Recording Non-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. For example: "Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate"
Trial Type*	Select **Non-Interventional**.
Non-Interventional Trial Type*	Select one of the following trial types: 1. **Observational**. Studies among cancer patients and healthy populations that involve no interventions or alteration of the participants. 2. **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*	1. Select the primary reason for conducting the trial. For valid values, refer to Primary Purpose Value Definitions. 2. If your trial does not fall into one of these categories, select **Other**, and note the type of trial in the corresponding text box. ⓘ The text box is displayed only after you have selected **Other**.
Study Model Code*	1. 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 2. 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*	1. 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 2. 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.
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.
Site Principal Investigator*	Click **Look Up Person** and search for the principal investigator. See Looking Up Registered Persons.