




WebDCU™ ALFSG

Annotated Form for CRF 00 [Enrollment]
Form ID: 27 DB Table Name: F00 DB View Name: vF00


No.	Item Description	Data Value
1	Date of initial hospital admission DB Name: [Q01] SAS Name: [DateAdm]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
2	Time of initial hospital admission DB Name: [Q02] SAS Name: [TimeAdm]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
3	Hospital transfer? DB Name: [Q03] SAS Name: [HospTrans]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
4	If Yes, date of transfer DB Name: [Q04] SAS Name: [TransDate]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
5	Date of Birth DB Name: [Q05] SAS Name: [DOB]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
6	Gender DB Name: [Q06] SAS Name: [Sex]	<input type="radio"/> 1 - Male <input type="radio"/> 2 - Female
7	Ethnicity DB Name: [Q07] SAS Name: [Ethnicity]	<input type="radio"/> 1 - Hispanic or Latino <input type="radio"/> 2 - Not Hispanic or Latino
8	Race (Check all that apply)	<input type="checkbox"/> Q08M1 - Black/African American <input type="checkbox"/> Q08M2 - Asian <input type="checkbox"/> Q08M3 - American Indian/Alaskan Native <input type="checkbox"/> Q08M4 - White <input type="checkbox"/> Q08M5 - Native Hawaiian/Other Pacific Islander <input type="checkbox"/> Q08M98 - Other
9	If other, specify DB Name: [Q09]	<input type="text"/> (50 char.)
10	Employment status before subject enrollment DB Name: [Q10]	<input type="radio"/> 1 - Employed-full time <input type="radio"/> 2 - Employed-part time <input type="radio"/> 3 - Medical disability <input type="radio"/> 4 - Student <input type="radio"/> 5 - Homemaker <input type="radio"/> 6 - Self-employed <input type="radio"/> 7 - Retired <input type="radio"/> 8 - Other capacity <input type="radio"/> 9 - Unemployed <input type="radio"/> 99 - Unknown
11	Years of education completed since starting 1st grade (Do not count repeated grades) DB Name: [Q11] SAS Name: [YrsEd]	<input type="text"/> years
12	Marital status DB Name: [Q12]	<input type="radio"/> 1 - Never married <input type="radio"/> 2 - Married <input type="radio"/> 3 - Divorced <input type="radio"/> 4 - Separated

		<input type="radio"/> 5 - Widowed <input type="radio"/> 6 - Significant Other <input type="radio"/> 99 - Unknown
14	Which version of the ALFSG protocol was approved by your IRB at the time of subject enrollment? Please double check. The following study visits/CRFs will be posted based on the selected protocol version. DB Name: [Q14]	<input type="radio"/> 1 - Prior to version 7 <input type="radio"/> 2 - Version 7 or higher
13	Subject is participating in the ALFSG-MBT study DB Name: [Q13]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
25	Version of the ALFSG-MBT protocol approved by your IRB at the time of subject enrollment DB Name: [Q25]	<input type="radio"/> 2 - ALFSG-MBT version 2 <input type="radio"/> 3 - ALFSG-MBT version 3 or higher
23	Primary reason subject is not participating in the ALFSG-MBT study If Q25 is 'ALFSG-MBT version 2' DB Name: [Q23]	<input type="radio"/> 1 - Not between 18 and 70 years of age <input type="radio"/> 2 - Pre-existing chronic renal failure <input type="radio"/> 3 - Contraindicated drug consumption <input type="radio"/> 4 - Chronic hemodialysis <input type="radio"/> 5 - Severe shock <input type="radio"/> 6 - Upper GI bleeding <input type="radio"/> 7 - ALF etiology exclusion <input type="radio"/> 8 - Acetaminophen allergy <input type="radio"/> 9 - Caffeine consumption 24 hours prior to enrollment <input type="radio"/> 10 - Inability to obtain informed consent <input type="radio"/> 11 - Consent declined <input type="radio"/> 98 - Other
24	Details of inability to obtain informed consent, consent declined, or other for ALFSG-MBT version 2 DB Name: [Q24]	<input type="text"/> <i>(200 char.)</i>
26	Primary reason subject is not participating in the ALFSG-MBT study If Q25 is 'ALFSG-MBT version 3 or higher' DB Name: [Q26]	<input type="radio"/> 1 - Not between 18 and 80 years of age <input type="radio"/> 2 - Pre-existing chronic renal failure <input type="radio"/> 3 - Contraindicated drug consumption <input type="radio"/> 4 - Chronic hemodialysis <input type="radio"/> 5 - Severe shock <input type="radio"/> 6 - Upper GI bleeding requiring endoscopy or RBC transfusion <input type="radio"/> 7 - ALF etiology exclusion <input type="radio"/> 8 - ALI due to APAP overdose <input type="radio"/> 9 - Acetaminophen allergy <input type="radio"/> 10 - Caffeine consumption 24 hours prior to enrollment <input type="radio"/> 11 - Inability to obtain informed consent <input type="radio"/> 12 - Consent declined <input type="radio"/> 98 - Other
27	Details of inability to obtain informed consent, consent declined, or other for ALFSG-MBT version 3 or higher DB Name: [Q27]	<input type="text"/> <i>(200 char.)</i>

15	Subject is participating in the ALFSG-ROTEM study DB Name: [Q15]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
20	Which version of the ALFSG-ROTEM protocol was approved by your IRB at the time of subject enrollment? DB Name: [Q20]	<input type="radio"/> 1 - ALFSG-ROTEM version 1 <input type="radio"/> 2 - ALFSG-ROTEM version 2 or higher
16	Primary reason subject is not participating in the ALFSG-ROTEM study If Q20 is 'ALFSG-ROTEM version 1' DB Name: [Q16]	<input type="radio"/> 1 - Site is not currently enrolling in ALF-ROTEM <input type="radio"/> 2 - Subject was not enrolled in ALFSG with hepatic encephalopathy (ALF) <input type="radio"/> 3 - Subject received plasma, platelet, or cryoprecipitate transfusions during the current admission for ALFSG, including at referring hospitals <input type="radio"/> 4 - Inability to obtain informed consent <input type="radio"/> 5 - Consent declined <input type="radio"/> 6 - Other
17	Specify details for declined consent or other for ALFSG-ROTEM version 1 DB Name: [Q17]	<input type="text"/> <i>(200 char.)</i>
21	Primary reason subject is not participating in the ALFSG-ROTEM study If Q20 is 'ALFSG-ROTEM version 2 or higher' DB Name: [Q21]	<input type="radio"/> 1 - Site is not currently enrolling in ALFSG-ROTEM <input type="radio"/> 2 - Inability to obtain informed consent <input type="radio"/> 3 - Consent declined <input type="radio"/> 4 - Other
22	Details of inability to obtain informed consent, consent declined, or other for ALFSG-ROTEM version 2 or higher DB Name: [Q22]	<input type="text"/> <i>(200 char.)</i>
f	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> <i>(250 char.)</i>

WebDCU™ ALFSG

Annotated Form for CRF 01 [ALI Admission]
Form ID: 28 DB Table Name: F01 DB View Name: vF01

No.	Item Description	Data Value
ALI Study Eligibility Criteria		
1	Acetaminophen: Jaundice/Illness < 2 wks DB Name: [Q01] SAS Name: [Lt2WksJaundic]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2	Or, all other: Jaundice/Illness < 26 wks DB Name: [Q02] SAS Name: [GtE2WksLt26WksJaundice]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
3	Previous sedatives DB Name: [Q03] SAS Name: [PrevSed]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
4	Altered mental status DB Name: [Q04] SAS Name: [AltMentStat]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
5	Previous FFP DB Name: [Q05] SAS Name: [FFP]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
6	INR ≥ 2.0 DB Name: [Q06] SAS Name: [INRGtE2p0]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
7	ALT of ≥ 10X ULN DB Name: [Q07] SAS Name: [ALTLtE10XULN]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
8	Tbili ≥ 3.0 mg/dL DB Name: [Q08] SAS Name: [TBiliGTE3p0]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
9	Has patient met eligibility criteria? DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Protocol exemption granted
10	If protocol exemption, explain. DB Name: [Q10]	<input type="text"/> (100 char.)
Admission		
11	Date of consent/admission to study DB Name: [Q11] SAS Name: [DateAdmStdy]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
12	Time of consent/admission to study DB Name: [Q12] SAS Name: [TimeAdmStudy]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
Physical Exam		
13	Peripheral edema DB Name: [Q13] SAS Name: [Per_Edema]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
14	Hepatomegaly DB Name: [Q14]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
15	Hyper-reflexia/clonus DB Name: [Q15] SAS Name: [HyperRef]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes



16	Pupillary Dilatation DB Name: [Q16] SAS Name: [PupDil]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<div data-bbox="443 170 1446 239" style="border: 1px solid black; height: 33px;"></div> <i>char.)</i> (250

No.	Item Description	Data Value
ALF Study Eligibility Criteria		
1	Jaundice/Illness < 8 wks DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2	Or, Jaundice/Illness ≥ 8 wks and < 26 wks DB Name: [Q02]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
3	Previous sedatives DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
4	Altered mental status DB Name: [Q04]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
5	Previous FFP DB Name: [Q05]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
6	INR ≥ 1.5 DB Name: [Q06]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
7	Has patient met eligibility criteria? DB Name: [Q07]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 2 - Protocol exemption granted
8	If protocol exemption, explain. DB Name: [Q08]	<input type="text"/> (100 char.)
9	History given by (relation to patient) DB Name: [Q09]	<input type="text"/> (30 char.)
Date of onset of hepatic coma grade prior to admission:		
10	Coma grade date I: DB Name: [Q10]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete
11	Coma grade date II: DB Name: [Q11]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete
12	Coma grade date III: DB Name: [Q12]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete
13	Coma grade date IV: DB Name: [Q13]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete
Admission		
14	Date of consent/admission to study DB Name: [Q14]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete
15	Time of consent/admission to study DB Name: [Q15] SAS Name: [TimeAdmStudy]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
Physical Exam		
16	Peripheral edema DB Name: [Q16] SAS Name: [Per_Edema]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
17	Hepatomegaly DB Name: [Q17]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
18	Hyper-reflexia/clonus DB Name: [Q18] SAS Name: [HyperRef]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes

19	Pupillary Dilatation DB Name: [Q19] SAS Name: [PupDil]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<div style="border: 1px solid gray; height: 30px; width: 100%;"></div> <i>char.)</i> (250

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Annotated Form for CRF 03 [Medical History]
Form ID: 82 DB Table Name: F03 DB View Name: vF03

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
1	History of present illness: DB Name: [Q01]	<div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p align="right"><i>(8000 char.)</i></p>
Specific symptoms Please record symptoms that existed prior to enrollment for the subject's current illness.		
2	Date of onset of first symptom DB Name: [Q02]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  <i>(dd-mmm-yyyy) Complete</i>
3	Nausea/Vomiting DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
4	Abdominal pain DB Name: [Q04]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
5	Rash DB Name: [Q05]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
6	Headache DB Name: [Q06]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
7	Malaise DB Name: [Q07]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
8	Fever DB Name: [Q08]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
9	Joint pains DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
10	Jaundice DB Name: [Q10]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
11	If Jaundice, date of onset DB Name: [Q11]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  <i>(dd-mmm-yyyy) Day/Month Optional</i>
12	Specify other symptoms DB Name: [Q12]	<input style="width: 100%; height: 20px;" type="text"/> <i>(150 char.)</i>
13	Previous health and illnesses (check all that apply and specify diagnosis where applicable and known)	<input type="checkbox"/> Q13M0 - None <input type="checkbox"/> Q13M1 - Collagen/vasc diseases <input type="checkbox"/> Q13M2 - Chronic liver disease <input type="checkbox"/> Q13M3 - Endocrine/diabetes <input type="checkbox"/> Q13M4 - Psychiatric disease <input type="checkbox"/> Q13M5 - Neuro/seizure <input type="checkbox"/> Q13M6 - Hypertension <input type="checkbox"/> Q13M7 - Heart disease <input type="checkbox"/> Q13M8 - Renal disease <input type="checkbox"/> Q13M9 - Pulmonary disease <input type="checkbox"/> Q13M10 - Substance abuse <input type="checkbox"/> Q13M11 - GI disease <input type="checkbox"/> Q13M12 - HIV/AIDs

		<input type="checkbox"/> Q13M13 - IDU at any time in past <input type="checkbox"/> Q13M98 - Other
13T1	Collagen/vasc diseases Description DB Name: [Q13T1]	<input type="text"/> (30 char.)
13T2	Chronic liver disease Description DB Name: [Q13T2]	<input type="text"/> (30 char.)
13T3	Endocrine/diabetes Description DB Name: [Q13T3]	<input type="text"/> (30 char.)
13T4	Psychiatric disease Description DB Name: [Q13T4]	<input type="text"/> (30 char.)
13T5	Neuro/seizure Description DB Name: [Q13T5]	<input type="text"/> (30 char.)
13T6	Hypertension Description DB Name: [Q13T6]	<input type="text"/> (30 char.)
13T7	Heart disease Description DB Name: [Q13T7]	<input type="text"/> (30 char.)
13T8	Renal disease Description DB Name: [Q13T8]	<input type="text"/> (30 char.)
13T9	Pulmonary disease Description DB Name: [Q13T9]	<input type="text"/> (30 char.)
13T10	Substance abuse Description DB Name: [Q13T10]	<input type="text"/> (30 char.)
13T11	GI disease Description DB Name: [Q13T11]	<input type="text"/> (30 char.)
13T12	HIV/AIDs Description DB Name: [Q13T12]	<input type="text"/> (30 char.)
13T13	IDU at any time in past Description DB Name: [Q13T13]	<input type="text"/> (30 char.)
13T98	Other Description DB Name: [Q13T98]	<input type="text"/> (30 char.)
14	Pre-ALI/ALF Karnofsky score DB Name: [Q14]	<input type="radio"/> 10 - 100 <input type="radio"/> 8 - 80 <input type="radio"/> 6 - 60 <input type="radio"/> 4 - 40 <input type="radio"/> 2 - 20 <input type="radio"/> 99 - Unknown <input type="radio"/> 9 - 90 <input type="radio"/> 7 - 70 <input type="radio"/> 5 - 50 <input type="radio"/> 3 - 30 <input type="radio"/> 1 - 10

C	Comments DB Name: [zNotes] SAS Name: [<i>char.</i> Comments]	<input type="text"/>	(250
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WebDCU™ ALFSG

Annotated Form for CRF 04 [Risk Factors and Past Medication]
Form ID: 83 DB Table Name: F04 DB View Name: vF04

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
Risk factors in last six months		
1	IDU DB Name: [Q01] SAS Name: [IDU]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2a	If IDU, check all that apply	<input type="checkbox"/> Q02M1 - Amphetamines <input type="checkbox"/> Q02M2 - Narcotics <input type="checkbox"/> Q02M3 - Cocaine <input type="checkbox"/> Q02M98 - Other
2b	If other, specify IDU DB Name: [Q02B]	<input type="text"/> (30 char.)
3	Usual intake of ETOH during the past 6 months 1 drink ETOH = • 12 oz or 1 can of beer • 1.5 oz liquor • 5 oz or 1 glass of wine • 12 oz or 1 wine cooler DB Name: [Q03]	<input type="radio"/> 1 - None (less than 1 drink per week) <input type="radio"/> 2 - 1 drink per week <input type="radio"/> 3 - 2 drinks per week <input type="radio"/> 4 - 3-6 drinks per week <input type="radio"/> 5 - 7-14 drinks per week <input type="radio"/> 6 - >14 drinks per week
4	Number of weeks using ETOH during the past 6 months DB Name: [Q04]	<input type="text"/> weeks
9	Known drug allergies? DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
10	Name drug(s) DB Name: [Q10]	<input type="text"/> (50 char.)
11	Type of reaction DB Name: [Q11]	<input type="radio"/> 1 - Hepatocellular <input type="radio"/> 2 - Mixed <input type="radio"/> 3 - Cholestatic
12	Rash? DB Name: [Q12]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
13	Lymphadenopathy DB Name: [Q13]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
14	Eosinophilia (i.e., absolute eosinophil count > 500/ml) DB Name: [Q14]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
6	Pre-study NAC treatment DB Name: [Q06]	<input type="radio"/> 1 - IV <input type="radio"/> 2 - Oral <input type="radio"/> 3 - None <input type="radio"/> 4 - Unknown
7	Date pre-study NAC started DB Name: [Q07]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete
15	Was pre-study NAC stopped prior to enrollment? DB Name: [Q15]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
8	If 'yes', date pre-study NAC stopped DB Name: [Q08]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete

Child Form ID: 99 Child DB Table Name: vF04C


List all medications taken in the 6 months prior to enrollment including information about acetaminophen overdose, toxins, herbs, mushrooms, OTC meds, vitamins, anesthetics, and anti TB agents. Combination drugs should be separated and entered on 2 different rows.

No.	A Medication name (Generic preferred) (50 char.)	B Date last taken DB	C Total dose/day DB	D Dose unit DB	E P.R.N. DB Name: [QE]	F Duration DB Name: [QF]	G Duration Unit DB	H Related to APAP Diagnosis?	I If APAP, single dose?	J If 'single dose', enter time taken:
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	DB Name: [QA]	Name: [QB]	Name: [QC]	Name: [QD]		Name: [QG]	DB Name: [QH]	DB Name: [QI]	DB Name: [QJ]
C	Comments DB Name: [zNotes] SAS Name: [Comments]		<input type="text"/> (250 char.)						


