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BY DOMAIN

BY VISIT

Did the subject experience any Adverse Events during the course of the study?	☐ Yes ☐ No

Project Name: GS-US-248-0120
Form: Adverse Event *[AE]*
Generated On: 07-31-2013 12:02:12

Adverse Event: (List diagnosis or each symptom separately)	
AE serious:	☐ Yes ☐ No
Start Date: (DD-MMM-YYYY)	/ /
End Date: (DD-MMM-YYYY)	/ /
Please check if Ongoing:	☐
Related to any of the Study Drugs: (All study drugs are to be considered in assessment of relationship to study drugs: GS-5885, GS-9451, Tegobuvir , RBV and PEG)	☐ Yes ☐ No
Related to Study Procedures:	☐ Yes ☐ No
Study Drug Action Taken - GS-5885:	☐ No change ☐ Interrupted ☐ Discontinued ☐ Dose Reduced
Study Drug Action Taken - GS-9451:	☐ No change ☐ Interrupted ☐ Discontinued ☐ Dose Reduced
Study Drug Action Taken - Tegobuvir:	☐ No change ☐ Interrupted ☐ Discontinued ☐ Dose Reduced ☐ Not Applicable

Study Drug Action Taken - RBV:	☐ No change ☐ Interrupted ☐ Discontinued ☐ Dose Reduced
Study Drug Action Taken - PEG:	☐ No change ☐ Interrupted ☐ Discontinued ☐ Dose Reduced ☐ Not Applicable
Severity:	☐ Mild ☐ Moderate ☐ Severe ☐ Life-Threatening
Other Action Taken: (Check all that apply) None:	☐
Medication Required:	☐
Other Treatment Required:	☐
Hospitalized/Prolonged Hospitalization:	☐
Hidden field for AE_AESER_ALERT	☐

Note: To add additional adverse events, please complete an additional form, by clicking on 'Add a new log line'.

If Adverse Event is Serious, please refer to the regulatory binder for an SAE Report form. Complete an SAE Report and E-mail or fax the SAE Report within 24 hours of the Reporter's knowledge of the event. Contact information for faxing and e-mailing this form is found in the study protocol in section 8.5.1.

A Serious Adverse Event is any adverse experience that results in any of the following outcomes:

(1) Death,

(2) Is life-threatening (at immediate risk of death at time of the event),

(3) Requires subject hospitalization or prolonged hospitalization,

(4) Persistent or significant disability/incapacity,

(5) Congenital abnormality/birth defect or

(6) Any other important Medical Event based on clinician's judgment or may require medical or surgical intervention to prevent one of the other serious criteria.

Refer to protocol for protocol-specific SAE definitions.

Select a response for each body system. If a body system is not examined, select "Not Done."

Body System	☐ Head, Neck & Thyroid ☐ Eyes, Ears, Nose, Throat, Mouth & Tongue ☐ Chest (Excluding breasts) ☐ Respiratory ☐ Cardiovascular ☐ Lymph Nodes ☐ Abdomen ☐ Skin, Nails & Hair ☐ Musculoskeletal ☐ Neurological ☐ Retinal Exam Results ☐ Other
If Body System is Other, please specify:	
Result:	☐ Abnormal ☐ Normal ☐ Not Done
If "Abnormal", please describe abnormal physical findings:	

If additional Body Systems are needed then click on 'Add New Log Line' at the bottom of the form.

Did the subject take any Medications from time of informed consent signing through study completion?	☐ Yes ☐ No

Project Name: GS-US-248-0120
Form: Concomitant Medication *[CM]*
Generated On: 07-31-2013 12:02:12

Drug Name:	
Indication: (Use Medical Terminology)	
Route:	☐ Inhalation ☐ Intradermal ☐ Intralesional ☐ Intramuscular ☐ Intranasal ☐ Intravenous ☐ Intraocular ☐ Intraperitoneal ☐ Oral ☐ Rectal ☐ Subcutaneous ☐ Sublingual ☐ Topical ☐ Vaginal ☐ Other
If "Other", please specify:	
Start Date: (DD-MMM-YYYY)	/ /
Stop Date: (DD-MMM-YYYY)	/ /
Please check if Ongoing:	☐

Note: To add additional concomitant medications, please complete an additional form, by clicking on 'Add a new log line'.

