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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-248-0121
Form: Adverse Event *[AE]*
Generated On: 07-31-2013 09:44:51

Adverse Event: (List diagnosis or each symptom separately)	
AE serious: (If the Adverse Event is Serious, please click the [?] help text to open the SAE Report Form in another window. Print and fill in all the information for the first three pages on the SAE form and fax to the appropriate CRO contact)	☐ 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, RBV and PEG)	☐ Yes ☐ No
Related to Study Procedures:	☐ Yes ☐ No
Study Drug Action Taken - GS-5885:	☐ No Change ☐ Interrupted ☐ Discontinued ☐ Not Applicable
Study Drug Action Taken - GS-9451:	☐ No Change ☐ Interrupted ☐ Discontinued ☐ Not Applicable
Study Drug Action Taken - RBV:	☐ No change ☐ Interrupted ☐ Discontinued ☐ Dose Reduced ☐ Not Applicable

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:	☐
Hospitalized/Prolonged Hospitalization:	☐
Other Treatment Required:	☐
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.

Contact information for faxing and e-mailing these forms:

Australia/New Zealand (PRA Pharmacovigilance)
Fax +1 (888) 772-6919
Phone +1 (800) 772-2215
Email: CHO_safety@praintl.com

USA/Canada (DCRI Pharmacovigilance)
Fax +1 (866) 668-7139
Phone +1 (866) 668-7799
Email: safetysurveillance@mc.duke.edu

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.

Project Name: GS-US-248-0121
Form: Complete Physical Examination *[PE]*
Generated On: 07-31-2013 09:44:51

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 ☐ 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. Enter the Result, and Abnormality if applicable, then click on ‘Save’. Specify the Body system under If Body System is Other, please specify then click on ‘Save’ again.

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

Project Name: GS-US-248-0121
Form: Concomitant Medication *[CM]*
Generated On: 07-31-2013 09:44:51

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-248-0121
Form: Death Report *[DEATH]*
Generated On: 07-31-2013 09:44:51

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.(Click the [?] help text to open the SAE Report Form in another window. Please fill in all appropriate information on the first three pages before faxing the forms to the appropriate CRO contact.)

Contact information for faxing and e-mailing these forms:

Australia/New Zealand (PRA Pharmacovigilance)
Fax +1 (888) 772-6919
Phone +1 (800) 772-2215
Email: CHO_safety@praintl.com

USA/Canada (DCRI Pharmacovigilance)
Fax +1 (866) 668-7139
Phone +1 (866) 668-7799
Email: safetysurveillance@mc.duke.edu

Please update the Adverse Event eCRF, as needed.

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

Project Name: GS-US-248-0121
Form: Demographics *[DM]*
Generated On: 07-31-2013 09:44:51

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

Name of Actual Treatment:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ PEG
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
PEG Date of First Dose: (DD-MMM-YYYY)	/ /
PEG Time of First Dose: (00:00-23:59)	:
PEG Dose:	
PEG Dose Units:	☐ mg ☐ ug ☐ tablets ☐ capsules

Name of Actual Treatment:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ PEG
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
PEG Date of First Dose: (DD-MMM-YYYY)	/ /
PEG Time of First Dose: (00:00-23:59)	:
PEG Dose:	
PEG Dose Units:	☐ mg ☐ ug ☐ tablets ☐ capsules

Project Name: GS-US-248-0121
Form: ECG *[EG]*
Generated On: 07-31-2013 09:44:51

Was an ECG performed?	☐ Yes ☐ No
If No, please comment why ECG was not done:	
Date of ECG:	/ /
Time of ECG (00:00-23:59):	:
Overall Assessment of ECG:	☐ Normal ☐ Abnormal
If Abnormal, please describe the abnormality:	
Significance of Abnormality:	☐ Not Clinically Significant ☐ Clinically Significant

Visit:

- ☐ Screening
- ☐ Initial Treatment Visits
- ☐ Baseline
- ☐ 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)
- ☐ Dose Administration
- ☐ 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
- ☐ Retreatment Substudy
- ☐ Baseline/Day 1 Retreatment
- ☐ Week 1 Retreatment
- ☐ Week 2 Retreatment
- ☐ Week 4 Retreatment

