



MedWatch Form (Pediatric)

General Instructions

This form should be completed for every Serious Adverse Event (SAE) that occurs from the time the patient signs the study consent document through their completion of the study.

The relevant information pertaining to the SAE must be reviewed by a physician investigator before the event is reported to the DCC, and the physician investigator must make the determination as to whether the adverse event is serious in nature, related to the study medication (or protocol), and unexpected.

SAEs should be reported to the DCC within 24 hours of knowledge of the event.

Complete sections A, B, C, and E. Section D does not apply to this study.

Specific Instructions

Serious in nature: Indicate whether or not the adverse event meets the criteria of a SAE.

1. results in inpatient hospitalization or prolongs existing hospitalization
2. event is life-threatening
3. results in death
4. results in significant or permanent disability
5. requires medical intervention to prevent permanent damage
6. results in a congenital anomaly or birth defect

Related to medication: Indicate whether or not the adverse event is considered to be related to the study drug(s) or study protocol, in the opinion of the physician investigator. An event is considered unrelated if there is no reasonable causal relationship between the study drug(s) and the adverse event.

Unexpected: Indicate whether or not the adverse event is considered to be unexpected, in the opinion of the physician investigator. An event is considered to be unexpected if it is not mentioned in the investigational drug brochure or packet insert and it is not considered to be related to the natural history or progression of HBV disease.

Initial reporter: Enter the information for the person reporting the SAE on behalf of the physician investigator. The SAE should be reported only after the physician investigator has reviewed all information relevant to the event and has responded to the questions of "serious in nature", "related to study medication (or protocol)", and "unexpected".