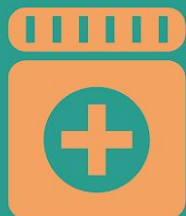


# THE NOBEL CONFERENCE®

GUSTAVUS ADOLPHUS COLLEGE

## Clinical Trials: What

Clinical trials are research studies that are done in humans. During drug development, researchers use numerous laboratory methods to investigate and predict the efficacy and safety of a given drug. While such methods are often state-of-the-art, they fail to comprehensively demonstrate how drugs interact with the human body. Clinical trials are used to make up for this shortcoming.



While the majority of cancer patients (>95%)<sup>1</sup> do not take part in clinical trials, new cancer treatments must pass clinical trial phases I-III in order to be approved by the FDA. Once on the market, drugs are monitored by the FDA to address any new concerns that arise.



## Clinical Trials: Who

# 22

the number of FDA approved anti-cancer therapeutics as of July 31st, 2018

## FDA Approval & Clinical Trials

## Clinical Trial Phases

## FDA Drug Approval

After a new drug/treatment is discovered and developed, the developers must submit an Investigational New Drug (IND) application in order to receive FDA approval for clinical trials. An IND must include animal and toxicity data, manufacturing plans, clinical trial protocol, and more. The FDA can approve the new drug or send it back to development. If the drug is approved, clinical trial phases I-III are continued until issues arise or the developer decides to file a New Drug Application (NDA). An NDA must include all study data, safety updates, patent information, and more. The FDA can approve the drug for the market or send it back to development. If marketed, the drug is monitored by the FDA to ensure its safety.

	Phase I	Phase II	Phase III	Phase IV
Purpose	Determine how drug interacts with body and dosage body can handle Expose acute side effects	Gather data to inform research questions regarding drug safety	Determine if drug delivers intended treatment to specific population Expose long-term side effects	Monitor drug safety after FDA approval (Post-Market Safety Monitoring)
Study Size	<100 volunteers	<300 volunteers	<3000 volunteers	>3000 volunteers
Participant Background	Healthy or have disease/condition	Have disease/condition	Have disease/condition	Have disease/condition
Duration	Several months	<2 years	1-4 years	n/a
Percentage Passing	70% of drugs pass	33% of drugs pass	25-30% of drugs pass	n/a