**Patient Responsibility**
As a participant in a clinical trial you are held responsible for the follow:

- Being compliant to study visit schedule
- Consulting with staff prior to any medication changes
- Taking all medications as instructed
- Informing staff in the event of ER or hospital visits
- Inform research staff about any changes in your health or new symptoms experienced after starting any investigational product

**What happens after the trial?**

After completion of the trial subjects have several options:

**Option A** - Open label/Long Term extension:
This period may or may not be offered as this is not a required period of a clinical trial. During this period the placebo component is usually removed and subject are granted the opportunity to receive the investigational product after completing the entire.

**Option B** – Enroll in another clinical trial
**Option C** – continue with standard of care medication

“Despite your benefit from the investigational drug this cannot be offered to you once the trial is completed unless it is FDA approved!”

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**Who We Are**

**About Us**

- Founded in 2005
- Specialize in clinical trials in Rheumatological diseases such as Lupus, Rheumatoid Arthritis, Osteoporosis, Osteoarthritis, Sjogren’s, Lupus Nephritis, Ankylosing Spondylitis, Scleroderma and Psoriatic Arthritis.
- Physicians
  - Alireza Nami, MD
  - John Brendese, MD
- Research staff
  - Vanica Pharoah, MHA, CCRP
  - Chelsea Rittase, MPH, CCRC
  - Paetyn Cage, BS
  - Rachel Stamps, BA
  - Edit Margaryan, MD

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Reinventing medicine one clinical trial at a time!
What is a Clinical Trial?

A clinical trial is a research study in which both healthy subjects and/or subjects with a specific diagnosis receive investigational treatments over a period of time. Treatment is given under the supervision of a physician (investigator) and other research professionals. Pharmaceutical and biotechnology companies carefully select qualified sites that have the appropriate staff, skills and resources available to safely administer these treatments to determine the benefit of these investigational drugs.

Clinical trials are conducted in phase I, II, III and IV. Phase I and II trials usually require a small population of patient whereas the later phases involve a larger number of patients. Some clinical trials may include the use of some FDA approved drugs to compare the effectiveness of the investigational drug in relation to those already approved and available to you through your insurance carriers.

Clinical trials have helped in the advancement of medicine. This process allows us to find and cure many diseases and illnesses and improve treatment options for patients with terminal/chronic illnesses. Every over the counter medication have gone through this process. These trials are conducted to determine the efficacy of these drugs, possible side effects, and long-term effect of use.

Who can participate?

All clinical trials have guidelines i.e. inclusion criteria’s (must meet all)/exclusion criteria’s (can’t meet any) that each participate must meet to qualify for the study. Some of the factors that may determine your eligibility for these clinical trials include but not limited to your age, gender, type, stage, severity of disease, previous treatment, other and past medical history, and mental status.

Remember, the accuracy of the information provided to the research staff is very important as it is used to determine if all inclusion criteria are met and all exclusion criteria are not met. These criteria are used to identify appropriate candidates, promote participant safety and ensure that the researcher, the pharmaceutical company sponsoring these trials learn and collect the information they need.

Risks and benefits

Benefits

- Free treatment, labs, and office visits
- A more extensive workup and personalized treatment plan
- Helping the research community and other like yourself gain a chance to more treatment options.
- The ability to first line treatment that may potentially improve your disease
- Patient stipend for travel

Risks

- No benefit or improvement and possible worsening of symptoms
- Possibilities of experiencing side effects
- There is a chance of receiving placebo opposed to the actual study drug.

“If your standard of care medication just isn’t working give research a try!”

“Despite any risk or benefit that may be experienced during participation in any clinical trial, there is an institutional review board (IRB) in place which ensures patient safety and protects patients from any misconduct that may occur”