

A GUIDE TO CLINICAL TRIALS

Massive Bio, Inc.



Everything You Need To Know About Clinical Trials

D	۸	0	С

- 2 What is a cancer clinical trial?
- 3 Who is eligible for clinical trials?
- 4 How successful are clinical trials?
- 5 Who pays for clinical trials?
- 6 Are clinical trial treatments safe?
- 7 What is next-generation sequencing (NGS)?
- 8 Is it good to participate in a clinical trial?
- 9 Can I choose which trial to enroll in?
- 10 Do I need to travel for a clinical trial?
- 11 How often do I need to go to the trial site for treatment?
- 12 Who receives a placebo in a clinical trial?
- 13 Can I participate in a trial before receiving treatment?
- 14 Can I participate anytime in my treatment process?
- 15 How does a patient find a clinical trial?
- 16 How does a patient enroll into a clinical trial?
- 17 How We Can Help
- 18 Contact information



What is a cancer clinical trial?

Clinical trials test new, promising methods of diagnosing, preventing, or treating cancer, after significant research and trial design has been completed. Clinical trials can also be used to learn if a new treatment is more effective or has less harmful side effects than the standard treatment.

All clinical trials go through phases 0-IV. Phase 0 is the first stage and begins with a few participants. When trials get to phase IV, that means the drug or treatment being studied has been approved by the FDA and is in the last phase before being approved for the general public.

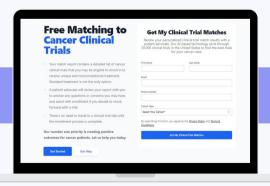




Who is eligible for clinical trials?

The eligibility criteria for enrolling in a clinical trial depends on the trial and is important to ensure that the participants are alike in terms of characteristics such as type of cancer, stage of cancer, general health, and previous treatments. It is important that participant's cancer cases are as similar as possible to ensure that the results of the trial are the result of an intervention being tested rather than other factors.

Massive Bio pre-screens your eligibility for clinical trials recruiting in the United States, considering disease type, disease stage, biomarker status, and geographical location among 100 more data points.



FIND TRIALS YOU'RE ELIGIBLE FOR NOW



How successful are clinical trials?

Without clinical trials, new ways to treat, diagnose, and prevent cancer cannot be discovered. Clinical trials are the way forward for finding more effective cancer treatments and targeted therapies for cancer patients with genetic mutations.

The success of a clinical trial depends on many factors. Cancer type, stage, biomarkers, and past treatment of the patient are just a few factors to take into consideration when determining the success rate of a drug in clinical trial. All the drugs that are effectively being used right now to treat cancer have gone through the vigorous clinical trial process. However, since we are using those drugs now to treat cancer, they would have had to be successful in treating certain cancers while in the evaluation or trial phase.





Who pays for clinical trials?



PATIENT COSTS AND RESEARCH COSTS

There are two types of costs associated with clinical trials, which are patient care costs and research costs.

Patient costs include doctors' visits, hospital stays, standard care treatments, lab tests, X-rays, and imaging tests. These costs are generally covered by insurance, but it depends on the insurance plan and provider that the patient has.

Research costs are not usually covered by insurance, but are commonly covered by the clinical trial's sponsor, which could be a government agency, pharmaceutical company, or non-profit organization. These costs include the study drug, lab tests performed for research, and any additional X-rays or imaging tests needed for the trial outside of normal care.

Massive Bio will help you navigate the cost of clinical trials and coverage by your insurance provider.



Are clinical trial treatments safe?



CLINICAL TRIALS ARE SAFE

- Clinical trials have eligibility criteria to ensure the patients participating in the trial are the type of patients that the study was designed to treat.
- Patients are carefully monitored and encouraged to share their experience, positive or negative, to understand the full effects of the treatment being studied.
- Patients will never be given a placebo instead of standard care. If there is a possibility that a placebo would be given, patients will be aware of it.
- In clinical trials, the number one priority is the safety
 of the patient. All clinical trials must first go through
 a detailed review by the Institutional Review Board
 (IRB). It is also important the patients understand
 they can discontinue participation in a clinical trial at
 any time.



