441 Clinical Trials, LLC

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What do we want to be?

We want to become a **reliable site** to carry out clinical studies.

Definition

In clinical research, a site (or clinical trial site) refers to the physical location where a clinical trial is conducted. It is the place where participants are enrolled, treated, monitored, and where study data is collected.
A site operates under the supervision of a qualified healthcare professional known as the Principal Investigator (PI), supported by a dedicated research team.

What is a Clinical Research Trial?

Clinical research is medical research that studies people to understand health and disease. Clinical research helps improve the way doctors treat and prevent illness. Through clinical research, researchers learn:

- How the body works
- How illness develops in people, such as how diseases get better or worse over time
- How the body handles a possible treatment
- Which behaviors help people stay healthy and prevent illness, and which behaviors raise the chance of illness

The goal is to use science to improve people's health care and health over time. The participants who join and take part in clinical research studies may or may not get any benefit for themselves.

Phases of Clinical Trials

What are clinical trial phases?

The stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics.

441 Clinical Trial, LLC Focus Phases

Phase 1

Phase 1 clinical trials is the first time the new treatment is being tested in people.

Phase 1 trials test for safety and tolerance of the new treatment by recruiting and closely monitoring a small group of people (<100 people).

Phase 2

Phase 2 clinical trials continue testing the safety and effectiveness of the new treatment.

Phase 2 trials recruit and closely monitor a larger group of people (100-300 people).

Phase 3

Phase 3 clinical trials focus on determining whether the new product is more effective than the current treatment option.

Phase 3 trials recruit 100s to 10000s of people.

Phase 4

Phase 4 clinical trials are new treatments that have been reviewed and approved by regulatory bodies and are now available to the public.

Phase 4 trials continue monitoring the long-term risks and benefits of the newly approved treatment.

Types of Clinical Trials

441 Clinical Trials, LLC will focus on the following types:

- Type 2 Diabetes
- Hypertension
- Gout
- Rheumatoid Arthritis
- Gastroesophageal reflux (Heartburn)
- Obesity
- Psoriasis
- Cardiovascular
- Irritable Bowel Syndrome (IBS)
- Asthma
- Ulcerative Colitis
- Anemia
- Other diagnosis

What happens during clinical research?

Before clinical research begins

Clinical research relies on people who join. People who are thinking about joining a study get information about the study to help them decide. Research staff are available to answer their questions. This process is called **informed consent**. It's the main way people get study information before deciding whether to join a study.

Informed consent is a process that includes a document that has important information about taking part in the study, including:

- A description of what will happen during the study
- Who can join the study
- How much of participants' time the study will take
- Any payments and costs, such as payment participants get from taking part and any costs participants may need to pay
- The known benefits and risks of taking part in the study

Other ways people can get information about a study may include:

- Asking the research study staff questions
- Reading brochures or websites
- Watching videos about the study

If someone has discussed the study with the research staff, has had their questions answered, and agrees to join the study, they sign the informed consent form. Even if they sign the informed consent, they can leave the study at any time and for any reason. If they decide to leave, they can talk to the research staff to do so safely.

What happens during clinical research?

During clinical research

Clinical research happens in many ways, depending on the type of study. They may take a few days, weeks, or even years.

Researchers may assign participants into different groups. This happens in studies that compare an intervention to something else. For example, researchers may:

- Compare 2 drugs to see which works better or has fewer unwanted side effects
- Compare a drug to a placebo (a substance or treatment that looks like the drug, and is given in the same way, but has no active drug)
- Compare getting a treatment to no treatment

How does joining a study affect participants' usual health care?

In most studies, participants can keep seeing their regular doctors. If needed, the research staff will work with participants' doctors to make sure that being in the study will not cause problems. In some studies, participants may have to change or limit their usual health care, such as stopping other medicines they take.

What happens during clinical research?

What if participants have health problems during clinical research?

Research staff will explain what to do if participants have health problems during the study. Usually, research staff ask participants to report health problems to them right away. Research staff include doctors and nurses who will work with participants and the participants' regular doctors to address the problem.

A group of experts may also oversee what is happening in the study. If they have a safety concern, they contact the researchers right away.

