



Getting Started in Clinical Research: A Primer

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What Will Cover?

- Define clinical research
- Methods of clinical research
- Dissemination of clinical research

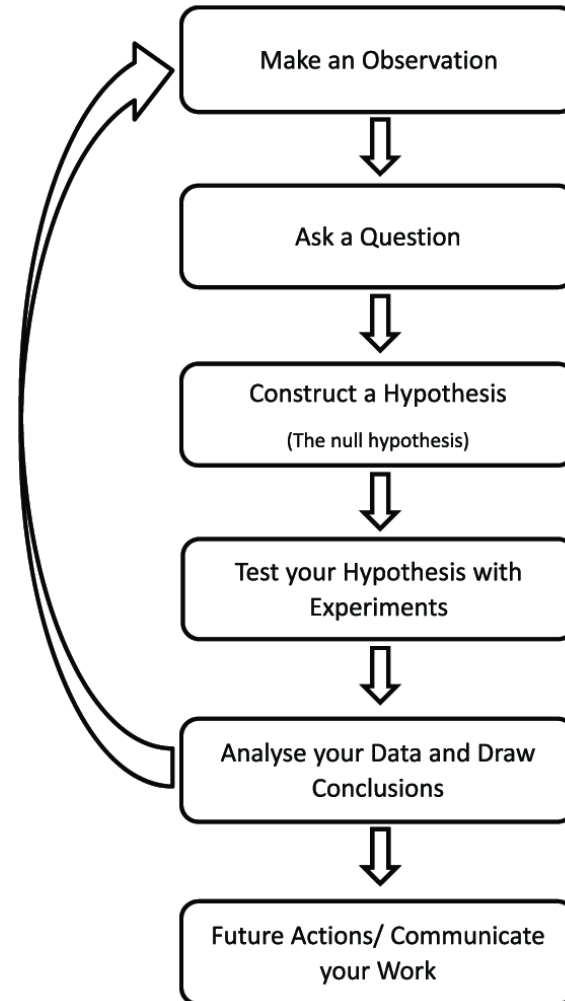


Learning Objectives

- Be able to:
 - Define clinical research and list different types of research (T0-T4)
 - Know the phases of a clinical trial (I-IV)
 - Describe differences between medical care and research
 - Define key concepts in clinical research
 - Know the main types of research study design and what types of research questions they answer
 - Discuss the common pitfalls of clinical research
 - Know how the results of research are disseminated

What Is Clinical Research?

