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BY DOMAIN

BY VISIT

Project Name: GS-US-248-0131
Form: 12-Lead ECG *[ECG12]*
Generated On: Aug-01-2013 07:00:08

Was an ECG performed?	☐ Yes ☐ No
If No, please comment why ECG was not done:	
Date of ECG:	/ /
Time of ECG:	:
HR Rate (bpm):	
PR Interval (msec):	
QRS Interval (msec):	
QT Interval (msec):	
QTcF Interval (msec) (Calculated)	
Overall Assessment of ECG:	☐ Normal ☐ Abnormal
If Abnormal, please describe the abnormality:	
Significance of Abnormality:	☐ Not Clinically Significant ☐ Clinically Significant

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

Project Name: GS-US-248-0131
Form: Adverse Event *[AE]*
Generated On: Aug-01-2013 07:00:08

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, Tegobuvir/Placebo , RBV/Placebo 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/Placebo: (Choose 'Not Applicable' if subject is participating in the Rescue Therapy substudy at the time of the AE)	☐ No change ☐ Interrupted ☐ Discontinued ☐ Dose Reduced ☐ Not Applicable

Study Drug Action Taken - RBV/Placebo:	☐ No change ☐ Interrupted ☐ Discontinued ☐ Dose Reduced
Study Drug Action Taken - PEG: (Choose 'Not Applicable if subject is not participating in the Rescue Therapy substudy at the time of the AE.)	☐ 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.

Project Name: GS-US-248-0131
Form: Complete Physical Exam plus Retinal *[PE]*
Generated On: Aug-01-2013 07:00:08

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.

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-248-0131
Form: Concomitant Medication *[CM]*
Generated On: Aug-01-2013 07:00:09

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-248-0131
Form: Death Report *[DEATH]*
Generated On: Aug-01-2013 07:00:09

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(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.)

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-248-0131
Form: Dose Administration (Day 1) *[PKEX]*
Generated On: Aug-01-2013 07:00:09

Name of Actual Treatment:	☐ GS-5885 ☐ GS-9451 ☐ Tegobuvir/Placebo ☐ RBV/Placebo
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-248-0131
Form: Dose Administration (Serial PK) *[PKEX2]*
Generated On: Aug-01-2013 07:00:09

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/Placebo ☐ RBV/Placebo
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-248-0131
Form: Dose Administration (Single PK) *[PKEX1]*
Generated On: Aug-01-2013 07:00:09

Check 'Not Applicable' box if Subject is participating in Serial PK Substudy at this visit:	☐
Name of Actual Treatment:	☐ GS-5885 ☐ GS-9451 ☐ Tegobuvir/Placebo ☐ RBV/Placebo
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-248-0131
Form: Dose Administration (Viral Dynamic Substudy) *[PKEX3]*
Generated On: Aug-01-2013 07:00:09

Name of Actual Treatment:	☐ GS-5885 ☐ GS-9451 ☐ Tegobuvir/Placebo ☐ RBV/Placebo
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
- ☐ Day 1
- ☐ Day 2
- ☐ Day 3
- ☐ Day 4
- ☐ Day 5
- ☐ Week 1
- ☐ Day 10
- ☐ 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
- ☐ 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 Month 6
- [ ] Rescue Therapy Substudy Follow-Up Visits
- [ ] 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 6
- [ ] Adverse Events
- [ ] Concomitant Medication
- [ ] Study Drug Administration
- [ ] Missed Dose Overdose Log
- [ ] Study Drug Accountability
- [ ] Pregnancy Report
- [ ] Death
- [ ] General Comments
- [ ] Unscheduled
- [ ] Study Completion
- [ ] Rescue Therapy Status

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
- [ ] Missed Dose and Overdose Log – Initial Treatment
- [ ] Missed Dose and Overdose Log – Rescue Treatment
- [ ] Pregnancy Report
- [ ] PK Plasma (Viral Dynamic Substudy Day 1)
- [ ] Prior HCV Treatment History
- [ ] Prior Response Classification
- [ ] Prior Response History - Breakthrough
- [ ] Prior Response History - Null or Partial
- [ ] Prior Response History - Relapser
- [ ] Randomization
- [ ] Rescue Therapy Status
- [ ] Single PK Plasma
- [ ] Serial PK Plasma

- [ ] 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//Placebo
- [ ] 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
- [ ] Vital Signs (Screening)
- [ ] Vital Signs with Weight
- [ ] 12-Lead ECG

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?	☐ 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-248-0131

Form: Investigator's Signature *[INVSIG]*

Generated On: Aug-01-2013 07:00:09

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 ☐ Batts-Ludwig ☐ Scheuer
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-248-0131
Form: Medical History *[MH]*
Generated On: Aug-01-2013 07:00:09

Please record date of diagnosis for Hepatitis C on row 1 and indicate if 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'.