WebDCU™ ALFSG

Annotated Form for CRF 05 [Neurological Exam]
Form ID: 65 DB Table Name: F05

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
1	Asterixis DB Name: [Q01]	<input type="radio"/> 0 - 0 = absent <input type="radio"/> 1 - 1 = present
2	Pupillary Reflexes DB Name: [Q02]	<input type="radio"/> 0 - 0 = reactive <input type="radio"/> 1 - 1 = fixed
3	Babinski DB Name: [Q03]	<input type="radio"/> 0 - 0 = absent <input type="radio"/> 1 - 1 = present [up-going great toe]
4	Reflexes-patellar DB Name: [Q04]	<input type="radio"/> 0 - 0 = normo-active <input type="radio"/> 1 - 1 = hypo-reflexia <input type="radio"/> 2 - 2 = hyper-reflexes
5	Reflexes-biceps DB Name: [Q05]	<input type="radio"/> 0 - 0 = normo-active <input type="radio"/> 1 - 1 = hypo-reflexia <input type="radio"/> 2 - 2 = hyper-reflexes
6	Posturing-decorticate DB Name: [Q06]	<input type="radio"/> 0 - 0 = no posturing <input type="radio"/> 1 - 1 = posturing
7	Posturing-decerebrate DB Name: [Q07]	<input type="radio"/> 0 - 0 = no posturing <input type="radio"/> 1 - 1 = posturing
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

WebDCU™ ALFSG

Annotated Form for CRF 06 [O-Log]
Form ID: 105 DB Table Name: F06 DB View Name: vF06

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete

If the subject is intubated, select 'No' for "Data Collected" in the header and enter a comment.

Standardized O-Log Cues:

- What city are you in?
 -if incorrect first answer, give logical cue according to your city location (for example, for Richmond, VA, "capital of Virginia.")
 -if incorrect to logical cue, give multiple choices: "are we in Miami, [your city], or Chicago"?
- What kind of place are we in?
 -if incorrect first answer, give logical cue: "this is where sick people go to be admitted."
 -if incorrect to logical cue, give multiple choices: "railway station, airport, hospital."
- What is the name of this hospital?
 -if incorrect first answer, make up logical cue for your hospital.
 -if incorrect to logical cue, give multiple choices: "[your hospital], Georgetown Hospital, Cornell Hospital."
NOTE: Give full credit (6 points) if patient answers both kind of place and hospital name at the same time.

- What is the name of this month?
 -if incorrect first answer, give logical cue: "it's the month after []".
 -if incorrect to logical cue, give multiple choices: month before, current month, month after current.
- What is the date of this month?
 -if incorrect first answer, give logical clue: "it's the day after []".
 -if incorrect to logical cue, give multiple choices: date before, date after, current date.
- What is the year?
 -if incorrect first answer, give logical cue: "it's the year before []".
 -if incorrect to logical cue, give multiple choices: current year, year before, year after

- What is the day of the week?
 -if incorrect first answer, give logical cue: "it's the day before []".
 -if incorrect to logical cue, give 3 multiple choices including the correct day of week.
- What time is it (show clock/watch to patient)?
 For this question, there are no cues, and patient receives 3 points for correct response or 0 points for incorrect response.
 A correct response should be within 30 minutes of the actual time.

For details of administering and scoring O-log, see: (<http://www.tbims.org/combi/olog/olograt.html>)

1	City DB Name: [Q01]	<input type="radio"/> 3 - (3) correct spontaneously or upon first free recall attempt <input type="radio"/> 2 - (2) correct upon logical cueing <input type="radio"/> 1 - (1) correct upon multiple choice cueing <input type="radio"/> 0 - (0) unable, incorrect, inappropriate response
2	Kind of place DB Name: [Q02]	<input type="radio"/> 3 - (3) correct spontaneously or upon first free recall attempt <input type="radio"/> 2 - (2) correct upon logical cueing <input type="radio"/> 1 - (1) correct upon multiple choice cueing <input type="radio"/> 0 - (0) unable, incorrect, inappropriate response
3	Name of hospital DB Name: [Q03]	<input type="radio"/> 3 - (3) correct spontaneously or upon first free recall attempt <input type="radio"/> 2 - (2) correct upon logical cueing <input type="radio"/> 1 - (1) correct upon multiple choice cueing <input type="radio"/> 0 - (0) unable, incorrect, inappropriate response
4	Month DB Name: [Q04]	<input type="radio"/> 3 - (3) correct spontaneously or upon first free recall attempt <input type="radio"/> 2 - (2) correct upon logical cueing <input type="radio"/> 1 - (1) correct upon multiple choice cueing <input type="radio"/> 0 - (0) unable, incorrect, inappropriate response
5	Date DB Name: [Q05]	<input type="radio"/> 3 - (3) correct spontaneously or upon first free recall attempt <input type="radio"/> 2 - (2) correct upon logical cueing <input type="radio"/> 1 - (1) correct upon multiple choice cueing <input type="radio"/> 0 - (0) unable, incorrect, inappropriate response
6	Year DB Name: [Q06]	<input type="radio"/> 3 - (3) correct spontaneously or upon first free recall attempt <input type="radio"/> 2 - (2) correct upon logical cueing

		<input type="radio"/> 1 - (1) correct upon multiple choice cueing <input type="radio"/> 0 - (0) unable, incorrect, inappropriate response
7	Day of week DB Name: [Q07]	<input type="radio"/> 3 - (3) correct spontaneously or upon first free recall attempt <input type="radio"/> 2 - (2) correct upon logical cueing <input type="radio"/> 1 - (1) correct upon multiple choice cueing <input type="radio"/> 0 - (0) unable, incorrect, inappropriate response
8	Clock time DB Name: [Q08]	<input type="radio"/> 3 - (3) correct spontaneously or upon first free recall attempt <input type="radio"/> 2 - (2) correct upon logical cueing <input type="radio"/> 1 - (1) correct upon multiple choice cueing <input type="radio"/> 0 - (0) unable, incorrect, inappropriate response
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<div style="border: 1px solid black; height: 20px; width: 100%;"></div> <p>(250 char.)</p>

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**Annotated Form for CRF 07 [Imaging/EEG/Biopsy]
Form ID: 106 DB Table Name: F07**

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes

Please document all imaging, EEG, and Biopsies performed from enrollment through the End of Study Visit.
Print more worksheets, as needed.

Child Form ID: 120 Child DB Table Name: vF07C1

1. Brain CT/MRI

No.	1A Date of brain CT/MRI DB Name: [QA]	1B Brain CT/MRI results DB Name: [QB]	1C Brain CT/MRI Application DB Name: [QC]	1D Cerebral edema? DB Name: [QD]	1E Intracranial hemorrhage DB Name: [QE]	1F Other brain CT/MRI abnormal findings (500 char.) DB Name: [QF]
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Child Form ID: 121 Child DB Table Name: vF07C2

2. EEG

No.	2A Date of EEG DB Name: [QA]	2B EEG result DB Name: [QB]	2C Nonspecific generalized slowing DB Name: [QC]	2D Triphasic waves DB Name: [QD]	2E Epileptiform discharges DB Name: [QE]	2F Other EEG abnormal findings (500 char.) DB Name: [QF]
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Child Form ID: 122 Child DB Table Name: vF07C3

3. Abdomen CT /MRI

No.	3A Date of abdomen CT/MRI DB Name: [QA]	3B Abdomen CT/MRI result DB Name: [QB]	3C Abdomen CT/MRI Application DB Name: [QC]	3D Small liver DB Name: [QD]	3E Large liver DB Name: [QE]	3F Nodular contour DB Name: [QF]	3G Vessels patent DB Name: [QG]	3H Splénomegaly DB Name: [QH]	3I Ascites DB Name: [QI]	3J Other abdomen CT/MRI abnormal findings (500 char.) DB Name: [QJ]
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Child Form ID: 123 Child DB Table Name: vF07C4

4. Abdomen ultrasound

No.	4A Date of ultrasound of abdomen DB Name: [QA]	4B Abdomen ultrasound result DB Name: [QB]	4C Small liver DB Name: [QC]	4D Large liver DB Name: [QD]	4E Nodular contour DB Name: [QE]	4F Vessels patent DB Name: [QF]	5G Splénomegaly DB Name: [QG]	4H Ascites DB Name: [QH]	4I Other abdomen ultrasound abnormal findings (500 char.) DB Name: [QI]
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Child Form ID: 124 Child DB Table Name: vF07C5


5. Liver biopsy

No.	5A Date of liver biopsy DB Name: [QA]	5B Liver biopsy result DB Name: [QB]	5C Hepatocellular necrosis DB Name: [QC]	5D If yes, specify (%) DB Name: [QD]	5E Inflammation DB Name: [QE]	5F Cholestasis DB Name: [QF]	5G Steatosis DB Name: [QG]	5H Cirrhosis DB Name: [QH]	5I Other liver biopsy abnormal findings / overall diagnosis (1000 char.) DB Name: [QI]
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C	Comments DB Name: [zNotes]	<div style="border: 1px solid black; height: 30px; width: 100%;"></div> <p align="center"><i>(250 char.)</i></p>
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Annotated Form for CRF 08 [Lab Data]
Form ID: 47 DB Table Name: F08 DB View Name: vF08




No.	Item Description	Data Value
a	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
1	Date of blood draw DB Name: [Q01]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
Blood		
2	Hemoglobin DB Name: [Q02] SAS Name: [Hemoglobin]	<input type="text"/> g/dL
3	Hematocrit DB Name: [Q03] SAS Name: [Hematocrit]	<input type="text"/> %
4	WBC DB Name: [Q04] SAS Name: [WBC]	<input type="text"/> X1000/mm ³
5	Differential: PMN DB Name: [Q05] SAS Name: [PMN]	<input type="text"/> %
6	Differential: Lymphocytes DB Name: [Q06] SAS Name: [Lymph]	<input type="text"/> %
7	Differential: Eosinophils DB Name: [Q07] SAS Name: [Eosin]	<input type="text"/> %
8	Differential: Monos DB Name: [Q08] SAS Name: [Monos]	<input type="text"/> %
9	Platelet count DB Name: [Q09] SAS Name: [Platelet_Cnt]	<input type="text"/> X1000/mm ³
Liver		
10	Prothrombin time DB Name: [Q10] SAS Name: [Prothrom_Sec]	<input type="text"/> seconds
11	Is the INR above the limit of detection? DB Name: [Q11] SAS Name: [INR]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 9 - Not done
13	INR value: DB Name: [Q13]	<input type="text"/>
14	ALT DB Name: [Q14] SAS Name: [ALT]	<input type="text"/> IU/L
15	AST DB Name: [Q15] SAS Name: [AST]	<input type="text"/> IU/L
16	Alk phos DB Name: [Q16] SAS Name: [Alk_Phosph]	<input type="text"/> IU/L
17	Albumin	<input type="text"/> gm/dL

	DB Name: [Q17] SAS Name: [Albumin]	
18	Total protein DB Name: [Q18] SAS Name: [Total_Protein]	<input type="text"/> gm/dL
19	Bilirubin DB Name: [Q19] SAS Name: [Bilirubin]	<input type="text"/> mg/dL
20	Glucose DB Name: [Q20] SAS Name: [Glucose]	<input type="text"/> mg/dL
21	Amylase DB Name: [Q21] SAS Name: [Amylase]	<input type="text"/> IU/L
22	CK DB Name: [Q22] SAS Name: [CK]	<input type="text"/> IU/L
23	Lipase DB Name: [Q23] SAS Name: [Lipase]	<input type="text"/> IU/L
Kidney/Electrolytes		
24	Creatinine DB Name: [Q24] SAS Name: [Creat]	<input type="text"/> mg/dL
25	BUN DB Name: [Q25] SAS Name: [BUN]	<input type="text"/> mg/dL
26	Na DB Name: [Q26] SAS Name: [NA]	<input type="text"/> mmol/L
27	K DB Name: [Q27] SAS Name: [K]	<input type="text"/> mmol/L
28	HCO3 DB Name: [Q28] SAS Name: [HCO3]	<input type="text"/> mmol/L
29	Chloride DB Name: [Q29] SAS Name: [Chloride]	<input type="text"/> mmol/L
30	Phosphate DB Name: [Q30] SAS Name: [Phosphate]	<input type="text"/> mg/dL
31	Magnesium DB Name: [Q31] SAS Name: [Magnesium]	<input type="text"/> mEq/L
32	Total calcium DB Name: [Q32] SAS Name: [Total_Calcium]	<input type="text"/> mg/dL
33	Ionized calcium DB Name: [Q33] SAS Name: [Ionized_Calcium]	<input type="text"/> mg/dL
34	Is the lactate above the limit of detection? DB Name: [Q34] SAS Name: [Lactate]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 9 - Not done

36	lactate value: DB Name: [Q36]	<input type="text"/>	mmol/L
Arterial/Toxins			
37	pH DB Name: [Q37] SAS Name: [PH]	<input type="text"/>	
38	pO ₂ DB Name: [Q38] SAS Name: [PO2]	<input type="text"/>	mmHg
39	pCO ₂ DB Name: [Q39] SAS Name: [PCO2]	<input type="text"/>	mmHg
40	Standard bicarbonate DB Name: [Q40] SAS Name: [St_BC]	<input type="text"/>	mEq/L
41	O ₂ saturation DB Name: [Q41] SAS Name: [O2]	<input type="text"/>	%
42	FiO ₂ DB Name: [Q42] SAS Name: [FIO2]	<input type="text"/>	%
43	Arterial ammonia DB Name: [Q43] SAS Name: [Arterial_Ammonia]	<input type="text"/>	umol/L
44	Venous ammonia DB Name: [Q44] SAS Name: [Venous_Ammonia]	<input type="text"/>	umol/L
45	Toxin screen positive (excluding acetaminophen) DB Name: [Q45] SAS Name: [Toxin_Screen]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes	
46	If yes, indicate drug(s) DB Name: [Q46]	<input type="text"/> (100 char.)	
47	Is the acetaminophen level below the limit of detection? DB Name: [Q47]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 9 - Not done	
49	acetaminophen level DB Name: [Q49] SAS Name: [Acetamin]	<input type="text"/>	mg/L
50	Date acetaminophen level collected DB Name: [Q50] SAS Name: [DateAcetamin]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete	
51	Collection Time DB Name: [Q51] SAS Name: [TimeAcetamin]	<input type="text"/> : <input type="text"/> Complete Time (24hr)	
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)	

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**Annotated Form for CRF 11 [Pre-Study Peak Lab Value]
Form ID: 88 DB Table Name: F11**

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
Liver		
13A	INR DB Name: [Q13A] SAS Name: [INR_Peak]	<input type="text"/>
13B	INR date DB Name: [Q13B] SAS Name: [INR_PeakD]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
14A	ALT DB Name: [Q14A] SAS Name: [ALT_Peak]	<input type="text"/> IU/L
14B	ALT date DB Name: [Q14B] SAS Name: [ALT_PeakDt]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
15A	AST DB Name: [Q15A] SAS Name: [AST_Peak]	<input type="text"/> IU/L
15B	AST date DB Name: [Q15B] SAS Name: [AST_PeakDt]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
19A	Bilirubin DB Name: [Q19A] SAS Name: [Blrb_Peak]	<input type="text"/> mg/dL
19B	Bilirubin date DB Name: [Q19B] SAS Name: [Blrb_PeakDt]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
Kidney/Electrolytes		
24A	Creatinine DB Name: [Q24A] SAS Name: [Crtn_Peak]	<input type="text"/> mg/dL
24B	Creatinine date DB Name: [Q24B] SAS Name: [Crtn_PeakDt]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

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**Annotated Form for CRF 12 [Daily Check Up]
Form ID: 90 DB Table Name: F12**