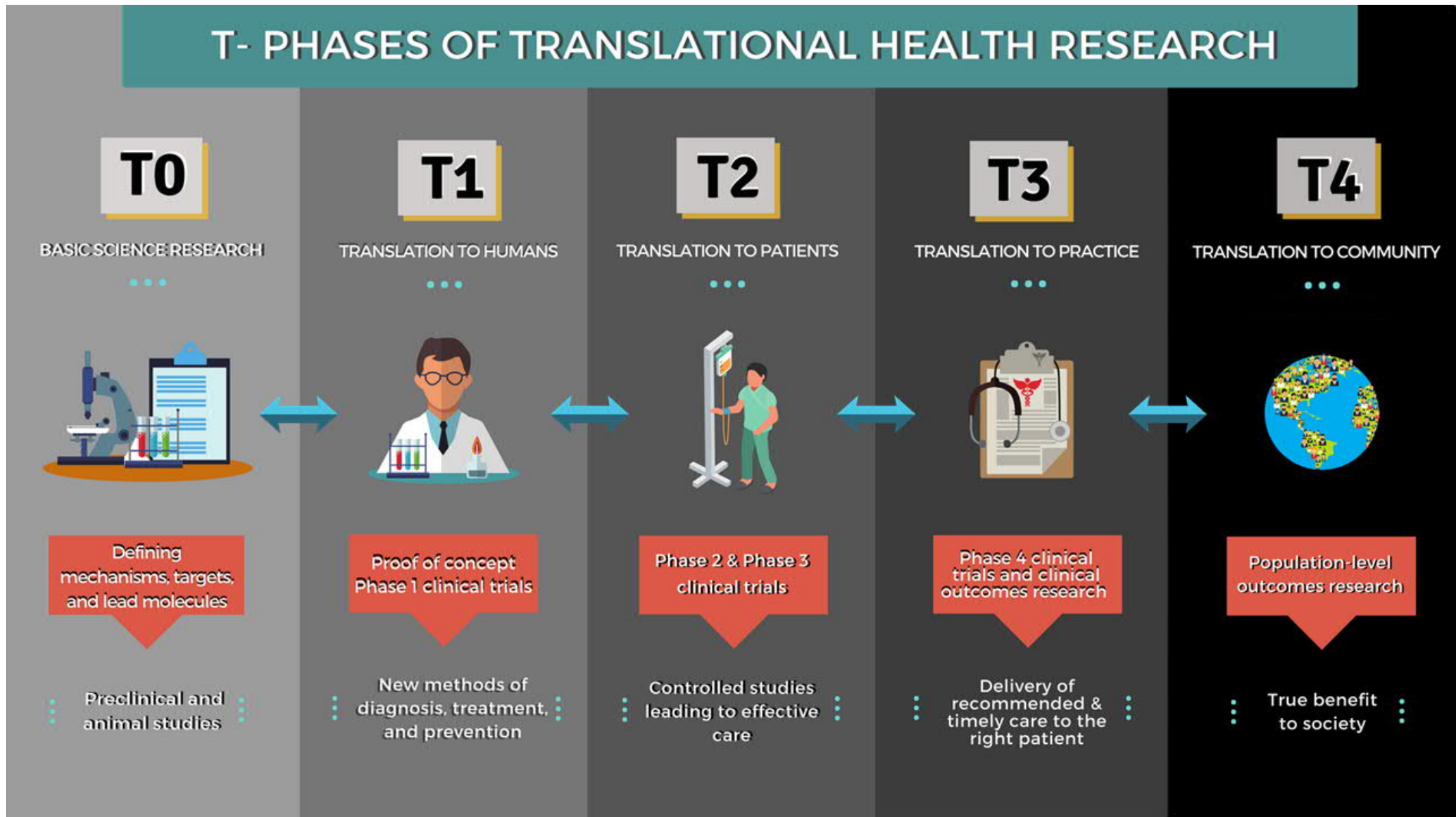
The Scientific Method



