

HALT-C Trial Q x Q

Endoscopy

Form # 23 Version A: 06/15/2000 (Rev. 12/21/2000)

Purpose of Form #23: The Endoscopy form is used to record the results of diagnostic endoscopy.

When to complete Form #23: This form should be completed for the following patients.

- **Lead-In Phase patients who are entering the Randomized Phase:** Week 24 visit (W24). An endoscopy procedure should be done at W24 if there has been no endoscopy performed within the previous 12 months. The endoscopy may be done up to four weeks after the end of the W24 visit window. If an endoscopy has been performed in the previous 12 months and source documentation is available, that information should be used to complete Form #23.
- **Express/Breakthrough/Relapser patients:** Baseline visit (R00). An endoscopy procedure should be done at R00 if there has been no endoscopy performed within the previous 12 months. The endoscopy may be done up to four weeks after the end of the R00 visit window. If an endoscopy has been performed in the previous 12 months and source documentation is available, that information should be used to complete Form #23.
- **Randomized patients:** Month 24 visit (M24) only if small, medium, or large varices were detected on the baseline endoscopy (as recorded on the W24 or R00 Form #23).
- **Randomized patients:** Month 48 visit (M48).

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. Enter the three-digit code corresponding to this visit.
- A4. Record the date of this visit using MM/DD/YYYY format.
- A5. Enter the initials of the person completing Section A of the form.

SECTION B: TO BE COMPLETED BY ENDOSCOPIST

- B1. Record the date of the endoscopy using MM/DD/YYYY format.
- Enter the 2 digit number for the month in the first 2 spaces provided (i.e., January = “01”, February = “02”, etc.) enter the 2 digit number for the day of the month in the second 2 spaces provided and the 4 digit number for the year in the final 4 spaces provided.
- B2. Was the endoscopy performed at a HALT-C clinical center?
- If the answer is YES, circle 1 and skip to Question B3.
 - If the answer is NO, circle 2 and continue to Question B2a.
- B2a. Record the name of the non-HALT-C facility where the endoscopy was performed. Forty characters (including punctuation and spaces) are provided.
- B3. Was the endoscopy normal?
- If the answer is YES, circle 1 and skip to Section F.
 - If the answer is NO, circle 2 and continue to Section C.

SECTION C: VARICES

C1. Was there evidence of esophageal varices?

Esophageal varices will be assessed in the distal 5 cm of the esophagus with air-insufflation of the esophagus.

- If the answer is YES, circle 1 and continue to Question C1a.
- If the answer is NO, circle 2 and continue to Question C2.

C1a. Use the following definitions to grade the size of the esophageal varices (corresponding to F1-F3 of the NIEC classification):

None (Grade 0):	No varices present.
Small (Grade 1):	Small, straight varices.
Medium (Grade 2):	Enlarged, tortuous varices which occupy less than 33% of the lumen of the esophagus.
Large (Grade 3):	Enlarged, tortuous varices which occupy more than 33% of the lumen of the esophagus.

- If the esophageal varices are Small, circle 1 and continue to Question C1b.
- If the esophageal varices are Medium, circle 2 and continue to Question C1b.
- If the esophageal varices are Large, circle 3 and continue to Question C1b.

C1b. Record the number of columns of varices seen. Continue to Question C1c.

C1c. Were there red signs?

Red signs: red wale marks, cherry red (hematocystic) spots, varix on varix.

- If the answer is YES, circle 1 and continue to Question C1d.
- If the answer is NO, circle 2 and continue to Question C2.

C1d. Use the following definitions to describe the type of red sign:

Red wale:	Red streaks along the long axis of the varices.
Cherry red (hematocystic) spot:	A blood blister along the axis of the varices.
Varix on varix:	A superficial vein overlying a varix.

- If red wale, circle 1 and continue to Question C2.
- If cherry red spot, circle 2 and continue to Question C2.
- If varix on varix, circle 3 and continue to Question C2.

C2. Was there evidence of gastric varices?

Gastric varices will be assessed and classified according to Sarin's classification.

Isolated gastric varices (IGV) type I: An isolated cluster of varices in the fundus of the stomach.

Isolated gastric varices (IGV) type II: Isolated varices in regions of the stomach other than in the fundus.

Gastro-esophageal varices (GOV) type I: Gastric varices in continuity with esophageal varices along the lesser curve of the stomach.

Gastro-esophageal varices (GOV) type II: Gastric varices in continuity with esophageal varices along the greater curve of the stomach.

- If the answer is YES, circle 1 and continue to Question C2a.
- If the answer is NO, circle 2 and continue to Section D.

C2a. Size of largest gastric varix:

- If the answer is <10 mm, circle 1 and continue to Question C2b.
- If the answer is \geq 10 mm, circle 2 and continue to Question C2b.