If very serious health problems happen to participants during the study, the researchers may stop the study.

Participants can choose to leave the study, called "withdrawal", at any time and for any reason. If they decide to leave, they can talk to the research staff to do so safely.

How do researchers collect data?

During the study, researchers collect data from participants to help answer their research question. They do this in different ways, such as:

- Surveys or questionnaires
- Getting images, such as X-rays or MRIs
- Taking measurements, such as height, weight, or blood pressure
- Taking samples of participants' blood or tissue to look at in a lab

Researchers may need to collect data from participants many times or only a few times.

What happens during clinical research?

Do participants have to pay any costs or do they get paid for taking part in clinical research?

The **informed consent** form describes the study's payment and costs. Some studies pay participants who take part, but the amount varies based on the study.

Many clinical studies pay for the cost of the intervention and any research-related tests and visits. Some studies may pay costs for research-related travel and lodging, such as costs for parking or meals.

How would we identify our participants?

To identify potential participants, we would use referrals from local physician and healthcare providers, FDA-approved advertising through IRBs (Institutional Review Board) on online platforms, and internal database through primary medicine services with prescreening visits that would take place in our office.

There are many people who do not have access to primary medical service in our state due to the lack of insurance and sufficient resources, which is why we would use our services to provide free or low-cost primary medical service to identify possible participants who could benefit from the studies.

We also plan to engage with local organizations and community leaders to ensure that underserved population are aware and have access to research opportunities.

Components of the site

1. Personnel

    1. Principal Investigator (PI): Responsible for the overall conduct of the study at the site.

    2. Sub-Investigators: Assist the PI in study-related tasks.

    3. Clinical Research Coordinators (CRCs): Manage day-to-day operations of the trial.

    4. Nurses, pharmacists, lab technicians, and other specialists according to the requirements of each clinical trial protocol.

    5. Administrative Staff: Responsible for hiring and all administrative events that entail their position.

Principal Investigator

JEAN F. RODNEY, MD

Medical Doctor from the State University of Haiti, Port Au Prince 1988

Board Certified Internal Medicine Specialist 2000

Medical License ME 84415 with no prior investigations

Currently works in Central Florida as an Internal Medicine physician in **Winter Haven Hospital.**