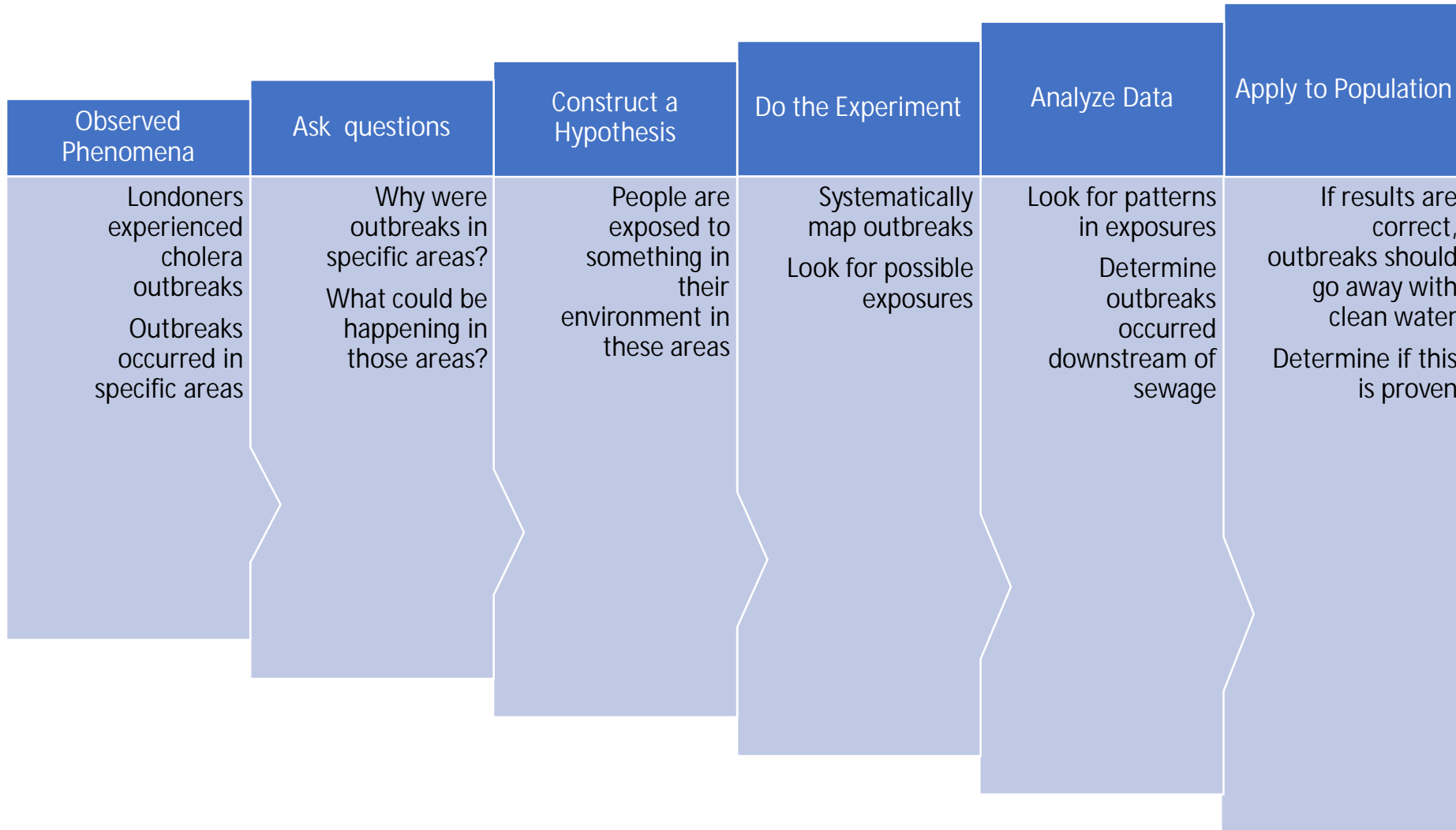
What Is Clinical Research?

