MRC Clinical Trials Unit | UCL

STOP-HCV Stratified Medicine for HepC

Attach Participant ID label

Form 10a - Serious Adverse Event
Version 3.0 01-Nov-2017

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

Event number on this date: ☐☐

☞ **Serious Adverse Events must be reported to mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817 within 24 hours of site awareness.**

☞ **DO NOT report events based on laboratory values in the absence of clinical symptoms as SAEs**

A. REPORT DETAILS

1. Date of site awareness of initial event: d d m m m y y y y

2. Participant's sex at birth: ☐ Male ☐ Female (needed on this CRF for MHRA compliance)

3. Weight (most recent): ☐☐☐ • ☐ kg (needed on this CRF for MHRA compliance)

4. Why was the event serious?

a. Resulted in death	☐ Yes	☐ No
b. Life-threatening	☐ Yes	☐ No
c. Required inpatient hospitalisation or prolongation of existing hospitalisation	☐ Yes	☐ No
d. Persistent or significant disability/incapacity	☐ Yes	☐ No
e. Congenital anomaly/birth defect	☐ Yes	☐ No
f. Other important medical condition	☐ Yes	☐ No

5a. Where did the SAE take place?

☐ Hospital ☐ Out-patient clinic
☐ Home ☐ Nursing home
☐ Other 5b. please specify: _____

B. DETAILS OF SERIOUS ADVERSE EVENT

Event Status
1= Resolved
2= Resolved with sequelae
3= Ongoing
4= Worsened
5= Fatal

Grade
Event grade should be determined using the GSI grading, see the protocol or MOOP for link.

1. Main diagnosis/symptom (Enter the MAIN EVENT in the first row, followed by any associated symptoms)	2. Event Status	3. Event dates	4. Grade (1-5)
	☐	a. Date of onset d d m m m y y y y b. Date of resolution d d m m m y y y y	☐

5a. Associated symptoms	5b. Grade (1-4)
	☐
	☐
	☐

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C. TRIAL MEDICATION

1. Drug Code*	2a. Total Daily RBV Dose (mg)	2b.Total Daily No. Pills (EXV/VIK/ MVT/HAR)	3. Date of first administration 4. Date of most recent (last) administration	5. Causal relationship to SAE	6. Expectedness Was the event one of the recognised undesirable effects of the trial medication?	7. Action taken due to SAE Ensure form 9 is updated
			First d d m m m y y y y Last d d m m m y y y y			
			First d d m m m y y y y Last d d m m m y y y y			
			First d d m m m y y y y Last d d m m m y y y y			
			First d d m m m y y y y Last d d m m m y y y y			
				1= Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related	1= Expected 2= Not Expected 3= Not Applicable (Relationship unlikely/not related)	0=None 1=Dose reduction 2=Treatment delayed 3=Treatment reduction & delayed 4= Treatment stopped

Drug Codes
EXV Exviera (Dasabuvir)
VIK Viekirax (Ombitasvir/Paritaprevir/Ritonavir)
MVT Maviret (Glecaprevir/Pibrentasvir)
RBV Ribavirin
HAR Harvoni (Sofosbuvir /Ledipasvir)

*all drugs administered orally

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D. CONCOMITANT MEDICATION

☞ If necessary continue on a separate sheet, and ensure **Form 08 - Concomitant Medication log** is updated
☞ **DO NOT** record medications used to treat the event

1. Drug	2. Total Daily Dose (include units)	3. If fixed dose combination, number of pills per day	4a. Route	5. Date of first administration 6. Date of most recent (last) administration	7. Causal relationship to SAE	8. Action taken due to SAE
			☐ b. Specify: _____	First d d m m m y y y y Last d d m m m y y y y	☐	☐
			☐ b. Specify: _____	First d d m m m y y y y Last d d m m m y y y y	☐	☐
			☐ b. Specify: _____	First d d m m m y y y y Last d d m m m y y y y	☐	☐
			☐ b. Specify: _____	First d d m m m y y y y Last d d m m m y y y y	☐	☐
			1= Oral 2= IM 3= IV 4= Topical 5= Other, specify		1= Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related	0=None 1=Dose reduction 2=Treatment delayed 3=Treatment reduction & delayed 4= Treatment stopped

E. EVENT NARRATIVE

☞ Type a complete narrative summary of the event on a separate page(s)

☞ Attach a Participant ID label at the top of each page and number and sign each attached page.

☞ The narrative should include: manifestation & progression of event, any treatments given in response to the event and any relevant tests carried out (e.g. WBC, neutrophil count), any likely causes of the event other than the medication specified on this form, and the rationale for assessment of relatedness and expectedness of the main event to the STOP-HCV-1 study drugs.

1. How many pages of narrative are attached? ☐☐

☞ **Completed CRFs and typed event narrative should be submitted by secure email to mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817.**

Investigator print and sign:	Person completing the form print and sign:
Date signed: d d m m m y y y y	Date Completed: d d m m m y y y y