



CLINICAL TRIALS

Key information for patients and caregivers

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UNDERSTANDING CLINICAL TRIALS: A COMPREHENSIVE OVERVIEW

Clinical trials are important research studies, preceded by profound research in pre-clinical models (tumour tissue cultures, organoids, animals) that have identified a drug with proven anti-cancer activity. Clinical trials involve patients in the testing of potential new medical treatments. Such studies help us learn about the safety and effectiveness of these treatments. They play a crucial role in advancing medical knowledge, improving cancer care, and enhancing the quality of life for people dealing with cancer.

Participating in a clinical trial not only offers patients an opportunity to access innovative treatments but also provides hope and possibly extends life or provides cure for those with cancer. By joining a trial, patients may experience benefits directly, such as receiving cutting-edge therapies that could positively impact their health outcomes. If you are thinking about joining a clinical trial, it's essential to talk to your doctor. Your attending physician can help you figure out if you are eligible and find the right trial for you. They can also connect you with the hospital or doctor in charge of the trial.

PURPOSE OF CLINICAL TRIALS: DESIGNING NEW DIAGNOSTIC AND TREATMENT STRATEGIES

Clinical trials are like testing grounds for new medical, radiation or surgical methods that aim to discover, prevent, diagnose, and treat cancer. Beyond this, they hold significant value for patients themselves. Clinical trials play a crucial role in improving how we manage cancer, and its treatment side effects, directly impacting the quality of life for those dealing with the disease. By participating in clinical trials, individuals contribute to the ongoing evolution of cancer care. This involvement not only gives patients access to potentially life-saving treatments but also inspires hope and extends the time available for those facing any stage of cancer.

IMPORTANCE OF CLINICAL TRIALS: ADVANCING CANCER CARE

Taking part in clinical trials has real impacts on the future of cancer care. Many individuals join trials not only to potentially benefit themselves but also to help future patients. The results from past trials have significantly extended lives, highlighting the ongoing importance of research.

When you engage in a clinical trial, you actively contribute to our understanding of cancer, helping to shape better care for future generations. In summary, clinical trials are a crucial part of medical research, providing hope for improved cancer care and treatment outcomes. By considering participation, individuals become active contributors to the ongoing pursuit of medical advancements that will shape the future of cancer management, for the benefit of both current and future patients.

MOTIVATIONS FOR JOINING CLINICAL TRIALS: DIVERSE PERSPECTIVES

Individuals participate in clinical trials for several reasons. Those with cancer may join to help themselves, as a clinical trial offers the possibility to access a new and promising treatment, they would otherwise not be able to receive. Individuals with specific risk factors may choose

to participate in trials not only to support future patients but also to aid family members, particularly in cases of inherited mutations, thus contributing to cancer prevention. Healthy volunteers play a crucial role in early cancer detection research. Overall, participants share a common goal of advancing cancer research and fostering scientific progress for the benefit of others.

In essence, clinical trials offer both hope and tangible benefits to patients, providing access to cutting-edge treatments while actively shaping the future of cancer care and treatment outcomes.

TYPES OF CLINICAL TRIALS: EXPLORING TREATMENT POSSIBILITIES

There are various types of clinical trials, each focusing on specific research questions. As per the United States National Cancer Institute, clinical trials can be grouped into the following categories:

- Treatment trials
- Prevention trials
- Screening trials
- Supportive care or Palliative care trials.

The majority of clinical trials are treatment trials, driven by the need for a deeper understanding of genetic changes leading to cancer. Researchers investigate targeted treatments tailored to specific genetic alterations within tumours to improve outcomes. These trials play a crucial role in answering questions about treatment effectiveness, side effects, and overall impact on patients' lives.

UNDERSTANDING THE MECHANICS OF CLINICAL TRIALS

Clinical trials follow distinct phases, each adhering to rigorous guidelines that determine participant eligibility. Becoming familiar with how clinical trials operate can assist you in making informed decisions about whether or not to participate.

ENSURING SAFETY IN CLINICAL TRIALS

Before individuals can enrol in a funded clinical trial, the proposed trial usually undergoes rigorous analysis by experts in relevant fields to ensure it is founded on sound scientific principles. While not mandatory, other sponsors of trials, including pharmaceutical companies, often seek expert opinions on the scientific validity of their trials.

When you participate in a clinical trial, your safety is prioritised through meticulous processes, including the informed consent procedure, thorough review, and approval of the trial protocol by an ethics committee, and health authorities, as well as continuous monitoring. These measures collectively safeguard participants throughout the trial duration.