What is Next-Generation Sequencing (NGS)?

Next-generation sequencing (NGS) is a technology used to determine the sequence of DNA or RNA to study genetic variation associated with diseases such as cancer.

WHY IS IT IMPORTANT?



It is important because it can help patients and their cancer care teams understand if specific genetic biomarkers are present in tumors. Knowing this type of information can open patients up to more treatment options, specifically targeted therapies that may be more effective than standard treatment.

Massive Bio recommends all cancer patients receive next-generation sequencing (NGS). If you decide to work with us to find a trial that is right for you, we will help organize getting genetic testing.



Is it good to participate in a clinical trial?

Participation in a clinical trial gives you access to the latest treatment, not yet available to the general public. Patients who enroll in trials also have additional care and attention by medical staff, because safety and effects from treatment are monitored closely.

Those who participate in a clinical trial also help advance cancer research for other patients affected by the same disease as them.





Can I choose which trial to enroll in?

The choice to enroll into a clinical trial is fully up to the patient. However, clinical trials do have eligibility criteria which a patient will need to meet in order to enroll.

Eligibility criteria can include:

- Age
- Sex
- Medical history
- Current health status
- Type of disease
- Stage of disease



OUR MOBILE APP CAN HELP YOU FIND CLINICAL TRIALS

The SYNERGY-AI Cancer Clinical Trial Finder App is available in the IOS and Google Play Stores Now.







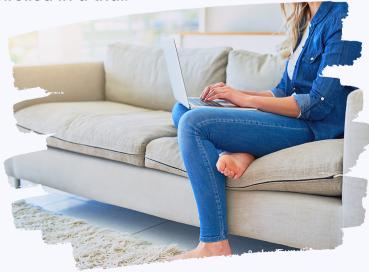




Do I need to travel for a clinical trial?

Travel may be necessary for some patients participating in clinical trials, but it depends on where the trial site is located in relation to home. Depending on the trial, travel could include driving, flying, or organizing a ride. In some cases, overnight stays may be required. Some trials will reimburse patients for travel expenses, but it is not always the case.

Massive Bio does its best to try and find clinical trials which patients are eligible near their home using our SYNERGY-AI Clinical Trial Matching System. The dedicated team of patient advocates onboard the patients. This means patients can stay in the comfort of their home until they are enrolled in a trial.





How often do I need to go to the trial site for treatment?

The frequency of visits depends on the trial, especially the stage. Generally, phase I clinical trials require more frequent visits due to being early stage and many times first-in-human, which requires more active monitoring. Later phase trials tend to have less frequent visits because those studying the drug know what to expect in terms of side effects, reactions, and the length of time the drug stays in the system.

The travel that is required for each patient's participation in a trial will be discussed before the patient enrolls into the clinical trial. Patients can make the decision as to whether or not the travel requirements will work for them and their schedule. If travel is required, some trial sponsors will cover the costs associated with traveling to the trial site.





Who receives a placebo in a clinical trial?

Placebos are not commonly used in oncology clinical trials.

Typically, if a patient does not receive the new researched treatment, they will receive the standard of care. Patients would never be given a placebo in place of an effective treatment for their cancer.

Placebo treatments are only used in cases when a new drug is being tested and there is no other known treatment for the cancer type. It is important that patients understand that if a placebo will be used in a clinical trial, they will know about it.





Can I participate in a clinical trial before receiving treatment?

Yes, there are many clinical trials that are targeted toward patients who have not yet received any treatment. Many times, the treatment includes an already approved drug for the specific cancer type in combination with a drug that is being studied. There are trials available for all lines of therapy. The eligibility criteria should be referenced for more information on the line of therapy that is being investigated.

Massive Bio's Clinical Trial Matching System, equipped with dedicated patient advocate support, can find clinical trials that are right for your case. Contact us today to find clinical trials you're eligible for.



