

TABLE OF CONTENTS

BY DOMAIN

ADVERSE EVENT SUMMARY	15
ADVERSE EVENTS	15
ADVERSE EVENT	16
COMPLETE PHYSICAL EXAMINATION	19
BASELINE/DAY 1	19
BASELINE/DAY 1 RESCUE THERAPY	19
EARLY TERMINATION (INITIAL TREATMENT)	19
EARLY TERMINATION (RESCUE THERAPY)	19
SCREENING	19
UNSCHEDULED	19
WEEK 12	19
WEEK 12 RESCUE THERAPY	19
WEEK 24	19
WEEK 24 RESCUE THERAPY	19
WEEK 48 RESCUE THERAPY	19
CONCOMITANT MEDICATION SUMMARY	20
CONCOMITANT MEDICATION	20
CONCOMITANT MEDICATION	21
CONCOMITANT MEDICATION	21
DEATH REPORT	22
DEATH	22
DEMOGRAPHICS	23
SCREENING	23
DOSE ADMINISTRATION (DAY 1)	24
BASELINE/DAY 1	24
DOSE ADMINISTRATION (SERIAL PK)	25
PK WEEK 2	25
DOSE ADMINISTRATION (SINGLE PK)	26
EARLY TERMINATION (INITIAL TREATMENT)	26
UNSCHEDULED	26
WEEK 1	26
WEEK 2	26
WEEK 4	26

WEEK 6	26
WEEK 8	26
WEEK 10	26
WEEK 12	26
WEEK 16	26
WEEK 20	26
WEEK 24	26
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	27
DAY 2	27
DAY 3	27
DAY 5	27
DAY 10	27
GENERAL COMMENTS	28
GENERAL COMMENTS	28
INCLUSION/EXCLUSION CRITERIA	33
SCREENING	33
INVESTIGATOR'S SIGNATURE	36
LIVER FIBROSIS ASSESSMENT	37
SCREENING	37
MEDICAL HISTORY	39
SCREENING	39
PK PLASMA (VIRAL DYNAMIC SUBSTUDY DAY 1)	40
DAY 1	40
PREGNANCY REPORT	41
PREGNANCY REPORT	41
RANDOMIZATION	42
BASELINE/DAY 1	42
REGISTRY SUBSTUDY	43
RESCUE THERAPY STATUS	44
RESCUE THERAPY SUBSTUDY	44
SERIAL PK PLASMA	45
PK WEEK 2	45
SINGLE PK PLASMA	46
DAY 2	46
DAY 3	46
DAY 5	46
DAY 10	46
EARLY TERMINATION (INITIAL TREATMENT)	46

UNSCHEDULED	46
WEEK 1	46
WEEK 2	46
WEEK 4	46
WEEK 6	46
WEEK 8	46
WEEK 10	46
WEEK 12	46
WEEK 16	46
WEEK 20	46
WEEK 24	46
STOP TREATMENT	47
WEEK 12	47
WEEK 24 RESCUE THERAPY	47
STUDY COMPLETION	48
STUDY COMPLETION	48
STUDY DRUG ACCOUNTABILITY - GS-5885 RESCUE THERAPY	49
STUDY DRUG ACCOUNTABILITY	49
STUDY DRUG ACCOUNTABILITY - GS-5885	50
STUDY DRUG ACCOUNTABILITY	50
STUDY DRUG ACCOUNTABILITY - GS-9451 RESCUE THERAPY	51
STUDY DRUG ACCOUNTABILITY	51
STUDY DRUG ACCOUNTABILITY - GS-9451	52
STUDY DRUG ACCOUNTABILITY	52
STUDY DRUG ACCOUNTABILITY - PEG RESCUE THERAPY	53
STUDY DRUG ACCOUNTABILITY	53
STUDY DRUG ACCOUNTABILITY - RBV RESCUE THERAPY	55
STUDY DRUG ACCOUNTABILITY	55
STUDY DRUG ACCOUNTABILITY - RBV	57
STUDY DRUG ACCOUNTABILITY	57
STUDY DRUG ACCOUNTABILITY - TEGOBUVIR RESCUE THERAPY	58
STUDY DRUG ACCOUNTABILITY	58
STUDY DRUG ACCOUNTABILITY - TEGOBUVIR	59
STUDY DRUG ACCOUNTABILITY	59
STUDY DRUG ADMINISTRATION - INITIAL TREATMENT	60
STUDY DRUG ADMINISTRATION	60
STUDY DRUG ADMINISTRATION - RESCUE THERAPY	61
STUDY DRUG ADMINISTRATION	61

