



Cohort Protocol (Adult)

Data Collection Timeline

		Protocol Visits						ALT Flare [¶]	HBe or HBs Loss	Liver Biopsy	Pregnancy [‡]
		Year 1				Years 2-6					
		Baseline* [†]	Week 12	Week 24	Week 48*	Weeks 72,120,168,216,264	Weeks 96,144,192,240,288*				
Screen											
SL: Screening Log	CC										
EC: Enrollment Criteria		CC									
BC: Baseline Eval - Coordinator		CC									
BP: Baseline Eval – Patient		PT									
BI: Baseline Eval – Investigator		PI									
QL: Quality of Life		PT			PT		PT				
SA: Symptom Assessment		PT	PT	PT	PT	PT	PT	PT	PT	PT	PT
FQ: Fatigue Questionnaire					PT		PT ^{††}				
FW: Follow-up Eval 12-week			CC								
FF: Follow-up Evaluation				CC	CC	CC	CC				
SV: Special Visit Form			As needed					CC	CC	CC	CC
FR: ALT Flare Resolution			As needed - at resolution of ALT flare					PI			
LB: Liver Biopsy^			As clinically indicated (bxs performed prior to or during course of study)							CC	
FE: Follow-Up Events			As needed					CC	CC		
HC: HCC Form			As needed								
PQ: Pregnancy Questionnaire		CC									
PP: Pregnancy Pre-delivery			As needed – during 1 st or 2 nd trimester & at or after 28 weeks gestation								CC
PF: Pregnancy Follow-up			As needed – 12, 24, and 72 weeks post delivery								CC
Genetics, whole blood (ml) [#]		5									
Immunol. ancillary, whole blood (ml) ^{#§}			50	50				50 ^{**}		30	
EDTA, whole blood (ml) [#]		15			15		15	10	10	10	10
SST, whole blood (ml) [#]		45	30	30	35	30	35	10	10	10	10

* Obtain fasting labs at annual visits. If a special visit occurs within the window of an annual visit, complete the data forms, self-assessment questionnaires, and blood volumes required for the annual visit (if the annual visit has not already been completed)

[†] The baseline evaluation may be completed over 2 visits with the second visit anytime up to or at the Week 12 visit.

If patient was enrolled prior to 8/15/11, complete the baseline HQ at the next protocol visit.

[^] If test is performed at a time other than baseline or annual evaluation, complete the Symptom Assessment and Special Visit Evaluation forms at the time of testing.

^{††} Completed at Weeks 48, 144, and 240.

[#] Collect sample if patient consent provided.

[§] For acute or flares at baseline collect 10ml whole blood SST and 50ml required for immunology sample.

^{**} Collect whole blood sample within 1-2 weeks of onset of flare, at the special visit 4 weeks following onset of flare, and the first protocol visit after the patient returns to the routine follow-up schedule (or before start of therapy for hepatitis B).

[†] Acute hepatitis patients: follow ALT flare schedule for Special Visits and sample collection. FE and FR forms are not completed.

[‡] When a pregnancy visit is completed as a Special Visit the sample collection volume is left to the discretion of the investigator.

CC	Clinical Coordinator
PT	Patient
PI	Physician Investigator

**Adult Questionnaires - Translations**

Questionnaire	Translations	Interpreter/Assistance Allowed*
Baseline Evaluation – Patient	Spanish Chinese Korean	Yes
Symptom Assessment	Spanish Chinese Korean	Yes
Quality of Life	Spanish Chinese Korean Vietnamese	Yes
Health Behavior	Spanish Chinese Korean	Yes
Fatigue Questionnaire	Spanish	No
CES-D	–	Yes
AUDIT	–	Yes

*Best practice for non-English reading patients - if the questionnaire is available in their language the patient should be encouraged to complete the questionnaire in that language on their own.