GLOBAL LYME ALLIANCE CLINICAL STUDY PARTICIPANT KIT

- FREQUENTLY ASKED QUESTIONS
- COMMON TERMS
- HOW TO FIND A CLINICAL TRIAL

GLOBAL LYME ALLIANCE

GLA.ORG/CLINICAL-TRIALS

Global Lyme Alliance

ABOUT CLINICAL TRIALS

FREQUENTLY ASKED QUESTIONS

Will I still see my regular doctor?
Yes, you will still be under the care of your regular doctor for your general health. You will see the study doctor or nurse for planned study visits.

Do I have to pay anything?
There is no charge for study-related medical care, including study visits, medications, treatments, and procedures. Transportation and other costs may be provided.

What should I think about before joining a clinical trial?
Before joining a clinical trial, it is important to learn as much as possible. Discuss your questions and concerns with members of the health care team conducting the trial. Also, discuss the trial with your health care provider to determine whether or not the trial is a good option based on your current treatment. Be sure you understand:

- what happens during the trial
- the type of health care you will receive
- any related costs once you are enrolled in the trial
- the benefits and risks associated with participating

How long is a clinical trial?
The length of each trial is different. Some last a few months, others last for several years. You are free to leave the trial at any time.

What are clinical trials?
A clinical trial, also known as a clinical study, is scientific research designed to test if a medicine or medical device is effective, safe, and well-tolerated for use by people. A study seeks to answer scientific questions and to find better ways to prevent, diagnose, or treat disease. Medical products, such as drugs and diagnostic tests, must be studied in clinical trials before they can be approved for public use.

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Who are the key people in a clinical trial?

If you are considering volunteering for a clinical trial, you should feel comfortable about asking the research team and others important questions to help you decide and through each step of your participation. Here are a few of the key people who can help.

Study coordinator is a nurse or other health care professional who manages the daily clinical trial activities. They play a critical role in ensuring that all guidelines are followed to help keep participants safe. The study coordinator is often the first point of contact for any questions you may have.

Principal investigator, also called the study doctor, is a medical doctor in charge of conducting the clinical trial at his or her medical facility. You will have an opportunity to ask the study doctor any questions during the informed consent process, as well as throughout the clinical trial. If you are seeing a specialty doctor, there is a chance that your doctor is also an investigator for a clinical trial.

Your family or friend -- it's a good idea to bring a family member or friend to your initial visit with the research team. They can be an extra set of ears to hear the information provided by the study team and can ask additional questions you might not consider. They can also take notes so you can focus on the discussion. Having a trusted family member or friend can also help you weigh your options for participating.

Is there a chance I might get a placebo?

In clinical trials that include placebos, quite often neither patients nor their doctors know who is receiving the placebo and who is being treated with the experimental drug. Many cancer clinical trials, as well as trials for other serious and life-threatening conditions, do not include placebo control groups. In these cases, all participants receive the experimental drug. Ask the trial coordinator whether there is a chance you may get a placebo rather than the experimental drug. Then, talk with your doctor about what is best for you.

How does clinical research make a difference to me and my family?

Only through clinical research can we gain insights and answers about the safety and effectiveness of treatments and procedures. Groundbreaking scientific advances in the present and the past were possible only because of participation of volunteers, both healthy and those with an illness, in clinical research. Clinical research requires complex and rigorous testing in collaboration with communities that are affected by the disease. As research opens new doors to finding ways to diagnose, prevent, treat, or cure disease and disability, clinical trial participation is essential to help us find the answers.

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ABOUT CLINICAL TRIALS

GLOSSARY OF COMMON TERMS

Accepts healthy volunteers
A type of eligibility criteria that indicates whether people who do not have the condition/disease being studied can participate in that clinical study.

Active comparator arm
An arm type in which a group of participants receives an intervention/treatment considered to be effective (or active) by health care providers.

Adverse event
An unfavorable change in the health of a participant, including abnormal laboratory findings, that happens during a clinical study or within a certain amount of time after the study has ended. This change may or may not be caused by the intervention/treatment being studied.

Age or age group
A type of eligibility criteria that indicates the age a person must be to participate in a clinical study. This may be indicated by a specific age or the following age groups:Child (birth-17)Adult (18-64)Older Adult (65+)

Arm
A group or subgroup of participants in a clinical trial that receives a specific intervention/ treatment, or no intervention, according to the trial's protocol.

Arm type
A general description of the clinical trial arm. It identifies the role of the intervention that participants receive. Types of arms include experimental arm, active comparator arm, placebo comparator arm, sham comparator arm, and no intervention arm.