Project Name: GS-US-248-0131
Form: Missed Dose and Overdose Log – Initial Treatment *[EXMSOV]*
Generated On: Aug-01-2013 07:00:09

Only enter a record for days on which the dairy indicates a missed dose or overdose of a study drug. Enter all dosing information for that day.

If a subject mistook an evening dose for the QD drugs GS-9451 or GS-5885 and this was indicated in the dairy, please enter them in the last two columns. If an evening dose of GS-9451 or GS-5885 were not taken, please leave the column blank.

Date (dd-mmm-yyyy)	/ /
Morning Dosing: Please record number of tablets taken: **Ribavirin**	
Morning Dosing: Please record number of capsules taken: **Tegobuvir**	
Morning Dosing: Please record number of tablets taken: **GS-9451**	
Morning Dosing: Please record number of tablets taken: **GS-5885**	
Evening Dosing: Please record number of tablets taken: **Ribavirin**	
Evening Dosing: Please record number of capsules taken: **Tegobuvir**	
Evening Dosing: Please record number of tablets taken: **GS-9451**	
Evening Dosing: Please record number of tablets taken: **GS-5885**	

If and overdose of study drug has been reported, please click on the [?] help text to open the Oversdose Form in another window. Fax or email the completed form to the appropriate CRO contact.

Project Name: GS-US-248-0131
Form: Missed Dose and Overdose Log – Rescue Treatment *[EXMSOV_RESCUE]*
Generated On: Aug-01-2013 07:00:09

Only enter a record for days on which the dairy indicates a missed dose or overdose of a study drug. Enter all dosing information for that day.

If a subject mistook an evening dose for the QD drugs GS-9451 or GS-5885 and this was indicated in the dairy, please enter them in the last two columns. If an evening dose of GS-9451 or GS-5885 were not taken, please leave the column blank.

Date (dd-mmm-yyyy)	/ /
Morning Dosing: Please record number of tablets taken: **Ribavirin**	
Morning Dosing: Please record number of tablets taken: **GS-9451**	
Morning Dosing: Please record number of tablets taken: **GS-5885**	
Evening Dosing: Please record number of tablets taken: **Ribavirin**	
Evening Dosing: Please record number of tablets taken: **GS-9451**	
Evening Dosing: Please record number of tablets taken: **GS-5885**	

If and overdose of study drug has been reported, please click on the [?] help text to open the Oversdose Form in another window. Fax or email the completed form to the appropriate CRO contact.

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
Time of PK Collection: (00:00-23:59)	:
Not Collected	☐
Please specify why this timepoint was not collected:	

Project Name: GS-US-248-0131
Form: Pregnancy Report *[PREGREP]*
Generated On: Aug-01-2013 07:00:09

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 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) **(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.)**	/ /

Treatment:	☐ Pegylated Interferon-alfa ☐ Ribavirin
Specify Peg:	☐ Peginterferon Alfa-2a (PEGASYS) ☐ Peginterferon Alfa-2b (PEG-INTRON)
Starting Dose:	
Dose Unit:	☐ ug/kg/week ☐ ug/week ☐ mg/day
Start Date: (DD-MMM-YYYY)	/ /
Stop Date: (DD-MMM-YYYY)	/ /
Start Year (yyyy)	/ /
Stop Year (yyyy)	/ /

Project Name: GS-US-248-0131
Form: Prior Response Classification *[PRC]*
Generated On: Aug-01-2013 07:00:10

Does subject meet protocol criteria for Breakthrough, Relapser, Null, or Partial Responder?	☐ Responder: Breakthrough ☐ Responder: Relapser ☐ Non-Responder: Null ☐ Non-Responder: Partial ☐ Protocol Criteria Not Met

Timepoint:	☐ Pretreatment HCV RNA ☐ Week 12 HCV RNA ☐ On Treatment HCV RNA Nadir (lowest HCV RNA value while on treatment) ☐ Breakthrough HCV RNA ☐ End of Treatment HCV RNA ☐ Post Treatment HCV RNA
Date of Collection:	/ /
Result:	
Units:	☐ IU/ml ☐ Copies/ml ☐ Other
If “Other”, please specify:	
Detectable/Undetectable:	☐ Detectable ☐ Undetectable
Assay:	☐ Rt-PCR ☐ TMA ☐ bDNA ☐ Other
If “Other”, please specify:	
Breakthrough Year of Collection (yyyy)	/ /

