	☐	☐
EXV Exviera (Dasabuvir) **VIK** Viekirax (Ombitasvir/Paritaprevir/Ritonavir) **MVT** Maviret (Glecaprevir/Pibrentasvir) **RBV** Ribavirin **HAR** Harvoni (Sofosbuvir /Ledipasvir)	1= Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related	1= Expected 2= Not Expected 3= Not Applicable (Relatedness unlikely/not related)	0=None 1=Dose reduction 2=Treatment delayed 3=Treatment reduction & delayed 4= Treatment stopped

9a. Is the participant taking any other concomitant medications? ☐ Yes ☐ No

If yes, please list the other medications the participant is taking and mark the relatedness in the box provided.

Relatedness
1= Definitely
2= Probably
3= Possibly
4= Unlikely
5= Not related

	Relatedness		Relatedness
b.	c. ☐	h.	j. ☐
d.	e. ☐	j.	k. ☐
f.	g. ☐	l.	m. ☐

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

☞ *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: ☐☐☐☐