## 4.1.d Study Phase

A close up of a sign

Description automatically generated

***Guidelines***

1. *Required for clinical trials only*
   1. ***Format****: Drop Down List. Must select one of the following (Early Phase I (Phase 0), Phase 1, Phase 1 / 2, Phase 2, Phase 2 /3, Phase 3, Phase 4, and Other)*
2. *References*
   1. [*https://clinicaltrials.gov/ct2/about-studies/glossary*](https://clinicaltrials.gov/ct2/about-studies/glossary)
   2. [*https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=45832*](https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=45832)
   3. [*https://prsinfo.clinicaltrials.gov/definitions.html#StudyPhase*](https://prsinfo.clinicaltrials.gov/definitions.html#StudyPhase)

*Clinical Trial Study Phase Definitions are described below.*

## Definitions:

**Phase**

The stage of a clinical trial studying a drug or biological product, based on definitions developed by the Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4.

**Early Phase 1 (or Phase 0)**

A phase of research used to describe exploratory trials conducted before traditional phase 1 trials to investigate how or whether a drug affects the body. They involve very limited human exposure to the drug and have no therapeutic or diagnostic goals (for example, screening studies, microdose studies).

**Phase 1**

A phase of research to describe clinical trials that focus on the safety of a drug. They are usually conducted with healthy volunteers, and the goal is to determine the drug's most frequent and serious adverse events and, often, how the drug is broken down and excreted by the body. These trials usually involve a small number of participants.

**Phase 1/2**

A study that tests the safety, side effects, and best dose of a new treatment. Phase I/II clinical trials also test how well a certain type of cancer or other disease responds to a new treatment. In the phase II part of the clinical trial, patients usually receive the highest dose of treatment that did not cause harmful side effects in the phase I part of the clinical trial. Combining phases I and II may allow research questions to be answered more quickly or with fewer patients.

**Phase 2**

A phase of research to describe clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

**Phase 2/3**

A study that tests how well a new treatment works for a certain type of cancer or other disease and compares the new treatment with a standard treatment. Phase II/III clinical trials may also provide more information about the safety and side effects of the new treatment. Combining phases II and III may allow research questions to be answered more quickly or with fewer patients.

**Phase 3**

A phase of research to describe clinical trials that gather more information about a drug's safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. These studies typically involve more participants.

**NIH-Defined Phase III Clinical Trial**

An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

**Phase 4**

A phase of research to describe clinical trials occurring after FDA has approved a drug for marketing. They include postmarket requirement and commitment studies that are required of or agreed to by the study sponsor. These trials gather additional information about a drug's safety, efficacy, or optimal use.

**N/A**

Trials without phases (for example, studies of devices or behavioral interventions).