Timepoint:	☐ Pretreatment HCV RNA ☐ Week 12 HCV RNA ☐ On Treatment HCV RNA Nadir (lowest HCV RNA value while on treatment) ☐ Breakthrough HCV RNA ☐ End of Treatment HCV RNA ☐ Post Treatment HCV RNA
Date of Collection:	/ /
Result:	
Units:	☐ IU/ml ☐ Copies/ml ☐ Other
If “Other”, please specify:	
Detectable/Undetectable:	☐ Detectable ☐ Undetectable
Assay:	☐ Rt-PCR ☐ TMA ☐ bDNA ☐ Other
If “Other”, please specify:	
Null or Partial Year of Collection (yyyy)	/ /

Timepoint:	☐ Pretreatment HCV RNA ☐ Week 12 HCV RNA ☐ On Treatment HCV RNA Nadir (lowest HCV RNA value while on treatment) ☐ Breakthrough HCV RNA ☐ End of Treatment HCV RNA ☐ Post Treatment HCV RNA
Date of Collection:	/ /
Result:	
Units:	☐ IU/ml ☐ Copies/ml ☐ Other
If “Other”, please specify:	
Detectable/Undetectable:	☐ Detectable ☐ Undetectable
Assay:	☐ Rt-PCR ☐ TMA ☐ bDNA ☐ Other
If “Other”, please specify:	
Relapser Year of Collection (yyyy)	/ /

Project Name: GS-US-248-0131
Form: Randomization *[RAND]*
Generated On: Aug-01-2013 07:00:10

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

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
Was subject enrolled due to study unblinding? ***if "Yes" check box***	☐

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
Time of PK Collection: (00:00-23:59)	:
Not Collected	☐
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-248-0131
Form: Single PK Plasma *[PK]*
Generated On: Aug-01-2013 07:00:10

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

Visit Dispensed:	☐ Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12 ☐ Week 16 ☐ Week 20 ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV/Placebo ☐ Tegobuvir/Placebo ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir/Placebo 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 ☐ Week 4 ☐ Week 8 ☐ Week 12 ☐ Week 16 ☐ Week 20 ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV/Placebo ☐ Tegobuvir/Placebo ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir/Placebo 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 ☐ Week 4 ☐ Week 8 ☐ Week 12 ☐ Week 16 ☐ Week 20 ☐ Unscheduled
Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ RBV/Placebo ☐ Tegobuvir/Placebo ☐ GS-5885 Rescue Therapy ☐ GS-9451 Rescue Therapy ☐ RBV Rescue Therapy ☐ Tegobuvir/Placebo 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-248-0131
Form: Study Drug Administration - Initial Treatment *[EX]*
Generated On: Aug-01-2013 07:00:10

Drug Name:	☐ GS-5885 ☐ GS-9451 ☐ Tegobuvir/Placebo ☐ RBV/Placebo
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-248-0131
Form: Study Drug Administration - Rescue Therapy *[EX_RESCUE]*
Generated On: Aug-01-2013 07:00:10

Drug Name:	☐ GS-5885 Rescue Therapy ☐ GS-9451 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 Week 24?	☐ 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-248-0131
Form: Subject Follow-Up Status *[DS]*
Generated On: Aug-01-2013 07:00:10

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 6

Project Name: GS-US-248-0131
Form: Subject Number *[SUBID]*
Generated On: Aug-01-2013 07:00:10

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

Project Name: GS-US-248-0131
Form: Urine Pregnancy Test (Baseline) *[PREGTEST1]*
Generated On: Aug-01-2013 07:00:10

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-248-0131
Form: Urine Pregnancy Test *[PREGTEST]*
Generated On: Aug-01-2013 07:00:10

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-248-0131
Form: Visit Date *[VISDT]*
Generated On: Aug-01-2013 07:00:10

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)	/ /
Was visit performed on the same day as Week 1	☐ Yes ☐ No
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:	

Project Name: GS-US-248-0131
Form: Vital Signs (Screening) *[VS1]*
Generated On: Aug-01-2013 07:00:10

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

Project Name: GS-US-248-0131
Form: Vital Signs with Weight *[VS2]*
Generated On: Aug-01-2013 07:00:10

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

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