Baseline characteristics
Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age, sex/gender, race and ethnicity, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment)..

Source: Clinicaltrials.gov and NIH.gov

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Clinical research
Medical research that involves people to test new treatments and therapies.

Clinical study
A research study involving human volunteers (also called participants) that is intended to add to medical knowledge. There are two types of clinical studies: interventional studies (also called clinical trials) and observational studies.

Clinical trial
Another name for an interventional study.

ClinicalTrials.gov identifier (NCT number)
The unique identification code given to each clinical study upon registration at ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419).

Collaborator
An organization other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.

Condition/disease
The disease, disorder, syndrome, illness, or injury that is being studied. On ClinicalTrials.gov, conditions may also include other health-related issues, such as lifespan, quality of life, and health risks.

Contact
The name and contact information for the person who can answer enrollment questions for a clinical study. Each location where the study is being conducted may also have a specific contact, who may be better able to answer those questions.

Early Phase 1 (formerly listed as Phase 0)
A phase of research used to describe exploratory trials conducted before traditional phase 1 trials to investigate how or whether a drug affects the body. They involve very limited human exposure to the drug and have no therapeutic or diagnostic goals (for example, screening studies, micro dose studies).

Source: Clinicaltrials.gov and NIH.gov

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Eligibility criteria
The key requirements that people who want to participate in a clinical study must meet or the characteristics they must have. Eligibility criteria consist of both inclusion criteria (which are required for a person to participate in the study) and exclusion criteria (which prevent a person from participating). Types of eligibility criteria include whether a study accepts healthy volunteers, has age or age group requirements, or is limited by sex.

Enrollment
The number of participants in a clinical study. The "estimated" enrollment is the target number of participants that the researchers need for the study.

Exclusion criteria
A type of eligibility criteria. Factors that do not allow a person to participate in a clinical study.

Expanded access
A way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the U.S. Food and Drug Administration (FDA). Also called compassionate use. There are different expanded access types. For more information, see FDA Expanded Access: Information for Patients.

Expanded access status
Available: Expanded access is currently available for this investigational treatment, and patients who are not participants in the clinical study may be able to gain access to the drug, biologic, or medical device being studied.

> **No longer available**: Expanded access was available for this intervention previously but is not currently available and will not be available in the future.
>
> **Temporarily not available**: Expanded access is not currently available for this intervention but is expected to be available in the future.
>
> **Approved for marketing**: The intervention has been approved by the U.S. Food and Drug Administration for use by the public.

Source: Clinicaltrials.gov and NIH.gov

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Expanded access type
Describes the category of expanded access under U.S. Food and Drug Administration (FDA) regulations. There are three types of expanded access:

Individual Patients: Allows a single patient, with a serious disease or condition who cannot participate in a clinical trial, access to a drug or biological product that has not been approved by the FDA. This category also includes access in an emergency situation.

Intermediate-size Population: Allows more than one patient (but generally fewer patients than through a Treatment IND/Protocol) access to a drug or biological product that has not been approved by the FDA. This type of expanded access is used when multiple patients with the same disease or condition seek access to a specific drug or biological product that has not been approved by the FDA.

Treatment IND/Protocol: Allows a large, widespread population access to a drug or biological product that has not been approved by the FDA. This Source: Clinicaltrials.gov and NIH.gov type of expanded access can only be provided if the product is already being developed for marketing for the same use as the expanded access use.

Experimental arm
An arm type in which a group of participants receives the intervention/treatment that is the focus of the clinical trial.

Gender-based eligibility
A type of eligibility criteria that indicates whether eligibility to participate in a clinical study is based a person's self-representation of gender identity or gender (yes, no). Gender is distinct from sex.

Group/cohort
A group or subgroup of participants in an observational study that is assessed for biomedical or health outcomes.

Healthy volunteer
A Healthy volunteer is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention.

Source: Clinicaltrials.gov and NIH.gov

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Inclusion criteria
A type of eligibility criteria. Factors that qualify a person to participate in a clinical trial.

Informed consent
A process used by researchers to communicate to potential and enrolled participants the risks and potential benefits of participating in a clinical study.Informed consent form (ICF)The document used in the informed consent or process.

Institutional Review Board (IRB)
A group of people who review, approve, and monitor the clinical study's protocol. Their role is to protect the rights and welfare of people participating in a study (referred to as human research subjects), such as reviewing the informed consent form. The group typically includes people with varying backgrounds, including a community member, to make sure that research activities conducted by an organization are completely and adequately reviewed. Also called an institutional review board, or IRB, or an ethics committee.

