What if I change my mind?

You can withdraw from the study at any time, for any reason. Even if you begin the study, you can change your mind at any point. The study doctor will discuss your care options with you if you decide to withdraw from the study.

Will my information remain confidential?

Participant information is confidential; however, your provider may be required by law to share your information in certain situations. If information from the trial is published or presented at scientific meetings, your name and other personal information will not be used. The clinical trial sponsor, and regulatory agencies, also may review the research files and medical records.

Thank you for your consideration.

We know participation in a clinical trial is a significant undertaking, and we genuinely thank you for taking the time to learn more. We wish you the very best as you navigate this challenging journey.

For more information about clinical trials, please contact:

Johnson &Johnson

FREESIA-3

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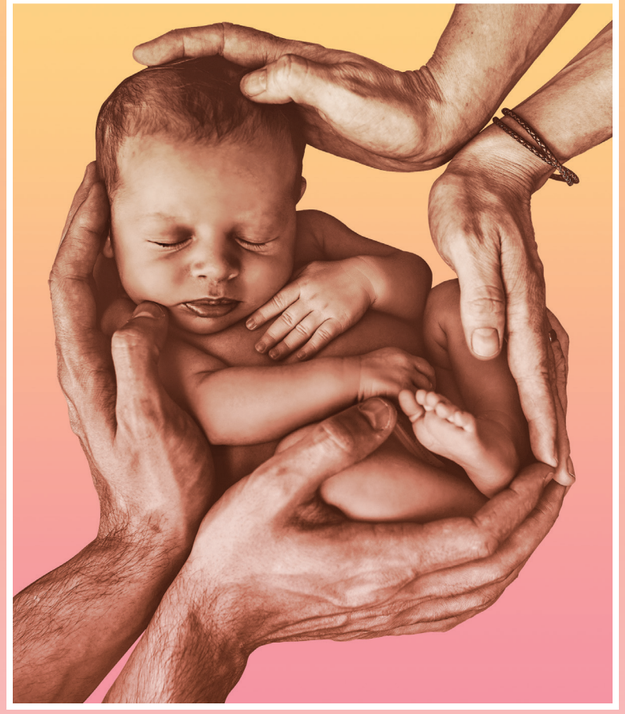
Understanding Clinical Trials



The image depicted contains models and is being used for illustrative purposes only.

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Clinical trials offer hope for many people and are a chance to help researchers find potential treatment options for others in the future. The information that follows will provide you with a basic understanding of clinical trials. The more you know about clinical trials, the better prepared you will be when deciding if participating in a clinical trial is the right choice for you.

We encourage you to have conversations with your doctor about all your options, including clinical trials. Consider asking questions such as:

- Is there a clinical trial going on right now for FNAIT?
- Do I qualify for this trial?
- What investigational medication is being studied?

What is a clinical trial?

A clinical research study, also called a clinical trial, is a carefully designed scientific evaluation of an investigational medication or treatment that is conducted by doctors and researchers.

Trials are conducted in four phases:

- **Phase 1** trials examine the safety of an investigational medication in healthy people
- **Phase 2** trials involve the assessment of safety, efficacy, and establishing the appropriate dosing regimens in patients
- **Phase 3** trials further evaluate the efficacy and safety of an investigational medication in patients
- **Phase 4** trials are conducted after an investigational medication has been approved to gather additional efficacy and safety information

Who can enroll in a clinical trial?

All clinical trials have a set of guidelines called eligibility criteria that determine who can participate. The eligibility criteria are based on factors such as age, gender, the type and stage of a condition, previous treatment history, and other medical conditions.

It is important to note that the eligibility criteria are not used to reject or accept people personally. Instead, the criteria are used to identify appropriate participants and help keep them safe.

Why should I enroll in a clinical trial?

You should only participate in a clinical trial if you and your care provider feel comfortable with the details of the trial and believe it is a good option for you. When you participate in a clinical trial, you also help others by contributing to medical research.

Is it safe to be in a clinical trial?

Research is conducted for many years before an investigational medication advances to a clinical trial. Negative effects are possible. You will be fully informed of all known risks and the potential for unknown risks before you start. During the trial, your study team will carefully monitor the health and safety of you and your baby. You should report any concerns to your study doctor.

What safeguards are in place?

In order to protect participants, federal regulations require that an institution creates an "institutional review board" (IRB) for all research studies that involve people. The board must approve all research before it begins and will periodically review ongoing research. The IRB's assessment involves a series of steps that include:

- Identifying the risks associated with the research compared with the risks the participants would be exposed to even if not enrolled in the study
- Determining that the risks will be minimized as much as possible
- Identifying potential benefits of the research
- Determining that the risks are reasonable considering the benefits to the participants, if any, and the importance of the knowledge to be gained
- Assuring potential participants will be given a fair, accurate description of the risks or discomforts and the anticipated benefits of the research
- Determining intervals of periodic review of the study

Will the research help me personally?

The purpose of this study is to evaluate the safety and efficacy of an investigational medication in pregnancies at risk for FNAIT. A clinical trial may or may not help you personally, but it will provide researchers with valuable information about treating FNAIT in the future.

How will I be informed of the benefits and risks?

Each clinical trial has a well-documented plan or protocol. Your study team will explain this plan to you, including what to expect and all known benefits and risks of the research. This information will be provided to you in an informed consent form. If you agree to participate in the study, you will be asked to sign the informed consent form and keep a copy for yourself.

If there is a change in your or your baby's health while you are participating, the study doctor will inform you immediately and will discuss your options, as your physical health and well-being are of paramount importance. You are encouraged to ask any questions at any time.

What do I have to do in a clinical trial?

Activities vary from one clinical trial to the next, but most require regular medical examinations. Some trials involve taking either an approved or investigational medication, while others involve a procedure. Your study doctor will discuss these details with you. You may be asked to record information about how you are doing. You also may be asked to return for follow-up visits to evaluate whether the research is producing the intended results.