FACILITIES

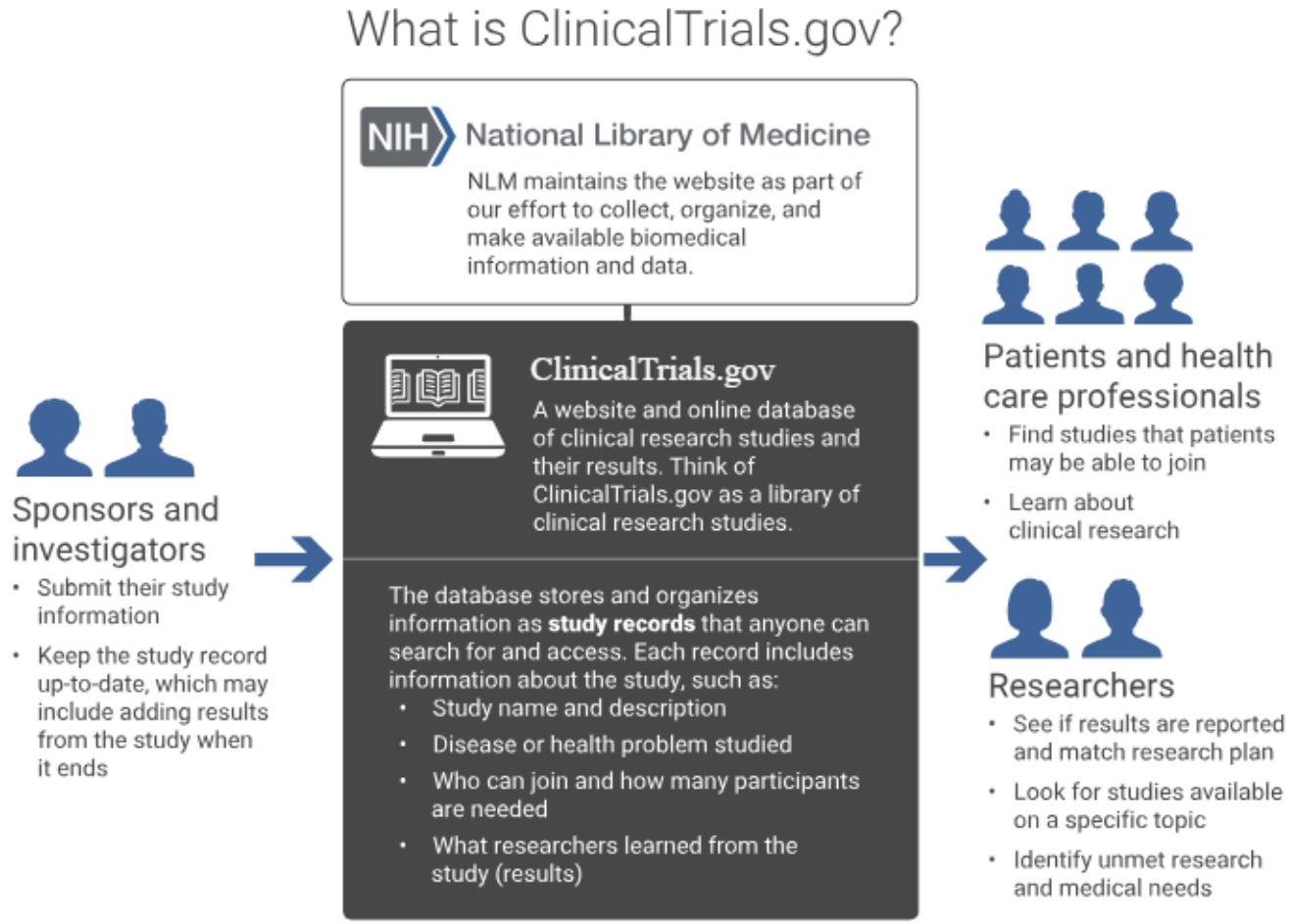
2. The current space of 890 square feet helps us optimize our work and personalize our service and patient care.

The facility consists of the following:

- 2 Examination rooms
- 1 Laboratory station
- 1 Secured (under lock & key) Pharmacy or investigational product storage
- 1 Storage Room
- 1 Bathroom
- 1 Waiting Room
- 1 Office with 4 individual workstations
- Archival space for documents and records
- Secure data management systems.

Main Responsibilities of a Site

We work strictly based on a clinical trial protocol previously authorized by the FDA and published in www.clinicaltrials.gov provided to us by the sponsor (pharmaceutical), which hires us to develop a specific study.



Main Responsibilities of a Site

•Recruitment and Enrollment: Identifying and screening potential participants. All participants must comply with 100% of the required inclusions for each protocol.

•Informed Consent: Ensuring participants understand the study and provide voluntary consent.

•Study Procedures: Administering investigational products, conducting exams, and collecting samples.

•Safety Monitoring: Recording adverse events and ensuring participant safety; access to 24/7 participant telephone service available for all participants.

•Data Collection: Documenting all study-related information according to the study protocol.

•Compliance: All personnel in contact with the patient must complete and be certified with the training required by the FDA to carry out medical studies following Good Clinical Practice (GCP), ethics, and regulatory guidelines.

Why Are Sites Important in Research?

- Frontline of Trial Execution: Sites are where the actual interaction with patients happens.
- Ensure Data Integrity: Proper training and adherence to protocol lead to high-quality data.
- Protect Participant Safety: Ongoing oversight and medical care are provided.
- Local Expertise: Sites bring knowledge of the community and patient population.

Conclusion

A site is a place where the practical part of the clinical trial occurs, with real patients, under medical supervision, and complying with ethical and scientific standards.

A site runs the clinical trial with real patients, ensuring that:

- It is to be done safely
- The data is reliable
- All ethical and regulatory requirements are met

We would be regulated directly by the FDA through the IRBs, which are the entities that regulate the protocols from start to finish. The sponsors will carry out periodic and constant monitoring at the beginning, during and at the end of each protocol through monitors who physically visit the site and make phone calls whenever necessary, internal audits and occasionally FDA inspectors would visit the site and evaluate the work done on the site.