- Study of health and illness in people using the scientific method
- Process of how we learn how to prevent, diagnose, and treat illness
- Involves human participants
- Helps translate basic research (done in labs) into new treatments and information to benefit patients
- There are many different types of clinical research
 - Clinical trials
 - Epidemiology, physiology and pathophysiology, health services, education, outcomes and mental health research

Types of Research



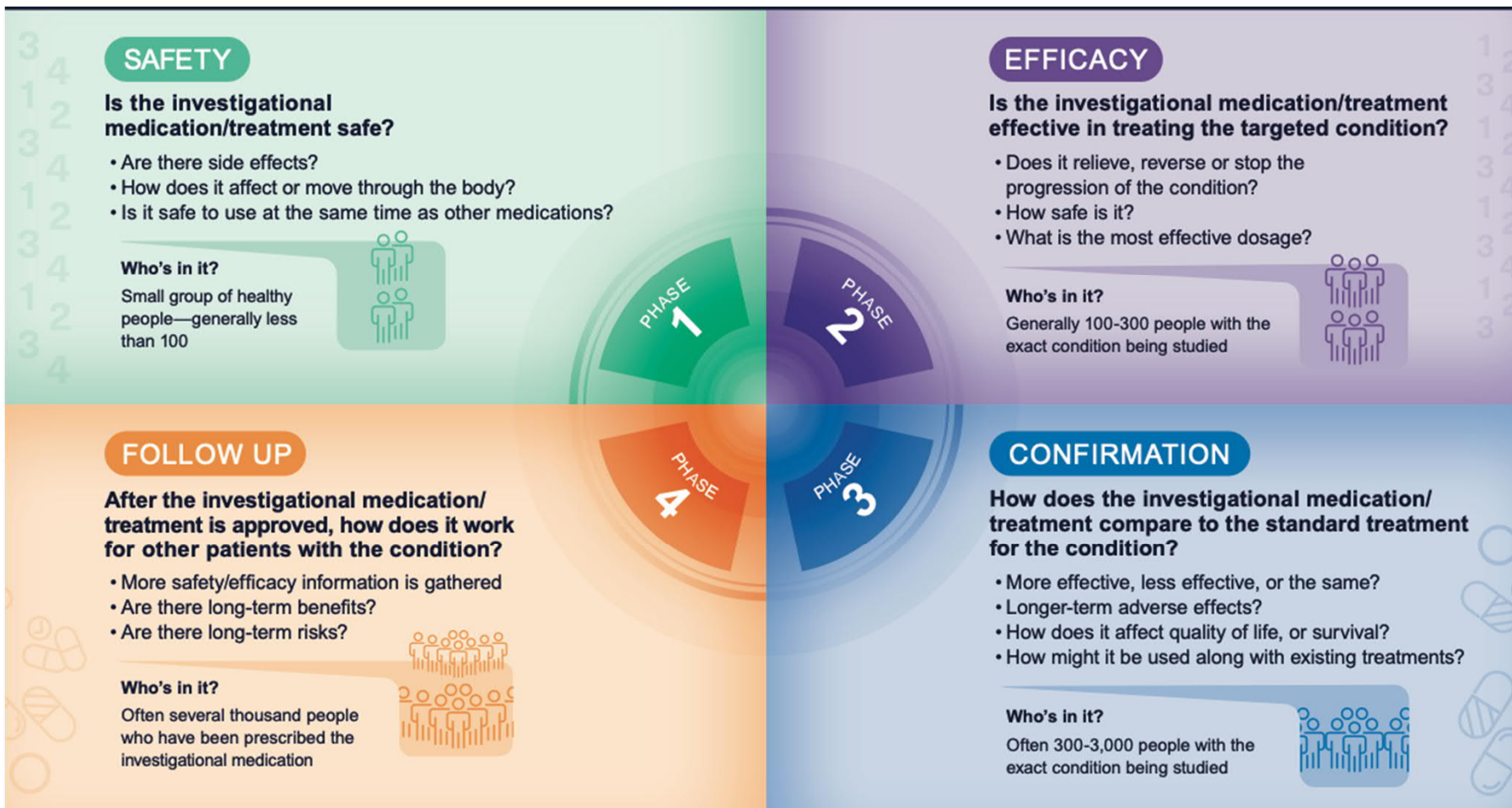
Epidemiology



What Are Clinical Trials?

- A specific type of clinical research
- An experiment designed to answer specific questions about possible new treatments or new ways of using existing treatments
- Done to determine whether new drugs or treatments are safe and effective
- Long, careful process which takes many years to complete
- First, doctors study a new treatment in the lab. Then they often study the treatment in animals. If a new treatment shows promise, doctors then test the treatment in people via a clinical trial

