



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 best option that fits your study. You may use the [Definitions](#) 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.

Edit Interventional Study Design

[Help](#) [Definitions](#)

* Study Type: Interventional

* § Primary Purpose: --Select--

* Study Phase: N/A
Use "N/A" for trials that do not involve drug or biologic products.

* § Interventional Study Model: --Select--

Model Description
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.

* § Number of Arms:

* § Masking:

- Participant
- Care Provider
- Investigator
- Outcomes Assessor
- None (Open Label)

Check all roles that are masked or check None (Open Label).

Masking Description
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.

* § Allocation: --Select--
Select N/A for single-arm studies.

* § Enrollment: Number of Subjects: type: --Select--

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

- Treatment
- Select--
- Treatment
- Prevention
- Diagnostic
- Supportive Care
- Screening
- Health Services Research
- Basic Science
- Device Feasibility
- Other

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.

Check all roles that are masked. Make sure that your selection is consistent with information recorded in related fields.

- Randomized
- Select--
- N/A
- Randomized
- Non-randomized

- Select--
- Select--
- Anticipated
- Actual

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. **Note:** "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