Project Name: GS-US-248-0120
Form: Death Report *[DEATH]*
Generated On: 07-31-2013 12:02:12

In addition to this eCRF, please refer to the regulatory binder for an SAE Report form. Complete an SAE Report and E-mail or fax the SAE Report within 24 hours of the Reporter's knowledge of the event. Please also send a copy of the discharge/death summary and autopsy report, if available.

Contact information for faxing and e-mailing these forms is found in the study protocol in section 8.5.1

Please update the Adverse Event eCRF, as needed.

Date of Death: (DD-MMM-YYYY)	/ /
Immediate Cause of Death:	

Date of Birth: (DD-MMM-YYYY)	/ /
Age:	
Sex:	☐ Male ☐ Female
Ethnicity:	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Not Permitted
Race:	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African Heritage ☐ Native Hawaiian or Pacific Islander ☐ White ☐ Not Permitted ☐ Other
If "Other", please specify:	
Year of Birth (yyyy)	/ /

Project Name: GS-US-248-0120
Form: Dose Administration (Day 1) *[PKEX]*
Generated On: 07-31-2013 12:02:12

Name of Actual Treatment:	☐ GS-5885 ☐ GS-9451 ☐ Tegobuvir ☐ RBV
Date of First Dose: (DD-MMM-YYYY)	/ /
Time of First Dose: (00:00-23:59)	:
Dose:	
Dose Units:	☐ mg ☐ ug ☐ tablets ☐ capsules
Dose Taken With Food	☐ Yes ☐ No

Project Name: GS-US-248-0120
Form: Dose Administration (Serial PK) *[PKEX2]*
Generated On: 07-31-2013 12:02:12

Dose Timepoint:	☐ Pre-PK Day Dose ☐ PK Day AM Dose ☐ PK Day PM Dose ☐ Post-PK Day AM Dose
Name of Actual Treatment:	☐ GS-5885 ☐ GS-9451 ☐ Tegobuvir ☐ RBV
Date of Dose: (DD-MMM-YYYY)	/ /
Time of Dose: (00:00-23:59)	:
Dose:	
Dose Units:	☐ mg ☐ ug ☐ tablets ☐ capsules
Dose Taken With Food:	☐ Yes ☐ No

Project Name: GS-US-248-0120
Form: Dose Administration (Single PK) *[PKEX1]*
Generated On: 07-31-2013 12:02:12

Check 'Not Applicable' box if Subject is participating in Serial PK Substudy at this visit:	☐
Name of Actual Treatment:	☐ GS-5885 ☐ GS-9451 ☐ Tegobuvir ☐ RBV
Date of Dose prior to Sample Draw: (DD-MMM-YYYY)	/ /
Time of Dose prior to Sample Draw: (00:00-23:59)	:
Dose:	
Dose Units:	☐ mg ☐ ug ☐ tablets ☐ capsules
Dose Taken With Food	☐ Yes ☐ No

Project Name: GS-US-248-0120
Form: Dose Administration (Viral Dynamic Substudy) *[PKEX3]*
Generated On: 07-31-2013 12:02:12

Name of Actual Treatment:	☐ GS-5885 ☐ GS-9451 ☐ Tegobuvir ☐ RBV
Date of Dose prior to Sample Draw: (DD-MMM-YYYY)	/ /
Time of Dose prior to Sample Draw: (00:00-23:59)	:
Dose:	
Dose Units:	☐ mg ☐ ug ☐ tablets ☐ capsules
Dose Taken With Food:	☐ Yes ☐ No

Visit:

- ☐ Screening
- ☐ Initial Treatment Visits
- ☐ Baseline/Day 1
- ☐ Week 1
- ☐ Week 2
- ☐ Week 4
- ☐ Week 6
- ☐ Week 8
- ☐ Week 10
- ☐ Week 12
- ☐ Week 16
- ☐ Week 20
- ☐ Week 24
- ☐ Early Termination (Initial Treatment)
- ☐ Study Drug Completion (Initial Treatment)
- ☐ PK and/or Viral Dynamic Substudies
- ☐ Day 1
- ☐ Day 2
- ☐ Day 3
- ☐ Day 5
- ☐ Day 10
- ☐ PK Week 2
- ☐ Post-Treatment Follow-Up Visits
- ☐ Post-Treatment Follow-Up Week 4
- ☐ Post-Treatment Follow-Up Week 8
- ☐ Post-Treatment Follow-Up Week 12
- ☐ Post-Treatment Follow-Up Week 16
- ☐ Post-Treatment Follow-Up Week 20
- ☐ Post-Treatment Follow-Up Week 24

- [ ] Post-Treatment Follow-Up Week 28
- [ ] Post-Treatment Follow-Up Month 7
- [ ] Rescue Therapy Substudy
- [ ] Baseline/Day 1 Rescue Therapy
- [ ] Week 1 Rescue Therapy
- [ ] Week 2 Rescue Therapy
- [ ] Week 4 Rescue Therapy
- [ ] Week 6 Rescue Therapy
- [ ] Week 8 Rescue Therapy
- [ ] Week 10 Rescue Therapy
- [ ] Week 12 Rescue Therapy
- [ ] Week 16 Rescue Therapy
- [ ] Week 20 Rescue Therapy
- [ ] Week 24 Rescue Therapy
- [ ] Week 28 Rescue Therapy
- [ ] Week 32 Rescue Therapy
- [ ] Week 36 Rescue Therapy
- [ ] Week 40 Rescue Therapy
- [ ] Week 44 Rescue Therapy
- [ ] Week 48 Rescue Therapy
- [ ] Early Termination (Rescue Therapy)
- [ ] Study Drug Completion (Rescue Therapy)
- [ ] Post-Rescue Therapy Follow-Up Week 4
- [ ] Post-Rescue Therapy Follow-Up Week 8
- [ ] Post-Rescue Therapy Follow-Up Week 12
- [ ] Post-Rescue Therapy Follow-Up Week 16
- [ ] Post-Rescue Therapy Follow-Up Week 20
- [ ] Post-Rescue Therapy Follow-Up Week 24
- [ ] Post-Rescue Therapy Follow-Up Week 28

- [ ] Post-Rescue Therapy Follow-Up Month 7
- [ ] Adverse Events
- [ ] Concomitant Medication
- [ ] Study Drug Administration
- [ ] Study Drug Accountability
- [ ] Pregnancy Report
- [ ] Death
- [ ] General Comments
- [ ] Unscheduled
- [ ] Study Completion

Form:

- [ ] Adverse Event
- [ ] Adverse Event Summary
- [ ] Complete Physical Examination
- [ ] Concomitant Medication
- [ ] Concomitant Medication Summary
- [ ] Death Report
- [ ] Demographics
- [ ] Dose Administration (Day 1)
- [ ] Dose Administration (Single PK)
- [ ] Dose Administration (Serial PK)
- [ ] Dose Administration (Viral Dynamic Substudy)
- [ ] General Comments
- [ ] Inclusion/Exclusion Criteria
- [ ] Investigator's Signature
- [ ] Liver Fibrosis Assessment
- [ ] Medical History
- [ ] Pregnancy Report
- [ ] Randomization
- [ ] Single PK Plasma
- [ ] Serial PK Plasma
- [ ] PK Plasma (Viral Dynamic Substudy Day 1)
- [ ] Stop Treatment
- [ ] Study Completion
- [ ] Study Drug Accountability - GS-5885
- [ ] Study Drug Accountability - GS-5885 Rescue Therapy
- [ ] Study Drug Accountability - GS-9451
- [ ] Study Drug Accountability - GS-9451 Rescue Therapy
- [ ] Study Drug Accountability - Tegobuvir
- [ ] Study Drug Accountability - Tegobuvir Rescue Therapy

	☐ Study Drug Accountability - PEG Rescue Therapy ☐ Study Drug Accountability - RBV ☐ Study Drug Accountability - RBV Rescue Therapy ☐ Study Drug Administration - Initial Treatment ☐ Study Drug Administration - Rescue Therapy ☐ Study Drug Completion (Initial Treatment) ☐ Study Drug Completion (Rescue Therapy) ☐ Subject Follow-Up Status ☐ Urine Pregnancy Test ☐ Urine Pregnancy Test (Baseline) ☐ Visit Date ☐ Vital Signs ☐ Rescue Therapy Status
General Comments:	
General Comments (Continued)	

Note: To add additional comments, please complete an additional form, by clicking on 'Add a new log line'.

