

HALT-C Trial Q X Q

Sustained Virologic Responder Follow-up Ancillary Study: CTP Score

Form #715 Version A: 05/01/2008

Purpose of Form #715: The CTP Score form is used to calculate a patient's Child-Turcotte-Pugh Score, which grades the severity of liver disease.

When to complete Form #715: This form should be completed once for all patients who consented to the Sustained Virologic Responder Follow-up Ancillary Study.

SECTION A: GENERAL INFORMATION

- A1. Affix the patient ID label in the space provided.
 - If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. The visit number, SVR, is pre-printed on the form and does not need to be data entered.
- A4. Record the date the form was completed visit using MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

SECTION B: CHILD-TURCOTTE-PUGH SCORING FOR GRADING SEVERITY OF LIVER DISEASE

If the patient was not seen in person for the study visit, use the most recent physical exam and lab data available from the medical record. Physical exam results should not be older than 6 months.

- B1. Serum albumin (g/dL)
Obtain the serum albumin result from your local lab or the most recent results from the patient's local medical provider.
 - Enter a score of 1 if the serum albumin result was greater than 3.5.
 - Enter a score of 2 if the serum albumin result was exactly 2.8, exactly 3.5, or between 2.8 and 3.5.
 - Enter a score of 3 if the serum albumin result was less than 2.8.

If the serum albumin was not tested and cannot be retested, data enter –9 and override with an explanation: "test not performed, cannot be retested" or a similar clear succinct explanation.

B2. Serum total bilirubin (mg/dL)

Obtain the serum total bilirubin result from your local lab.

Use the first row of bilirubin scores for any patient who (a) does not have Gilbert's Syndrome, (b) does not have a hemolytic disorder, or (c) is not taking ribavirin.

- For these patients, enter a score of 1 if the serum total bilirubin result was less than 2.0.
- For these patients, enter a score of 2 if the serum total bilirubin result was exactly 2.0, exactly 3.0, or between 2.0 and 3.0
- For these patients, enter a score of 3 if the serum total bilirubin result was greater than 3.0.

Use the second row of bilirubin scores for any patient who (a) has Gilbert's Syndrome, (b) has a hemolytic disorder, or (c) is taking ribavirin. Any patient with Gilbert's syndrome should have this fact documented on Form # 3, Screening Medical History.

- For these patients, enter a score of 1 if the serum total bilirubin result was less than 4.0.
- For these patients, enter a score of 2 if the serum total bilirubin result was exactly 4.0, exactly 7.0, or between 4.0 and 7.0
- For these patients, enter a score of 3 if the serum total bilirubin result was greater than 7.0.

If the serum total bilirubin was not tested and cannot be retested, data enter –9 and override with an explanation: "test not performed, cannot be retested" or a similar clear succinct explanation.

B3. Prothrombin time (INR)

Obtain the prothrombin time result from your local lab. Prothrombin time results should be reported and used for calculations only as International Normalized Ratios (INR) because of variations in methods used and reference ranges for controls.

- Enter a score of 1 if the PT-INR result was less than 1.7.
- Enter a score of 2 if the PT-INR result was exactly 1.7, exactly 2.3, or between 1.7 and 2.3.
- Enter a score of 3 if the PT-INR result was greater than 2.3.

If the PT-INR was not tested and cannot be retested, data enter –9 and override with an explanation: "test not performed, cannot be retested" or a similar clear succinct explanation.

If the PT-INR cannot be completed or would be invalid because the patient is on anticoagulant therapy(e.g. coumadin), a default PT-INR score of "1" should be recorded. Put a field level comment stating: "Patient on coumadin".

B4. Ascites

If data of an imaging study is available, then the determination of ascites should be based on that imaging study. If a medical record of a recent abdominal imaging is not available, the PI should determine whether there is a history consistent with ascites.

If the patient is not being seen at the study site and the visit is completed by review of the medical record, and the medical record has no recent abdominal imaging, the PI should determine whether there is history consistent with ascites.

- Enter 1 if there was no evidence of ascites.
- Enter 2 if the patient had mild ascites (readily controlled by standard medical therapies).
- Enter 3 if the patient had severe ascites (difficult to control or uncontrollable by optimal, maximally tolerated medical therapies).

If the patient has ascites, complete Form #763 (Clinical Outcome), if applicable.

B5. Encephalopathy

If the patient is not being seen at the study site and the visit is completed by review of the medical record, and the medical record has no recent determination of whether the patient presented with encephalopathy, the PI should determine whether there is history consistent with encephalopathy.

- Enter 1 if the patient has no encephalopathy.
- Enter 2 if the patient has mild encephalopathy (easily controlled by standard medical therapies).
- Enter 3 if the patient has severe encephalopathy (difficult to control or uncontrollable by optimal, maximally tolerated medical therapies).

If the patient has hepatic encephalopathy, complete Form #763 (Clinical Outcome), if applicable.

B6. Total CTP Score

- Enter the sum of the scores for items B1 – B5. The possible range is 5 to 15.
- If there is a –9 entered for any score on items B1 – B5, the Total CTP score cannot be calculated. Record a –9 for the Total CTP score.

If the CTP score is 7 or higher, complete Form #763 (Clinical Outcome).

Child-Turcotte-Pugh Score for Grading Severity of Liver Disease

Modified Child-Turcotte-Pugh Score				
Variable	Units	# of points		
		1	2	3
Serum albumin	(g/dL)	>3.5	2.8-3.5	<2.8
Serum total bilirubin (No Gilbert's Syndrome; No hemolytic diseases; Not receiving ribavirin)	(mg/dL)	<2.0	2.0-3.0	>3.0
Serum total bilirubin (In presence of Gilbert's Syndrome, a hemolytic disorder [e.g., patients receiving ribavirin]) ‡	(mg/dL)	<4.0	4.0-7.0	>7.0
Prothrombin Time	(INR)	<1.7	1.7-2.3	>2.3
Ascites		None	mild*	severe+
Encephalopathy		None	mild*	severe+

albumin score
3.5 = 2

NO ribavirin
NO Gilbert's

Pt is on ribavirin
or has Gilbert's

Definition of Ascites from Protocol:
Abdominal fluid which is:
a. mild, moderate or marked on U/S
b. progressive on serial PE
c. requires diuretic therapy
Mild, barely detectable on PE needs U/S confirmation of mild, moderate or marked.

Minimal fluid around liver on Ultrasound

Is the ascites or encephalopathy mild or severe? The PI will make a clinical judgment.

*Mild means readily controlled by standard medical therapies.

+Severe means difficult to control or uncontrollable by optimal, maximally tolerated medical therapies.

Prothrombin time results should be reported and used for calculations only as International Normalized Ratios (INR), because of variations in methods used and reference ranges for controls (expressed in seconds).

‡ Note that if, in the opinion of the investigator, the patient has Gilbert's syndrome or a hemolytic disorder (e.g., patients receiving ribavirin) the level of the serum total bilirubin may be increased to as high as 3.99 mg/dL without considering the total bilirubin to be sufficiently elevated for the patient to receive a score of 2 in the CTP scoring system.

The score is calculated as the sum of the scores for albumin, bilirubin, prothrombin time, ascites and encephalopathy (range 5-15). Class A is defined as 5-6, class B 7-9 and class C 10-15.