

HALT-C Trial

Local Lab

Form # 30 Version C: 04/22/2004

SECTION A: GENERAL INFORMATION

A1. Affix ID Label Here → [ ]

A2. Patient initials: \_ \_ \_

A3. Visit number: \_ \_ \_

A4. Date form completed: MM / DD / YYYY \_ \_ / \_ \_ / \_ \_ \_ \_

A5. Initials of person completing form: \_ \_ \_

A6. Date of blood draw: \_ \_ / \_ \_ / \_ \_ \_ \_

SECTION B0. FASTING INFORMATION

B0a. Time of blood draw: (HH:MM) \_ \_ : \_ \_ AM ..... 1
PM ..... 2

B0b. Date patient last ate/drank: (MM/DD/YYYY) \_ \_ / \_ \_ / \_ \_ \_ \_

B0c. Time patient last ate/drank: (HH:MM) \_ \_ : \_ \_ AM ..... 1
PM ..... 2

SECTION B. COMPLETE BLOOD COUNT

When to complete Section B
Complete at all study visits, except for the 2nd screening visit.

B1. WBC \_ \_ . \_ x10^3/mm^3

B2. Neutrophils \_ \_ . \_ x10^3/mm^3

B3. Hematocrit \_ \_ . \_ %

B4. Hemoglobin \_ \_ . \_ (g/dL)

B5. Platelets \_ \_ . \_ x10^3/mm^3

Patient ID: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**SECTION C: SERUM CHEMISTRIES**

**When to complete Section C**

All patients: complete at screening (S00)

In addition:

- Lead-in patients: complete at baseline (W00) and W20.
- Express + Breakthrough/Relapser patients: complete at R00.
- Randomized phase: complete at M12, M18, M24, M30, M36, M42, M48.
- Week 20 responders: complete at W48, W60, W72.

C1. BUN                                    \_\_\_\_ \_\_\_\_ \_\_\_\_ (mg/dL)

C2. Creatinine                            \_\_\_\_ \_\_\_\_ . \_\_\_\_ (mg/dL)

C3. Glucose                                    \_\_\_\_ \_\_\_\_ \_\_\_\_ (mg/dL)

C4. Triglycerides                            \_\_\_\_ \_\_\_\_ \_\_\_\_ (mg/dL)

**SECTION D. SERUM URIC ACID**

**When to complete Section D**

All patients: complete at screening (S00).

In addition:

- Lead-in patients: complete at baseline (W00) and W20.
- Week 20 responders: complete at W48.
- Express + Breakthrough/Relapser patients: complete at R00.

D1. URIC ACID                            \_\_\_\_ \_\_\_\_ . \_\_\_\_ (mg/dL)

**SECTION E. LIVER CHEMISTRIES**

**When to complete Section E**

Complete at screening visit 1 and all subsequent visits, except Screening Visit 2.

- E1. AST (SGOT) \_\_\_\_\_ (U/L)  
 a. Upper limit of normal (from lab report): \_\_\_\_\_ (U/L)
- E2. ALT (SGPT) \_\_\_\_\_ (U/L)  
 a. Upper limit of normal (from lab report): \_\_\_\_\_ (U/L)
- E3. Alkaline phosphatase \_\_\_\_\_ (U/L)  
 a. Upper limit of normal (from lab report): \_\_\_\_\_ (U/L)
- E4. Total bilirubin \_\_\_\_\_ (mg/dL)
- E5. Albumin \_\_\_\_\_ (g/dL)
- E6. Globulin \_\_\_\_\_ (g/dL) **or** Total Protein \_\_\_\_\_ (g/dL)

**SECTION F. PROTHROMBIN TIME**

**When to complete Section F**

All patients: complete at screening (S00).

- In addition:
- Lead-in patients: complete at baseline (W00), W12, W20.
  - Express + Breakthrough/Relapser patients: complete at R00.
  - Randomized phase: complete at all study visits, M09 – M54.
  - Week 20 responders: complete at W36, W48, W60, W72.

F1. Prothrombin Time \_\_\_\_\_ (INR)

**SECTION G: TSH**

**When to complete Section G**

- In addition:
- Lead-in patients: complete at W12, W20.
  - Randomized phase: complete at M12, M18, M24, M30, M36, M42, M48.
  - Week 20 responders: complete at W36, W48, W72.

G1. TSH \_\_\_\_\_ mU/L

Patient ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**SECTION H: URINALYSIS**

**When to complete Section H**

In addition: - Randomized phase: complete at M12, M24, M36, M48.  
- Week 20 responders: complete at W48.

H1. Protein:                    0 ..... 1  
                                      1+ ..... 2  
                                      2+ ..... 3  
                                      3+ ..... 4  
                                      4+ ..... 5

H2. Heme:                    0 ..... 1  
                                      1+ ..... 2  
                                      2+ ..... 3  
                                      3+ ..... 4  
                                      4+ ..... 5

**SECTION I. PREGNANCY TESTING**

**When to complete Section I**  
**(Complete for female patients only)**

In addition: - Lead-in patients: complete at baseline (W00), W04, W08, W12, W16, W20, W24.  
- Express + Breakthrough/Relapser patients: complete at R00.  
- Randomized phase: complete at M09, M12.  
- Week 20 responders: complete at W30, W36, W42, W48.

I1. Pregnancy test:            Positive..... 1  
    Negative ..... 2  
    Not applicable..... -1