Recording Trial Details - Include 20170907

How to Complete the Trial Details Section

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

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"
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. Select **N/A** for observational and ancillary-correlative trials.
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.
Trial Type*	Select the trial type indicated in the protocol.

2. If you selected interventional as the trial type, select or enter the appropriate information in the following fields. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Primary Purpose*	a. Select the primary reason for conducting the trial. For valid values, refer to Primary Purpose Value Definitions. b. Optionally, if the primary purpose is **Other**, type a detailed description of the trial's purpose in the text field provided. The text field is displayed only after you have selected **Other**. The limit is 200 characters; the system counts down the character numbers as you type.
Secondary Purpose	a. 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. b. If the secondary purpose is **Other**, enter a detailed description of the trial's purpose in the text field provided.
Accrual Disease Terminology*	Click to select the disease terminology used to report subject accruals for this trial.

3. If you selected non-interventional as the trial type, select or enter the appropriate information in the following fields. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions

Non-Interventional Trial Type*	Select one of the following trial types:
	• **Observational**. Studies among cancer patients and healthy populations that involve no interventions or alteration of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.
	• **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.

Primary Purpose*	a. Select the primary reason for conducting the trial. For valid values, refer to Primary Purpose Value Definitions. b. If none of the values is appropriate, select **Other**, and then enter the same Non-Interventional Study Type you selected earlier, either ***`Observational`*** or ***`Ancillary -Correlative`*** , in the text field. ⓘ The text field is displayed only after you have selected **Other**. The limit is 200 characters; the system counts down the character numbers as you type.
Study Model Code*	a. Select the primary strategy for subject identification and follow-up. The following list provides valid values. • **Cohort**. Group of individuals, initially defined and composed, with common characteristics (e.g., condition, birth year), who are examined or traced over a given time period • **Case-control**. Group of individuals with specific characteristics (e.g., conditions or exposures) compared to group(s) with different characteristics, but otherwise similar • **Case-only**. Single group of individuals with specific characteristics • **Case-crossover**. Characteristics of case immediately prior to disease onset (sometimes called the hazard period) compared to characteristics of same case at a prior time (i.e., control period) • **Ecologic or community studies**. Geographically defined populations, such as countries or regions within a country, compared on a variety of environmental (e.g., air pollution intensity, hours of sunlight) and/or global measures not reducible to individual level characteristics (e.g., health care system, laws or policies median income, average fat intake, disease rate) • **Family-based**. Studies conducted among family members, such as genetic studies within families or twin studies and studies of family environment • **Other**. Any model not described above b. If the study model is **Other**, type a detailed description of the trial's study model in the text field provided. ⓘ The text field is displayed only after you have selected Other.
Time Perspective Code*	a. Select the temporal relationship of observation period to time of subject enrollment. The following list provides valid values. • **Prospective** - Look forward using periodic observations collected predominantly following subject enrollment • **Retrospective** - Look back using observations collected predominantly prior to subject selection and enrollment • **Cross-sectional** - Observations or measurements made at a single point in time, usually at subject enrollment • **Other** - Any time perspective not described above b. If the time perspective is **Other**, type a detailed description of the trial's time perspective in the text field provided. ⓘ The text field is displayed only after you have selected Other. The limit is 200 characters; the system counts down the character numbers as you type.
Site Principal Investigator*	Click **Look Up Person** and search for the principal investigator. For instructions, refer to Looking Up Registered Persons.