Date informed Consent Signed: (DD-MMM-YYYY)	/ /
Under which protocol version was the subject enrolled?	☐ Original ☐ Amendment 1 ☐ Amendment 2
Was subject a Screen Failure?	☐ Yes ☐ No
Did the subject meet all eligibility criteria?	☐ Yes ☐ No

If "No", Please complete the following (Please tick all Inclusion criteria not met or Exclusion criteria met):

Inclusion/Exclusion criteria:

- ☐ Inclusion 1
- ☐ Inclusion 2
- ☐ Inclusion 3
- ☐ Inclusion 4
- ☐ Inclusion 5
- ☐ Inclusion 6
- ☐ Inclusion 7
- ☐ Inclusion 8
- ☐ Inclusion 9
- ☐ Inclusion 10
- ☐ Inclusion 11
- ☐ Inclusion 12
- ☐ Inclusion 13
- ☐ Inclusion 14
- ☐ Inclusion 15
- ☐ Inclusion 16
- ☐ Exclusion 1
- ☐ Exclusion 2
- ☐ Exclusion 3
- ☐ Exclusion 4
- ☐ Exclusion 5
- ☐ Exclusion 6
- ☐ Exclusion 7
- ☐ Exclusion 8
- ☐ Exclusion 9
- ☐ Exclusion 10
- ☐ Exclusion 11
- ☐ Exclusion 12
- ☐ Exclusion 13

	☐ Exclusion 14 ☐ Exclusion 15 ☐ Exclusion 16 ☐ Exclusion 17 ☐ Exclusion 18 ☐ Exclusion 19 ☐ Exclusion 20 ☐ Exclusion 21 ☐ Exclusion 22 ☐ Exclusion 23 ☐ Exclusion 24 ☐ Exclusion 25 ☐ Exclusion 26
Inclusion criteria not met/Exclusion criteria met?	☐
If subject that did not meet inclusion/exclusion criteria was enrolled, please provide an explanation.	
For subjects who are screen failures but meet eligibility criteria - ONLY: Provide the most significant reason why the subject was not randomized in the IWRS.	☐ Adverse Event ☐ Investigator Decision ☐ Subject Withdrew Consent ☐ Lost to Follow-Up ☐ Outside of Visit Window ☐ Study Enrollment Closed ☐ Other
If "Other", specify:	

Project Name: GS-US-248-0120

Form: Investigator's Signature *[INVSIG]*

Generated On: 07-31-2013 12:02:12

By entering my Medidata password, I affirm that I have reviewed and evaluated the case reportforms and verify that they accurately reflect the information in the source documents for thissubject. I understand source documentation can include (but is not limited to) medical records,laboratory results, x-rays, electronic communications, etc.	

LIVER BIOPSY

Check if Biopsy not done:	☐
Date of Liver Biopsy: (DD-MMM-YYYY)	/ /
Fibrosis Staging Method:	☐ Metavir ☐ Ishak ☐ Knodell
Fibrosis Staging Result:	☐ F0 ☐ F0-F1 ☐ F1 ☐ F1-F2 ☐ F2 ☐ F2-F3 ☐ F3 ☐ F3-F4 ☐ F4 ☐ F5 ☐ F6
Cirrhosis:	☐ Yes ☐ No

NON-INVASIVE ALTERNATIVE TO LIVER BIOPSY

Check if not done:	☐
Date of Procedure: (DD-MMM-YYYY)	/ /

Method:	☐ FibroTest ☐ FibroScan ☐ Acoustic Radiation Force Impulse Imaging ☐ Other
If Method is Other, please specify:	
Result:	
Cirrhosis	☐ Yes ☐ No

Project Name: GS-US-248-0120
Form: Medical History *[MH]*
Generated On: 07-31-2013 12:02:12

Please record date of diagnosis for Hepatitis C on row 1 and confirm as ongoing by checking the 'Ongoing' box.