Intervention/treatment
A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise.

Interventional study (clinical trial)
A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Investigator
A researcher involved in a clinical study. Related terms include site principal investigator, site sub-investigator, study chair, study director, and study principal investigator.

Investigational product
A test article (also called study drug) or medical device (also called study device) that is studied in clinical trials for safety and effectiveness.

Source: Clinicaltrials.gov and NIH.gov

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No intervention arm
An arm type in which a group of participants does not receive any intervention/treatment during the clinical trial.

Observational study
A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment. A patient registry is a type of observational study.

Other adverse event
An adverse event that is not a serious adverse event, meaning that it does not result in death, is not life-threatening, does not require inpatient hospitalization or extend a current hospital stay, does not result in an ongoing or significant incapacity or interfere substantially with normal life functions, and does not cause a congenital anomaly or birth defect; it also does not put the participant in danger and does not require medical or surgical intervention to prevent one of the results listed above.

Outcome measure
For clinical trials, a planned measurement described in the protocol that is used to determine the effect of an intervention/treatment on participants. For observational studies, a measurement or observation that is used to describe patterns of diseases or traits, or associations with exposures, risk factors, or treatment. Types of outcome measures include primary outcome measure and secondary outcome measure.

Patient registry
A type of observational study that collects information about patients' medical conditions and/or treatments to better understand how a condition or treatment affects patients in the real world.

Patient volunteer/participant
A person with a known health problem who participates in a clinical trial to better understand, diagnose, treat or cure that condition.

Source: Clinicaltrials.gov and NIH.gov

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Phases of clinical trials

The stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4. Not Applicable is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions.

Phase 1

A phase of research to describe clinical trials that focus on the safety of a drug. They are usually conducted with healthy volunteers, and the goal is to determine the drug's most frequent and serious adverse events and, often, how the drug is broken down and excreted by the body. These trials usually involve a small number of participants.

Phase 2

A phase of research to describe clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

Phase 3

A phase of research to describe clinical trials that gather more information about a drug's safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. These studies typically involve more participants.

Phase 4

A phase of research to describe clinical trials occurring after FDA has approved a drug for marketing. They include post-market requirement and commitment studies that are required of or agreed to by the study sponsor. These trials gather additional information about a drug's safety, efficacy, or optimal use.

Placebo

Is a pill or a liquid that looks like the new treatment being tested, but does not have any treatment value from active ingredients. It is given in the same way as the active drug or intervention/ treatment being studied.

Source: Clinicaltrials.gov and NIH.gov

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Primary outcome measure
In a clinical study's protocol, the planned outcome measure that is the most important for evaluating the effect of an intervention/treatment. Most clinical studies have one primary outcome measure, but some have more than one.

Primary purpose
The main reason for the clinical trial. The types of primary purpose are treatment, prevention, diagnostic, supportive care, screening, health services research, basic science, and other.

Principal investigator (PI)
The person who is responsible for the scientific and technical direction of the entire clinical study.

Protocol
A Protocol is a carefully designed plan to safeguard the participants' health and answer specific research questions. It is a written description of the required clinical study plan that details who is eligible to take part, along with any tests, procedures, medicines, dosages, length of study and information to be gathered. It may also include relevant scientific background and statistical information.

Randomization
Randomization is the process by which two or more alternative treatments are assigned to volunteers by chance rather than by choice.

Research
Systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions. Includes clinical research.

Research team
Principal Investigator, sub-investigator and clinical research coordinator involved with study.

Responsible party
The person responsible for submitting information about a clinical study to ClinicalTrials.gov and updating that information. Usually the study sponsor or investigator.

Source: Clinicaltrials.gov and NIH.gov

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Side effect
Any undesired actions or effects of a medicine. Examples may include headache, nausea, hair loss, skin irritation or other physical problems. Study drugs are monitored for both immediate and long-term side effects.

Single- or Double-Blind Studies
Single- or double-blind studies (also called single- or double-masked studies) are studies in which the participants do not know which medicine is being used, so they can describe what happens without bias.

Sponsor (sponsoring organization)
The organization or person who initiates the study and who has authority and control over the study.

Study coordinator
A nurse or other health care professional who manages the daily logistics of a clinical trial.

Study design
The investigative methods and strategies used in the clinical study.

