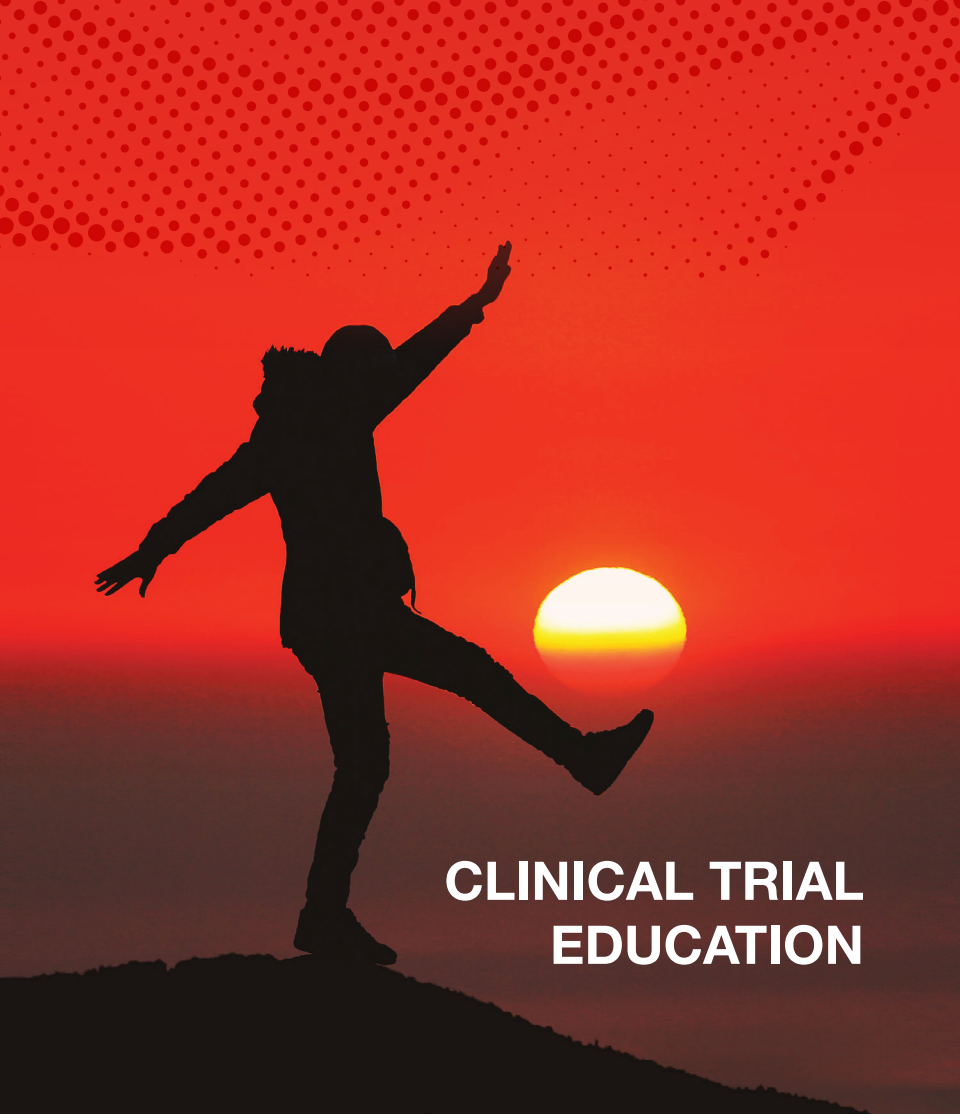

ENERGY
STUDY

Clinical trials offer hope for many people and are a chance to help researchers find potential treatments for others in the future or learn more about a disease state. The information that follows will provide you with a basic understanding about 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 wAIHA?
- Do I qualify for this trial?
- What drug or treatment is being studied?
- What are the potential risks and benefits?

What is a clinical trial?

A clinical trial, also called a clinical research study, is a carefully designed scientific evaluation of an investigational medication, device, or procedure that is conducted by doctors and researchers to determine if an experimental drug, device, or procedure is safe and effective.

Trials are conducted in four phases:

1. Phase I trials examine the safety of an investigational medicine in healthy people
2. Phase 2 trials involve assessment of safety and additional efficacy and establishing the appropriate dosing regimen while testing safety in patients.
3. Phase 3 trials further evaluate the efficacy and safety of an investigational treatment in patients.
4. Phase 4 trials are conducted after an investigational medicine has been approved to gather additional information on the investigational medicine.

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 disease, 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?

When you participate in a clinical trial you 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 care team regularly and carefully monitors your health and safety. You should report any concerns to your study physician, and you can decide to stop participation at any time.

What safeguards are in place?

Federal regulations help protect participants in research studies and require that an institution creates an "institutional review board" (IRB) if it performs 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 receive 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, and
- determining intervals of periodic review of the study.

Will the research help me personally?

A clinical trial may or may not help you personally, but it will provide researchers with valuable information about treating wAIHA in the future.

How much will I know about the benefits and risks?

Each clinical trial has a well-documented plan, or protocol, about what you will need to know and what is expected. You will be fully informed about the plan including all known benefits and risks of the research. You are encouraged to ask any questions at any time. If you decide to enroll, you will be asked to sign an informed consent form.

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 medicine, while others involve a procedure. 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.

What if I change my mind?

You can quit the study at any time, for any reason. Even if you begin the study, you can change your mind at any point.

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, as well as the U.S. Food and Drug Administration, also may review the research files and medical records.

Learn more about clinical trials

For more information about clinical trials, please visit our website at globaltrialfinder.janssen.com/about-clinical-trials

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