Clinical trials play an important role in the development of new treatments for psoriatic disease and advancing medical research. Newly developed treatments go through clinical trials under the supervision of physicians and other research professionals to help understand their safety and efficacy.

What are the different phases of clinical trials?

There are four phases of clinical trials. All phases involve human participants or volunteers. Each phase is different depending on who can participate, how long the trial takes and what type of information the researchers are trying to understand.

**Phase I** generally involves 20 to 100 healthy participants and lasts for several months. This phase aims to study how the body processes a treatment. Researchers are also investigating the possible side effects of the treatment at different dosage levels.

**Phase II** has hundreds of patient participants and lasts from several months to 2 years. This phase aims to study how safe and effective a new treatment is compared to a currently approved treatment.

**Phase III** may have hundreds to thousands of patient participants and lasts several years. Like Phase II, this phase aims to study how safe and effective a new treatment is compared to a currently approved treatment but over a longer period of time with more participants. This helps researchers to understand more about the possible benefits and side effects of the new treatment. Results from Phase III trials are often published in scientific journals and on ClinicalTrials.gov. Researchers will also submit findings from Phase III studies that are clinically meaningful to the U.S. Food and Drug Administration for review and possible approval of the new treatment.

**Phase IV** (also called Post Marketing Surveillance Trials) are done after a drug or treatment has been approved and is on the market. These are different from other clinical trial phases because they are observational – they compare the treatment with others on the market and monitor long-term effectiveness and safety.
What are some questions to ask before enrolling in a clinical trial?

Informed consent is having the right to know and understand what will happen during a clinical trial before agreeing to participate. Understanding what to expect during a clinical trial is important and can help you decide whether participating in a trial is best for you. The following are some questions that you might have about a trial that will be discussed in the informed consent document.

The physicians and research staff of a clinical trial are responsible for helping you understand information about the trial. You can always ask questions if you do not understand something about the study or if you have other concerns.

1. What is the main purpose of the study? And how long will the trial last?
2. Do I have to pay for any part of the study? If so, will insurance cover these costs? Will I be reimbursed for other expenses?
3. Does the trial involve a placebo or a currently approved treatment?
4. What are the possible risks and benefits of the treatments? How will patient safety be monitored?
5. What kind of medical care and tests are involved in the trial? How often will I have to visit the hospital or clinic?
6. Will I be able to continue to see my own health care provider during the trial?
7. Do I have to stop my current treatment before starting the trial? If so, for how long?
8. If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?
9. What happens if I decide to quit the study?
10. Will results of the trial be provided to me?

We also recommend speaking with your current health care provider if you are considering participating in a clinical trial. This can be helpful in making a decision on whether a trial is most appropriate for you.

What should I do next?

Contact our Patient Navigation Center if you have questions about enrolling in a clinical trial or if you want to learn more about treatment options (find contact information below).