- [ ] Week 6 Retreatment
- [ ] Week 8 Retreatment
- [ ] Week 10 Retreatment
- [ ] Week 12 Retreatment
- [ ] Week 16 Retreatment
- [ ] Week 20 Retreatment
- [ ] Week 24 Retreatment
- [ ] Week 28 Retreatment
- [ ] Week 32 Retreatment
- [ ] Week 36 Retreatment
- [ ] Week 40 Retreatment
- [ ] Week 44 Retreatment
- [ ] Week 48 Retreatment
- [ ] Early Termination (Retreatment)
- [ ] Post-Retreatment Follow-Up Week 4
- [ ] Post-Retreatment Follow-Up Week 8
- [ ] Post-Retreatment Follow-Up Week 12
- [ ] Post-Retreatment Follow-Up Week 16
- [ ] Post-Retreatment Follow-Up Week 20
- [ ] Post-Retreatment Follow-Up Week 24
- [ ] Post-Retreatment Follow-Up Week 28
- [ ] Post-Retreatment 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)
- [ ] ECG
- [ ] General Comments
- [ ] Inclusion/Exclusion Criteria
- [ ] Inclusion/Exclusion Criteria (Retreatment)
- [ ] Investigator's Signature
- [ ] Liver Fibrosis Assessment
- [ ] Medical History
- [ ] Pregnancy Report
- [ ] Randomization
- [ ] Stop Treatment
- [ ] Study Completion
- [ ] Study Drug Accountability - GS5885
- [ ] Study Drug Accountability - GS5885 Retreatment
- [ ] Study Drug Accountability - GS9451
- [ ] Study Drug Accountability - GS9451 Retreatment
- [ ] Study Drug Accountability - PEG
- [ ] Study Drug Accountability - PEG Retreatment
- [ ] Study Drug Accountability - RBV
- [ ] Study Drug Accountability - RBV Retreatment
- [ ] Study Drug Administration - Initial Treatment
- [ ] Study Drug Administration - Retreatment

	☐ Study Drug Completion (Initial Treatment) ☐ Study Drug Completion (Retreatment) ☐ Subject Follow-Up Status ☐ Subject Number ☐ Urine Pregnancy Test ☐ Urine Pregnancy Test (Baseline) ☐ Visit Date ☐ Vital Signs
General Comments:	
General Comments (Continued)	

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

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 ☐ Exclusion 1 ☐ Exclusion 2
Inclusion criteria not met/Exclusion criteria met?	☐
If subject that did not meet inclusion/exclusion criteria was enrolled,please provide an explanation.	

Project Name: GS-US-248-0121
Form: Inclusion/Exclusion Criteria *[IE]*
Generated On: 07-31-2013 09:44:52

Date Informed Consent Signed: (DD-MMM-YYYY)	/ /
Under which protocol version was the subject enrolled?	☐ 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
- [ ] Inclusion 17
- [ ] 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 ☐ Exclusion 27 ☐ Exclusion 28 ☐ Exclusion 29
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-248-0121

Form: Investigator's Signature *[INVSIG]*

Generated On: 07-31-2013 09:44:52

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 ☐ HepaScore ☐ Other
If Method is Other, please specify:	
Result:	
Cirrhosis	☐ Yes ☐ No

Project Name: GS-US-248-0121
Form: Medical History *[MH]*
Generated On: 07-31-2013 09:44:52

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'.

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'.(Click the [?] help text to open the Pregnancy Report Form in another window. Please fill in all information before faxing the forms to the appropriate CRO contact.)

Contact information for faxing and e-mailing these forms is found in the study protocol in section 8.5

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

Contact information for faxing and e-mailing these forms:

Australia/New Zealand (PRA Pharmacovigilance)
Fax +1 (888) 772-6919
Phone +1 (800) 772-2215
Email: CHO_safety@praintl.com

USA/Canada (DCRI Pharmacovigilance)
Fax +1 (866) 668-7139
Phone +1 (866) 668-7799
Email: safetysurveillance@mc.duke.edu

Last Menstrual Period: (DD-MMM-YYYY)	/ /
Pregnancy Confirmed: (DD-MMM-YYYY)	/ /
Estimated Date of Delivery: (DD-MMM-YYYY) **(Click the [?] help text to open the Pregnancy Outcome Report Form in another window. Please fill in all information on the first 3 pages before faxing the forms to the appropriate CRO contact.)**	/ /

Note: All baseline tests and procedures, including ECGs, must be completed prior to randomization and dosing/dispensing of study drugs.