In addition, click on the 'Add a new Log line' link below and add any relevant medical history.

Condition:	
Start Date: (DD-MMM-YYYY)	/ /
Stop Date: (DD-MMM-YYYY)	/ /
Check if Condition is Ongoing:	☐

Note: To add additional Medical History entries, please complete an additional form, by clicking on 'Add a new log line'.

Will a serial PK profile be collected for this subject?	☐ Yes ☐ No

IF YES, COMPLETE THE REMAINDER OF THIS FORM

Date of PK Collection: (DD-MMM-YYYY)	/ /
Dose Time Point:	☐ Collection Time 4.0 Hours Post-dose ☐ Collection Time 6.0 Hours Post-dose ☐ Collection Time 8.0 Hours Post-dose
Not Collected	☐
Time of PK Collection: (00:00-23:59)	:
Please specify why this timepoint was not collected:	

Project Name: GS-US-248-0120
Form: Pregnancy Report *[PREGREP]*
Generated On: 07-31-2013 12:02:12

If a pregnancy occurs, please complete as much information as possible on this form.

In addition to this eCRF, refer to the regulatory binder and complete the 'Pregnancy Report' and email or fax the report within 24 hours of the Reporter's knowledge of the event. When the outcome of the pregnancy is known, complete the 'Pregnancy Outcome Report'.

Contact information for faxing and e-mailing these forms to the CRO during the conduct of the study is found in the study protocol in section 8.5.1. Additional reporting details may be found in protocol section 8.7.

Please also report the pregnancy to the Ribavirin Pregnancy Registry at ribavirinpregnancyregistry.com

Last Menstrual Period: (DD-MMM-YYYY)	/ /
Pregnancy Confirmed: (DD-MMM-YYYY)	/ /
Estimated Date of Delivery: (DD-MMM-YYYY)	/ /

Note: All baseline tests and procedures, including ECGs, must be completed prior to randomization and dosing/dispensing of GS-5885, GS-9451, Tegobuvir, or RBV.

Was the Subject Randomized?	☐ Yes ☐ No
4-Digit Subject Number as assigned by IWR system	
Will the subject participate in the PK Substudy?	☐ Yes ☐ No
Date of PK Substudy Consent (DD-MMM-YYYY)	/ /
Will the subject participate in the Viral Dynamic Substudy?	☐ Yes ☐ No
Date of Viral Dynamic Substudy Consent: (DD-MMM-YYYY)	/ /
Will the subject participate in Pharmacogenomic Testing?	☐ Yes ☐ No
Date of Pharmacogenomic Testing Consent: (DD-MMM-YYYY)	/ /
RANDNUM+Z_SUBID	

Which Registry study is the subject eligible to enroll in?	☐ None ☐ SVR Registry (248-0122) ☐ Sequence Registry (248-0123) ☐ NA, Site Not Participating
Will the subject enroll in the registry study?	☐ Yes ☐ No
If No, state the primary reason why the subject will not enroll?	☐ Subject is not interested in participating ☐ Subject will receive other HCV treatment ☐ Lost to follow-up ☐ Other
Other, specify	

Will subject enroll into Rescue Therapy substudy?	☐ Yes ☐ No

Will a serial PK profile be collected for this subject?	☐ Yes ☐ No

IF YES, COMPLETE THE REMAINDER OF THIS FORM

Date of PK Collection: (DD-MMM-YYYY)	/ /
PK Time Point:	☐ Collection Time Pre-dose ☐ Collection Time 1.0 Hour Post-dose ☐ Collection Time 2.0 Hours Post-dose ☐ Collection Time 3.0 Hours Post-dose ☐ Collection Time 4.0 Hours Post-dose ☐ Collection Time 6.0 Hours Post-dose ☐ Collection Time 8.0 Hours Post-dose ☐ Collection Time 10.0 Hours Post-dose ☐ Collection Time 12.0 Hours Post-dose ☐ Collection Time 24.0 Post-dose
Not Collected	☐
Time of PK Collection: (00:00-23:59)	:
Please specify why this timepoint was not collected:	
Collection Time 24.0 Hours Post-Dose: Not Collected	☐
Collection Time 24.0 Hours Post-Dose: Date of PK Collection: (DD-MMM-YYYY)	/ /
Collection Time 24.0 Hours Post-Dose: Time of PK Collection: (00:00-23:59)	:
Collection Time 24.0 Hours Post-Dose: Please specify why this timepoint was not collected:	

