Recording Interventional Trial Details - Include 20170907

How to Complete the Trial Details Section

In the various fields, specify the appropriate information. The following table describes the fields. An asterisk (*) indicates a required field.

Instructions for recording Trial Details

Field Label	Description/Instructions
Title*	Enter the official name of the protocol provided by the study principal investigator or sponsor. (Limit 4000 characters) For example: "Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate"
Trial Type*	Select **Interventional** (the default).
Primary Purpose*	1. Select the primary reason for conducting the trial. For valid values, refer to Primary Purpose Value Definitions. 2. If the primary purpose is **Other**, enter a detailed description of the trial's purpose in the text field provided. ⓘ The text field is displayed only after you have selected Other.

Secondary Purpose	1. Select one of the following reasons for conducting the trial.
	
	• **Ancillary-Correlative**. A trial that is secondary to another trial, or a type of trial that tests for a relationship between a condition and a potential causal factor of the condition.
	  ○ **Ancillary.** Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Report only those studies that can be linked to individual patient or participant data.
	  ○ **Correlative.** Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Report only those studies that can be linked to individual patient or participant data.
	• **Other**. Any purpose other than Ancillary-Correlative.
	
	2. If the secondary purpose is **Other**, enter a detailed description of the trial's secondary purpose in the text field provided.

Phase*	Select the phase or stage of the clinical trial as defined by the US FDA, from the drop-down list. For valid values, refer to Trial Phase Value Definitions.
Is this a Pilot?	Select **Yes** or **No** from the drop-down list to indicate whether the trial you are registering is a pilot trial.
Site Principal Investigator*	Click **Look Up Person** and follow the instructions in Looking Up Registered Persons to select the site principal investigator.