HALT-C Trial

Clinical Conditions at End of Study

Form # 16   Version A: 12/17/2004 (Rev. 04/13/2005)

SECTION A: GENERAL INFORMATION

A.1. Affix ID Label Here →   __ __ - __ __ __ - __

A.2. Patient initials: __ __ __

A.3. Visit number: __ __ __

A.4. Visit Date: MM / DD / YYYY   __ __ / __ __ / __ __ __ __

A.5. Initials of person completing form: __ __ __   PI Signature required.

SECTION B: CLINICAL CONDITIONS

ASK THE PATIENT ABOUT THE FOLLOWING CLINICAL CONDITIONS AND COMPARE WITH THE HISTORY OF THE CLINICAL CONDITIONS PRIOR TO THE BASELINE HALT-C VISIT.

B	Clinical Conditions	Has the patient ever been diagnosed with the condition?	Was the diagnosis present at enrollment in HALT-C?	Was it diagnosed after enrolling in HALT-C?	Has it become better or worse since enrollment diagnosis?
		a.	b.	c.	d.
1	Porphyria cutanea tarda	YES ..... 1 (go to column b) NO .... 2 (go to #2) DK....... -8 (go to #2)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #2) WORSE .... 2 (go to #2) NO CHANGE .. 3 (go to #2) DK.................. -8 (go to #2)

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B	Clinical Conditions	Has the patient ever been diagnosed with the condition? a.	Was the diagnosis present at enrollment in HALT-C? b.	Was it diagnosed after enrolling in HALT-C? c.	Has it become better or worse since enrollment diagnosis? d.
2	Diabetes, type 1	YES ..... 1 (go to column b) NO .... 2 (go to #3) DK....... -8 (go to #3)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #3) WORSE .... 2 (go to #3) NO CHANGE .. 3 (go to #3) DK.................. -8 (go to #3)
3	Diabetes, type 2	YES ..... 1 (go to column b) NO .... 2 (go to #4) DK....... -8 (go to #4)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #4) WORSE .... 2 (go to #4) NO CHANGE .. 3 (go to #4) DK.................. -8 (go to #4)
4	Essential mixed cryoglobulinemia with skin lesions	YES ..... 1 (go to column b) NO .... 2 (go to #5) DK....... -8 (go to #5)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #5) WORSE .... 2 (go to #5) NO CHANGE .. 3 (go to #5) DK.................. -8 (go to #5)
5	Essential mixed cryoglobulinemia with mononeuritis multiplex	YES ..... 1 (go to column b) NO .... 2 (go to #6) DK....... -8 (go to #6)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #6) WORSE .... 2 (go to #6) NO CHANGE .. 3 (go to #6) DK.................. -8 (go to #6)

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6	HCV-associated renal disease	YES ..... 1 (go to column b) NO .... 2 (go to #7) DK....... -8 (go to #7)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #7) WORSE .... 2 (go to #7) NO CHANGE .. 3 (go to #7) DK.................. -8 (go to #7)
7	Hyperthyroidism	YES ..... 1 (go to column b) NO .... 2 (go to #8) DK....... -8 (go to #8)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #8) WORSE .... 2 (go to #8) NO CHANGE .. 3 (go to #8) DK.................. -8 (go to #8)
8	Hypothyroidism	YES ..... 1 (go to column b) NO .... 2 (go to #9) DK....... -8 (go to #9)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #9) WORSE .... 2 (go to #9) NO CHANGE .. 3 (go to #9) DK.................. -8 (go to #9)
9	Lichen planus	YES ..... 1 (go to column b) NO .... 2 (go to #10) DK....... -8 (go to #10)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #10) WORSE .... 2 (go to #10) NO CHANGE .. 3 (go to #10) DK.................. -8 (go to #10)