STUDY DRUG COMPLETION (INITIAL TREATMENT)	62
STUDY DRUG COMPLETION (INITIAL TREATMENT)	62
STUDY DRUG COMPLETION (RESCUE THERAPY)	63
STUDY DRUG COMPLETION (RESCUE THERAPY)	63
SUBJECT FOLLOW-UP STATUS	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 8	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 12	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 16	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 20	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 24	64
POST-TREATMENT FOLLOW-UP WEEK 4	64
POST-TREATMENT FOLLOW-UP WEEK 8	64
POST-TREATMENT FOLLOW-UP WEEK 12	64
POST-TREATMENT FOLLOW-UP WEEK 16	64
POST-TREATMENT FOLLOW-UP WEEK 20	64
POST-TREATMENT FOLLOW-UP WEEK 24	64
SUBJECT NUMBER	65
URINE PREGNANCY TEST (BASELINE)	66
BASELINE/DAY 1	66
URINE PREGNANCY TEST	67
BASELINE/DAY 1 RESCUE THERAPY	67
EARLY TERMINATION (INITIAL TREATMENT)	67
EARLY TERMINATION (RESCUE THERAPY)	67
POST-RESCUE THERAPY FOLLOW-UP MONTH 7	67
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	67
POST-RESCUE THERAPY FOLLOW-UP WEEK 8	67
POST-RESCUE THERAPY FOLLOW-UP WEEK 12	67
POST-RESCUE THERAPY FOLLOW-UP WEEK 16	67
POST-RESCUE THERAPY FOLLOW-UP WEEK 20	67
POST-RESCUE THERAPY FOLLOW-UP WEEK 28	67
POST-TREATMENT FOLLOW-UP MONTH 7	67
POST-TREATMENT FOLLOW-UP WEEK 4	67
POST-TREATMENT FOLLOW-UP WEEK 8	67
POST-TREATMENT FOLLOW-UP WEEK 12	67
POST-TREATMENT FOLLOW-UP WEEK 16	67
POST-TREATMENT FOLLOW-UP WEEK 20	67
POST-TREATMENT FOLLOW-UP WEEK 24	67

POST-TREATMENT FOLLOW-UP WEEK 28	67
UNSCHEDULED	67
WEEK 4	67
WEEK 4 RESCUE THERAPY	67
WEEK 8	67
WEEK 8 RESCUE THERAPY	67
WEEK 12	67
WEEK 12 RESCUE THERAPY	67
WEEK 16	67
WEEK 16 RESCUE THERAPY	67
WEEK 20	67
WEEK 20 RESCUE THERAPY	67
WEEK 24	67
WEEK 24 RESCUE THERAPY	67
WEEK 28 RESCUE THERAPY	67
WEEK 32 RESCUE THERAPY	67
WEEK 36 RESCUE THERAPY	67
WEEK 40 RESCUE THERAPY	67
WEEK 44 RESCUE THERAPY	67
WEEK 48 RESCUE THERAPY	67
VISIT DATE	68
BASELINE/DAY 1	68
BASELINE/DAY 1 RESCUE THERAPY	68
DAY 2	68
DAY 3	68
DAY 5	68
DAY 10	68
EARLY TERMINATION (INITIAL TREATMENT)	68
EARLY TERMINATION (RESCUE THERAPY)	68
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	68
POST-RESCUE THERAPY FOLLOW-UP WEEK 12	68
POST-RESCUE THERAPY FOLLOW-UP WEEK 24	68
POST-TREATMENT FOLLOW-UP WEEK 4	68
POST-TREATMENT FOLLOW-UP WEEK 12	68
POST-TREATMENT FOLLOW-UP WEEK 24	68
SCREENING	68
UNSCHEDULED	68
WEEK 1	68