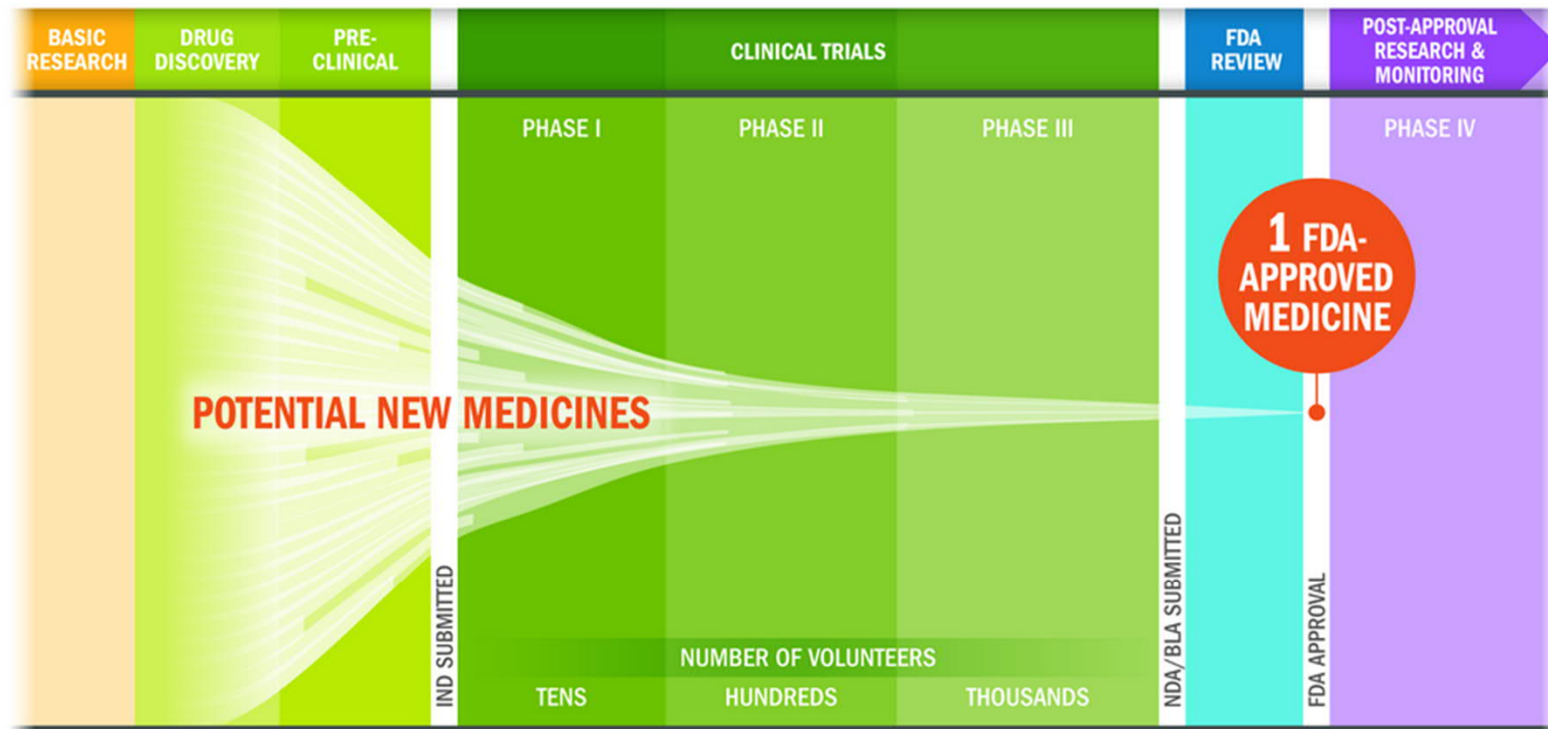
Phases Of Clinical Trials



Biopharmaceutical Research and Development

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

From drug discovery through FDA approval, developing a new medicine takes at least 10 years on average and costs an average of \$2.6 billion.* Less than 12% of the candidate medicines that make it into Phase I clinical trials will be approved by the FDA.

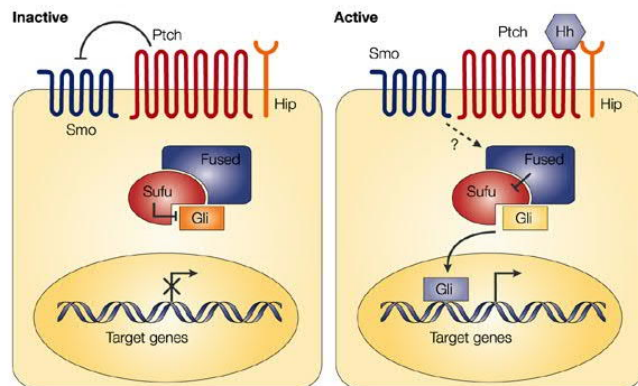
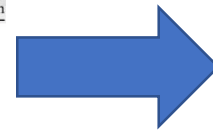
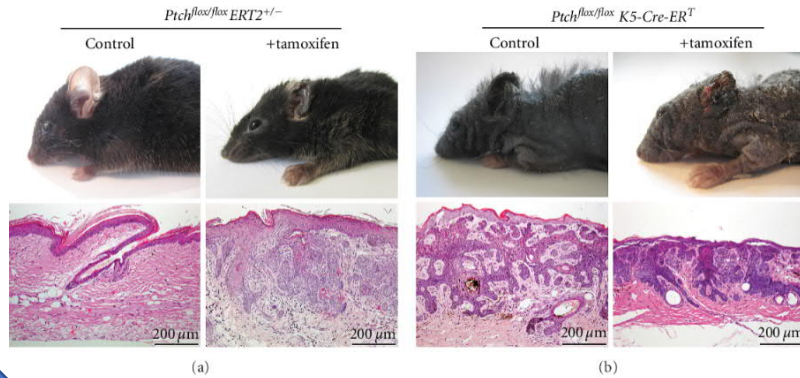


Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

* The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be \$2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug," Nov. 2014. Tufts CSDD & School of Medicine., and US FDA Infographic, "Drug Approval Process," <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> (accessed Jan. 20, 2015).

Basal Cell Carcinoma- From Surgery to Medication



Nature Reviews | Cancer



Clinical Research vs Medical Care

- People often confuse a clinical research or clinical trials with medical care
- Medical care means the doctor develops a plan of care for an individual patient using treatments thought to work
- In a clinical research study the research team must follow a set plan called the “study protocol”
- Clinical research is an experiment
 - In a placebo controlled clinical trial participants may not receive treatment
- By its nature, that means the answer to the research question is still unknown
- Participants may not directly benefit from participation

Key Concepts of Clinical Research