No.	Item Description	Data Value
a	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
ICU Checklist		
1	In ICU DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2	ICP Monitor DB Name: [Q02]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
3	CXR DB Name: [Q03]	<input type="radio"/> 0 - Normal <input type="radio"/> 1 - Abnormal <input type="radio"/> 2 - Not Done
9	Complications (Check all that apply)	<input type="checkbox"/> Q09M1 - None <input type="checkbox"/> Q09M2 - Seizures <input type="checkbox"/> Q09M3 - Arrhythmia <input type="checkbox"/> Q09M4 - GI Bleeding <input type="checkbox"/> Q09M5 - ARDS <input type="checkbox"/> Q09M6 - Infection <input type="checkbox"/> Q09M7 - Other bleeding (specify)
10	If other bleeding, specify DB Name: [Q10]	<input type="text"/> (100 char.)
11	Treatments (Check all that apply)	<input type="checkbox"/> Q11M1 - None <input type="checkbox"/> Q11M2 - Head up <input type="checkbox"/> Q11M3 - Acid suppressant <input type="checkbox"/> Q11M4 - Ventilator <input type="checkbox"/> Q11M5 - Supplemental O ₂ <input type="checkbox"/> Q11M6 - Lactulose <input type="checkbox"/> Q11M7 - Rifaximin <input type="checkbox"/> Q11M8 - Mannitol <input type="checkbox"/> Q11M9 - Pressors (specify) <input type="checkbox"/> Q11M10 - Hypertonic saline <input type="checkbox"/> Q11M11 - Barbiturate <input type="checkbox"/> Q11M12 - Hypothermia <input type="checkbox"/> Q11M13 - Anti-convulsant <input type="checkbox"/> Q11M14 - Sedatives (propofol) <input type="checkbox"/> Q11M15 - Paralytics <input type="checkbox"/> Q11M16 - Vitamin K <input type="checkbox"/> Q11M17 - Transfusion: RBC <input type="checkbox"/> Q11M18 - Transfusion: Plasma (FFP) <input type="checkbox"/> Q11M19 - Transfusion: rVIIa <input type="checkbox"/> Q11M20 - Transfusion: Platelets <input type="checkbox"/> Q11M21 - NAC oral <input type="checkbox"/> Q11M22 - NAC IV <input type="checkbox"/> Q11M23 - ELAD/BAL <input type="checkbox"/> Q11M24 - Hepatocyte transfusions <input type="checkbox"/> Q11M25 - Hemodialysis <input type="checkbox"/> Q11M26 - CVVH
12	If pressors treatments, specify (Check all that apply)	<input type="checkbox"/> Q12M1 - Dopamine <input type="checkbox"/> Q12M2 - Epinephrine

		<input type="checkbox"/> Q12M3 - Neosynephrine (Phenylephrine) <input type="checkbox"/> Q12M4 - Norepinephrine (levophed) <input type="checkbox"/> Q12M5 - Vasopressin
13	Specific therapies (Check all that apply)	<input type="checkbox"/> Q13M1 - None <input type="checkbox"/> Q13M2 - Pen G/Silibynin (for mushroom poisoning) <input type="checkbox"/> Q13M3 - Acyclovir (HSV) <input type="checkbox"/> Q13M4 - Nucleoside/Nucleotide analogue <input type="checkbox"/> Q13M5 - Corticosteroids (Autoimmune hepatitis) <input type="checkbox"/> Q13M6 - Antibiotic Prophylaxis <input type="checkbox"/> Q13M7 - Antibiotic therapy
If ICP monitored:		
14	Daily Min ICP value DB Name: [Q14]	<input type="text"/> mmHg
15	Daily Max ICP value DB Name: [Q15]	<input type="text"/> mmHg
16	Type of monitor DB Name: [Q16]	<input type="radio"/> 1 - Epidural <input type="radio"/> 2 - Subdural <input type="radio"/> 3 - Intraparenchymal <input type="radio"/> 4 - Intraventricular <input type="radio"/> 98 - Other
21	If other, specify type of monitor DB Name: [Q21]	<input type="text"/> (100 char.)
17	Complications of monitoring DB Name: [Q17]	<input type="radio"/> 0 - None <input type="radio"/> 1 - Hemorrhage <input type="radio"/> 2 - Infection <input type="radio"/> 3 - Other
18	If other, specify complications DB Name: [Q18]	<input type="text"/> (30 char.)
19	Primary reason for ICP withdrawal DB Name: [Q19]	<input type="radio"/> 1 - Malfunction <input type="radio"/> 2 - Complications <input type="radio"/> 3 - Improvement <input type="radio"/> 4 - Other
20	If other, specify primary reason DB Name: [Q20]	<input type="text"/> (100 char.)
C	Comments DB Name: [zNotes]	<input type="text"/> (250 char.)




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Annotated Form for CRF 13 [Vital Signs]
Form ID: 85 DB Table Name: F13 DB View Name: vF13


No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
1	Pulse DB Name: [Q01] SAS Name: [Pulse]	<input type="text"/> beats/min
2	Systolic Blood Pressure DB Name: [Q02] SAS Name: [BPSys]	<input type="text"/> mmHg
3	Diastolic Blood Pressure DB Name: [Q03] SAS Name: [BPDias]	<input type="text"/> mmHg
4	Respiration DB Name: [Q04] SAS Name: [Respiration]	<input type="text"/> breaths/min
5	Min Temperature (Prior 24 hours) DB Name: [Q05] SAS Name: [MinTemp]	<input type="text"/> °C
6	Max Temperature (Prior 24 hours) DB Name: [Q06] SAS Name: [MaxTemp]	<input type="text"/> °C
7	Height (Day 1 only) DB Name: [Q07] SAS Name: [Height]	<input type="text"/> cm
8	Weight (Day 1 only) DB Name: [Q08] SAS Name: [Weight]	<input type="text"/> kg
9	Were any imaging, EEGs, or biopsies performed? If this is not the first assessment, document any performed since the last assessment. DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

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Annotated Form for CRF 14 [Infections]
Form ID: 87 DB Table Name: F14




No.	Item Description	Data Value
a	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
<p>Infections: Indicate positive cultures through day 7 by signifying study day of first positive sample. Although this form should be capture infections through day 7 and antibiotic treatment through hospitalization, this form should be data entered under the 'admission visit'.</p>		
1	Positive cultures? DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2b	Blood: Date DB Name: [Q02B] SAS Name: [Blood]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
2c	Blood: Organism (check all that apply)	<input type="checkbox"/> Q02CM1 - S.aureus <input type="checkbox"/> Q02CM2 - S.epid <input type="checkbox"/> Q02CM3 - Enterococcus <input type="checkbox"/> Q02CM4 - E.coli <input type="checkbox"/> Q02CM5 - Klebsiella <input type="checkbox"/> Q02CM6 - Fungus
2c1	Blood: Organism Other DB Name: [Q02C] SAS Name: [OT_Bld]	<input type="text"/> (50 char.)
2d	Blood:outcome DB Name: [Q02D] SAS Name: [OC_Bld]	<input type="radio"/> 1 - Resolved <input type="radio"/> 2 - Cause of death <input type="radio"/> 3 - Unknown importance
3b	Tracheal aspirate: Date DB Name: [Q03B] SAS Name: [TracAsp]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
3c	Tracheal aspirate: Organism (check all that apply)	<input type="checkbox"/> Q03CM1 - S.aureus <input type="checkbox"/> Q03CM2 - S.epid <input type="checkbox"/> Q03CM3 - Enterococcus <input type="checkbox"/> Q03CM4 - E.coli <input type="checkbox"/> Q03CM5 - Klebsiella <input type="checkbox"/> Q03CM6 - Fungus
3c1	Tracheal aspirate: Organism Other DB Name: [Q03C] SAS Name: [OT_Trac]	<input type="text"/> (50 char.)
3d	Tracheal aspirate: outcome DB Name: [Q03D] SAS Name: [OC_Trac]	<input type="radio"/> 1 - Resolved <input type="radio"/> 2 - Cause of death <input type="radio"/> 3 - Unknown importance
4b	Urine: Date DB Name: [Q04B] SAS Name: [Urine]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
4c	Urine: Organism (check all that apply)	<input type="checkbox"/> Q04CM1 - S.aureus <input type="checkbox"/> Q04CM2 - S.epid <input type="checkbox"/> Q04CM3 - Enterococcus <input type="checkbox"/> Q04CM4 - E.coli

		<input type="checkbox"/> Q04CM5 - Klebsiella <input type="checkbox"/> Q04CM6 - Fungus
4c1	Urine: Organism Other DB Name: [Q04C] SAS Name: [OT_Ur]	<input type="text"/> (50 char.)
4d	Urine: outcome DB Name: [Q04D] SAS Name: [OC_Ur]	<input type="radio"/> 1 - Resolved <input type="radio"/> 2 - Cause of death <input type="radio"/> 3 - Unknown importance
5b	Catheters (vascular): Date DB Name: [Q05B] SAS Name: [Catheters]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
5c	Catheters (vascular): Organism (check all that apply)	<input type="checkbox"/> Q05CM1 - S.aureus <input type="checkbox"/> Q05CM2 - S.epid <input type="checkbox"/> Q05CM3 - Enterococcus <input type="checkbox"/> Q05CM4 - E.coli <input type="checkbox"/> Q05CM5 - Klebsiella <input type="checkbox"/> Q05CM6 - Fungus
5c1	Catheters (vascular): Organism Other DB Name: [Q05C] SAS Name: [OT_Cath]	<input type="text"/> (50 char.)
5d	Catheters (vascular): outcome DB Name: [Q05D] SAS Name: [OC_Cath]	<input type="radio"/> 1 - Resolved <input type="radio"/> 2 - Cause of death <input type="radio"/> 3 - Unknown importance
6b	Wounds: Date DB Name: [Q06B] SAS Name: [Wounds]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
6c	Wounds: Organism (check all that apply)	<input type="checkbox"/> Q06CM1 - S.aureus <input type="checkbox"/> Q06CM2 - S.epid <input type="checkbox"/> Q06CM3 - Enterococcus <input type="checkbox"/> Q06CM4 - E.coli <input type="checkbox"/> Q06CM5 - Klebsiella <input type="checkbox"/> Q06CM6 - Fungus
6c1	Wounds: Organism Other DB Name: [Q06C] SAS Name: [OT_Wnd]	<input type="text"/> (50 char.)
6d	Wounds: outcome DB Name: [Q06D] SAS Name: [OC_Wnd]	<input type="radio"/> 1 - Resolved <input type="radio"/> 2 - Cause of death <input type="radio"/> 3 - Unknown importance
7b	Ascites: Date DB Name: [Q07B] SAS Name: [Ascites]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
7c	Ascites: Organism (check all that apply)	<input type="checkbox"/> Q07CM1 - S.aureus <input type="checkbox"/> Q07CM2 - S.epid <input type="checkbox"/> Q07CM3 - Enterococcus <input type="checkbox"/> Q07CM4 - E.coli

		<input type="checkbox"/> Q07CM5 - Klebsiella <input type="checkbox"/> Q07CM6 - Fungus
7c1	Ascites: Organism Other DB Name: [Q07C] SAS Name: [OT_Asc]	<input type="text"/> (50 char.)
7d	Ascites: outcome DB Name: [Q07D] SAS Name: [OC_Asc]	<input type="radio"/> 1 - Resolved <input type="radio"/> 2 - Cause of death <input type="radio"/> 3 - Unknown importance
8b	Other evidence infection: Date DB Name: [Q08B] SAS Name: [OtherEvInf]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
8c	Other evidence infection: specify DB Name: [Q08C] SAS Name: [OtherEvInfTxt]	<input type="text"/> (100 char.)
8d	Other evidence: outcome DB Name: [Q08D] SAS Name: [OC_OtherEvInf]	<input type="radio"/> 1 - Resolved <input type="radio"/> 2 - Cause of death <input type="radio"/> 3 - Unknown importance
10	Did subject receive antibiotic treatment during hospitalization? DB Name: [Q10]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
11	Did subject receive antibiotic prophylaxis during hospitalization? DB Name: [Q11]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

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**Annotated Form for CRF 15 [Transplant]
Form ID: 108 DB Table Name: F15**






No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
Added to waiting list (first time only)		
1	Put on waiting list? DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2	If yes, date first time put on waiting list DB Name: [Q02]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
3	If yes, time first time put on waiting list DB Name: [Q03]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
4	If no, primary reason for not being added to waiting list DB Name: [Q04]	<input type="radio"/> 1 - Not sick enough <input type="radio"/> 6 - Active psychiatric disease <input type="radio"/> 2 - Irreversible brain damage <input type="radio"/> 7 - Medically unsuitable <input type="radio"/> 3 - Sepsis <input type="radio"/> 8 - Other <input type="radio"/> 4 - Active substance use <input type="radio"/> 9 - Patient already on list <input type="radio"/> 5 - Inadequate social support
5	If other, specify reason for not being added to waiting list DB Name: [Q05]	<input type="text"/> (100 char.)
Removed from waiting list (first time only)		
6	Removed from waiting list prior to being transplanted? DB Name: [Q06]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
7	If Yes, date first time removed from waiting list DB Name: [Q07]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
8	If Yes, time first time removed from waiting list DB Name: [Q08]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
9	If yes, primary reason for being removed from waiting list DB Name: [Q09]	<input type="radio"/> 1 - Improved <input type="radio"/> 2 - Irreversible brain damage <input type="radio"/> 3 - Sepsis <input type="radio"/> 4 - Medically unsuitable <input type="radio"/> 5 - Other
10	If other, specify reason for being removed from waiting list DB Name: [Q10]	<input type="text"/> (100 char.)
Liver Transplant (first transplant only)		
11	Transplanted? DB Name: [Q11]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
12	If yes, date of first transplant DB Name: [Q12]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
13	If yes, time of first transplant DB Name: [Q13]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
14	Type of transplant(Check all that apply)	<input type="checkbox"/> Q14M1 - Orthotopic <input type="checkbox"/> Q14M2 - Auxiliary



		<input type="checkbox"/> Q14M3 - Split liver <input type="checkbox"/> Q14M4 - Living donor <input type="checkbox"/> Q14M5 - ABO compatible liver
15	Resected liver weight DB Name: [Q15]	<input type="text"/> gms
16	Immediate complications during transplant hospitalization DB Name: [Q16]	<input type="radio"/> 1 - PNF (Primary Non-function) <input type="radio"/> 3 - Biliary <input type="radio"/> 5 - None <input type="radio"/> 2 - Hepatic artery thrombosis <input type="radio"/> 4 - Bleeding <input type="radio"/> 98 - Other
17	If 'other', specify: DB Name: [Q17]	<input type="text"/> (100 char.)
Immunosuppression associated with first transplant		
18	Immunosuppression used within the first 72 hours of OLT. (Check all that apply)	<input type="checkbox"/> Q18M1 - ATG <input type="checkbox"/> Q18M2 - Azathioprine <input type="checkbox"/> Q18M3 - Cyclosporine <input type="checkbox"/> Q18M4 - Daclizumab <input type="checkbox"/> Q18M5 - Mycophenolate <input type="checkbox"/> Q18M6 - OKT3 <input type="checkbox"/> Q18M7 - Prednisone <input type="checkbox"/> Q18M8 - Sirolimus <input type="checkbox"/> Q18M9 - Tacrolimus <input type="checkbox"/> Q18M98 - Other
19	If other, specify immunosuppression DB Name: [Q19]	<input type="text"/> (100 char.)
Donor Graft #1 associated with first transplant		
20	Recipient Blood Group DB Name: [Q20]	<input type="radio"/> 1 - A <input type="radio"/> 2 - B <input type="radio"/> 3 - O <input type="radio"/> 4 - AB
21	Donor Blood Group DB Name: [Q21]	<input type="radio"/> 1 - A <input type="radio"/> 2 - B <input type="radio"/> 3 - O <input type="radio"/> 4 - AB
22	Biliary anastomosis DB Name: [Q22]	<input type="radio"/> 1 - Duct to duct <input type="radio"/> 2 - Roux-en-y
23	Donor Gender DB Name: [Q23]	<input type="radio"/> 1 - Male <input type="radio"/> 2 - Female
24	Donor Age DB Name: [Q24]	<input type="text"/> years
25	Cold ischemia time DB Name: [Q25]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
26	Warm ischemia time DB Name: [Q26]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
27	Narrative Summary DB Name: [Q27]	<input type="text"/> char.) (1500)
Re-Transplanted		
28	Re-transplanted? DB Name: [Q28]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
29	If yes, date of re-transplant DB Name: [Q29]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete

B	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/>	(250 <i>char.</i>)
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WebDCU™ ALFSG

Annotated Form for CRF 16 [Diagnosis]
Form ID: 96 DB Table Name: F16 DB View Name: vF16

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text" value="v"/> <input type="text"/>  (dd-mmm-yyyy) Complete
Acetaminophen		
1	Acetaminophen overdose (Medication information regarding APAP overdose is captured on Form 04.) DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2	If yes, specify type DB Name: [Q02]	<input type="radio"/> 1 - Suicide attempt <input type="radio"/> 2 - Unintentional <input type="radio"/> 3 - Unknown
3	If unintentional or unknown, motivation of overdose DB Name: [Q03]	<input type="radio"/> 1 - MD recommended <input type="radio"/> 2 - Self initiated
4	If therapeutic intent, primary indication DB Name: [Q04]	<input type="radio"/> 1 - Acute pain syndrome (i.e. < 1 week of symptoms) <input type="radio"/> 2 - Infectious process <input type="radio"/> 3 - Sub-acute pain (i.e. 1-4 week of symptoms) <input type="radio"/> 4 - Chronic pain (> 4 weeks of symptoms) <input type="radio"/> 98 - Other
93	If other indication, specify DB Name: [Q93]	<input type="text"/> (100 char.)
Any ALI/ALF in pregnancy		
7	Any ALI/ALF in pregnancy DB Name: [Q07]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
8	HELLP? DB Name: [Q08]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
9	AFLP? DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
10	Weeks gestation at enrollment? DB Name: [Q10]	<input type="text"/> weeks
11	Delivered? DB Name: [Q11]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
12	If delivered, date of delivery DB Name: [Q12]	<input type="text"/> <input type="text" value="v"/> <input type="text"/>  (dd-mmm-yyyy) Complete
13	Fetal status at week 3:Baby DB Name: [Q13]	<input type="radio"/> 1 - Dead <input type="radio"/> 2 - Alive
14	If death, specify date DB Name: [Q14]	<input type="text"/> <input type="text" value="v"/> <input type="text"/>  (dd-mmm-yyyy) Complete
15	If baby alive, date of hospital discharge DB Name: [Q15]	<input type="text"/> <input type="text" value="v"/> <input type="text"/>  (dd-mmm-yyyy) Complete
16	If not delivered, estimated date of	<input type="text"/> <input type="text" value="v"/> <input type="text"/>  (dd-mmm-yyyy) Complete

	confinement (EDC) DB Name: [Q16]	
17	Gravida DB Name: [Q17]	<input type="text"/>
18	Para DB Name: [Q18]	<input type="text"/>
19	Pre-eclampsia? DB Name: [Q19]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
20	Eclampsia? DB Name: [Q20]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
21	Prior pregnancy: Pre-eclampsia? DB Name: [Q21]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
22	Prior pregnancy: Eclampsia? DB Name: [Q22]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
23	Complication? DB Name: [Q23]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
24	Intra-abdominal hematoma? DB Name: [Q24]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
25	Hepatic rupture? DB Name: [Q25]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
26	C-Section? DB Name: [Q26]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
Autoimmune hepatitis (AIH)		
27	Autoimmune hepatitis (AIH)? DB Name: [Q27]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
28	Positive serologies? DB Name: [Q28]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
29	Biopsy performed? DB Name: [Q29]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
30	Prednisone begun? DB Name: [Q30]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
31	If yes, specify prednisone start date DB Name: [Q31]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
32	Other immunosuppressant? DB Name: [Q32]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
33	If yes, specify immunosuppressant name DB Name: [Q33]	<input type="text"/> (25 char.)
34	If yes, immunosuppressant start date DB Name: [Q34]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
Budd Chiari Syndrome		
35	Budd Chiari Syndrome? DB Name: [Q35]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
36	Risk factor (Check all that apply)	<input type="checkbox"/> Q36M1 - Blood dyscrasia <input type="checkbox"/> Q36M2 - Clotting disorder <input type="checkbox"/> Q36M98 - Other
37	If other cause, specify: DB Name: [Q37]	<input type="text"/> (25 char.)

