



Understanding Clinical Research

Clinical trials are conducted to collect data evaluating the **safety** and **benefit** (efficacy) of a new drug in development. Research is typically conducted in four separate phases.

PHASE I

Phase I trials are the first set of studies with human participants, designed to assess the safety and tolerability of a drug. These monitor how a drug interacts with the body and help to determine correct dosage.



PHASE II

Phase II trials are designed to evaluate drug safety and benefit (efficacy) in people with the disease or condition being studied and determine the potential short-term adverse effects and risks associated with a drug.

PHASE III

Phase III trials measure drug safety and benefit (efficacy) and monitor for any adverse reactions. These studies are longer in duration and provide most of the safety data needed for regulatory approval.

PHASE IV

Phase IV trials are conducted once a drug has been approved by FDA during Post-Market Safety Monitoring and are designed to monitor for any adverse effects over a longer time period.

Why Participate in Clinical Research?

- ✓ Help future patients by contributing to research and science.
- ✓ Advance the understanding of a disease or condition.
- ✓ Gain access to potential therapies before they become available.

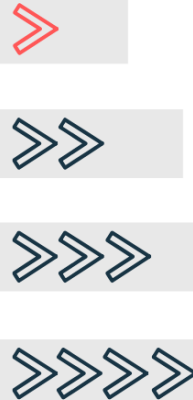


Understanding Clinical Research

70%

*of Phase I drugs
move on to a
Phase II trial.*

Clinical trials are conducted to collect data evaluating the **safety** and **benefit** (efficacy) of a new drug in development. Research is typically conducted in four separate phases.



What is a Phase I Clinical Trial?

Phase I trials are the first set of studies with human participants, designed to assess the safety and tolerability of a drug. These monitor how a drug interacts with the body and help to determine correct dosage.



Can include just a few or a hundred people.



Studies how a drug is absorbed, metabolized and excreted.



Can last several months.

Why Participate in Clinical Research?

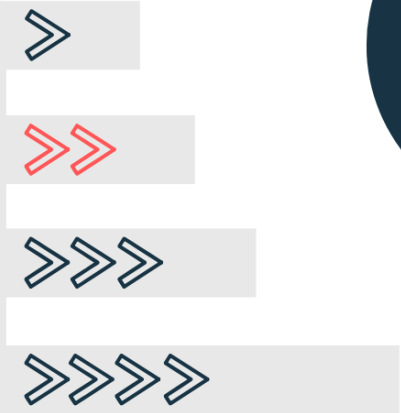
- ✓ Help future patients by contributing to research and science.
- ✓ Advance the understanding of a disease or condition.
- ✓ Gain access to potential therapies before they become available.



Understanding Clinical Research

33%
of Phase II drugs
move on to a
Phase III trial.

Clinical trials are conducted to collect data evaluating the **safety** and **benefit** (efficacy) of a new drug in development. Research is typically conducted in four separate phases.



What is a Phase II Clinical Trial?

Phase II trials are designed to evaluate drug safety and benefit (efficacy) in people with the disease or condition being studied and determine the potential short-term adverse effects and risks associated with a drug.



Can include just a few or several hundred people.



A placebo can be introduced.



Can last several months to two years.

Why Participate in Clinical Research?

- ✓ Help future patients by contributing to research and science.
- ✓ Advance the understanding of a disease or condition.
- ✓ Gain access to potential therapies before they become available.

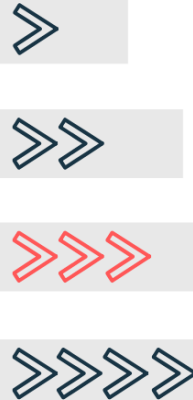


Understanding Clinical Research

25-30%

*of Phase III drugs
move on to a
Phase IV study.*

Clinical trials are conducted to collect data evaluating the **safety** and **benefit** (efficacy) of a new drug in development. Research is typically conducted in four separate phases.



What is a Phase III Clinical Trial?

Phase III trials measure drug safety and benefit (efficacy) and monitor for any adverse reactions. These studies are longer in duration and provide most of the safety data needed for regulatory approval.



Can include a few hundred to a few thousand people.



Sometimes known as pivotal studies.



Can last several (1-4) years.

Why Participate in Clinical Research?

- ✓ Help future patients by contributing to research and science.
- ✓ Advance the understanding of a disease or condition.
- ✓ Gain access to potential therapies before they become available.