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10	Vitiligo	YES ..... 1 (go to column b) NO .... 2 (go to #11) DK....... -8 (go to #11)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #11) WORSE .... 2 (go to #11) NO CHANGE .. 3 (go to #11) DK.................. -8 (go to #11)
11	Psoriasis	YES ..... 1 (go to column b) NO .... 2 (go to #12) DK....... -8 (go to #12)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #12) WORSE .... 2 (go to #12) NO CHANGE .. 3 (go to #12) DK.................. -8 (go to #12)
12	Non-Hodgkin's B cell lymphoma	YES ..... 1 (go to column b) NO .... 2 (go to #13) DK....... -8 (go to #13)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #13) WORSE .... 2 (go to #13) NO CHANGE .. 3 (go to #13) DK.................. -8 (go to #13)
13	Lymphoma, other	YES ..... 1 (go to column b) NO .... 2 (go to #14) DK....... -8 (go to #14)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #14) WORSE .... 2 (go to #14) NO CHANGE .. 3 (go to #14) DK.................. -8 (go to #14)

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		a.	b.	c.	d.
14	Sarcoidosis	YES ..... 1 (go to column b) NO .... 2 (go to #15) DK....... -8 (go to #15)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES........1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #15) WORSE .... 2 (go to #15) NO CHANGE .. 3 (go to #15) DK.................. -8 (go to #15)
15	Systemic lupus erythematosus	YES ..... 1 (go to column b) NO .... 2 (go to #16) DK....... -8 (go to #16)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES........1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #16) WORSE .... 2 (go to #16) NO CHANGE .. 3 (go to #16) DK.................. -8 (go to #16)
16	Rheumatoid arthritis	YES ..... 1 (go to column b) NO .... 2 (go to #17) DK....... -8 (go to #17)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES........1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #17) WORSE .... 2 (go to #17) NO CHANGE .. 3 (go to #17) DK.................. -8 (go to #17)
17	Sicca syndrome	YES ..... 1 (go to column b) NO .... 2 (go to #18) DK....... -8 (go to #18)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #18) WORSE .... 2 (go to #18) NO CHANGE .. 3 (go to #18) DK.................. -8 (go to #18)

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18	Myositis (auto-immune)	YES ..... 1 (go to column b) NO .... 2 (go to #19) DK....... -8 (go to #19)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #19) WORSE .... 2 (go to #19) NO CHANGE .. 3 (go to #19) DK.................. -8 (go to #19)
19	Non-correctable visual loss	YES ..... 1 (go to column b) NO .... 2 (go to #20) DK....... -8 (go to #20)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #20) WORSE .... 2 (go to #20) NO CHANGE .. 3 (go to #20) DK.................. -8 (go to #20)
20	Pulmonary disorders: infiltrates, bronchiolitis obliterans, interstitial pneumonitis	YES ..... 1 (go to column b) NO .... 2 (go to #21) DK....... -8 (go to #21)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #21) WORSE .... 2 (go to #21) NO CHANGE .. 3 (go to #21) DK.................. -8 (go to #21)
21	Pancreatitis	YES ..... 1 (go to column b) NO .... 2 (go to #22) DK....... -8 (go to #22)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #22) WORSE .... 2 (go to #22) NO CHANGE .. 3 (go to #22) DK.................. -8 (go to #22)

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22	Colitis: ulcerative, hemorrhagic/ischemic	YES ..... 1 (go to column b) NO .... 2 (go to #23) DK....... -8 (go to #23)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......... 1 (go to #23) WORSE .... 2 (go to #23) NO CHANGE .. 3 (go to #23) DK.................. -8 (go to #23)
23	Neuropsychiatric: bipolar disorder; suicidal ideation; relapse to drug addiction	YES ..... 1 (go to column b) NO .... 2 (END OF FORM) DK....... -8 (END OF FORM)	YES......1 (go to column d) NO........2 (go to column c) DK ....-8 (go to column c)	YES ....1 (go to column d) NO ....2 (go to column d) DK.........-8 (go to column d)	BETTER.......1 (END OF FORM) WORSE ....2 (END OF FORM) NO CHANGE 3 (END OF FORM) DK............. -8 (END OF FORM)

Signature of HALT-C Investigator: _____