38	Specify risk factor of blood dyscrasia DB Name: [Q38]	<input type="text"/>	(50 char.)
39	Specify risk factor of clotting disorder DB Name: [Q39]	<input type="text"/>	(50 char.)
40	Specify risk factor of other cause DB Name: [Q40]	<input type="text"/>	(50 char.)
41	Diagnosis established by (Check all that apply)	<input type="checkbox"/> Q41M1 - Liver biopsy <input type="checkbox"/> Q41M2 - CT <input type="checkbox"/> Q41M3 - MRI <input type="checkbox"/> Q41M4 - Angiography	
42	Therapy, other than transplant (Check all that apply)	<input type="checkbox"/> Q42M1 - Anticoagulation <input type="checkbox"/> Q42M2 - TIPSS <input type="checkbox"/> Q42M3 - Surgical shunt <input type="checkbox"/> Q42M98 - Other	
43	If other, specify therapy DB Name: [Q43]	<input type="text"/>	

DILI

44	DILI? DB Name: [Q44]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
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Child Form ID: 117 Child DB Table Name: vF16C





No.	A Suspect drug name (50 char.) DB Name: [QA]	B Prior use of same drug? DB Name: [QB]	C Duration: Year (years) DB Name: [QC]	D Duration: Month (months) DB Name: [QD]	E Causality assessment DB Name: [QE]
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Hepatitis A

52	Hepatitis A? DB Name: [Q52]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes	
53	Risk factor in past 4 months (Check all that apply)	<input type="checkbox"/> Q53M1 - Food <input type="checkbox"/> Q53M2 - Water <input type="checkbox"/> Q53M3 - Household contacts <input type="checkbox"/> Q53M4 - MSM (Men having sex with men) <input type="checkbox"/> Q53M98 - Other	
54	If other, specify risk factor DB Name: [Q54]	<input type="text"/>	

Hepatitis B




55	Hepatitis B? DB Name: [Q55]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes	
56	Risk factors in past 6 months (Check all that apply)	<input type="checkbox"/> Q56M1 - Multiple sexual partners <input type="checkbox"/> Q56M2 - IDU <input type="checkbox"/> Q56M3 - MSM (Men having sex with men) <input type="checkbox"/> Q56M4 - STD <input type="checkbox"/> Q56M98 - Other	
57	Prior positive HBsAg? DB Name: [Q57]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes	
58	If yes, date of positive HBsAg DB Name: [Q58]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete	
59	History of hepatitis B	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes	

	DB Name: [Q59]	
60	If yes, date of hepatitis B DB Name: [Q60]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
Mushroom intoxication		
61	Mushroom intoxication? DB Name: [Q61]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
62	Time of ingestion DB Name: [Q62]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
63	Date of ingestion DB Name: [Q63]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
64	Muscarinic symptoms? (vomiting, diarrhea, sweating) DB Name: [Q64]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
65	If yes, time of onset DB Name: [Q65]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
66	Other persons affected? DB Name: [Q66]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
Shock/ischemia		
67	Shock/ischemia? DB Name: [Q67]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
68	Cardiac cause of shock? DB Name: [Q68]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
69	If yes, result of Echocardiogram: Left ventricular ejection fraction DB Name: [Q69]	<input type="text"/> %
70	Mean PA systolic pressure DB Name: [Q70]	<input type="text"/> mm of Hg
71	Date of echocardiogram DB Name: [Q71]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
72	Arrhythmia DB Name: [Q72]	<input type="radio"/> 1 - Atrial <input type="radio"/> 2 - Ventricular <input type="radio"/> 3 - No arrhythmia
73	Hypotension (SBP <90 or MAP<50)? DB Name: [Q73]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
74	If yes, Date of SBP<90 or MAP<50 DB Name: [Q74]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
75	If yes, Time of SBP<90 or MAP<50 DB Name: [Q75]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
76	Pressors given? DB Name: [Q76]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
77	Specify pressor: (check all that apply)	<input type="checkbox"/> Q77M1 - Dopamine <input type="checkbox"/> Q77M2 - Epinephrine <input type="checkbox"/> Q77M3 - Neosynephrine (phenylephrine) <input type="checkbox"/> Q77M4 - Norepinephrine (levophed) <input type="checkbox"/> Q77M5 - Vasopressin
Other viruses		
78	Other viruses?	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes

	DB Name: [Q78]	
79	Virus type DB Name: [Q79]	<input type="radio"/> 1 - CMV <input type="radio"/> 4 - HSV I <input type="radio"/> 2 - EBV <input type="radio"/> 5 - VZV <input type="radio"/> 3 - HHV 6 <input type="radio"/> 98 - Other virus type
80	Specify 'other virus' type: DB Name: [Q80]	<input type="text"/> (50 char.)
81	Immunosuppressed? DB Name: [Q81]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
82	Skin rash? DB Name: [Q82]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
83	Skin biopsy/swab? DB Name: [Q83]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
84	Vaginal swab? DB Name: [Q84]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
85	Antibody results DB Name: [Q85]	<input type="text"/> (100 char.)
86	DNA quant DB Name: [Q86]	<input type="text"/> IU or copies/mL
Diagnosis		
87	Primary cause of ALI/ALF DB Name: [Q87]	<input type="radio"/> 1 - 1. Acetaminophen <input type="radio"/> 9 - 9. Hepatitis E <input type="radio"/> 2 - 2. Any ALI/ALF in pregnancy <input type="radio"/> 10 - 10. Mushroom intoxication <input type="radio"/> 3 - 3. Autoimmune hepatitis <input type="radio"/> 11 - 11. Shock/ischemia <input type="radio"/> 4 - 4. Budd-Chiari syndrome <input type="radio"/> 12 - 12. Wilson's disease <input type="radio"/> 5 - 5. DILI <input type="radio"/> 13 - 13. Indeterminate <input type="radio"/> 6 - 6. Hepatitis A <input type="radio"/> 14 - 14. Other viruses <input type="radio"/> 7 - 7. Hepatitis B (+/- delta) <input type="radio"/> 15 - 15. Other <input type="radio"/> 8 - 8. Hepatitis C
88	Specify other diagnosis if applicable: DB Name: [Q88]	<input type="text"/> (100 char.)
89	How was final diagnosis established? (Check all that apply)	<input type="checkbox"/> Q89M1 - Hx <input type="checkbox"/> Q89M2 - Tissue/histology <input type="checkbox"/> Q89M3 - Lab <input type="checkbox"/> Q89M98 - Other
90	If other, specify DB Name: [Q90]	<input type="text"/> (100 char.)
94	Narrative summary / Interval history DB Name: [Q94]	<input type="text"/> char.) (3000)
91	Last name of reviewing site investigator: DB Name: [Q91]	<input type="text"/> (15 char.)
92	Date of site investigator review: DB Name: [Q92]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> char.) (250)




WebDCU™ ALFSG

Annotated Form for CRF 17 [Discharge Summary]
Form ID: 86 DB Table Name: F17 DB View Name: vF17

No.	Item Description	Data Value
A	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
Outcome at the time of summary		
1	Was the subject discharged to home? DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2	If yes, date of discharge home: DB Name: [Q02]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
3	Was the subject discharged to another facility? DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
4	If yes, date of discharge to another facility: DB Name: [Q04]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
5	If yes, where? DB Name: [Q05]	<input type="text"/> (100 char.)
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

WebDCU™ ALFSG


Annotated Form for CRF 18 [LTFU Part 1 - Outcome]
Form ID: 91 DB Table Name: F18

No.	Item Description	Data Value																
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes																
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text" value="v"/> <input type="text"/>  (dd-mmm-yyyy) Complete																
1	Data collection method (Check all that apply) If chart review, complete this form only with new information since the last visit.	<input type="checkbox"/> Q01M1 - Chart <input type="checkbox"/> Q01M2 - Phone <input type="checkbox"/> Q01M3 - Clinic visit																
11	If question 1 is 'chart review', what is the most recent date of subject contact documented in the chart? DB Name: [Q11]	<input type="text"/> <input type="text" value="v"/> <input type="text"/>  (dd-mmm-yyyy) Complete																
If patient alive:																		
2	Was the subject transplanted? DB Name: [Q02]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown																
3	Subject hospitalized since last visit? (Exclude the enrolling event.) DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes																
4	If yes, hospital admission date closest to ALF discharge. If the subject was hospitalized more than once since the last visit, enter the date of hospitalization that occurred first. If more than one hospitalization, then please explain in Comments. DB Name: [Q04]	<input type="text"/> <input type="text" value="v"/> <input type="text"/>  (dd-mmm-yyyy) Complete																
5	Reason for hospitalization. DB Name: [Q05]	<input type="text"/> <i>(200 char.)</i>																
6	Diagnosis as of this visit DB Name: [Q06]	<table border="0"> <tr> <td><input type="radio"/> 1 - 1. Acetaminophen</td> <td><input type="radio"/> 9 - 9. Hepatitis E</td> </tr> <tr> <td><input type="radio"/> 2 - 2. Any ALI/ALF in pregnancy</td> <td><input type="radio"/> 10 - 10. Mushroom intoxication</td> </tr> <tr> <td><input type="radio"/> 3 - 3. Autoimmune hepatitis</td> <td><input type="radio"/> 11 - 11. Shock/ischemia</td> </tr> <tr> <td><input type="radio"/> 4 - 4. Budd-Chiari syndrome</td> <td><input type="radio"/> 12 - 12. Wilson's disease</td> </tr> <tr> <td><input type="radio"/> 5 - 5. DILI</td> <td><input type="radio"/> 13 - 13. Indeterminate</td> </tr> <tr> <td><input type="radio"/> 6 - 6. Hepatitis A</td> <td><input type="radio"/> 14 - 14. Other viruses</td> </tr> <tr> <td><input type="radio"/> 7 - 7. Hepatitis B (+/- delta)</td> <td><input type="radio"/> 15 - 15. Other</td> </tr> <tr> <td><input type="radio"/> 8 - 8. Hepatitis C</td> <td></td> </tr> </table>	<input type="radio"/> 1 - 1. Acetaminophen	<input type="radio"/> 9 - 9. Hepatitis E	<input type="radio"/> 2 - 2. Any ALI/ALF in pregnancy	<input type="radio"/> 10 - 10. Mushroom intoxication	<input type="radio"/> 3 - 3. Autoimmune hepatitis	<input type="radio"/> 11 - 11. Shock/ischemia	<input type="radio"/> 4 - 4. Budd-Chiari syndrome	<input type="radio"/> 12 - 12. Wilson's disease	<input type="radio"/> 5 - 5. DILI	<input type="radio"/> 13 - 13. Indeterminate	<input type="radio"/> 6 - 6. Hepatitis A	<input type="radio"/> 14 - 14. Other viruses	<input type="radio"/> 7 - 7. Hepatitis B (+/- delta)	<input type="radio"/> 15 - 15. Other	<input type="radio"/> 8 - 8. Hepatitis C	
<input type="radio"/> 1 - 1. Acetaminophen	<input type="radio"/> 9 - 9. Hepatitis E																	
<input type="radio"/> 2 - 2. Any ALI/ALF in pregnancy	<input type="radio"/> 10 - 10. Mushroom intoxication																	
<input type="radio"/> 3 - 3. Autoimmune hepatitis	<input type="radio"/> 11 - 11. Shock/ischemia																	
<input type="radio"/> 4 - 4. Budd-Chiari syndrome	<input type="radio"/> 12 - 12. Wilson's disease																	
<input type="radio"/> 5 - 5. DILI	<input type="radio"/> 13 - 13. Indeterminate																	
<input type="radio"/> 6 - 6. Hepatitis A	<input type="radio"/> 14 - 14. Other viruses																	
<input type="radio"/> 7 - 7. Hepatitis B (+/- delta)	<input type="radio"/> 15 - 15. Other																	
<input type="radio"/> 8 - 8. Hepatitis C																		
7	List DILI agent if applicable DB Name: [Q07]	<input type="text"/> <i>(100 char.)</i>																
8	Specify other viruses if applicable DB Name: [Q08]	<input type="text"/> <i>(100 char.)</i>																

9	Specify other diagnosis DB Name: [Q09]	<input type="text"/> (100 char.)
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

WebDCU™ ALFSG

Annotated Form for CRF 19 [LTFU Part 2 - Complications]
Form ID: 92 DB Table Name: F19

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
Complications since the last visit. If this is the first follow up assessment, enter all complications that have occurred since hospital discharge. (Check all that apply)		
1	Neurological	<input type="checkbox"/> Q01M0 - None <input type="checkbox"/> Q01M1 - Neuropathy <input type="checkbox"/> Q01M2 - Seizure <input type="checkbox"/> Q01M3 - CVA <input type="checkbox"/> Q01M4 - Headache <input type="checkbox"/> Q01M5 - Speech <input type="checkbox"/> Q01M6 - Tremors <input type="checkbox"/> Q01M7 - Global impairment <input type="checkbox"/> Q01M99 - Unknown
2	Pulmonary	<input type="checkbox"/> Q02M0 - None <input type="checkbox"/> Q02M1 - Pneumonia <input type="checkbox"/> Q02M2 - Effusion <input type="checkbox"/> Q02M3 - Tracheostomy <input type="checkbox"/> Q02M99 - Unknown
3	Cardiac	<input type="checkbox"/> Q03M0 - None <input type="checkbox"/> Q03M1 - Arrhythmia <input type="checkbox"/> Q03M2 - CHF <input type="checkbox"/> Q03M3 - MI <input type="checkbox"/> Q03M99 - Unknown
4	Renal	<input type="checkbox"/> Q04M0 - None <input type="checkbox"/> Q04M1 - HD < 3 months <input type="checkbox"/> Q04M2 - HD ≥ 3 months <input type="checkbox"/> Q04M3 - CVVH <input type="checkbox"/> Q04M99 - Unknown
5	Liver-Biliary	<input type="checkbox"/> Q05M0 - None <input type="checkbox"/> Q05M1 - Leak <input type="checkbox"/> Q05M2 - Stricture <input type="checkbox"/> Q05M3 - Stone/sludge <input type="checkbox"/> Q05M4 - PTC <input type="checkbox"/> Q05M5 - ERCP <input type="checkbox"/> Q05M6 - Surgical revision <input type="checkbox"/> Q05M99 - Unknown
6	Liver-Vascular	<input type="checkbox"/> Q06M0 - None <input type="checkbox"/> Q06M7 - HAT <input type="checkbox"/> Q06M1 - HA stenosis <input type="checkbox"/> Q06M2 - IVC <input type="checkbox"/> Q06M3 - Portal vein <input type="checkbox"/> Q06M4 - Angioplasty/stent <input type="checkbox"/> Q06M5 - Anti-coagulants

