Trial Phase Value Definitions

When you specify trial data in CTRP, the system requires you to specify the phase of investigation, as defined by the US FDA for trials involving investigational new drugs. The following table provides a definition of each phase and maps the ClinicalTrials.gov values to the CTRP values:

CTRP Phase Value	ClinicalTrials.gov Phase Value	Definition
Early Phase I	Early Phase 1 (Formerly listed as "Phase 0")	Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See FDA guidance on exploratory IND studies for more information.
I	Phase 1	Includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and /or patients.
I/II	Phase 1/Phase 2	Trials that are a combination of phases 1 and 2.
II	Phase 2	Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in participants with the disease or condition under study and to determine the common short-term side effects and risks.
II/III	Phase 2/Phase 3	Trials that are a combination of phases 2 and 3.
III	Phase 3	Includes trials conducted after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug.
IV	Phase 4	Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use.
NA	N/A	Trials without phases (for example, studies of devices or behavioral interventions).