

General Instructions

This form captures a premature discontinuation from study medication or study participation. Discontinuation from study medication and study participation can occur at the same or different times throughout the course of the study.

If the patient prematurely discontinues study medication every attempt should be made to have the patient continue study participation.

If the patient discontinues study medication and participation at the same time, complete one form. If the patient discontinues study medication and participation at different times, complete two forms, one for discontinuation of treatment and another for discontinuation of study.

Specific Instructions

Patient ID: Record the Patient ID in the top right hand corner.

Date Form Completed: Record the date the form was completed.

Time period: Check the box to indicate when the premature discontinuation occurs, during the treatment or the follow-up period.

Study medication/ participation: Check one or both boxes to indicate if the patient is discontinuing study medication or study participation.

If the patient discontinues study medication or a patient in the control group discontinues study participation prior to reaching the treatment week 24 timepoint, complete the equivalent of the Week 24 visit.

If the patient discontinues study medication or a patient in the control group discontinues study participation between the treatment week 24 and treatment week 48 timepoints, complete the equivalent of the Week 48 visit.

If the patient (treated or control) discontinues study participation during the follow-up period, complete the equivalent of the Week 96 visit (Follow-Up Week 48).

Reason disc'd med: Check all that apply to indicate the reason(s) for the premature discontinuation of study medication.

Virological non-response is defined as a failure to achieve at least 1- \log_{10} IU/mL decline in HBV DNA after the first 24 weeks of treatment by the quantitative HBV DNA assay, which will be confirmed on re-testing 4 weeks later.

Virological breakthrough is defined as a $> 1\text{-}\log_{10}$ IU/ml increase in HBV DNA level from nadir in a participant with an initial virological response or redetection of HBV DNA after becoming undetectable, and will be confirmed on re-testing 4 weeks later in a participant with either an initial or partial virological response and who has been compliant with study medications.

Last dose entecavir: Record the date that the last dose of entecavir was taken.

Last dose peg: Record the date of the last injection of peg-interferon.



Discontinuation of Treatment or Study (Pediatric)

- Reason disc'd study: Check all that apply to indicate the reason(s) for the premature discontinuation of study participation. If the reason of investigator discretion or other, specify the reason in the field provided.
- Date withdrawn: Indicate the date the patient withdrew from the study, e.g. date withdrew consent for further participation or is considered to be withdrawn from the study, e.g. last protocol visit for a patient lost to follow-up.
- Date of last contact: Indicate the date of last successful contact with the patient, whether in-person, via telephone, or email.