		<input type="checkbox"/> Q06M6 - Surgical revision <input type="checkbox"/> Q06M99 - Unknown
7	Re-operation after transplant	<input type="checkbox"/> Q07M0 - None <input type="checkbox"/> Q07M1 - Biliary <input type="checkbox"/> Q07M2 - Vascular <input type="checkbox"/> Q07M3 - Intra-abd bleed <input type="checkbox"/> Q07M4 - Intra-abd sepsis <input type="checkbox"/> Q07M5 - Wound related <input type="checkbox"/> Q07M98 - Other <input type="checkbox"/> Q07M99 - Unknown
7t	If other, specify re-operation DB Name: [Q07T]	<input type="text"/> (50 char.)
8	CMV disease	<input type="checkbox"/> Q08M0 - None <input type="checkbox"/> Q08M1 - Blood <input type="checkbox"/> Q08M2 - Lung <input type="checkbox"/> Q08M3 - Liver <input type="checkbox"/> Q08M98 - Other <input type="checkbox"/> Q08M99 - Unknown
8t	If other, specify CMV disease DB Name: [Q08T]	<input type="text"/> (50 char.)
9	Bacterial infection	<input type="checkbox"/> Q09M0 - None <input type="checkbox"/> Q09M1 - Bacteremia <input type="checkbox"/> Q09M2 - Cholangitis <input type="checkbox"/> Q09M3 - Hepatic abscess <input type="checkbox"/> Q09M4 - Intra-abdominal <input type="checkbox"/> Q09M98 - Other <input type="checkbox"/> Q09M99 - Unknown
9t	If other, specify bacterial infection DB Name: [Q09T]	<input type="text"/> (50 char.)
10	Fungal infection	<input type="checkbox"/> Q10M0 - None <input type="checkbox"/> Q10M1 - Fluconazole <input type="checkbox"/> Q10M2 - Amphotericin <input type="checkbox"/> Q10M3 - Blood <input type="checkbox"/> Q10M4 - Lung <input type="checkbox"/> Q10M98 - Other <input type="checkbox"/> Q10M99 - Unknown
10t	If other, specify fungal infection DB Name: [Q10T]	<input type="text"/> (50 char.)
11	Diabetes mellitus	<input type="checkbox"/> Q11M0 - None <input type="checkbox"/> Q11M1 - Oral agent <input type="checkbox"/> Q11M2 - Insulin <input type="checkbox"/> Q11M3 - Diet only <input type="checkbox"/> Q11M99 - Unknown
12	Hypertension	<input type="checkbox"/> Q12M0 - None <input type="checkbox"/> Q12M1 - Drug therapy <input type="checkbox"/> Q12M2 - Diet <input type="checkbox"/> Q12M99 - Unknown
13	Hyperlipidemia	<input type="checkbox"/> Q13M0 - None

		<input type="checkbox"/> Q13M1 - Drug therapy <input type="checkbox"/> Q13M2 - Diet <input type="checkbox"/> Q13M99 - Unknown
14	Additional Narrative Summary DB Name: [Q14]	<div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>(1500 char.)</p>
15	Were any imaging, EEGs, or biopsies performed? If this is not the first assessment, document any performed since the last assessment. DB Name: [Q15]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
C	Comments DB Name: [zNotes]	<div style="border: 1px solid black; height: 40px; width: 100%;"></div> <p>(250 char.)</p>





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**Annotated Form for CRF 21 [LTFU Part 4 - Substance abuse]
Form ID: 94 DB Table Name: F21**

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text" value="v"/> <input type="text"/> <input type="text" value="12"/> <input type="text" value="12"/> (dd-mmm-yyyy) Complete
Substance abuse since ALF/ALI		
1	Suicidal intent/gesture DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
2	If yes, specify DB Name: [Q02]	<input type="text"/> (200 char.)
3	Suicidal intent/gesture date DB Name: [Q03]	<input type="text"/> <input type="text" value="v"/> <input type="text"/> <input type="text" value="12"/> <input type="text" value="12"/> (dd-mmm-yyyy) Complete
4	Acetaminophen overdose DB Name: [Q04]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
5	Acetaminophen overdose date DB Name: [Q05]	<input type="text"/> <input type="text" value="v"/> <input type="text"/> <input type="text" value="12"/> <input type="text" value="12"/> (dd-mmm-yyyy) Complete
6	Psychiatric illness DB Name: [Q06]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
7	If yes, specify DB Name: [Q07]	<input type="text"/> (200 char.)
8	Alcohol abuse/alcoholism DB Name: [Q08]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
9	CAGE: Cut down DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
10	CAGE: Annoyed DB Name: [Q10]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
11	CAGE: Guilty DB Name: [Q11]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
12	CAGE: Eye opener DB Name: [Q12]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
13	Illicit drug use DB Name: [Q13]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
14	If yes, specify DB Name: [Q14]	<input type="text"/> (200 char.)
C	Comments DB Name: [zNotes]	<input type="text"/> (250 char.)

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Annotated Form for CRF 22 [LTFU Part 5]
Form ID: 95 DB Table Name: F22 DB View Name: vF22


No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
Demographics		
1	Current employment status DB Name: [Q01]	<input type="radio"/> 1 - Employed-full time <input type="radio"/> 6 - Self-employed <input type="radio"/> 2 - Employed-part time <input type="radio"/> 7 - Retired <input type="radio"/> 3 - Medical disability <input type="radio"/> 8 - Other capacity <input type="radio"/> 4 - Student <input type="radio"/> 9 - Unemployed <input type="radio"/> 5 - Homemaker <input type="radio"/> 99 - Unknown
2	Occupation DB Name: [Q02]	<input type="text"/> (50 char.)
3	Current Karnofsky score DB Name: [Q03]	<input type="radio"/> 10 - 100 <input type="radio"/> 8 - 80 <input type="radio"/> 6 - 60 <input type="radio"/> 4 - 40 <input type="radio"/> 2 - 20 <input type="radio"/> 9 - 90 <input type="radio"/> 7 - 70 <input type="radio"/> 5 - 50 <input type="radio"/> 3 - 30 <input type="radio"/> 1 - 10 <input type="radio"/> 99 - Unknown
4	Current years of education completed since starting 1st grade (Do not count repeated grades) DB Name: [Q04]	<input type="text"/> years
5	Current marital status DB Name: [Q05]	<input type="radio"/> 1 - Never married <input type="radio"/> 4 - Separated <input type="radio"/> 99 - Unknown <input type="radio"/> 2 - Married <input type="radio"/> 5 - Widowed <input type="radio"/> 3 - Divorced <input type="radio"/> 6 - Significant Other
6	Current health insurance (Check all that apply)	<input type="checkbox"/> Q06M1 - No insurance <input type="checkbox"/> Q06M2 - Private insurance (including HMO, PPO, IPO, etc) <input type="checkbox"/> Q06M3 - Medicare <input type="checkbox"/> Q06M4 - Medicaid <input type="checkbox"/> Q06M99 - Unknown
Liver Histology List		
7	Liver Histology List:	<input type="checkbox"/> Q07M1 - Not done
8a	Liver histology 1: Date DB Name: [Q08A]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
8b	Liver histology 1: Findings (Check all that apply)	<input type="checkbox"/> Q08B1 - Hepatitis <input type="checkbox"/> Q08B2 - Cirrhosis <input type="checkbox"/> Q08B3 - Rejection
8c	Liver histology 2: Date DB Name: [Q08C]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
8d	Liver histology 2: Findings (Check all that apply)	<input type="checkbox"/> Q08D1 - Hepatitis <input type="checkbox"/> Q08D2 - Cirrhosis <input type="checkbox"/> Q08D3 - Rejection
8e	Liver histology 3: Date DB Name: [Q08E]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
8f	Liver histology 3: Findings (Check all that apply)	<input type="checkbox"/> Q08F1 - Hepatitis <input type="checkbox"/> Q08F2 - Cirrhosis <input type="checkbox"/> Q08F3 - Rejection
9	Fluency DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes

10	English as first language DB Name: [Q10]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
11	Vision DB Name: [Q11]	<input type="radio"/> 0 - Normal <input type="radio"/> 1 - Impaired
12	If impaired, specify aides (Check all that apply)	<input type="checkbox"/> Q12M1 - Glasses <input type="checkbox"/> Q12M2 - Bifocals <input type="checkbox"/> Q12M98 - Other
12d	Specify other vision aides DB Name: [Q12D]	<input type="text"/> (50 char.)
13	Hearing DB Name: [Q13]	<input type="radio"/> 0 - Normal <input type="radio"/> 1 - Impaired
14	If impaired, specify aides	<input type="checkbox"/> Q14M1 - Left <input type="checkbox"/> Q14M2 - Right <input type="checkbox"/> Q14M98 - Other
14d	Specify other hearing aides DB Name: [Q14D]	<input type="text"/> (50 char.)
15	Ambulation DB Name: [Q15]	<input type="radio"/> 0 - Normal <input type="radio"/> 1 - Impaired
16	If impaired, specify DB Name: [Q16]	<input type="radio"/> 1 - Slow <input type="radio"/> 2 - With assistance
17	If with assistance, specify type (Check all that apply)	<input type="checkbox"/> Q17M1 - Cane-single footed <input type="checkbox"/> Q17M2 - Cane 4-footed <input type="checkbox"/> Q17M3 - Walker <input type="checkbox"/> Q17M4 - Wheelchair <input type="checkbox"/> Q17M5 - Transfer
18	Hand tremors DB Name: [Q18]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
19	If yes, specify arm	<input type="checkbox"/> Q19M1 - Left <input type="checkbox"/> Q19M2 - Right
20	Type DB Name: [Q20]	<input type="radio"/> 1 - Rest <input type="radio"/> 2 - Intent
Trails Test (For clinic visits only)		
21e	Test A: Time: Minutes DB Name: [Q21E]	<input type="text"/> minutes
21f	Test A: Time: Seconds DB Name: [Q21F]	<input type="text"/> seconds
21b	Test A: Errors DB Name: [Q21B] SAS Name: [TRAILS_A_ERR]	<input type="text"/>
21c	Test A: Standard Score: rating DB Name: [Q21C] SAS Name: [TRAILS_A_RATING]	<input type="radio"/> 1 - Pos <input type="radio"/> 0 - Neg
21d	Test A: Standard Score DB Name: [Q21D] SAS Name: [TRAILS_A_SCORE]	<input type="text"/>
22e	Test B: Time: Minutes DB Name: [Q22E]	<input type="text"/> minutes
22f	Test B: Time: Seconds DB Name: [Q22F]	<input type="text"/> seconds
22b	Test B: Errors DB Name: [Q22B] SAS Name: [TRAILS_B_ERR]	<input type="text"/>

22c	Test B: Standard Score: rating DB Name: [Q22C] SAS Name: [TRAILSB_RATING]	<input type="radio"/> 1 - Pos <input type="radio"/> 0 - Neg
22d	Test B: Standard Score DB Name: [Q22D] SAS Name: [TRAILSB_SCORE]	<input type="text"/>
C	Comments DB Name: [zNotes]	<input type="text"/> (250 char.)

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Annotated Form for CRF 23 [RBANS Test]
Form ID: 98 DB Table Name: F23 DB View Name: vF23

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate] SAS Name: [DateFormComp]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
1	RBANS test form version DB Name: [Q01] SAS Name: [RBANS_FORM]	<input type="radio"/> 1 - Form A <input type="radio"/> 2 - Form B
Immediate memory		
2	List learning total score DB Name: [Q02] SAS Name: [IM_LIST_TOT]	<input type="text"/>
3	Story memory total score DB Name: [Q03] SAS Name: [IM_STORY_TOT]	<input type="text"/>
4	Index score DB Name: [Q04] SAS Name: [IM_INDEX]	<input type="text"/>
Visuospatial/constructional		
5	Figure copy total score DB Name: [Q05] SAS Name: [VC_FIGURE_TOT]	<input type="text"/>
6	Line orientation total score DB Name: [Q06] SAS Name: [VC_LINE_TOT]	<input type="text"/>
7	Index score DB Name: [Q07] SAS Name: [VC_INDEX]	<input type="text"/>
Language		
8	Picture naming total score DB Name: [Q08] SAS Name: [LA_PIC_TOT]	<input type="text"/>
9	Semantic fluency total score DB Name: [Q09] SAS Name: [LA_SEM_TOT]	<input type="text"/>
10	Index score DB Name: [Q10] SAS Name: [LA_INDEX]	<input type="text"/>
Attention		
11	Digit span total score DB Name: [Q11] SAS Name: [AT_DIGIT_TOT]	<input type="text"/>
12	Coding total score DB Name: [Q12] SAS Name: [AT_CODING_TOT]	<input type="text"/>
13	Index score DB Name: [Q13] SAS Name: [AT_INDEX]	<input type="text"/>
Delayed memory		
14	List recall total score DB Name: [Q14] SAS Name: [DM_LISTRCL_TOT]	<input type="text"/>

15	List recognition total score DB Name: [Q15] SAS Name: [DM_LISTRCG_TOT]	<input type="text"/>
16	Story recall total score DB Name: [Q16] SAS Name: [DM_STORYRCL_TOT]	<input type="text"/>
17	Figure recall total score DB Name: [Q17] SAS Name: [DM_FIGURERCL_TOT]	<input type="text"/>
18	Total score DB Name: [Q18] SAS Name: [DM_TOT]	<input type="text"/>
19	Index score DB Name: [Q19] SAS Name: [DM_INDEX]	<input type="text"/>
Sum		
20	Sum of index Sum = Q4+Q7+Q10+Q13+Q19 DB Name: [Q20] SAS Name: [INDEX_TOT]	<input type="text"/>
21	Total scale score DB Name: [Q21] SAS Name: [SCALE_TOT]	<input type="text"/>
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> <i>(250 char.)</i>

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Annotated Form for CRF 24 [SF-36 Health Survey]
Form ID: 29 DB Table Name: F24

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
C	Completion method DB Name: [QC] SAS Name: [METHOD]	<input type="radio"/> 1 - Completed in person <input type="radio"/> 2 - Completed at home <input type="radio"/> 3 - Completed via phone
1	In general, would you say your health is DB Name: [Q01] SAS Name: [SF36_1]	<input type="radio"/> 1 - (1) Excellent <input type="radio"/> 2 - (2) Very good <input type="radio"/> 3 - (3) Good <input type="radio"/> 4 - (4) Fair <input type="radio"/> 5 - (5) Poor
2	Compared to one year ago , how would you rate your health in general <u>now</u> ? DB Name: [Q02] SAS Name: [SF36_2]	<input type="radio"/> 1 - (1) Much better now than one year ago <input type="radio"/> 2 - (2) Somewhat better now than one year ago <input type="radio"/> 3 - (3) About the same as one year ago <input type="radio"/> 4 - (4) Somewhat worse now than one year ago <input type="radio"/> 5 - (5) Much worse now than one year ago
3. The following items are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?		
3a	Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports: DB Name: [Q03A] SAS Name: [SF36_3A]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
3b	Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf: DB Name: [Q03B] SAS Name: [SF36_3B]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
3c	Lifting or carrying groceries: DB Name: [Q03C] SAS Name: [SF36_3C]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
3d	Climbing several flights of stairs: DB Name: [Q03D] SAS Name: [SF36_3D]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
3e	Climbing one flight of stairs: DB Name: [Q03E] SAS Name: [SF36_3E]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
3f	Bending, kneeling, or stooping: DB Name: [Q03F] SAS Name: [SF36_3F]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
3g	Walking more than one mile : DB Name: [Q03G] SAS Name: [SF36_3G]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
3h	Walking several blocks: DB Name: [Q03H] SAS Name: [SF36_3H]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
3i	Walking one block: DB Name: [Q03I] SAS Name: [SF36_3I]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
3j	Bathing or dressing yourself: DB Name: [Q03J] SAS Name: [SF36_3J]	<input type="radio"/> 1 - (1) Yes, limited a lot <input type="radio"/> 2 - (2) Yes, limited a little <input type="radio"/> 3 - (3) No, not limited at all
4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u> ?		