Project Name: GS-US-248-0120
Form: Single PK Plasma *[PK]*
Generated On: 07-31-2013 12:02:13

Was Single PK Plasma Sample collected?	☐ Yes ☐ No
Date of PK Collection: (DD-MMM-YYYY)	/ /
Time of PK Collection: (00:00-23:59)	:

Has the subject been instructed to stop treatment by the IWR system?	☐ Yes ☐ No
Did subject stop ALL study drug treatment including PEG/RBV at Week 24 based on response based treatment criteria using investigator's discretion?	☐ Yes ☐ No

Did the subject complete the protocol-planned duration of the study?	☐ Yes ☐ No
If "No", please specify reason for study discontinuation.	☐ Adverse Event ☐ Death ☐ Pregnancy ☐ Efficacy Failure ☐ Protocol Violation ☐ Subject Withdrew Consent ☐ Lost to Follow-Up ☐ Investigator Decision ☐ Study Discontinued by Sponsor

Project Name: GS-US-248-0120
Form: Study Drug Accountability - GS-5885 Rescue Therapy *[DA1_RS]*
Generated On: 07-31-2013 12:02:13

Visit Dispensed:	☐ Baseline Rescue Therapy ☐ Week 4 Rescue Therapy ☐ Week 8 Rescue Therapy ☐ Week 12 Rescue Therapy ☐ Week 16 Rescue Therapy ☐ Week 20 Rescue Therapy ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ Tegobuvir ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir Rescue Therapy ☐ PEG Rescue Therapy
Date Dispensed:	/ /
5-Digit Bottle Number:	
Number of Tablets Dispensed:	
Date Returned:	/ /
Number of Tablets Returned:	
Study Drug Not Returned:	☐

Project Name: GS-US-248-0120
Form: Study Drug Accountability - GS-5885 *[DA1]*
Generated On: 07-31-2013 12:02:13

Visit Dispensed:	☐ Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12 ☐ Week 16 ☐ Week 20 ☐ Unscheduled
Drug Name:	☒ GS-5885 ☐ GS-9451 ☐ RBV ☐ Tegobuvir ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir Rescue Therapy ☐ PEG Rescue Therapy
Date Dispensed:	/ /
5-Digit Bottle Number:	
Number of Tablets Dispensed:	
Date Returned:	/ /
Number of Tablets Returned:	
Study Drug Not Returned:	☐

Project Name: GS-US-248-0120
Form: Study Drug Accountability - GS-9451 Rescue Therapy *[DA2_RS]*
Generated On: 07-31-2013 12:02:13

Visit Dispensed:	☐ Baseline Rescue Therapy ☐ Week 4 Rescue Therapy ☐ Week 8 Rescue Therapy ☐ Week 12 Rescue Therapy ☐ Week 16 Rescue Therapy ☐ Week 20 Rescue Therapy ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ Tegobuvir ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir Rescue Therapy ☐ PEG Rescue Therapy
Date Dispensed:	/ /
5-Digit Bottle Number:	
Number of Tablets Dispensed:	
Date Returned:	/ /
Number of Tablets Returned:	
Study Drug Not Returned:	☐

Project Name: GS-US-248-0120
Form: Study Drug Accountability - GS-9451 *[DA2]*
Generated On: 07-31-2013 12:02:13

Visit Dispensed:	☐ Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12 ☐ Week 16 ☐ Week 20 ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ Tegobuvir ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir Rescue Therapy ☐ PEG Rescue Therapy
Date Dispensed:	/ /
5-Digit Bottle Number:	
Number of Tablets Dispensed:	
Date Returned:	/ /
Number of Tablets Returned:	
Study Drug Not Returned:	☐