WEEK 1 RESCUE THERAPY	68
WEEK 2	68
PK WEEK 2	68
WEEK 2 RESCUE THERAPY	68
WEEK 4	68
WEEK 4 RESCUE THERAPY	68
WEEK 6	68
WEEK 6 RESCUE THERAPY	68
WEEK 8	68
WEEK 8 RESCUE THERAPY	68
WEEK 10	68
WEEK 10 RESCUE THERAPY	68
WEEK 12	68
WEEK 12 RESCUE THERAPY	68
WEEK 16	68
WEEK 16 RESCUE THERAPY	68
WEEK 20	68
WEEK 20 RESCUE THERAPY	68
WEEK 24	68
WEEK 24 RESCUE THERAPY	68
WEEK 28 RESCUE THERAPY	68
WEEK 32 RESCUE THERAPY	68
WEEK 36 RESCUE THERAPY	68
WEEK 40 RESCUE THERAPY	68
WEEK 44 RESCUE THERAPY	68
WEEK 48 RESCUE THERAPY	68
VITAL SIGNS	69
BASELINE/DAY 1	69
BASELINE/DAY 1 RESCUE THERAPY	69
EARLY TERMINATION (INITIAL TREATMENT)	69
EARLY TERMINATION (RESCUE THERAPY)	69
SCREENING	69
UNSCHEDULED	69
WEEK 1	69
WEEK 1 RESCUE THERAPY	69
WEEK 2	69
WEEK 2 RESCUE THERAPY	69
WEEK 4	69

WEEK 4 RESCUE THERAPY	69
WEEK 6	69
WEEK 6 RESCUE THERAPY	69
WEEK 8	69
WEEK 8 RESCUE THERAPY	69
WEEK 10	69
WEEK 10 RESCUE THERAPY	69
WEEK 12	69
WEEK 12 RESCUE THERAPY	69
WEEK 16	69
WEEK 16 RESCUE THERAPY	69
WEEK 20	69
WEEK 20 RESCUE THERAPY	69
WEEK 24	69
WEEK 24 RESCUE THERAPY	69
WEEK 28 RESCUE THERAPY	69
WEEK 32 RESCUE THERAPY	69
WEEK 36 RESCUE THERAPY	69
WEEK 40 RESCUE THERAPY	69
WEEK 44 RESCUE THERAPY	69
WEEK 48 RESCUE THERAPY	69

BY VISIT

SCREENING	68
VISIT DATE	68
INCLUSION/EXCLUSION CRITERIA	33
DEMOGRAPHICS	23
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
MEDICAL HISTORY	39
LIVER FIBROSIS ASSESSMENT	37
BASELINE/DAY 1	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST (BASELINE)	66
RANDOMIZATION	42
DOSE ADMINISTRATION (DAY 1)	24
WEEK 1	68

VISIT DATE	68
VITAL SIGNS	69
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
WEEK 2	68
VISIT DATE	68
VITAL SIGNS	69
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
WEEK 4	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
WEEK 6	68
VISIT DATE	68
VITAL SIGNS	69
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
WEEK 8	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
WEEK 10	68
VISIT DATE	68
VITAL SIGNS	69
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
WEEK 12	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST	67
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46

STOP TREATMENT	47
WEEK 16	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
WEEK 20	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
WEEK 24	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST	67
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
EARLY TERMINATION (INITIAL TREATMENT)	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST	67
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
STUDY DRUG COMPLETION (INITIAL TREATMENT)	62
STUDY DRUG COMPLETION (INITIAL TREATMENT)	62
DAY 1	40
PK PLASMA (VIRAL DYNAMIC SUBSTUDY DAY 1)	40
DAY 2	68
VISIT DATE	68
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	27
SINGLE PK PLASMA	46
DAY 3	68
VISIT DATE	68
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	27

SINGLE PK PLASMA	46
DAY 5	68
VISIT DATE	68
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	27
SINGLE PK PLASMA	46
DAY 10	68
VISIT DATE	68
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	27
SINGLE PK PLASMA	46
PK WEEK 2	68
VISIT DATE	68
DOSE ADMINISTRATION (SERIAL PK)	25
SERIAL PK PLASMA	45
POST-TREATMENT FOLLOW-UP WEEK 4	68
VISIT DATE	68
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-TREATMENT FOLLOW-UP WEEK 8	67
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-TREATMENT FOLLOW-UP WEEK 12	68
VISIT DATE	68
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-TREATMENT FOLLOW-UP WEEK 16	67
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-TREATMENT FOLLOW-UP WEEK 20	67
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-TREATMENT FOLLOW-UP WEEK 24	68
VISIT DATE	68
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-TREATMENT FOLLOW-UP WEEK 28	67
URINE PREGNANCY TEST	67
POST-TREATMENT FOLLOW-UP MONTH 7	67
URINE PREGNANCY TEST	67

