


Visit date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd/mon/yyyy)	Study subject ID 1701- <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	Participant initials <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> E.g. <u>Smith</u> John SMJO	
Phone-based visit questionnaire			

Name of the site personnel completing the form:		
Visit (please select the applicable visit):	<input type="checkbox"/> Week 4	<input type="checkbox"/> EoT (Week 8)

## SECTION A: ADVERSE EVENTS

### 1. Have you experienced any side effects since last contact?


- ☐ No (skip to question 2)  
☐ Yes (If yes, please collect data)

Participant Reported					Nurse Assessment	
AE term	Severity	Action taken with study drug	Start date	End date	Relatedness <sup>+</sup>	SAE?
	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate* <input type="checkbox"/> Severe* <input type="checkbox"/> Life threatening*	<input type="checkbox"/> Drug withdrawn <input type="checkbox"/> Drug interrupted <input type="checkbox"/> No action <input type="checkbox"/> Not applicable	--/ /-- (dd/mon/yy)	--/ /-- (dd/mon/yy) or <input type="checkbox"/> Ongoing	<input type="checkbox"/> Not related <input type="checkbox"/> Unlikely <input type="checkbox"/> Possibly <input type="checkbox"/> Probably	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate* <input type="checkbox"/> Severe* <input type="checkbox"/> Life threatening*	<input type="checkbox"/> Drug withdrawn <input type="checkbox"/> Drug interrupted <input type="checkbox"/> No action <input type="checkbox"/> Not applicable	--/ /-- (dd/mon/yy)	--/ /-- (dd/mon/yy) or <input type="checkbox"/> Ongoing	<input type="checkbox"/> Not related <input type="checkbox"/> Unlikely <input type="checkbox"/> Possibly <input type="checkbox"/> Probably	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate* <input type="checkbox"/> Severe* <input type="checkbox"/> Life threatening*	<input type="checkbox"/> Drug withdrawn <input type="checkbox"/> Drug interrupted <input type="checkbox"/> No action <input type="checkbox"/> Not applicable	--/ /-- (dd/mon/yy)	--/ /-- (dd/mon/yy) or <input type="checkbox"/> Ongoing	<input type="checkbox"/> Not related <input type="checkbox"/> Unlikely <input type="checkbox"/> Possibly <input type="checkbox"/> Probably	<input type="checkbox"/> Yes <input type="checkbox"/> No

+ refer to protocol section 7.2 for definitions of relatedness

**\*ALL MODERATE, SEVERE AND LIFE THREATENING ADVERSE EVENTS MUST BE REVIEWED BY A SITE INVESTIGATOR.**

Investigator review	
Date of review by an investigator: ____/____/____	
Signature of site Investigator _____	
Action required? Yes <input type="checkbox"/> No <input type="checkbox"/>	
If yes, specify:	


Visit date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd/mon/yyyy)	Study subject ID 1701- <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	Participant initials <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> E.g. <u>Smith</u> John SMJO	 <b>SMART-C</b>
Phone-based visit questionnaire			

## SECTION B: CONCOMITANT MEDICATION

### 2. Have you started, stopped, or changed any medication since last contact?

- ☐ No (skip to Section C)  
☐ Yes (If yes, please collect data)

Medication name	Indication	Start date	End date
		--/ /-- (dd/mon/yy)	--/ /-- (dd/mon/yy) or <input type="checkbox"/> Ongoing
		--/ /-- (dd/mon/yy)	--/ /-- (dd/mon/yy) or <input type="checkbox"/> Ongoing
		--/ /-- (dd/mon/yy)	--/ /-- (dd/mon/yy) or <input type="checkbox"/> Ongoing
		--/ /-- (dd/mon/yy)	--/ /-- (dd/mon/yy) or Ongoing
		--/ /-- (dd/mon/yy)	--/ /-- (dd/mon/yy) or Ongoing

Visit date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd/mon/yyyy)	Study subject ID 1701- <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	Participant initials <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> E.g. <u>Smith</u> John SMJO	
Phone-based visit questionnaire			

### SECTION C: ADHERENCE QUESTIONNAIRE

3. Since last contact, how many **DAYS** did you **MISS** taking GLECAPREVIR/PIBRENTASVIR?

If participant didn't miss any dose, STOP. Otherwise, please continue with next question.

4. Why did you miss taking GLECAPREVIR/PIBRENTASVIR? *Check all that apply.*

Side effects.....☐

Forgot to take.....☐

Other reason.....☐

If other reason, briefly describe reason \_\_\_\_\_