Visit Dispensed:	☐ Baseline Rescue Therapy ☐ Week 4 Rescue Therapy ☐ Week 8 Rescue Therapy ☐ Week 12 Rescue Therapy ☐ Week 16 Rescue Therapy ☐ Week 20 Rescue Therapy ☐ Week 24 Rescue Therapy ☐ Week 28 Rescue Therapy ☐ Week 32 Rescue Therapy ☐ Week 36 Rescue Therapy ☐ Week 40 Rescue Therapy ☐ Week 44 Rescue Therapy ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ Tegobuvir ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir Rescue Therapy ☑ PEG Rescue Therapy
Date Dispensed:	/ /
5-Digit Lot Number	
Number of Syringes Dispensed:	

Date Returned:	/ /
Number of Unused Syringes Returned:	
Study Drug Not Returned:	☐

Project Name: GS-US-248-0120
Form: Study Drug Accountability - RBV Rescue Therapy *[DA4_RS]*
Generated On: 07-31-2013 12:02:13

Visit Dispensed:	☐ Baseline Rescue Therapy ☐ Week 4 Rescue Therapy ☐ Week 8 Rescue Therapy ☐ Week 12 Rescue Therapy ☐ Week 16 Rescue Therapy ☐ Week 20 Rescue Therapy ☐ Week 24 Rescue Therapy ☐ Week 28 Rescue Therapy ☐ Week 32 Rescue Therapy ☐ Week 36 Rescue Therapy ☐ Week 40 Rescue Therapy ☐ Week 44 Rescue Therapy ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ Tegobuvir ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir Rescue Therapy ☐ PEG Rescue Therapy
Date Dispensed:	/ /
6-Digit Lot Number:	
Number of Tablets Dispensed:	

Date Returned:	/ /
Number of Tablets Returned:	
Study Drug Not Returned:	☐

Project Name: GS-US-248-0120
Form: Study Drug Accountability - RBV *[DA4]*
Generated On: 07-31-2013 12:02:13

Visit Dispensed:	☐ Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12 ☐ Week 16 ☐ Week 20 ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ Tegobuvir ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir Rescue Therapy ☐ PEG Rescue Therapy
Date Dispensed:	/ /
6-Digit Lot Number:	
Number of Tablets Dispensed:	
Date Returned:	/ /
Number of Tablets Returned:	
Study Drug Not Returned:	☐

Project Name: GS-US-248-0120
Form: Study Drug Accountability - Tegobuvir Rescue Therapy *[DA3_RS]*
Generated On: 07-31-2013 12:02:13

Visit Dispensed:	☐ Baseline Rescue Therapy ☐ Week 4 Rescue Therapy ☐ Week 8 Rescue Therapy ☐ Week 12 Rescue Therapy ☐ Week 16 Rescue Therapy ☐ Week 20 Rescue Therapy ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ Tegobuvir ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir Rescue Therapy ☐ PEG Rescue Therapy
Date Dispensed:	/ /
5-Digit Bottle Number:	
Number of Capsules Dispensed:	
Date Returned:	/ /
Number of Capsules Returned:	
Study Drug Not Returned:	☐

Project Name: GS-US-248-0120
Form: Study Drug Accountability - Tegobuvir *[DA3]*
Generated On: 07-31-2013 12:02:13

Visit Dispensed:	☐ Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12 ☐ Week 16 ☐ Week 20 ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ Tegobuvir ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir Rescue Therapy ☐ PEG Rescue Therapy
Date Dispensed:	/ /
5-Digit Bottle Number:	
Number of Capsules Dispensed:	
Date Returned:	/ /
Number of Capsules Returned:	
Study Drug Not Returned:	☐

Project Name: GS-US-248-0120
Form: Study Drug Administration - Initial Treatment *[EX]*
Generated On: 07-31-2013 12:02:13

Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ Tegobuvir ☐ RBV
Dose:	
Dose Units / Frequency:	☐ capsules/day ☐ tablets/day ☐ Other
If “Other”, please specify:	
Start Date: (DD-MMM-YYYY)	/ /
Stop Date: (DD-MMM-YYYY)	/ /
Ongoing:	☐
Check box if study drug was permanently discontinued:	☐