FUNDING CLINICAL TRIALS: UNDERSTANDING FINANCIAL RESPONSIBILITIES

The financing of a clinical trial involves collaboration between the study sponsor and the patient's health insurance carrier. Generally, the sponsor and the insurance carrier cover most, if not all, of the trial-related costs. However, participants may be responsible for expenses related to treatments and procedures not covered by their insurance. Before enrolling in a study, it is

advisable to inquire about the specific costs covered by your health plan and those supported by the study. This ensures a clear understanding of your potential financial commitments in advance.

Participating in a clinical trial abroad

Participating in a clinical trial abroad involves significant challenges, as it not only requires physical endurance but also regular consultations, follow-up tests, and a potential extended stay in another country. The emotional burden of being separated from friends and family, along with the financial aspect of covering transportation and accommodation expenses, may make participation difficult. Moreover, certain examinations considered routine in the trial location may not be standard in the patient's home country, resulting in additional costs not covered by the study organizer. While it is advised to consult the patient's health insurance carrier, they often provide limited assistance in such cases.

Participating in a clinical trial in Europe

In Europe, there is a form designed to cover the costs of planned treatment abroad, including participation in clinical trials, through the patient's healthcare insurance.

Known as the S2 form, it authorizes planned health treatment ([Planned medical treatment - Employment, Social Affairs & Inclusion - European Commission \(europa.eu\)](#)) in another EU or EFTA (European Free Trade Association) country for individuals legally residing in an EU country. Regardless of nationality, you are entitled to benefits similar to those of residents in the host country, with the option to have a percentage of costs covered in advance. Issued by your health insurance authority, the S2 must be submitted to the health insurance authority in the country where you plan to receive treatment ([Public Access Interface \(europa.eu\)](#)).

Participating in a clinical trial outside Europe

For more information, consult the website of the United States government, the National Cancer Institute: [Clinical Trials Information - NCI \(cancer.gov\)](#).

SERVICES OFFERING TRIAL SEARCH ASSISTANCE TO PATIENTS

Identifying the right clinical trials can be challenging for individuals unfamiliar with registry databases, as they require knowledge of specific keywords and the ability to navigate various inclusion and exclusion criteria. Due to the complexity and technical language of these registries, finding trials independently may not be easy. To assist patients in overcoming these challenges while searching for trials, several services are available, including:

- **My Cancer Navigator (MCN)**: [We help patients \(anticancerfund.org\)](#) – This free service offered by the AntiCancer Fund (ACF) provides expert assistance in trial searches in English, French and Dutch. Its experienced researchers can rapidly identify potentially suitable clinical trials for patients.
- **Cancer Commons**: [Cancer Commons - Help for those with advanced cancer](#) – This is another complimentary service that provides informed treatment guidance and referrals to navigate the complexities of cancer care. Their experts look at how the patient is currently being cared for, check different tests and treatment plans, and give the patient personally curated resources and options.

Additionally, there are organizations developing AI-supported databases where individuals can independently search for trials, such as CureWiki ([Curewiki | find the right clinical trial](#)) and myTomorrows ([myTomorrows – Helping patients discover and access treatments](#)). As these platforms aim to connect trial investigators with patients, they primarily focus on this service, lacking the comprehensive support provided by others to patients and their caregivers.

CLINICAL TRIALS REGISTRIES AND DATABASE

There are different trial registries currently available that allow you to search for information about trial protocols and results in English:

- The EU Clinical Trials Register: [Clinical Trials Register](#)
- The Clinical Trials Information System (CTIS): [Search for clinical trials - EMA \(euclinicaltrials.eu\)](#)
- The U.S. National Library of Medicine: [Home | ClinicalTrials.gov \(Advanced Search - ClinicalTrials.gov old version website\)](#)
- The International Clinical Trials Registry Platform: [ICTRP Search Portal \(who.int\)](#). This is a consolidated database which includes information from all three databases mentioned above and many more.

There are also international ([Clinical Trial Discovery \(findclinicaltrials.eu\)](#)), treatment-specific ([CRI Clinical Trial Finder \(careboxhealth.com\)](#)) and disease-specific databases ([Clinical trial finder - Pancreatic Cancer UK](#)) available online, in different languages.

These databases primarily serve as interfaces to assist patients in searching for clinical trials. While they rely on and link back to Clinical Trials Information System (CTIS) of EudraCT ([EudraCT Public website - Home page \(europa.eu\)](#)), their capabilities are limited by the constraints of these registries.

REMEMBER! If you are thinking of joining a clinical trial, it's essential to talk to your doctor.



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