SCHEDULE A CALL WITH A PATIENT ADVOCATE NOW



Can I participate in a clinical trial anytime in my treatment process?

Clinical trials can be considered any time throughout the cancer journey. There are trials available for all lines of therapy, including first line, with many different types of treatment. Many times, patients are advised not to wait until they have no other options left to consider a trial. By considering a clinical trial, patients are taking an active role in a decision that affects their life with consideration in planning for the future.



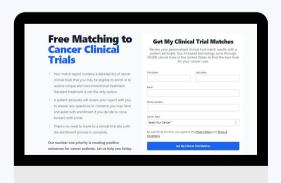


How does a patient find a clinical trial that is right for them?

Massive Bio's Al-based Clinical Trial Matching System (CTMS) and dedicated clinical and patient advocate teams help patients find, qualify for, and enroll into clinical trials that are right for them.

We take into consideration disease type, disease stage, biomarker status, and geographical location among 100 more data points to sort through thousands of clinical trials available in the United States to find the best option for you.

Our number one priority is creating positive outcomes for cancer patients. Let us help you today.



CONTACT US
TODAY FOR TRIAL
MATCHING



How does a patient enroll into a clinical trial?

Once Massive Bio receives records for a patient who is interested in a clinical trial, they are reviewed and screened in detail with the inclusion and exclusion criteria of the trial, utilizing Massive Bio's Artificial Intelligence Clinical Trial Matching System (CTMS). If the patient is deemed eligible for a trial, Massive Bio will reach out to the Primary Investigator (PI) and other team members at the site that is closest to the patient's home in order to assist with getting the patient scheduled for a screening visit.

Upon arrival at the site, the trial will again be discussed with the patient and consent will be signed, if the patient is in agreement. The patient will then be screened according to the criteria in which the Sponsor of the clinical trial has requested. Screening may include laboratory work-up, scans, EKGs, among other criteria.

If the patient meets all criteria for the clinical trial, they will begin receiving treatment and be followed very closely by both the clinical trial team and Massive Bio for added support.



How We Can Help

At Massive Bio, our mission is to enable cancer patients to have equal access to cutting-edge therapies and clinical trials, regardless of their location and/or financial stability.

Our Artificial Intelligence (AI) powered Clinical Trial Matching System connects patients and their treating oncologists to clinical trials according to their unique cancer case.

We enlist dedicated staff to collect medical records and treatment history and match patients to eligible trials near their home. We provide full support throughout your enrollment process to ensure logistics are handled so you can concentrate on your health.



Massive Bio Launches Industry's First NASA-Style, Oncology Clinical Trial Command Center



The National Cancer Institute Awarded Contract to Develop an Oncology Based Artificial Intelligence-Enabled Clinical Trial Recruitment Tool



Contact Information



Fiona Evans Lead Patient Advocate Phone: 646.586.2753

Email:

fevans@massivebio.com



Jackie Bement Patient Advocate Phone: 646.453.7362

Email:

jbement@massivebio.com

Email

Support@massivebio.com

Website

www.massivebio.com

A patient advocate will contact you in 24 hours after downloading this guide to further discuss your eligibility for clinical trials. To begin receiving your complimentary clinical trial matching results, complete the Synergy-Al agreement below.

SYNERGY-Al Clinical Trial Matching











Sources

January 14, 2., December 10, 2., & November 30, 2. (n.d.). Making cancer clinical trials available to more patients. Retrieved February 11, 2021, from https://www.cancer.gov/news-events/cancer-currents-blog/2019/expanding-clinical-trial-eligibility-criteria

Paying for cancer clinical trials. (n.d.). Retrieved February 11, 2021, from https://www.cancer.gov/about-cancer/treatment/clinical-trials/paying

Rosenzweig, A. (2020, January 30). 5 reasons why it's safe to participate in clinical trials. Retrieved February 11, 2021, from https://www.pancan.org/news/5-reasons-clinical-trials-safe/