Project Name: GS-US-248-0120
Form: Study Drug Administration - Rescue Therapy *[EX_RESCUE]*
Generated On: 07-31-2013 12:02:13

Drug Name:	☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ Tegobuvir Rescue Therapy ☐ RBV Rescue Therapy ☐ PEG Rescue Therapy
Dose:	
Dose Units / Frequency:	☐ capsules/day ☐ tablets/day ☐ ug/week ☐ Other
If “Other”, please specify:	
Start Date: (DD-MMM-YYYY)	/ /
Stop Date: (DD-MMM-YYYY)	/ /
Ongoing:	☐
Check box if study drug was permanently discontinued:	☐

Did subject complete study drug treatment through the protocol mandated duration of therapy?	☐ Yes ☐ No
If “No”, please specify reason for study drug discontinuation:	☐ Adverse Event ☐ Death ☐ Pregnancy ☐ Efficacy Failure ☐ Protocol Violation ☐ Subject Withdrew Consent ☐ Lost to Follow-Up ☐ Investigator Decision ☐ Randomized but Subject Never Dosed with Study Drug ☐ Study Discontinued by Sponsor

Did subject complete the rescue therapy study drug through Week 24 or Week 48 as described in the protocol?	☐ Yes ☐ No
If “No”, please specify reason for study drug discontinuation	☐ Adverse Event ☐ Death ☐ Pregnancy ☐ Efficacy Failure ☐ Protocol Violation ☐ Subject Withdrew Consent ☐ Lost to Follow-Up ☐ Investigator Decision ☐ Study Discontinued by Sponsor

Project Name: GS-US-248-0120
Form: Subject Follow-Up Status *[DS]*
Generated On: 07-31-2013 12:02:13

Provide the subject status:

If subject has discontinued, please complete the Study Completion form. For female subjects of childbearing potential, please also continue to complete the follow-up Urine Pregnancy Tests until Month 7.

Project Name: GS-US-248-0120
Form: Subject Number *[SUBID]*
Generated On: 07-31-2013 12:02:13

Screening Number (XXX):	
Subject Initials (XXX):	
SCRNID + SUBJINIT	

Project Name: GS-US-248-0120
Form: Urine Pregnancy Test (Baseline) *[PREGTEST1]*
Generated On: 07-31-2013 12:02:13

Is female subject of childbearing potential?	☐ Yes ☐ No
Date Test Performed: (DD-MMM-YYYY)	/ /
Test Result:	☐ Negative ☐ Positive ☐ Not Done

Note: A positive urine pregnancy test must be immediately confirmed with a serum pregnancy test, and the subject must not be enrolled.

Project Name: GS-US-248-0120
Form: Urine Pregnancy Test *[PREGTEST]*
Generated On: 07-31-2013 12:02:14

Is female subject of childbearing potential?	☐ Yes ☐ No
Date Test Performed: (DD-MMM-YYYY)	/ /
Test Result:	☐ Negative ☐ Positive ☐ Not Done

Note: A positive urine pregnancy test must be immediately confirmed with a serum pregnancy test.

Project Name: GS-US-248-0120
Form: Visit Date *[VISDT]*
Generated On: 07-31-2013 12:02:14

Was Post-Treatment Follow-Up Week 4 visit performed?	☐ Yes ☐ No
Was Post-Rescue Therapy Follow-Up Week 4 visit performed?	☐ Yes ☐ No
Visit Date: (DD-MMM-YYYY)	/ /
Reason for Unscheduled Visit: (Check all that apply) Evaluation of AE and/or Concomitant Medications:	☐
Vital Signs:	☐
Physical Exam:	☐
ECG:	☐
PK:	☐
Lab Evaluations:	☐
Study Drug Adjustment or Dispensation:	☐
Other:	☐
Other, Specify:	

Weight:	kg/ lb
Height:	cm/ in
Blood Pressure Systolic: (mmHg)	
Blood Pressure Diastolic: (mmHg)	
Pulse (beats/minute):	
Respiration: (breaths/minute)	
Temperature:	Celsius/ Fahrenheit