What is a clinical trial?

The National Institute of Health define Clinical trials as “research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. Clinical trials are one of the final stages of a long and careful research process. The process often begins in a laboratory (lab), where scientists first develop and test new ideas”. A clinical trial is a research study conducted in human volunteers.

Each clinical trial has a master plan called a protocol. This plan explains how the trial will work. The trial is led by a principal investigator (PI), who often is a doctor. The PI prepares the protocol for the clinical trial.

The protocol outlines what will be done during the clinical trial and why. Each medical center that does the study uses the same protocol.

Key information in a protocol includes

- How many patients will take part in the clinical trial;
- Who is eligible to take part in the clinical trial;
- What tests patients will get and how often they will get them;
- What type of data will be collected during the clinical trial; and
- Detailed information about the treatment plan.

Why Participate in a Clinical Trial?

Clinical trials are a key research tool for advancing medical knowledge and patient care. Clinical research is done only if doctors don’t know whether a new approach works well in people and is safe and which treatments or strategies work best for certain illnesses or groups of people.

Benefits:

Taking part in a clinical trial can have many benefits. For example, you may gain access to new treatments before they're widely available. If a new treatment is proven to work and you're in the group getting it, you might be among the first to benefit. If you're in a clinical trial and don't get the new strategy being tested, you may receive the current standard care for your condition. This treatment might be as good as, or better than, the new approach. You also will have the support of a team of health care providers, who will likely monitor your health closely.

Risks:

- The new strategies and treatments being studied aren't always better than current standard care.
- Even if a new approach benefits some participants, it may not work for you.
- A new treatment may have side effects or risks that doctors don't know about or expect. This is especially true during phase I and phase II clinical trials. The risk of side effects might be even greater for trials with cutting-edge approaches, such as gene therapy or new biological treatments. RMA has only participated in phase III trials, by this phase a lot of information is already know about a specific drug.
- Health insurance and health care providers don't always cover all patient care costs for clinical trials. Renal Medicine Research staff will explain to you all the financial details, for the most part all the costs are covered and will not billed to you.

How do Clinical Trials Work?

All clinical trials have guidelines about who can participate. These guidelines help to produce reliable results. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in that clinical trial, while others need healthy participants.

Clinical trials are conducted in different "phases". The trials at each phase have a different purpose and help scientists answer different questions. Generally, clinical trials go through 4 phases of studies.

- Phase I trials: clinical trials test new treatments in small groups of people for safety and side effect
- Phase II trials: clinical trials look at how well treatments work and further review these treatments for safety
- Phase III: the third and last pre-approval round of testing of a drug is conducted on large populations of afflicted patients.clinical trials use larger groups of people

to confirm how well treatments work, further examine side effects, and compare new treatments with other available treatments

- Phase III studies usually test the new drug in comparison with the standard therapy currently being used for the disease in question. The results of these trials usually provide the information that is included in the package insert and labeling.
- Phase IV: after a drug has been approved by the FDA, phase IV studies are conducted to compare the drug to a competitor, explore additional patient populations, or to further study any adverse events.

What is informed consent?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. Before your participation in a clinical trial begins, the study doctor and the Renal Medicine Research staff will explain the details of the study. These details are contained in an “informed consent form”.

Physician investigators who conduct research at Renal Medicine Associates are required to have fulfilled training and certification in the principles of protection of human subjects and in the conduct of clinical research to the highest ethical and moral standards (known as GCP or Good Clinical Practice). This includes having completed training in issues related to potential financial conflicts of interest.