

CANCER EXPLAINED PRESENTS

A PLAIN-LANGUAGE GUIDE

UNDERSTANDING TRIAL PHASES

What Phase 1, 2, 3, and 4 actually mean

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A CANCER EXPLAINED HANDOUT · BASED ON **NCI** · UPDATED **2026-07-05**
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Understanding Trial Phases

What Phase 1, 2, 3, and 4 actually mean

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1 Phase 1 — Is it safe?

- [ ] Small groups of people, usually 15 to 30.
- [ ] Finds a safe dose, how the treatment should be given, and what side effects appear.
- [ ] Participants are monitored very closely.

2 Phase 2 — Does it work?

- [ ] Usually fewer than 100 people with a specific cancer type.
- [ ] Studies whether the treatment has an effect against that cancer while continuing to track safety.

3 Phase 3 — Is it better than what we have?

- [ ] Hundreds to thousands of participants, often at many hospitals.
- [ ] Compares the new approach with the current standard treatment, usually by random assignment.
- [ ] Positive Phase 3 results are the usual basis for FDA approval.

4 Phase 4 — What happens long-term?

- [ ] Runs after a treatment is approved and in use.
- [ ] Tracks long-term safety, side effects, and benefits in much larger groups.

THE BOTTOM LINE

Each phase answers a different question — ask your care team which phase a trial is in and what that means for you.

Sources: NCI: What are clinical trials? (cancer.gov/research/participate/clinical-trials/what-are-clinical-trials) · NCI: Clinical trials information (cancer.gov/research/participate/clinical-trials)

Learn more in plain language: cancerexplained.org/clinical-trials/how-they-work · **Updated:** 2026-07-05

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