



Attach Participant ID label

Randomisation Date:

d	d	m	m	m	y	y	y	y
---	---	---	---	---	---	---	---	---

Page number:

--	--

Start a new page when necessary.

- ☞ Record trial drugs from enrolment and update during the trial.
- ☞ A "STOP" should be reported if a participant stopped taking trial drug for 2 consecutive days or more.
- ☞ START and STOP should not be used together for changes to dose or frequency - use CHANGE instead.
- ☞ A change in both dose and frequency should be reported as one CHANGE on the same row.
- ☞ Please return by secure email to mrctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817 after every new entry.

Row #	a. Drug Code (see codes below)			b. Type of Action (see codes below)	c. Total Daily RBV Dose (mg)	d. Total Daily No. Pills (EXV/VIK/HAR/MVT)	e. Date of Action dd/mmm/yyyy									f. Main Reason (see codes below)	g. Extra Information	Initials and Date dd/mmm/yy
	R	B	V				0	3	0	C	T	2	0	1	5			
/	R	B	V	START	1200		0	3	0	C	T	2	0	1	5	1		MG 04-Oct-15
/	R	B	V	CHANGE	600		2	6	D	E	C	2	0	1	5	5	Anaemia	MG 27-Dec-15
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		
9																		
10																		
11																		

Drug Codes

EXV Exviera (Dasabuvir) (250 mg)
 VIK Viekirax (Ombitasvir/Paritaprevir/Ritonavir) (12.5/75/50 mg)
 MVT Maviret (Glecaprevir/Pibrentasvir) (100/40 mg)
 RBV Ribavirin
 HAR Harvoni (Sofosbuvir /Ledipasvir) (400/90 mg)

Main reason for Action

- 1=Start/restart
- 2=Drug lost/ran out
- 3=Hepatitis C treatment failure
- 4=Patient (describe in Extra Information)
- 5=Adverse event (describe in Extra Information)
- 6=End of Treatment (EOT)
- 7=Other (describe in Extra Information)

Type of Action

START
 STOP
 CHANGE (change of dose and/or frequency)

For office use only:

Date form received at CTU: dd - mmm - yyyy

Date form entered onto database : dd - mmm - yyyy

Initials of data enterer:

--	--	--	--