DISCONTINUATION of TREATMENT or STUDY (DS)

DATA SECTION	COMPLETION INSTRUCTIONS
PURPOSE	To capture information related to premature discontinuation of treatment or study participation.
PERSON(S) RESPONSIBLE	Study Coordinator/study physician
SOURCE(S) OF INFORMATION	Patient or medical record
WHEN TO ADMINISTER FORM:	At the time of premature discontinuation from treatment or study. Only complete this form when all attempts to retain patient participation have been exhausted or at the time of an adverse event that precludes continued use of the study medication or further participation in the study.
	SPECIFIC INSTRUCTIONS:
PATIENT ID	Record the Patient ID number in the top left hand corner of the page.
DATE OF DISCONTINUATION	Record the date (month/day/year) that the decision is made to prematurely discontinue study medication or participation in the study. Complete the form as soon as the patient prematurely discontinues study medication or participation in the study.
TIME PERIOD	Record the time period that reflects the status of the patient in the study, as in the treatment or the follow-up phase of the study.
DISCONTINUATION TYPE	Check only one response to indicate whether the patient is prematurely discontinuing use of study medication, study participation, or both. If the patient prematurely discontinues study medication, make every effort to keep them in the study and follow them according to the follow-up visit schedule. If they agree to return for the follow-up visits, even though they prematurely discontinue study medication, check “Study medication”. If the patient prematurely discontinues study medication and refuses to continue participation in the study, check “Both”. If the patient is no longer taking study medication (they have successfully competed the treatment period or have previously discontinued study drug) and then the patient discontinues study participation during the follow-up period, check “Study participation”.
REASON FOR DISCONTINUATION	**Study Medication**: Record the reason(s) that study medication is prematurely discontinued and the date and time of the last dose of study medication taken by the patient before they discontinued treatment. Patient intolerance of study medication: patient cannot tolerate study medication as determined by physician or patient. Patient preference: patient prefers to prematurely discontinue study medication. Patient not compliant with study protocol (excluding pregnancy): in the opinion of the investigator, the patient should not continue to take study medication due to lack of compliance with study protocol. Patient pregnant or patient’s partner pregnant: if at anytime during the course of the study the patient or the patient’s partner become pregnant, study drug must be immediately discontinued.

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	Adverse event: occurrence of an adverse event that in the opinion of the investigator precludes further participation in the study. Patient taking medication(s) that conflicts with study medication: the patient is taking medication that has a known or potential interaction with the study medication. Other: any reason that is not already listed. If yes, record the reason in the space provided. Last Dose of Study Medication: record the date and time of the last dose of study medication taken. **Study Participation**: Record the reason(s) that study participation is prematurely discontinued and the date of the last successful in-person or telephone contact with the patient. Patient lost to follow-up: during the course of the study the patient cannot be located or contacted. Patient on alternative therapy: if at any time during the course of the study the patient begins to take another medication or therapy intended to treat their liver disease. Patient refuses to continue participation in study: during the course of the study, the patient either in writing or verbally indicates that they are not willing to continue participation in the study. Patient preference, other than refusal: if the patient discontinues study participation for any reason not included in the list, specify the reason for premature discontinuation. Date of last contact: record the date of the last contact with the patient, regardless of whether the contact was in person, via telephone, etc.
COMMENTS	Record any additional comments to provide information not already captured on the form.