RESCUE THERAPY SUBSTUDY	44
RESCUE THERAPY STATUS	44
BASELINE/DAY 1 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST	67
WEEK 1 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
WEEK 2 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
WEEK 4 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
WEEK 6 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
WEEK 8 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
WEEK 10 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
WEEK 12 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST	67
WEEK 16 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
WEEK 20 RESCUE THERAPY	68
VISIT DATE	68

VITAL SIGNS	69
URINE PREGNANCY TEST	67
WEEK 24 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST	67
STOP TREATMENT	47
WEEK 28 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
WEEK 32 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
WEEK 36 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
WEEK 40 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
WEEK 44 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
URINE PREGNANCY TEST	67
WEEK 48 RESCUE THERAPY	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST	67
EARLY TERMINATION (RESCUE THERAPY)	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST	67

STUDY DRUG COMPLETION (RESCUE THERAPY)	63
STUDY DRUG COMPLETION (RESCUE THERAPY)	63
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	68
VISIT DATE	68
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 8	67
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 12	68
VISIT DATE	68
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 16	67
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 20	67
URINE PREGNANCY TEST	67
SUBJECT FOLLOW-UP STATUS	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 24	68
VISIT DATE	68
SUBJECT FOLLOW-UP STATUS	64
POST-RESCUE THERAPY FOLLOW-UP WEEK 28	67
URINE PREGNANCY TEST	67
POST-RESCUE THERAPY FOLLOW-UP MONTH 7	67
URINE PREGNANCY TEST	67
ADVERSE EVENTS	15
ADVERSE EVENT SUMMARY	15
CONCOMITANT MEDICATION	20
CONCOMITANT MEDICATION SUMMARY	20
CONCOMITANT MEDICATION	21
STUDY DRUG ADMINISTRATION	60
STUDY DRUG ADMINISTRATION - INITIAL TREATMENT	60
STUDY DRUG ADMINISTRATION - RESCUE THERAPY	61
STUDY DRUG ACCOUNTABILITY	50
STUDY DRUG ACCOUNTABILITY - GS-5885	50
STUDY DRUG ACCOUNTABILITY - GS-9451	52
STUDY DRUG ACCOUNTABILITY - TEGOBUVIR	59

STUDY DRUG ACCOUNTABILITY - RBV	57
STUDY DRUG ACCOUNTABILITY - GS-5885 RESCUE THERAPY	49
STUDY DRUG ACCOUNTABILITY - GS-9451 RESCUE THERAPY	51
STUDY DRUG ACCOUNTABILITY - TEGOBUVIR RESCUE THERAPY	58
STUDY DRUG ACCOUNTABILITY - RBV RESCUE THERAPY	55
STUDY DRUG ACCOUNTABILITY - PEG RESCUE THERAPY	53
PREGNANCY REPORT	41
PREGNANCY REPORT	41
DEATH	22
DEATH REPORT	22
GENERAL COMMENTS	28
GENERAL COMMENTS	28
UNSCHEDULED	68
VISIT DATE	68
VITAL SIGNS	69
COMPLETE PHYSICAL EXAMINATION	19
URINE PREGNANCY TEST	67
DOSE ADMINISTRATION (SINGLE PK)	26
SINGLE PK PLASMA	46
STUDY COMPLETION	48
STUDY COMPLETION	48
RESCUE THERAPY STATUS	44
INVESTIGATOR'S SIGNATURE	36
SUBJECT NUMBER	65

Project Name: GS-US-248-0120

Form: Adverse Event Summary [AES]

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

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

Project Name: GS-US-248-0120

Form: Adverse Event [AE]

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

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.

Project Name: GS-US-248-0120

Form: Adverse Event [AE]

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

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-248-0120
Form: Complete Physical Examination [PE]
Generated On: 07-31-2013 12:02:12

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.

