Clinical Research Associates, Inc.

- CRA is a clinical trial site. Our responsibilities are to **recruit** patients, **coordinate** clinical trials, **monitor** our patients' health and well-being, and **report** data to trial sponsors.
- Our primary goal is to **protect the safety and human rights** of our patients at all times. Second to that is to monitor a medicine's or device's **effectiveness**.

CLINICAL RESEARCH ASSOCIATES, INC.

CLINICAL RESEARCH ASSOCIATES, INC.

Understanding Clinical Trials

Clinical Trials: Three Phases, or Hurdles for Safety

PHASE 1

12 to 18 months

Trials to test whether the body can tolerate the product. Often involves comparing against a placebo with no active ingredients. Usually fewer than 100 people are involved in this study.

PHASE 2

Up to 2 years

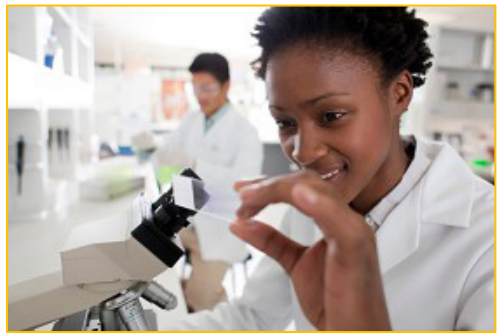
Identifying the maximum tolerated dose, the best dosing schedule, and if the immune system is having the desired responses. Usually a few hundred to a few thousand people.

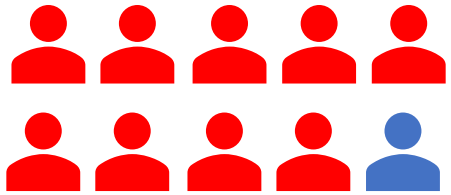
PHASE 3

2+ years

"Does this product prevent infections, or help to reduce the severity of disease?" Involves thousands of people, including some at risk of infection.

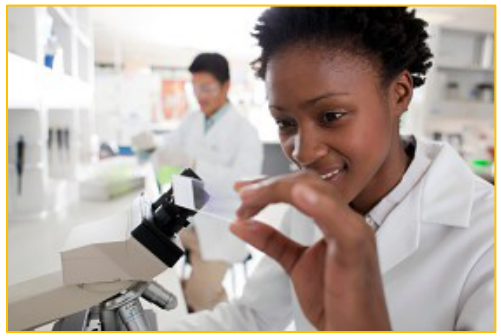
How Do We Know If Medicine Works?

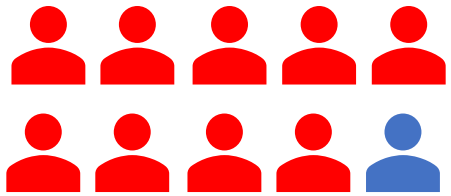




- In every trial phase, the medicine is experimental. At this point in development, we call it the **investigational product**.
- In a Phase 3 trial, we have lots of data about **safety.** However, we do not yet know if the IP will be **effective** to use in people (for example, if it will prevent infection or reduce the severity of illness).

How Do We Know If Medicine Works? Cont.





- Clinical trials are **event based**, meaning researchers are looking for the occurrence of an event.
- For example, researchers want to know if a person contracted the virus that a vaccine is supposed to prevent.
- If the event occurs, did the patient receive the **investigational product or a placebo**?
- The ratio of patients who contracted the virus and received the placebo vs patients who received the IP is known as the **efficacy rate**.
- A 90% efficacy rate means that 9 out of 10 people in the study who contracted the illness received the placebo.

CLINICAL RESEARCH ASSOCIATES, INC.

Enrolling in a Clinical Trial: Patient Rights, Responsibilities, and Experiences

Who Can Participate?

- In general, anyone who is healthy and well-managed on medications may be eligible to participate.
- Some studies only include patients who experience a certain condition, like treatments for cancer, heartburn, or migraines.
- Some individuals with **pre-existing conditions** may participate. This is because everyone needs to take medicine, and we need to know that the IP is safe and effective for everyone.

Who Should Stay Home?

- Many individuals with pre-existing conditions are **not allowed** to participate in clinical research. Each study has its own **inclusion and exclusion criteria.**
- The health and safety of every patient is the most important part of a research study.
- Some conditions and medications might make it impossible to tell if the vaccine works, while others can make it unwise for a person to participate.
- Each study has different criteria. The study recruiter will discuss these with you upon initial contact.

Joining and Leaving a Study is Voluntary. Always.

- It is your choice to join the study. Take your time in deciding.
- If you do want to join this study:
  - You can leave whenever you want for any reason.
  - You may only join one study at a time.
- This study may be of no direct benefit to an individual patient. However, you and others may benefit in the future from information learned in the study.

Patient Rights

- There is a history of human research being used to harm individuals and groups.
- The global medical community has formed rules for conducting clinical trials under severe penalty.
  - **Nuremburg Code**, 1947
  - **Declaration of Helsinki**, 1964
  - **Belmont Report**, 1978
- There are several levels of research patient protections, from federal governmental oversight and regulations (CFR) to independent organizations (IRBs or ethics boards).

Patient Rights Cont.:

- You have rights *and* responsibilities if you join this study. We review these with patients thoroughly upon their initial visit during the **Informed Consent** process.
- During Informed Consent, the study coordinator will outline the **events of the trial, along with potential benefits, risks**, **and contact information** for follow up. Every patient and research site keeps a copy of the informed consent form.
- Every clinical trial investigator, coordinator, and associate must undergo training for **Good Clinical Practices**. GCP is the international ethical, scientific, and practical standard to which all clinical research is conducted.

What It's Like to Be a Patient

- We will monitor your health. This includes:
  - A **physical exam** on your first visit, including checking your weight, temperature, blood pressure, heart & lungs.
  - Talking to you about your **health history** and discussing the medicines you take.
  - **Labs**: urine, blood, nasal swab, and other basic health screens.

What It's Like to Be a Patient, Cont.

- 24-7 Access. You can call us any time to discuss serious health issues.
- **Study-Related Care:** Some studies provide additional health care to patients. For example, a heartburn study will provide an endoscopy at no cost, and patients will receive medicine for 20 weeks following the control period.
- **Compensation** is provided to offset travel, time-off, or childcare expenses. Compensation amount is determined by an Independent Review Board.

Why Should Someone Join a Clinical Trial?

- Clinical trials help advance life saving medicine.
- The only way we can know if a medicine works for everyone is if we test it with everyone.
- Your participation may help someone else feel safe taking medicine in the future.
- Study Related Care: Can be beneficial, but ends when the study ends.

CLINICAL RESEARCH ASSOCIATES, INC.

How to get involved

- Learn more about **current studies**: clinicalresearchassociates.com/studies/
- **Sign up for email updates**, for reminders about current and upcoming studies: clinicalresearchassociates.com/welcome/
- **Watch and share** our two-and-a-half minute introduction video: www.youtube.com/watch?v=oNN0bOo6eeA&t=1s
- Like us on Facebook, Instagram, and LinkedIn for culture and industry news

Questions?