Study ID
Identifiers that are assigned to a clinical study by the study's sponsor, funders, or others. They include unique identifiers from other trial study registries and National Institutes of Health grant numbers. Note: ClinicalTrials.gov assigns a unique identification code to each clinical study registered on ClinicalTrials.gov. Also called the NCT number, the format is "NCT" followed by an 8-digit number (for example, NCT00000419).

Study type
Describes the nature of a clinical study. Study types include interventional studies (also called clinical trials), observational studies (including patient registries), and expanded access.

Source: Clinicaltrials.gov and NIH.gov

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Types of Clinical Trials

Diagnostic trials determine better tests or procedures for diagnosing a particular disease or condition.

Natural history studies provide valuable information about how disease and health progress.

Prevention trials look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning.

Quality of life trials (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with a chronic illness.

Screening trials test the best way to detect certain diseases or health conditions.

Treatment trials test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

U.S. Food and Drug Administration (FDA)

An agency within the U.S. Department of Health and Human Services. The FDA is responsible for protecting the public health by making sure that human and veterinary drugs, vaccines and other biological products, medical devices, the Nation's food supply, cosmetics, dietary supplements, and products that give off radiation are safe, effective, and secure.

Source: Clinicaltrials.gov and NIH.gov

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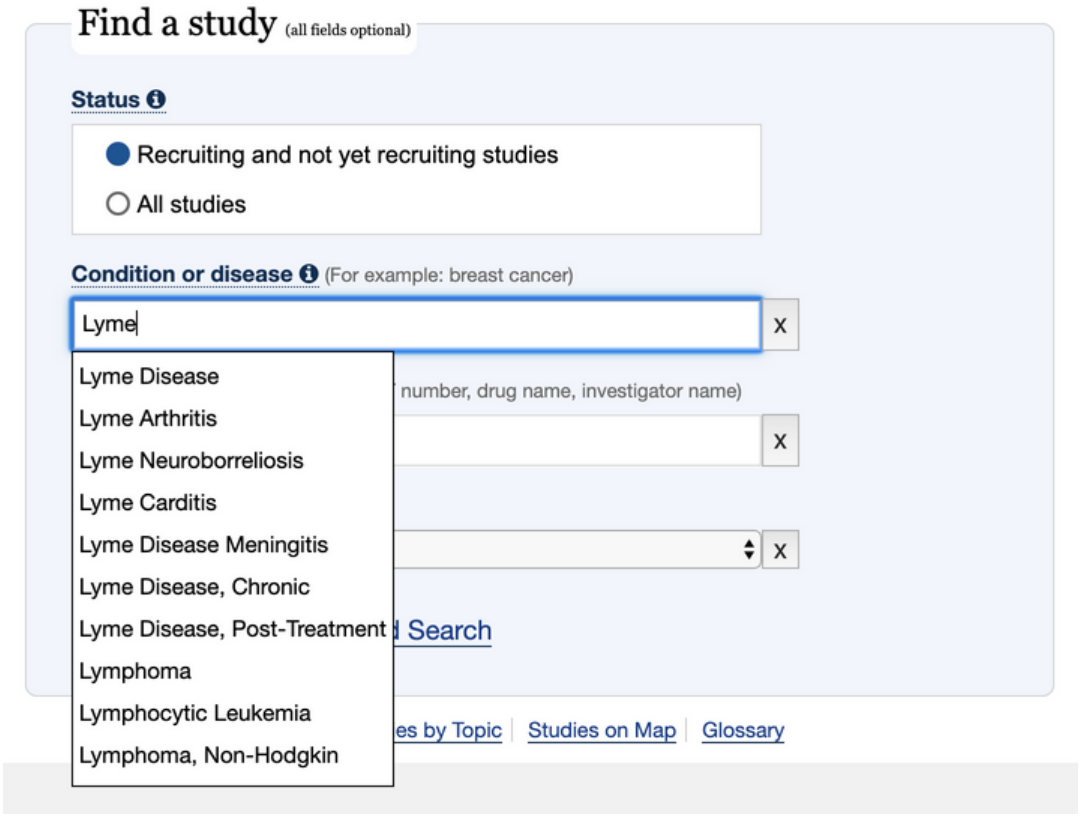
HOW TO FIND A CLINICAL TRIAL

USING CLINICALTRIALS.GOV TO FIND A CLINICAL TRIAL

When you volunteer for a clinical study you become a part of the discovery of new treatments and diagnostic tools.

Search for a clinical trial using ClinicalTrials.gov

Tips for searching: To start, search using key terms and/or words to find studies that are recruiting participants. See example below:



Use filters like recruiting, distance, eligibility criteria to help find studies that are most relevant to you.