Project Name: GS-US-248-0120

Form: Concomitant Medication Summary [CMS]

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

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:

Project Name: GS-US-248-0120

Form: Demographics [DM]

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

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

Project Name: GS-US-248-0120

Form: General Comments [CO]

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

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
-

Project Name: GS-US-248-0120

Form: General Comments [CO]

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

- ☐ 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
-

Project Name: GS-US-248-0120

Form: General Comments [CO]

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

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
-

Project Name: GS-US-248-0120
Form: General Comments [CO]
Generated On: 07-31-2013 12:02:12

- ☐ 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'.

Project Name: GS-US-248-0120

Form: Inclusion/Exclusion Criteria [IE]

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

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
-

Project Name: GS-US-248-0120
Form: Inclusion/Exclusion Criteria [IE]
Generated On: 07-31-2013 12:02:12

- ☐ 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 report forms and verify that they accurately reflect the information in the source documents for this subject. I understand source documentation can include (but is not limited to) medical records, laboratory results, x-rays, electronic communications, etc.

Project Name: GS-US-248-0120
Form: Liver Fibrosis Assessment [BIOPSY]
Generated On: 07-31-2013 12:02:12

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)

Project Name: GS-US-248-0120
Form: Liver Fibrosis Assessment [BIOPSY]
Generated On: 07-31-2013 12:02:12

Method:	<div><input type="checkbox"/> FibroTest</div> <div><input type="checkbox"/> FibroScan</div> <div><input type="checkbox"/> Acoustic Radiation Force Impulse Imaging</div> <div><input type="checkbox"/> Other</div>
If Method is Other, please specify:	<div></div>
Result:	<div></div>
Cirrhosis	<div><input type="checkbox"/> Yes</div> <div><input type="checkbox"/> No</div>

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:	<input type="text"/>
------------	----------------------

Start Date: (DD-MMM-YYYY)	<input type="text" value="/ /"/>
---------------------------	----------------------------------

Stop Date: (DD-MMM-YYYY)	<input type="text" value="/ /"/>
--------------------------	----------------------------------

Check if Condition is Ongoing:	<input type="checkbox"/>
--------------------------------	--------------------------

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

Project Name: GS-US-248-0120

Form: PK Plasma (Viral Dynamic Substudy Day 1) [PKS1]

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

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)

Project Name: GS-US-248-0120
Form: Randomization [RAND]
Generated On: 07-31-2013 12:02:12

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

Project Name: GS-US-248-0120

Form: Registry Substudy [REGISTRY]

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

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-248-0120

Form: Rescue Therapy Status *[RTS]*

Generated On: 07-31-2013 12:02:13

Will subject enroll into Rescue Therapy substudy?

☐ Yes

☐ No

Project Name: GS-US-248-0120

Form: Serial PK Plasma [PKS]

Generated On: 07-31-2013 12:02:13

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)

:

Project Name: GS-US-248-0120

Form: Stop Treatment [SPTREAT]

Generated On: 07-31-2013 12:02:13

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

Project Name: GS-US-248-0120

Form: Study Completion [STUDCOMP]

Generated On: 07-31-2013 12:02:13

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 [DAI_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:

☐

Project Name: GS-US-248-0120

Form: Study Drug Accountability - PEG Rescue Therapy [DA5_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:

5-Digit Lot Number

Number of Syringes Dispensed:

Project Name: GS-US-248-0120

Form: Study Drug Accountability - PEG Rescue Therapy [DA5_RS]

Generated On: 07-31-2013 12:02:13

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:

Project Name: GS-US-248-0120

Form: Study Drug Accountability - RBV Rescue Therapy [DA4_RS]

Generated On: 07-31-2013 12:02:13

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:

☐

Project Name: GS-US-248-0120

Form: Study Drug Completion (Initial Treatment) [SDRGCOMP]

Generated On: 07-31-2013 12:02:13

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

Project Name: GS-US-248-0120

Form: Study Drug Completion (Rescue Therapy) [SDRGCOMP2]

Generated On: 07-31-2013 12:02:13

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:

Project Name: GS-US-248-0120

Form: Vital Signs [VS]

Generated On: 07-31-2013 12:02:14

Weight:

kg/ lb

Height:

cm/ in

Blood Pressure Systolic: (mmHg)

Blood Pressure Diastolic: (mmHg)

Pulse (beats/minute):

Respiration: (breaths/minute)

Temperature:

Celsius/
Fahrenheit