C2b. Red spot:

- If a red spot was present, circle 1 and continue to Question C2c.
- If a red spot was absent, circle 2 and continue to Question C2c.

C2c. Isolated gastric varices (IGV) type I:

- If the answer is YES, circle 1 and continue to Question C2d.
- If the answer is NO, circle 2 and continue to Question C2d.

C2d. Isolated gastric varices (IGV) type II:

- If the answer is YES, circle 1 and continue to Question C2e.
- If the answer is NO, circle 2 and continue to Question C2e.

C2e. Gastro-esophageal varices (GOV) type I:

- If the answer is YES, circle 1 and continue to Question C2f.
- If the answer is NO, circle 2 and continue to Question C2f.

C2f. Gastro-esophageal varices (GOV) type II:

- If the answer is YES, circle 1 and continue to Section D.
- If the answer is NO, circle 2 and continue to Section D.

SECTION D: PORTAL HYPERTENSIVE GASTROPATHY

D1. Was there evidence of portal hypertensive gastropathy?

Portal hypertensive gastropathy will be scored based on the definitions provided below (from Sarin's Portal Hypertensive Gastropathy Scoring System). If the patient has any of these symptoms, they are considered to have portal hypertensive gastropathy.

Mucosal mosaic pattern:	Small polygonal areas demarcated by a distinct white-to-yellow border and with a slight central bulge, which have a mosaic, fish scale-like appearance upon endoscopy.
Red marks:	Flat or slightly bulging red lesions seen in the gastric mucosa.
Gastral antral vascular ectasia (GAVE):	Presence of flat or slightly raised red stripe-like lesions radiating from the pylorus to the antrum and body of the stomach for a variable distance.

- If the answer is YES, circle 1 and continue to Question D1a.
- If the answer is NO, circle 2 and continue to Section E.

D1a. Use the following definitions to describe mucosal mosaic pattern:

Absent:	No mucosal mosaic pattern is present.
Minor:	The color of the mucosa is pink.
Severe:	There is diffuse erythema (redness) present.

- If the mucosal mosaic pattern is Absent, circle 0 and continue to Question D1b.
- If the mucosal mosaic pattern is Minor, circle 1 and continue to Question D1b.
- If the mucosal mosaic pattern is Severe, circle 2 and continue to Question D1b.

D1b. Use the following definitions to describe red marks. Black-brown spots represent old submucosal hemorrhage and should not be scored.

None:	No red marks are present.
Localized (Isolated):	Isolated discrete spots.
Diffuse (Confluent):	Confluent areas of submucosal hemorrhage.

- If there are No red marks, circle 0 and continue to Question D1c.
- If there are Localized or Isolated red marks, circle 1 and continue to Question D1c.
- If there are Diffuse or Confluent red marks, circle 2 and continue to Question D1c.

D1c. Gastral antral vascular ectasia?

Absent:	No gastral antral vascular ectasia lesions are present.
Present:	Presence of flat or slightly raised red stripe-like lesions radiating from the pylorus to the antrum and body of the stomach for a variable distance.

- If the answer is Present, circle 1 and continue to Section E.
- If the answer is Absent, circle 2 and continue to Section E.

SECTION E: OTHER FINDINGS

E1. Were there any other findings?

- If the answer is YES, circle 1 and continue to Question E1a.
- If the answer is NO, circle 2 and skip to Section F.

E1a. Describe the abnormal finding(s). Sixty characters (including punctuation and spaces) are provided.

SECTION F: SOURCE DOCUMENTATION

Please specify and attach available type(s) of source documentation. A second copy of the photos must be sent to the DCC for central review. Refer to the Manual of Operations for more details.

A source document is a part of the patient's medical record which serves to validate data collected on the data entry forms. The appropriate source documents should be attached to this form with all identifying patient information, such as patient name and medical record number blacked out. The HALT-C trial requires the following source documents for each endoscopy:

F1. Is there a written report of the endoscopy findings?

- If the answer is YES, circle 1 and continue to Question F2.
- If the answer is NO, circle 2 and continue to Question F2.

F2. Are there pictures/photographs from the "Lower 5cm of esophagus looking down at GE junction"?

- If the answer is YES, circle 1 and continue to Question F3.
- If the answer is NO, circle 2 and continue to Question F3.

F3. Are there "Retroflex in stomach cardia, looking at fundus" pictures/photographs?

- If the answer is YES, circle 1 and continue to Question F4.
- If the answer is NO, circle 2 and continue to Question F4.

F4. Are there pictures/photographs "In mid-body of stomach looking toward antrum"?

- If the answer is YES, circle 1 and the form is complete.
- If the answer is NO, circle 2 and the form is complete.