Select the best option that fits your study. You may use the Definitions option if you are unsure of the type of study design. If your study falls into multiple categories, select the primary model and then within the model description field, provide additional details.

Select only one: This field is for studies that involve drugs and/or biological products ONLY. The definitions for each phase is consistent with the terminology in 21 CFR § 312.21 and 312.85.

Select the primary purpose that is aligned with the main objective of the intervention(s) being evaluated by the clinical trial. You may use the Definitions option located at the top of the page if you are unsure of what you should select.

You may use this section to provide additional details about an Interventional Study Model that is complicated. Note that this section is optional and should not be completed unless it adds value.

You may use this section to provide additional details about the Masking Description that is complicated. Note that this section is optional and should not be completed unless it adds value.

Enter the estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study. *Enrolled* means a participant’s, or their legally authorized representative’s, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for a study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.

If you have any additional questions, you may contact the CTD group at 305-243-3195 or email us at ctgovum@miami.edu