4a	Cut down on the amount of time you spent on work or other activities DB Name: [Q04A] SAS Name: [SF36_4A]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
4b	Accomplished less than you would like DB Name: [Q04B] SAS Name: [SF36_4B]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
4c	Were limited in the kind of work or other activities DB Name: [Q04C] SAS Name: [SF36_4C]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
4d	Had difficulty performing the work or other activities (for example, it took extra effort) DB Name: [Q04D] SAS Name: [SF36_4D]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?		
5a	Cut down on the amount of time you spent on work or other activities DB Name: [Q05A] SAS Name: [SF36_5A]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
5b	Accomplished less than you would like DB Name: [Q05B] SAS Name: [SF36_5B]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
5c	Didn't do work or other activities as carefully as usual DB Name: [Q05C] SAS Name: [SF36_5C]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
6	During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? DB Name: [Q06] SAS Name: [SF36_6]	<input type="radio"/> 1 - (1) Not at all <input type="radio"/> 2 - (2) Slightly <input type="radio"/> 3 - (3) Moderately <input type="radio"/> 4 - (4) Quite a bit <input type="radio"/> 5 - (5) Extremely
7	How much bodily pain have you had during the past 4 weeks ? DB Name: [Q07] SAS Name: [SF36_7]	<input type="radio"/> 1 - (1) None <input type="radio"/> 2 - (2) Very mild <input type="radio"/> 3 - (3) Mild <input type="radio"/> 4 - (4) Moderate <input type="radio"/> 5 - (5) Severe <input type="radio"/> 6 - (6) Very severe
8	During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? DB Name: [Q08] SAS Name: [SF36_8]	<input type="radio"/> 1 - (1) Not at all <input type="radio"/> 2 - (2) Slightly <input type="radio"/> 3 - (3) Moderately <input type="radio"/> 4 - (4) Quite a bit <input type="radio"/> 5 - (5) Extremely
9. These questions are about how you feel and how things have been with you during the past 4 weeks . For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...		
9a	Did you feel full of pep? DB Name: [Q09A] SAS Name: [SF36_9A]	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time <input type="radio"/> 3 - (3) A good bit of the time <input type="radio"/> 4 - (4) Some of the time <input type="radio"/> 5 - (5) A little of the time <input type="radio"/> 6 - (6) None of the time
9b	Have you been a very nervous	

	<p>person? DB Name: [Q09B] SAS Name: [SF36_9B]</p>	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time <input type="radio"/> 5 - (5) A little of the time <input type="radio"/> 6 - (6) None of the time	<input type="radio"/> 3 - (3) A good bit of the time <input type="radio"/> 4 - (4) Some of the time
9c	<p>Have you felt so down in the dumps nothing could cheer you up? DB Name: [Q09C] SAS Name: [SF36_9C]</p>	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time <input type="radio"/> 5 - (5) A little of the time <input type="radio"/> 6 - (6) None of the time	<input type="radio"/> 3 - (3) A good bit of the time <input type="radio"/> 4 - (4) Some of the time
9d	<p>Have you felt calm and peaceful? DB Name: [Q09D] SAS Name: [SF36_9D]</p>	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time <input type="radio"/> 5 - (5) A little of the time <input type="radio"/> 6 - (6) None of the time	<input type="radio"/> 3 - (3) A good bit of the time <input type="radio"/> 4 - (4) Some of the time
9e	<p>Did you have a lot of energy? DB Name: [Q09E] SAS Name: [SF36_9E]</p>	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time <input type="radio"/> 5 - (5) A little of the time <input type="radio"/> 6 - (6) None of the time	<input type="radio"/> 3 - (3) A good bit of the time <input type="radio"/> 4 - (4) Some of the time
9f	<p>Have you felt downhearted and blue? DB Name: [Q09F] SAS Name: [SF36_9F]</p>	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time <input type="radio"/> 5 - (5) A little of the time <input type="radio"/> 6 - (6) None of the time	<input type="radio"/> 3 - (3) A good bit of the time <input type="radio"/> 4 - (4) Some of the time
9g	<p>Did you feel worn out? DB Name: [Q09G] SAS Name: [SF36_9G]</p>	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time <input type="radio"/> 5 - (5) A little of the time <input type="radio"/> 6 - (6) None of the time	<input type="radio"/> 3 - (3) A good bit of the time <input type="radio"/> 4 - (4) Some of the time
9h	<p>Have you been a happy person? DB Name: [Q09H] SAS Name: [SF36_9H]</p>	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time <input type="radio"/> 5 - (5) A little of the time <input type="radio"/> 6 - (6) None of the time	<input type="radio"/> 3 - (3) A good bit of the time <input type="radio"/> 4 - (4) Some of the time
9i	<p>Did you feel tired? DB Name: [Q09I] SAS Name: [SF36_9I]</p>	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time <input type="radio"/> 5 - (5) A little of the time <input type="radio"/> 6 - (6) None of the time	<input type="radio"/> 3 - (3) A good bit of the time <input type="radio"/> 4 - (4) Some of the time
10	<p>During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)? DB Name: [Q10] SAS Name: [SF36_10]</p>	<input type="radio"/> 1 - (1) All of the time <input type="radio"/> 2 - (2) Most of the time	<input type="radio"/> 3 - (3) Some of the time <input type="radio"/> 4 - (4) A little of the time <input type="radio"/> 5 - (5) None of the time
11. How TRUE or FALSE is each of the following statements for you?			
11a	<p>I seem to get sick a little easier than other people DB Name: [Q11A] SAS Name: [SF36_11A]</p>	<input type="radio"/> 1 - (1) Definitely true <input type="radio"/> 2 - (2) Mostly true	<input type="radio"/> 3 - (3) Don't know <input type="radio"/> 4 - (4) Mostly false <input type="radio"/> 5 - (5) Definitely false
11b	<p>I am as healthy as anybody I know DB Name: [Q11B] SAS Name: [SF36_11B]</p>	<input type="radio"/> 1 - (1) Definitely true <input type="radio"/> 2 - (2) Mostly true	<input type="radio"/> 3 - (3) Don't know <input type="radio"/> 4 - (4) Mostly false <input type="radio"/> 5 - (5) Definitely false
11c	<p>I expect my health to get worse DB Name: [Q11C] SAS Name: [SF36_11C]</p>	<input type="radio"/> 1 - (1) Definitely true <input type="radio"/> 2 - (2) Mostly true	<input type="radio"/> 3 - (3) Don't know <input type="radio"/> 4 - (4) Mostly false <input type="radio"/> 5 - (5) Definitely false
11d	<p>My health is excellent DB Name: [Q11D] SAS Name: [SF36_11D]</p>	<input type="radio"/> 1 - (1) Definitely true <input type="radio"/> 2 - (2) Mostly true	<input type="radio"/> 3 - (3) Don't know <input type="radio"/> 4 - (4) Mostly false <input type="radio"/> 5 - (5) Definitely false
D	<p>Comments DB Name: [zNotes] SAS Name: [Comments]</p>	<input type="text"/>	

(250 char.)

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**Annotated Form for CRF 25 [CDC HRQOL-14]
Form ID: 76 DB Table Name: F25**




No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text" value="▼"/> <input type="text"/> <input type="text" value="12"/> <input type="text" value="12"/> (dd-mmm-yyyy) Complete
1	Completion method DB Name: [Q01] SAS Name: [METHOD]	<input type="radio"/> 1 - Completed in person <input type="radio"/> 2 - Completed at home <input type="radio"/> 3 - Completed via phone
2	Would you say that in general your health is: DB Name: [Q02] SAS Name: [QOL_2]	<input type="radio"/> 1 - (1) Excellent <input type="radio"/> 2 - (2) Very good <input type="radio"/> 3 - (3) Good <input type="radio"/> 4 - (4) Fair <input type="radio"/> 5 - (5) Poor
3	Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good? (If none, enter zero) DB Name: [Q03] SAS Name: [QOL_3]	<input type="text"/> days
4	Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good? (If none, enter zero) DB Name: [Q04] SAS Name: [QOL_4]	<input type="text"/> days
5	During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation? (If none, enter zero) DB Name: [Q05] SAS Name: [QOL_5]	<input type="text"/> days
6	Are you LIMITED in any way in any activities because of any impairment or health problem? (If no, skip to question 11) DB Name: [Q06] SAS Name: [QOL_6]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
7	What is the MAJOR impairment or health problem that limits your	<input type="text"/> <i>(200 char.)</i>

	activities? DB Name: [Q07] SAS Name: [QOL_7]	
8	For HOW LONG have your activities been limited because of your major impairment or health problem? Please give the length of time, for example:6 months, or 3 ½ years, or 2 weeks, etc. DB Name: [Q08] SAS Name: [QOL_8]	<input type="text"/> (15 char.)
9	Because of any impairment or health problem, do you need the help of other persons with your PERSONAL CARE needs, such as eating, bathing, dressing, or getting around the house? DB Name: [Q09] SAS Name: [QOL_9]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
10	Because of any impairment or health problem, do you need the help of other persons in handling your ROUTINE needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes? DB Name: [Q10] SAS Name: [QOL_10]	<input type="radio"/> 1 - (1) Yes <input type="radio"/> 2 - (2) No
11	During the past 30 days, for about how many days did PAIN make it hard for you to do your usual activities, such as self-care, work, or recreation? (If none, enter zero) DB Name: [Q11] SAS Name: [QOL_11]	<input type="text"/> days
12	During the past 30 days, for about how many days have you felt SAD, BLUE, or DEPRESSED? (If none, enter zero) DB Name: [Q12] SAS Name: [QOL_12]	<input type="text"/> days
13	During the past 30 days, for about how many days have you felt WORRIED, TENSE, or ANXIOUS? (If none, enter zero) DB Name: [Q13] SAS Name: [QOL_13]	<input type="text"/> days

14	During the past 30 days, for about how many days have you felt you did NOT get ENOUGH REST OR SLEEP? (If none, enter zero) DB Name: [Q14] SAS Name: [QOL_14]	<input type="text"/> days
15	During the past 30 days, for about how many days have you felt VERY HEALTHY AND FULL OF ENERGY? (If none, enter zero) DB Name: [Q15] SAS Name: [QOL_15]	<input type="text"/> days
D	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)


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Annotated Form for CRF 26 [End of Study]
Form ID: 44 DB Table Name: F26 DB View Name: vF26

No.	Item Description	Data Value
3	End of study status: DB Name: [Q03]	<input type="radio"/> 4 - Completed study <input type="radio"/> 1 - Consent withdrawn <input type="radio"/> 2 - Lost to follow up <input type="radio"/> 3 - Death <input type="radio"/> 98 - Other
1	Date of end of study For subjects who withdraw consent, enter date of withdrawal of consent. For subjects who die, enter date of death. DB Name: [Q01]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
4	Specify details regarding early termination DB Name: [Q04]	<input type="text"/> (250 char.)
10	Date last known to be alive DB Name: [Q10]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
5	Was an autopsy performed? DB Name: [Q05]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
7	Primary cause of death DB Name: [Q07]	<input type="text"/> (250 char.)
6	Category of primary cause of death (Check all that apply)	<input type="checkbox"/> Q06M1 - Liver related <input type="checkbox"/> Q06M2 - Infection/sepsis <input type="checkbox"/> Q06M3 - Cardiac <input type="checkbox"/> Q06M4 - Neurological (cerebral edema, cerebral vascular accident) <input type="checkbox"/> Q06M5 - Multi-organ failure <input type="checkbox"/> Q06M6 - Intraoperative <input type="checkbox"/> Q06M7 - Cancer <input type="checkbox"/> Q06M98 - Other <input type="checkbox"/> Q06M99 - Unknown
The site PI must review and affirm the accuracy of the information reflected in all of the case report forms for this study participant. Please complete the section below after this review and affirmation is complete.		
8	Last name of reviewing principal investigator: DB Name: [Q08]	<input type="text"/> (15 char.)
9	Date of PI review and affirmation: DB Name: [Q09]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
C	Comments DB Name: [zNotes]	<input type="text"/> (250 char.)

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Annotated Form for CRF 27 [Glasgow Coma Scale]
Form ID: 97 DB Table Name: F27 DB View Name: vF27

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
1	Was the subject intubated at the time of assessment? DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2	Was the subject paralyzed at the time of assessment? DB Name: [Q02]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
3	Was the subject sedated at the time of assessment? DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
4	Coma grade (best estimate) DB Name: [Q04]	<input type="radio"/> 0 - 0 (no coma) <input type="radio"/> 1 - I <input type="radio"/> 2 - II <input type="radio"/> 3 - III <input type="radio"/> 4 - IV
5	Eye opening DB Name: [Q05]	<input type="radio"/> 4 - Spontaneous (4) <input type="radio"/> 3 - To voice (3) <input type="radio"/> 2 - To pain (2) <input type="radio"/> 1 - None (1)
6	Verbal Response DB Name: [Q06]	<input type="radio"/> 5 - Oriented (5) <input type="radio"/> 4 - Confused (4) <input type="radio"/> 3 - Inappropriate words (3) <input type="radio"/> 2 - Incomprehensible sounds (2) <input type="radio"/> 1 - None (1)
7	Motor response DB Name: [Q07]	<input type="radio"/> 6 - Obeys commands (6) <input type="radio"/> 5 - Localizes pain (5) <input type="radio"/> 4 - Withdraw (pain) (4) <input type="radio"/> 3 - Flexion (pain) (3) <input type="radio"/> 2 - Extension (pain) (2) <input type="radio"/> 1 - None (1)
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

WebDCU™ ALFSG


Annotated Form for CRF 28 [Outcome Lab Data]

Form ID: 109 DB Table Name: F28

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
For subjects who discharge, die, or transplant prior to Day 7: At the Outcome visit, please check 'data collected?' as no.		
For subjects who discharge, die or transplant after Day 7: At the Outcome visit, please enter the lab data collected prior to discharge, death or transplant, whichever comes first.		
At STFU and LTFU visit, this form should be completed if new information is available.		
1	Last lab date DB Name: [Q01]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
2	Hemoglobin DB Name: [Q02]	<input type="text"/> g/dL
4	WBC DB Name: [Q04]	<input type="text"/> X1000/mm ³
9	Platelet count DB Name: [Q09]	<input type="text"/> X1000/mm ³
10	Prothrombin time DB Name: [Q10]	<input type="text"/> seconds
13	INR DB Name: [Q13]	<input type="text"/>
14	ALT DB Name: [Q14]	<input type="text"/> IU/L
15	AST DB Name: [Q15]	<input type="text"/> IU/L
16	Alk phosph DB Name: [Q16]	<input type="text"/> IU/L
17	Albumin DB Name: [Q17]	<input type="text"/> gm/dL
19	Total Bilirubin DB Name: [Q19]	<input type="text"/> mg/dL
24	Creatinine DB Name: [Q24]	<input type="text"/> mg/dL
25	Weight DB Name: [Q25]	<input type="text"/> kg
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input style="width: 100%; height: 40px;" type="text"/> (250 char.)

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Annotated Form for CRF 29 [Serological Exam]
Form ID: 110 DB Table Name: F29

No.	Item Description	Data Value
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
Serological Parameters		
1	Anti-HAV (IgM) DB Name: [Q01]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
2	HBsAg DB Name: [Q02]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
3	Anti-HBc DB Name: [Q03]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
4	Anti-HBc (IgM) DB Name: [Q04]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
5	HBeAg DB Name: [Q05]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
6	Anti-HBs DB Name: [Q06]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
7	HBV-DNA DB Name: [Q07]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
8	If HBV-DNA is positive, specify value DB Name: [Q08]	<input type="text"/> IU/mL
9	Anti-HDV DB Name: [Q09]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
10	Anti-HCV DB Name: [Q10]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
11	HCV-RNA DB Name: [Q11]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
12	If HCV-RNA is positive, specify value DB Name: [Q12]	<input type="text"/> IU/mL
13	Anti-HEV DB Name: [Q13]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
14	Anti-HIV DB Name: [Q14]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
15	β-hCG DB Name: [Q15]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Not done
Miscellaneous		
16a	Anti-smooth muscle antibodies (ASMA)-ratio 1: DB Name: [Q16A]	<input type="text"/>
16b	or Anti-smooth muscle antibodies (ASMA) -decimal DB Name: [Q16B]	<input type="text"/>
16c	Anti-smooth muscle antibodies (ASMA) state DB Name: [Q16C]	<input type="radio"/> 1 - Negative <input type="radio"/> 2 - Not done
17a	Antinuclear antibodies (ANA) -ratio 1: DB Name: [Q17A]	<input type="text"/>
17b	or Antinuclear antibodies (ANA) -decimal DB Name: [Q17B]	<input type="text"/>

17c	Antinuclear antibodies (ANA) state DB Name: [Q17C]	<input type="radio"/> 1 - Negative <input type="radio"/> 2 - Not done
18a	Antimitochondrial antibodies (AMA) - ratio 1: DB Name: [Q18A]	<input type="text"/>
18b	or Antimitochondrial antibodies (AMA) - decimal DB Name: [Q18B]	<input type="text"/>
18c	Antimitochondrial antibodies (AMA) state DB Name: [Q18C]	<input type="radio"/> 1 - Negative <input type="radio"/> 2 - Not done
19a	Anti-liver/kidney microsome (LKM) - ratio 1: DB Name: [Q19A]	<input type="text"/>
19b	or Anti-liver/kidney microsome (LKM) - decimal DB Name: [Q19B]	<input type="text"/>
19c	Anti-liver/kidney microsome (LKM) state DB Name: [Q19C]	<input type="radio"/> 1 - Negative <input type="radio"/> 2 - Not done
20	Serum Copper DB Name: [Q20]	<input type="text"/> $\mu\text{g/ml}$
21	Urine Copper DB Name: [Q21]	<input type="text"/> $\mu\text{g}/24 \text{ hr}$
22	Ceruloplasmin DB Name: [Q22]	<input type="text"/> mg/dL
23	Slit-lamp exam (KF rings) DB Name: [Q23]	<input type="radio"/> 1 - Positive <input type="radio"/> 2 - Negative <input type="radio"/> 3 - Inconclusive <input type="radio"/> 4 - Not done
C	Comments DB Name: [zNotes]	<input type="text"/> (250 char.)


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Annotated Form for CRF 31 [LTFU 3 months]
Form ID: 112 DB Table Name: F31

No.	Item Description	Data Value
a	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
1	Was the subject transplanted? DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown
2	Subject hospitalized since last visit? DB Name: [Q02]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
3	If yes, hospital admission date closest to ALF discharge. (If more than one hospitalization, then please explain in General Comments) DB Name: [Q03]	<input type="text"/> <input type="button" value="v"/> <input type="text"/>  (dd-mmm-yyyy) Complete
4	Reason for hospitalization. DB Name: [Q04]	<input type="text"/> (200 char.)
C	Comments DB Name: [zNotes]	<input type="text"/> char.) (250




WebDCU™ ALFSG

Annotated Form for CRF 32 [Acute Rejection]
Form ID: 113 DB Table Name: F32

No.	Item Description	Data Value
1	Date of acute rejection DB Name: [Q01]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
2	Liver Bx DB Name: [Q02]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
3	Steroid pulse DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
4	Antilymphocyte antibodies DB Name: [Q04]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
5	If yes, specify antilymphocyte antibodies DB Name: [Q05]	<input type="radio"/> 1 - ATG <input type="radio"/> 2 - OKT3 <input type="radio"/> 98 - Other
6	If other, specify DB Name: [Q06]	<input type="text"/> (30 char.)
B	Comments DB Name: [zNotes] SAS Name: [Comments]	<input style="width: 100%; height: 40px;" type="text"/> (250 char.)

