



PHASES OF CLINICAL TRIALS

PHASE 1



This phase can be referred to “first in humans” since it is the first time the treatment is being tested on people. Testing is done on a small number of participants (100 or fewer). The goal of phase 1 is to determine the correct dosage, dosage schedule, how the treatment should be delivered, and potential side effects. The main purpose is to ensure no major safety issues are associated with the treatment. Many different tumor types can be included in phase 1 testing.

PHASE 2



This phase includes a specific patient population for whom the treatment is targeting. Testing is done on a larger number of participants (approximately 100). The main purpose is to monitor side effects and the effectiveness of the treatment.

PHASE 3



This phase includes randomized testing of the new treatment against the control group (people who do not receive the treatment). The results will be compared to the standard treatment. Testing is done on a greater number of participants (1000 or more).

PHASE 4



This phase takes place once the treatment has received approval. Once on the market, the treatment continues to be monitored in this phase.