Abstracting Non-Interventional Trial Design - Include 20170907

How to Abstract Non-Interventional Trial Design

1. Search for the trial of interest. For instructions, refer to Searching for Trials in PA.
2. In the search results, click the NCI Trial Identifier link for that trial. The Trial Identification page appears.
3. On the **Trial Identification** page, check out the trial. For instructions, refer to Checking In and Checking Out Trials. (This checkout step is optional for Super Abstractors.)
4. On the **Scientific Data** menu, under **Non-interventional Trial Design**, click Design Details. The Non-Interventional Trial Design - Design Details page appears.
5. In the various fields, specify the appropriate information. The following table describes the fields. An asterisk (*) indicates a required field.

Field	Description/Instruction
Study Type*	Select **Non-Interventional**. (Selected by default)
Expanded Access?	If the trial is an Expanded Access trial, select **Yes**. Otherwise, select **No**. An Expanded Access trial describes the procedure for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in a controlled clinical study. Expanded Access records are used to register all types of non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access and parallel track. If you import an Expanded Access trial from ClinicalTrials.gov (whether via the Registration or PA web application), the system automatically sets this value to Yes. Otherwise, the default is No. The system does not include this attribute in the TSR, in the XML output to ClinicalTrials.gov, in the trial data sent to Cancer.gov, or in the set of trials provided to the NCI Clinical Trials API. When a trial is listed as Expanded Access at the trial level in CTRP, the Expanded Access use of the drug/device will most likely be required by another interventional trial with an IND/IDE that is Available for Expanded Access. For instructions on configuring the separate Expanded Access fields as part of the IND/IDE for a trial, refer to Abstracting INDs and IDEs. Also, consider specifying each of these trials as an Associated Trial for the other. For instructions, refer to Associating Trials.

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*	1. Select the primary reason for conducting the trial. For valid values, refer to Primary Purpose Value Definitions. 2. 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**.
Trial Phase*	Select the current phase of the trial. 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.

Study Model*	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*	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.
Biospecimen Retention	Select the DNA retention indicator from one of the following: • **None Retained** - No samples retained • **Samples With DNA** - Samples retained, with potential for extraction of DNA from at least one of the types of samples retained (e.g., frozen tissue, whole blood) • **Samples Without DNA** - Samples retained, with no potential for DNA extraction from any retained samples (e.g., fixed tissue, plasma)
Biospecimen Description	Specify all types of biospecimens to be retained (e.g., whole blood, serum, white cells, urine, tissue).
Number of Groups /Cohorts*	Enter the number of treatment groups/cohorts in the trial. Enter 1 for a single-group study. Many observational studies have one group /cohort; case control studies typically have two.
Target Enrollment*	Type the target number of subjects in the study. • Do not give a range. • Add the number of subjects in each arm or phase together to get the total enrollment if needed. • Use the informed consent document to help you to identify the target enrollment if the protocol is unclear.

6. Click **Save**.