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**Annotated Form for CRF 33 [STFU Outcome]
Form ID: 115 DB Table Name: F33**

No.	Item Description	Data Value																
A	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes																
B	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text" value="▼"/> <input type="text"/>  (dd-mmm-yyyy) Complete																
1	Narrative summary/Interval history DB Name: [Q01]	<div style="border: 1px solid black; height: 116px; width: 100%;"></div> <p>(2000 char.)</p>																
2	Patient seen for this study visit? DB Name: [Q02]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes																
3	Alive? DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes																
4	Discharged since last assessment DB Name: [Q04]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes																
5	if Yes, date of discharge DB Name: [Q05]	<input type="text"/> <input type="text" value="▼"/> <input type="text"/>  (dd-mmm-yyyy) Complete																
6	Subject transplanted since last visit? DB Name: [Q06]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Unknown																
7	Subject hospitalized since last visit? DB Name: [Q07]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes																
8	If yes, hospital admission date closest to ALI discharge. (If more than one hospitalization, then please explain in General Comments). DB Name: [Q08]	<input type="text"/> <input type="text" value="▼"/> <input type="text"/>  (dd-mmm-yyyy) Complete																
9	Reason for hospitalization DB Name: [Q09]	<input style="width: 100%;" type="text"/> <p>(200 char.)</p>																
10	Patient Status (as of the date of this form completion) DB Name: [Q10]	<input type="radio"/> 1 - Improved -follow up at month 3 <input type="radio"/> 2 - Not improved -return for next short term follow up visit (Does not apply at week 12 weeks STFU) <input type="radio"/> 3 - Met ALF Criteria and moved to ALF protocol																
11	Has the diagnosis changed since last assessment? DB Name: [Q11]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes																
12	If yes, what is diagnosis changed to? DB Name: [Q12]	<table style="width: 100%; border: none;"> <tr> <td><input type="radio"/> 1 - 1. Acetaminophen</td> <td><input type="radio"/> 9 - 9. Hepatitis E</td> </tr> <tr> <td><input type="radio"/> 2 - 2. Any ALI/ALF in pregnancy</td> <td><input type="radio"/> 10 - 10. Mushroom intoxication</td> </tr> <tr> <td><input type="radio"/> 3 - 3. Autoimmune hepatitis</td> <td><input type="radio"/> 11 - 11. Shock/ischemia</td> </tr> <tr> <td><input type="radio"/> 4 - 4. Budd-Chiari syndrome</td> <td><input type="radio"/> 12 - 12. Wilson's disease</td> </tr> <tr> <td><input type="radio"/> 5 - 5. DILI</td> <td><input type="radio"/> 13 - 13. Indeterminate</td> </tr> <tr> <td><input type="radio"/> 6 - 6. Hepatitis A</td> <td><input type="radio"/> 14 - 14. Other viruses</td> </tr> <tr> <td><input type="radio"/> 7 - 7. Hepatitis B (+/- delta)</td> <td><input type="radio"/> 15 - 15. Other</td> </tr> <tr> <td><input type="radio"/> 8 - 8. Hepatitis C</td> <td></td> </tr> </table>	<input type="radio"/> 1 - 1. Acetaminophen	<input type="radio"/> 9 - 9. Hepatitis E	<input type="radio"/> 2 - 2. Any ALI/ALF in pregnancy	<input type="radio"/> 10 - 10. Mushroom intoxication	<input type="radio"/> 3 - 3. Autoimmune hepatitis	<input type="radio"/> 11 - 11. Shock/ischemia	<input type="radio"/> 4 - 4. Budd-Chiari syndrome	<input type="radio"/> 12 - 12. Wilson's disease	<input type="radio"/> 5 - 5. DILI	<input type="radio"/> 13 - 13. Indeterminate	<input type="radio"/> 6 - 6. Hepatitis A	<input type="radio"/> 14 - 14. Other viruses	<input type="radio"/> 7 - 7. Hepatitis B (+/- delta)	<input type="radio"/> 15 - 15. Other	<input type="radio"/> 8 - 8. Hepatitis C	
<input type="radio"/> 1 - 1. Acetaminophen	<input type="radio"/> 9 - 9. Hepatitis E																	
<input type="radio"/> 2 - 2. Any ALI/ALF in pregnancy	<input type="radio"/> 10 - 10. Mushroom intoxication																	
<input type="radio"/> 3 - 3. Autoimmune hepatitis	<input type="radio"/> 11 - 11. Shock/ischemia																	
<input type="radio"/> 4 - 4. Budd-Chiari syndrome	<input type="radio"/> 12 - 12. Wilson's disease																	
<input type="radio"/> 5 - 5. DILI	<input type="radio"/> 13 - 13. Indeterminate																	
<input type="radio"/> 6 - 6. Hepatitis A	<input type="radio"/> 14 - 14. Other viruses																	
<input type="radio"/> 7 - 7. Hepatitis B (+/- delta)	<input type="radio"/> 15 - 15. Other																	
<input type="radio"/> 8 - 8. Hepatitis C																		

13	List DILI agent if applicable DB Name: [Q13]	<input type="text"/> (100 char.)
14	Specify other viruses if applicable DB Name: [Q14]	<input type="text"/> (100 char.)
15	Specify other diagnosis if applicable DB Name: [Q15]	<input type="text"/> (100 char.)
16	Last name of reviewing principal investigator: DB Name: [Q16]	<input type="text"/> (15 char.)
17	Date of PI review and affirmation: DB Name: [Q17]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
C	Comments DB Name: [zNotes]	<input type="text"/> (200 char.)

WebDCU™ ALFSG

**Annotated Form for CRF 34 [21 Day Status]
Form ID: 147 DB Table Name: F34**

No.	Item Description	Data Value
A	Date of assessment DB Name: [zFormDate]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
1	At 21 days post ALI or ALF admission (whichever comes first), what is the vital status of the subject? DB Name: [Q01]	<input type="radio"/> 1 - Alive <input type="radio"/> 2 - Dead <input type="radio"/> 99 - Unknown
B	Comments DB Name: [zNotes]	<input type="text"/> (250 char.)


WebDCU™ ALFSG

Annotated Form for CRF 37 [ALF-MBT Admission]
Form ID: 155 DB Table Name: F37 DB View Name: vF37

No.	Item Description	Data Value
55	Protocol under which this subject was enrolled DB Name: [Q55]	<input type="radio"/> 2 - ALFSG-MBT version 2 <input type="radio"/> 3 - ALFSG-MBT version 3 or higher
MBT Inclusion Criteria		
1	Is the subject 18 to 70 years of age? DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
56	Is the subject 18 to 80 years of age? DB Name: [Q56]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
MBT Exclusion Criteria		
2	Pre-existing New York Heart Association stage III / IV heart failure? DB Name: [Q02]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
3	Evidence of pre-existing chronic renal failure requiring hemodialysis? DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
4	Chronic hemodialysis prior to hospital admission? DB Name: [Q04]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
5	Severe obstructive lung disease (FEV ₁ <50% of predicted on previous spirometry)? DB Name: [Q05]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
6	Severe shock, defined as MAP <70 mmHg despite >15 µg/kg/min dopamine, >0.1 µg/kg/min epinephrine, or >0.1 norepinephrine µg/kg/min? DB Name: [Q06]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
7	Extensive small bowel resection (>50 cm)? DB Name: [Q07]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
8	Any evidence of upper GI bleeding at MBT study enrollment? DB Name: [Q08]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
57	Any evidence of upper GI bleeding at study enrollment requiring intervention <i>Endoscopy or RBC transfusion specifically for upper GI bleeding</i> DB Name: [Q57]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
9	Liver transplantation prior to MBT study enrollment? (Listing for LT does not preclude participation in the trial.) DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
10	Pregnancy or breastfeeding woman? (Pregnancy related non-APAP ALI or ALF may be considered for entry following the delivery of the baby and assuming the mother does not wish to breastfeed or collect breast milk)	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes


	during the study period.) DB Name: [Q10]	
11	Allergic to acetaminophen (such as Tylenol® or any other acetaminophen-containing medications)? DB Name: [Q11]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
12	Participation in other clinical studies evaluating other experimental treatments or procedures? (Participation in observatory studies is not an exclusion.) DB Name: [Q12]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
13	Patient in whom enteral drugs or fluids are contra-indicated? DB Name: [Q13]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
14	The patient either does not have an appropriately placed naso/orogastric tube in situ or cannot tolerate taking the drug preparation orally (200 ml)? DB Name: [Q14]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
15	Budd-Chiari Syndrome? DB Name: [Q15]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
16	Non-APAP ALI or ALF caused by malignancy? DB Name: [Q16]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
17	ALF caused by known or suspected herpes simplex virus requiring acyclovir therapy? DB Name: [Q17]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
18	Moderate or severe ARDS, as defined by Berlin Criteria? DB Name: [Q18]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
19	Subject received amiodarone or an HMG-CoA reductase inhibitor (Statin) in the 30 days prior to MBT study enrollment? DB Name: [Q19]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
58	Subject received amiodarone in the 30 days prior to MBT study enrollment DB Name: [Q58]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
59	APAP ALI DB Name: [Q59]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
20	Consumption of any food or beverage that contains caffeine in the 24 hours prior to MBT study enrollment? DB Name: [Q20]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
21	Consumption of alcohol in the 24 hours prior to MBT study enrollment? DB Name: [Q21]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
22	Smoking cigarettes in the 8 hours prior to MBT study enrollment? DB Name: [Q22]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
Consumption of any of the following drugs that may interfere with the metabolism of ¹³ C-Methacetin in the 48 hours prior to MBT study enrollment		






23	Acyclovir (Zovirax) <i>Consumption of this drug is not an exclusion criteria under protocol version 3 or higher</i> DB Name: [Q23]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
24	Allopurinol (Zyloprim, Aloprim) DB Name: [Q24]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
25	Carbamazepine (Tegretol, Tegretol XR , Equetro, Carbatrol, Epitol, Teril) DB Name: [Q25]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
26	Cimetidine (Tagamet) DB Name: [Q26]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
27	Ciprofloxacin (Cipro, Cipro XR, Proquin XR) DB Name: [Q27]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
28	Daidzein (Isoflavone) DB Name: [Q28]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
29	Disulfiram (Antabuse, Antabus) DB Name: [Q29]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
30	Echinacea (Echinacea purpurea, Echinacea angustifolia) DB Name: [Q30]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
31	Enoxacin (Penetrex) DB Name: [Q31]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
32	Famotidine (Pepcid) <i>Consumption of this drug is not an exclusion criteria under protocol version 3 or higher</i> DB Name: [Q32]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
33	Fluvoxamine (Luvox) DB Name: [Q33]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
34	Methoxsalen (Uvadex) DB Name: [Q34]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
35	Mexilitene (Mexitil) DB Name: [Q35]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
36	Montelukast (Singulair) DB Name: [Q36]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
37	Norfloxacin (Noroxin) DB Name: [Q37]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
38	Phenylpropanolamine (Proin) DB Name: [Q38]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
39	Phenytoin (Dilantin) DB Name: [Q39]	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes
40	Propafenone (Rythmol)	<input type="radio"/> 0 - No	<input type="radio"/> 1 - Yes



	DB Name: [Q40]	
41	Rifampin (Rifadin) DB Name: [Q41]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
42	Terbinafine (Lamisil) DB Name: [Q42]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
43	Ticlodipine (Ticlid) DB Name: [Q43]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
44	Thiabendazole (Mintezol) DB Name: [Q44]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
45	Verapamil (Calan, Isoptin) DB Name: [Q45]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
46	Zileuton (Zyflo) DB Name: [Q46]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
47	Oral contraceptives (Birth control pills) DB Name: [Q47]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
MBT Study Admission		
48	Does the subject have gastroparesis? DB Name: [Q48]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
49	Subject height DB Name: [Q49]	<input type="text"/>
50	Height unit DB Name: [Q50]	<input type="radio"/> 1 - inches <input type="radio"/> 2 - cm
51	Legally Authorized Representative (LAR) DB Name: [Q51]	<input type="radio"/> 1 - Medical power of attorney <input type="radio"/> 2 - Spouse <input type="radio"/> 3 - Child <input type="radio"/> 4 - Other
52	Specify LAR DB Name: [Q52]	<input type="text"/> <i>(250 char.)</i>
53	Date of consent/admission to MBT study DB Name: [Q53]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  <i>(dd-mmm-yyyy) Complete</i>
54	Time of consent/admission to MBT study DB Name: [Q54]	<input type="text"/> : <input type="text"/> <i>Complete Time (24hr)</i>
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> <i>(250 char.)</i>

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Annotated Form for CRF 39 [ALF-MBT Administration]
Form ID: 157 DB Table Name: F39 DB View Name: vF39

No.	Item Description	Data Value
a	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
1	MBT device number DB Name: [Q01]	<input type="text"/>
2	MBT test number DB Name: [Q02]	<input type="text"/>
Prior to MBT Substrate Administration Study Day Specific ALF-MBT Administration Criteria		
3	Is this the "Day 1" MBT test? DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
68	Informed consent was obtained prior to initiating study procedures DB Name: [Q68]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
9	Subject has not smoked on the day of the breath test, prior to the test DB Name: [Q09]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
10	Subject has not consumed alcohol in the past 24 hours DB Name: [Q10]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
11	Subject has not consumed caffeine within 24 hours prior to test DB Name: [Q11]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
5	Subject has not ingested oral medications in the last 1 hour DB Name: [Q05]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
6	Subject has not received general anesthesia in the last 24 hours DB Name: [Q06]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
7	There is no suspicion that aspiration may occur DB Name: [Q07]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
8	Subject is not on concurrent use of vasopressors DB Name: [Q08]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
12	Has the subject ingested acetaminophen-related medications (e.g. Tylenol) within the past 24 hours? DB Name: [Q12]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
13	Date of last acetaminophen ingestion DB Name: [Q13]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
14	Time of last acetaminophen ingestion DB Name: [Q14]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
15	Acetaminophen dose administered DB Name: [Q15]	<input type="text"/> mg
16	Is the subject currently on N- acetyl cysteine (NAC)? DB Name: [Q16]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
17	Route of NAC ingestion DB Name: [Q17]	<input type="radio"/> 1 - Oral <input type="radio"/> 2 - Continuous IV

18	Date of last meal or tube feeding (must be at least 6 hours prior to MBT test for solid food or 4 hours prior to MBT test for tube feeding) DB Name: [Q18]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
19	Time of last meal or tube feeding (must be at least 6 hours prior to MBT test for solid food or 4 hours prior to MBT test for tube feeding) DB Name: [Q19]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
Renal Replacement Therapy (RRT)		
20	Is the subject on RRT at the time of substrate and/or breath test administration? DB Name: [Q20]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
21	RRT start date DB Name: [Q21]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
22	RRT start time DB Name: [Q22]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
23	RRT stop date DB Name: [Q23]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
24	RRT stop time DB Name: [Q24]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
Molecular Adsorbent Recirculating System (MARS)		
63	Is the subject on MARS at the time of substrate and/or breath test administration? DB Name: [Q63]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
64	MARS start date DB Name: [Q64]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
65	MARS start time DB Name: [Q65]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
66	MARS stop date DB Name: [Q66]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
67	MARS stop time DB Name: [Q67]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
MBT Coma Grade and Vitals		
25	West Haven Scale Grade DB Name: [Q25]	<input type="radio"/> 0 - (0) Normal, no clinical signs or symptoms <input type="radio"/> 1 - (1) Trivial lack of awareness (euphoria or anxiety, shortened attention span, impaired performance of addition, inverted sleep pattern) <input type="radio"/> 2 - (2) Lethargy or apathy (minimal disorientation for time or place, inappropriate behavior, subtle personality change, impaired performance of subtraction, asterixis) <input type="radio"/> 3 - (3) Somnolence to semi-stupor, but responsive to verbal stimuli (confusion, gross disorientation) <input type="radio"/> 4 - (4) Coma (unresponsive to verbal or noxious stimuli)
26	Systolic blood pressure DB Name: [Q26]	<input type="text"/> mm Hg
27	Diastolic blood pressure DB Name: [Q27]	<input type="text"/> mm Hg
28	Heart rate DB Name: [Q28]	<input type="text"/> beats / min
29	Respiratory rate DB Name: [Q29]	<input type="text"/> breaths / min
30	Weight DB Name: [Q30]	<input type="text"/>
31	Weight unit	<input type="radio"/> 1 - lbs <input type="radio"/> 2 - kg