Was the Subject Randomized?	☐ Yes ☐ No
4-Digit Subject Number as assigned by IWR system	
Treatment Arm	☐ Arm 1 (GS-5885/GS-9451/RBV/PEG) ☐ Arm 2 (RBV/PEG)
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	☐

Project Name: GS-US-248-0121
Form: Retreatment Substudy Status *[RTS]*
Generated On: 07-31-2013 09:44:52

Will the subject enroll in the retreatment sub-study?	☐ Yes ☐ No
Did the subject have a confirmed viral relapse?	☐ Yes ☐ No
Did the subject have a viral breakthrough?	☐ Yes ☐ No
Will the subject need to complete the Screening Retreatment Visit?	☐ Yes ☐ No

Will the subject be stopping treatment after 24 weeks of retreatment? (Note: Subjects who meet eRVR criteria from Week 4 to Week 20 of the retreatment substudy should stop retreatment at Week 24)	☐ Yes ☐ No

Does the subject meet Early Responder criteria to continue current treatment?	☐ Yes ☐ No
Has the subject been instructed to stop treatment by the IWR system?	☐ 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-248-0121
Form: Study Drug Accountability - GS-5885 Retreatment *[DA1_RT]*
Generated On: 07-31-2013 09:44:52

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

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

Project Name: GS-US-248-0121
Form: Study Drug Accountability - GS-9451 Retreatment *[DA3_RT]*
Generated On: 07-31-2013 09:44:52

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

Project Name: GS-US-248-0121
Form: Study Drug Accountability - GS-9451 *[DA3]*
Generated On: 07-31-2013 09:44:52

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

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

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

Project Name: GS-US-248-0121
Form: Study Drug Accountability - PEG *[DA5]*
Generated On: 07-31-2013 09:44:52

Visit Dispensed:	☐ Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12 ☐ Week 16 ☐ Week 20 ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☑ PEG ☐ GS-5885 Retreatment ☐ GS-9451 Retreatment ☐ RBV Retreatment ☐ PEG Retreatment
Date Dispensed:	/ /
Lot Number	
Number of Syringes Dispensed:	
Date Returned:	/ /
Number of Unused Syringes Returned:	
Study Drug Not Returned:	☐

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

Number of Tablets Returned:	
Study Drug Not Returned:	☐

Project Name: GS-US-248-0121
Form: Study Drug Accountability - RBV *[DA4]*
Generated On: 07-31-2013 09:44:52

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

Project Name: GS-US-248-0121
Form: Study Drug Administration - Initial Treatment *[EX]*
Generated On: 07-31-2013 09:44:52

Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV ☐ PEG
Dose:	
Dose Units / Frequency:	☐ ug/week ☐ 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-248-0121
Form: Study Drug Administration - Retreatment *[EX_RETREAT]*
Generated On: 07-31-2013 09:44:52

Drug Name:	☐ GS-5885 Retreatment ☐ GS-9451 Retreatment ☐ RBV Retreatment ☐ PEG Retreatment
Dose:	
Dose Units / Frequency:	☐ ug/week ☐ 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-248-0121
Form: Study Drug Completion (Initial Treatment) *[SDRGCOMP]*
Generated On: 07-31-2013 09:44:52

Did subject complete study drug treatment through the response guided 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 study drug re-treatment through the protocol-planned duration of the study?	☐ 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-248-0121
Form: Subject Follow-Up Status *[DS]*
Generated On: 07-31-2013 09:44:53

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-248-0121
Form: Subject Number *[SUBID]*
Generated On: 07-31-2013 09:44:53

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

Project Name: GS-US-248-0121
Form: Urine Pregnancy Test (Baseline) *[PREGTEST1]*
Generated On: 07-31-2013 09:44:53

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-248-0121
Form: Urine Pregnancy Test *[PREGTEST]*
Generated On: 07-31-2013 09:44:53

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-248-0121
Form: Visit Date *[VISDT]*
Generated On: 07-31-2013 09:44:53

Was Post-Treatment Follow-Up Week 4 visit performed?	☐ Yes ☐ No
Was Post-Retreatment 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:	☐
Lab Evaluations:	☐
Study Drug Adjustment or Dispensation:	☐
Other:	☐
Other, Specify:	

Project Name: GS-US-248-0121
Form: Vital Signs *[VS]*
Generated On: 07-31-2013 09:44:53

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