	DB Name: [Q31]	
32	Was blood drawn for acetaminophen adduct assay? DB Name: [Q32]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
33	Date of blood draw for acetaminophen adduct assay (must be prior to substrate ingestion) DB Name: [Q33]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
34	Time of blood draw for acetaminophen adduct assay (must be prior to substrate ingestion) DB Name: [Q34]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
35	Is subject receiving supplemental oxygen via nasal cannula? DB Name: [Q35]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
36	Amount of supplemental oxygen via nasal cannula DB Name: [Q36]	<input type="text"/> L / min
37	Is subject receiving supplemental oxygen via face mask / trach mask / ventilator? DB Name: [Q37]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
38	Amount of FiO2 being delivered DB Name: [Q38]	<input type="text"/> %
MBT Baseline Breath Test		
39	Start date of baseline breath test DB Name: [Q39]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
40	Start time of baseline breath test DB Name: [Q40]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
41	Stop time of baseline breath test DB Name: [Q41]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
42	Was the baseline breath test ever interrupted? DB Name: [Q42]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
43	Explain the baseline breath test interruption DB Name: [Q43]	<input type="text"/> (250 char.)
MBT Substrate Administration		
44	Is the subject ventilated? DB Name: [Q44]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
45	Route of administration of substrate DB Name: [Q45]	<input type="radio"/> 1 - Mouth <input type="radio"/> 2 - Naso-enteric tube <input type="radio"/> 3 - Orogastric tube
46	Substrate ingestion time DB Name: [Q46]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
69	Were the entire contents of the substrate ingested? (If the contents of the substrate were not entirely ingested, the MBT breath collection must not be initiated). DB Name: [Q69]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
MBT Breath Collection		
47	Was the MBT breath collection initiated? DB Name: [Q47]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes

48	Explain why the MBT breath collection was not initiated DB Name: [Q48]	<input type="text"/> (250 char.)
49	How is the breath being collected? DB Name: [Q49]	<input type="radio"/> 1 - Nasal cannula <input type="radio"/> 2 - Endotracheal tube
50	Does the subject have a nasogastric or dohoff tube in place? DB Name: [Q50]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
51	Does subject have an enteric tube in left nostril? DB Name: [Q51]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
52	Does subject have an enteric tube in right nostril? DB Name: [Q52]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
53	MBT breath collection start time DB Name: [Q53]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
54	MBT breath collection stop time DB Name: [Q54]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
55	Was the MBT breath collection ever interrupted? DB Name: [Q55]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
56	Explain the MBT breath collection interruption DB Name: [Q56]	<input type="text"/> (250 char.)
57	Was the MBT breath collection terminated early? DB Name: [Q57]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
58	Explain why the MBT breath collection was terminated early DB Name: [Q58]	<input type="text"/> (250 char.)
Post MBT Vitals		
59	Post MBT Systolic blood pressure DB Name: [Q59]	<input type="text"/> mm Hg
60	Post MBT Diastolic blood pressure DB Name: [Q60]	<input type="text"/> mm Hg
61	Post MBT Heart rate DB Name: [Q61]	<input type="text"/> beats / min
62	Post MBT Respiratory rate DB Name: [Q62]	<input type="text"/> breaths / min
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

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Annotated Form for CRF 41 [ALF-MBT Adverse Event]
Form ID: 159 DB Table Name: FAE DB View Name: vFAE

No.	Item Description	Data Value
This CRF is optional and should only be completed, if the subject experiences an Adverse Event.		
1	Adverse Event Name DB Name: [AEName]	<input style="width: 100%; height: 20px;" type="text"/> <i>(100 char.)</i>
<p>Grade: Please refer to Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03.</p> <p>Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:</p> <ul style="list-style-type: none"> • Grade 1 - Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. • Grade 2 - Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental Activities of Daily Living. • Grade 3 - Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care Activities of Daily Living. • Grade 4 - Life-threatening consequences; urgent intervention indicated. • Grade 5 - Death related to AE. 		
2	Grade DB Name: [Q02]	<input type="radio"/> 1 - Grade 1 <input type="radio"/> 2 - Grade 2 <input type="radio"/> 3 - Grade 3 <input type="radio"/> 4 - Grade 4 <input type="radio"/> 5 - Grade 5
3	Serious? DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
4	Relatedness to study intervention DB Name: [Q04]	<input type="radio"/> 1 - Unrelated <input type="radio"/> 2 - Unlikely <input type="radio"/> 3 - Reasonable possibility <input type="radio"/> 4 - Definitely
5	Date of onset DB Name: [Q05]	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <i>(dd-mmm-yyyy) Complete</i>
6	Time of onset DB Name: [Q06]	<input style="width: 30px;" type="text"/> : <input style="width: 30px;" type="text"/> <i>Complete Time (24hr)</i>
7	Outcome DB Name: [Q07]	<input type="radio"/> 1 - Resolved <input type="radio"/> 2 - Resolved w/ sequelae <input type="radio"/> 3 - Continuing- Follow up is required <input type="radio"/> 4 - Continuing at end of study (No follow up is required) <input type="radio"/> 5 - Continuing at time of death <input type="radio"/> 98 - Unknown
8	Date of resolution DB Name: [Q08]	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <i>(dd-mmm-yyyy) Complete</i>
9	Actions taken with study intervention (Check all that apply)	<input type="checkbox"/> Q09M1 - None <input type="checkbox"/> Q09M2 - Study intervention interrupted <input type="checkbox"/> Q09M3 - Study intervention discontinued <input type="checkbox"/> Q09M4 - Study intervention modified
Complete the remainder of the form for SAEs only.		
Q10	Describe event or problem DB Name: [Q10] SAS Name: [C17447]	<input style="width: 100%; height: 80px;" type="text"/> <i>(8000 char.)</i>
Q11	Relevant tests/ laboratory data,	

	including dates DB Name: [Q11] SAS Name: [C20395]	<input style="width: 100%; height: 60px;" type="text"/> <p><i>char.)</i> (1000)</p>
Q12	Other relevant history, including pre-existing medical conditions DB Name: [Q12] SAS Name: [C20397]	<input style="width: 100%; height: 60px;" type="text"/> <p><i>char.)</i> (1000)</p>
Q13	Last name of reporting site investigator DB Name: [Q13]	<input style="width: 90%; height: 20px;" type="text"/> <p><i>(50 char.)</i></p>
Q14	Date of reporting site investigator signature DB Name: [Q14]	<input style="width: 40px; height: 20px;" type="text"/> <input style="width: 40px; height: 20px;" type="text"/> <input style="width: 40px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p><i>(dd-mmm-yyyy) Complete</i></p>
C	General Comments: DB Name: [zNotes]	<input style="width: 100%; height: 40px;" type="text"/> <p><i>char.)</i> (250)</p>


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**Annotated Form for CRF 43 [ALF-MBT Lab Data]
Form ID: 161 DB Table Name: F43**

No.	Item Description	Data Value
1	Date of blood draw DB Name: [Q01]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
2	Time of blood draw DB Name: [Q02]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
3	WBC DB Name: [Q03]	<input type="text"/> x1000/mm ³
4	Platelet count DB Name: [Q04]	<input type="text"/> x1000/mm ³
5	Is the INR above the limit of detection? DB Name: [Q05]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Not done
6	INR value DB Name: [Q06]	<input type="text"/> 0.5 - 10.0
16	ALT DB Name: [Q16]	<input type="text"/> IU/L
17	AST DB Name: [Q17]	<input type="text"/> IU/L
7	Bilirubin DB Name: [Q07]	<input type="text"/> mg/dL
8	Creatinine DB Name: [Q08]	<input type="text"/> mg/dL
9	Phosphate DB Name: [Q09]	<input type="text"/> mg/dL
10	Is the lactate above the level of detection? DB Name: [Q10]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes <input type="radio"/> 99 - Not done
11	Lactate value DB Name: [Q11]	<input type="text"/> mmol/L
12	PH DB Name: [Q12]	<input type="text"/>
13	Standard bicarbonate DB Name: [Q13]	<input type="text"/> mEq/L
14	Arterial ammonia DB Name: [Q14]	<input type="text"/> umol/L
15	Venous ammonia DB Name: [Q15]	<input type="text"/> umol/L
C	General Comments: DB Name: [zNotes]	<input type="text"/> (250 char.)



WebDCU™ ALFSG

**Annotated Form for CRF 45 [ALFSG-ROTEM Admission]
Form ID: 170 DB Table Name: F45 DB View Name: vF45**




No.	Item Description	Data Value
ALFSG-ROTEM Exclusion Criteria		
ALFRotemVersion	ALFSG-ROTEM protocol version DB Name: [ALFRotemVersion]	<input type="radio"/> ALFSG-ROTEM version 1 <input type="radio"/> ALFSG-ROTEM version 2 or higher
1	Has the subject received plasma, platelet, or cryoprecipitate transfusions during the current admission for ALF, including at referring hospitals? DB Name: [Q01]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
2	Is the subject enrolled in the STOP-ALF protocol (ornithine phenylacetate)? DB Name: [Q02]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
ALFSG-ROTEM Study Admission		
3	Date of consent/admission to ALFSG-ROTEM study DB Name: [Q03]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
4	Time of consent/admission to ALFSG-ROTEM study DB Name: [Q04]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input style="width: 100%; height: 40px;" type="text"/> (250 char.)

WebDCU™ ALFSG

Annotated Form for CRF 46 [ALFSG-ROTEM Blood Collection]
Form ID: 171 DB Table Name: F46

No.	Item Description	Data Value
a	Data Collected? DB Name: [zDataCollected]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
1	Date of ALFSG-ROTEM blood draw DB Name: [Q01]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
2	Time of ALFSG-ROTEM blood draw DB Name: [Q02]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
3	Is the subject receiving NAC at the time of this ALFSG-ROTEM? DB Name: [Q03]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
11	ROTEM device number DB Name: [Q11]	<input type="text"/> (50 char.)
12	Is the subject on MARS at the time of blood collection / processing? DB Name: [Q12]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
4	Date of ALFSG-ROTEM sample processing DB Name: [Q04]	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
5	Time of ALFSG-ROTEM sample processing DB Name: [Q05]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
6	Type of ALFSG-ROTEM blood collection DB Name: [Q06]	<input type="radio"/> 1 - Daily <input type="radio"/> 2 - Post-transfusion
13	Sample processing deviation DB Name: [Q13]	<input type="radio"/> 1 - Sample processed outside of window <input type="radio"/> 2 - Study coordinator unavailable <input type="radio"/> 3 - Equipment / reagents unavailable <input type="radio"/> 4 - Device failed quality control <input type="radio"/> 96 - Other <input type="radio"/> 99 - None
14	Reason for sample processing deviation DB Name: [Q14]	<input type="text"/> (200 char.)
7	Concomitant anticoagulant medication at the time of ALFSG-ROTEM blood draw DB Name: [Q07]	<input type="radio"/> 0 - None <input type="radio"/> 1 - IV heparin <input type="radio"/> 2 - SC heparin <input type="radio"/> 3 - Enoxaparin <input type="radio"/> 4 - Aspirin <input type="radio"/> 5 - Warfarin <input type="radio"/> 6 - Clopidogrel <input type="radio"/> 7 - Other anticoagulant
8	Specify other concomitant anticoagulation medication at the time of ALFSG-ROTEM blood draw DB Name: [Q08]	<input type="text"/> (50 char.)
9	Any issues or complications?	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes


	DB Name: [Q09]	
10	Specify issue or complication DB Name: [Q10]	<input type="text"/> (200 char.)
<p>If Fibrinogen or PTT information is available on this study day, provide values in the 'General Comments' section below. Enter Fibrinogen results in the mg/dL unit of measurement and PTT in seconds.</p> <p>If coagulation testing was not performed on this study day, report this in the 'General Comments' section.</p>		
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

No.	Item Description	Data Value
1	Complication event DB Name: [Q01]	<input type="radio"/> 1 - Bleeding <input type="radio"/> 2 - Thrombotic
2	Complication date DB Name: [Q02]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
3	Approximate complication time DB Name: [Q03]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
4	Complication event type DB Name: [Q04]	<input type="radio"/> 1 - Spontaneous <input type="radio"/> 2 - Post-procedure
5	Bleeding location (Check all that apply)	<input type="checkbox"/> Q05M1 - Upper GI <input type="checkbox"/> Q05M2 - Lower GI <input type="checkbox"/> Q05M3 - CVC <input type="checkbox"/> Q05M4 - Liver <input type="checkbox"/> Q05M5 - Intracranial <input type="checkbox"/> Q05M96 - Other
6	Specify other bleeding location DB Name: [Q06]	<input type="text"/> (200 char.)
7	Thrombotic location (Check all that apply)	<input type="checkbox"/> Q07M1 - DVT <input type="checkbox"/> Q07M2 - Portal vein <input type="checkbox"/> Q07M3 - CVC / RRT catheter <input type="checkbox"/> Q07M4 - RRT circuit <input type="checkbox"/> Q07M5 - Ischemic stroke <input type="checkbox"/> Q07M6 - Myocardial infarction <input type="checkbox"/> Q07M96 - Other
8	Specify other thrombotic location DB Name: [Q08]	<input type="text"/> (200 char.)
9	Anticoagulant added to RRT circuit DB Name: [Q09]	<input type="radio"/> 1 - Heparin <input type="radio"/> 2 - Citrate <input type="radio"/> 3 - Prostacyclin <input type="radio"/> 4 - None <input type="radio"/> 96 - Other
10	Specify other anticoagulant added to RRT circuit DB Name: [Q10]	<input type="text"/> (200 char.)
12	RRT modality DB Name: [Q12]	<input type="radio"/> 1 - CVVH (continuous venovenous hemofiltration) <input type="radio"/> 2 - CVVHD (continuous venovenous hemodialysis) <input type="radio"/> 3 - CVVHDF (continuous venovenous hemodiafiltration) <input type="radio"/> 4 - IHD (intermittent)
13	RRT start date DB Name: [Q13]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
14	RRT start time DB Name: [Q14]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
15	RRT stop date DB Name: [Q15]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
16	RRT stop time DB Name: [Q16]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
17	Any complications of	

	RRT? DB Name: [Q17]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
18	Required intervention? DB Name: [Q18]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
19	Bleeding treatments (Check all that apply)	<input type="checkbox"/> Q19M0 - None <input type="checkbox"/> Q19M1 - Platelets <input type="checkbox"/> Q19M2 - FFP <input type="checkbox"/> Q19M3 - Cryoprecipitate <input type="checkbox"/> Q19M4 - RBCs <input type="checkbox"/> Q19M5 - Topical thrombin <input type="checkbox"/> Q19M6 - Tamponade <input type="checkbox"/> Q19M96 - Other
20	Specify other bleeding treatments DB Name: [Q20]	<input type="text"/> <i>(200 char.)</i>
21	Thrombotic anticoagulation treatments (Check all that apply)	<input type="checkbox"/> Q21M0 - None <input type="checkbox"/> Q21M1 - Enoxaparin <input type="checkbox"/> Q21M2 - Heparin <input type="checkbox"/> Q21M96 - Other
22	Specify other thrombotic anticoagulation treatments DB Name: [Q22]	<input type="text"/> <i>(200 char.)</i>
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

WebDCU™ ALFSG

Annotated Form for CRF 48 [ALFSG-ROTEM Transfusion/Infusion]
Form ID: 173 DB Table Name: F48

No.	Item Description	Data Value
1	Transfusion / infusion date DB Name: [Q01]	<input type="text"/> <input type="text"/> <input type="text"/>  (dd-mmm-yyyy) Complete
2	End time of transfusion / infusion DB Name: [Q02]	<input type="text"/> : <input type="text"/> Complete Time (24hr)
11	Did the transfusion occur prior to ALFSG-ROTEM enrollment? DB Name: [Q11]	<input type="radio"/> 0 - No <input type="radio"/> 1 - Yes
3	Transfusion / infusion type DB Name: [Q03]	<input type="radio"/> 1 - Platelets <input type="radio"/> 2 - FFP <input type="radio"/> 3 - Cryoprecipitate <input type="radio"/> 4 - RBCs <input type="radio"/> 5 - rFVIIa <input type="radio"/> 96 - Other
4	Specify other transfusion / infusion type DB Name: [Q04]	<input type="text"/> (200 char.)
5	Indication for treatment DB Name: [Q05]	<input type="radio"/> 1 - Bleeding <input type="radio"/> 2 - Prophylaxis
6	Reason for prophylaxis DB Name: [Q06]	<input type="radio"/> 1 - Central line <input type="radio"/> 2 - Dialysis catheter <input type="radio"/> 3 - ICP monitor <input type="radio"/> 4 - Liver biopsy <input type="radio"/> 5 - Abnormal lab value <input type="radio"/> 96 - Other procedure
13	Specify details of abnormal lab value DB Name: [Q13]	<input type="text"/> (200 char.)
7	Specify name of other procedure DB Name: [Q07]	<input type="text"/> (200 char.)
8	Volume of transfusion DB Name: [Q08]	<input type="text"/> units
9	Decision for treatment guided by? DB Name: [Q09]	<input type="radio"/> 1 - Standard labs <input type="radio"/> 2 - TEG / ROTEM <input type="radio"/> 3 - Physician discretion <input type="radio"/> 96 - Other
12	Specify other decision for treatment guided by DB Name: [Q12]	<input type="text"/> (200 char.)
10	CRF ID # corresponding to event (on Form 46: ALF-ROTEM Bleeding / Thrombotic Complication) DB Name: [Q10]	<input type="text"/>
C	Comments DB Name: [zNotes] SAS Name: [Comments]	<input type="text"/> (250 char.)

