Clinical Research & You

An Introduction to Clinical Trials

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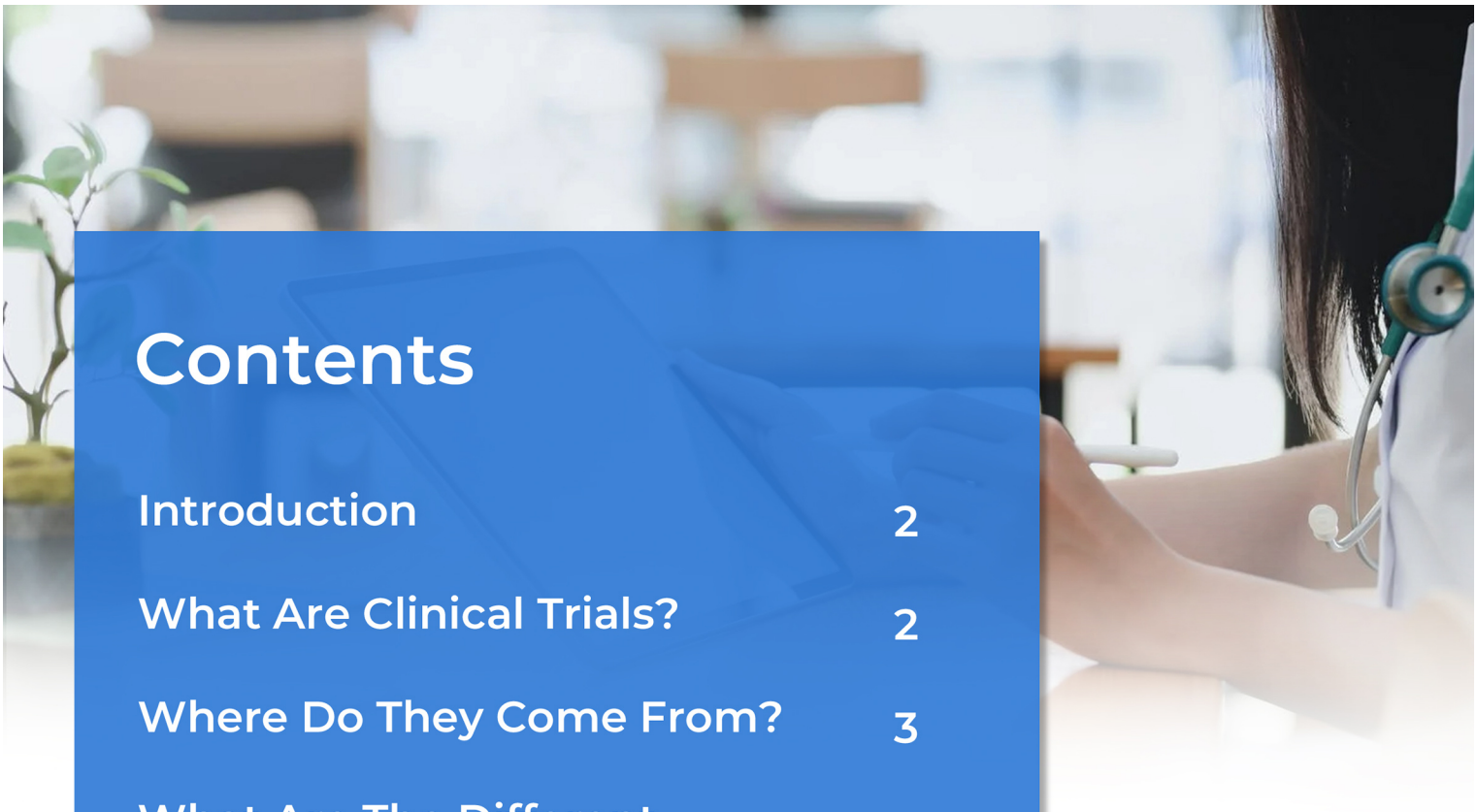

Contents

02 - ebook-1.jpg

Introduction

Clinical Trials are a part of the medical framework that has allowed progress in medicine, treatment, and overall care to all citizens of the world. Clinical Research campaigns have been led to fight major pandemics like cholera, influenza, typhus, smallpox, and measles. Clinical Research has also contributed to affordable pharmaceuticals, also known as generic drugs. Clinical Research is a unique type of research because it involves human subjects which enables scientist to look further into determinants of how well a treatment will work. Characteristics of the patients such as age, sex, race, weight, height, and other genetic factors, can help determine approximately how well a new medication or treatment will work. Clinical Research relies on participation from all demographics to ensure there is enough accurate information to help all populations with research to the new medication or treatment. This E-book is aimed at providing you a snapshot of the process and answer common questions people have about Clinical Research Trials.

What Are Clinical Trials?

Clinical Trials are medical research studies involving people as the subjects. These trials look at preventing disease, new treatments, diagnosing disease, and controlling symptoms. The earliest clinical trials consisted of changes in diet to improve health, introduction of certain fluids to treat symptoms and changing treatment methods to control disease. Now most clinical trials consist of innovative medication that have shown positive results in laboratory test and are in need of additional information for the FDA to approve for distribution.

03 - ebook-2.jpg

Where do Clinical Trials come from?

Clinical Trials, like most research studies, come from questions about health issues in the environment or how treatment can be improved to increase quality of life for patients. These questions or inquiries can come from Researchers who have spent an extensive time learning about the disease and are interested in ways of improving current medication or treatment uses. Some ideas for studies are generated through patient and physician relationships, where patients may find undisclosed side-effects in their current medication. The general public also plays an important role of helping identify important concerns of the community and push for research in specific areas.

What are the Different Phases of Clinical Trials?

PHASE I trials are studies that assess the safety of a new drug or device. The study researchers evaluate the safety of the drug or device, the best dose or schedule to use, and what types of side effects occur. This phase usually has a small treatment group, 20 to 100 participants. This phase trials are often called non-blinded or non-randomized studies because all people involved know what medicine is being used.

PHASE 2 trials are studies that test efficacy (the capacity for beneficial change) of a drug or device. This study involves a larger group of patients and last for several months. Most phase II studies are considered randomized trials where one treatment group receives the research medication and another receive a placebo. Often in these trials both the patients and the researchers are blinded and are unaware who is receiving experimental drug.

PHASE 3 trials are studies to confirm the effectiveness of the experimental drug or device. These trials usually consist of the largest number of patients and can last several years. The experimental drug or device is compared with commonly used treatment or a placebo. Researchers will monitor side effects and track changes to quality of life, of the participants in the study.

PHASE 4 trials are studies of medicines or treatments after they have been approved by the FDA, but requires the manufacturer to monitor its effects. These trials help discover if there are different ways to administer, to find additional risks or benefits of the drug or treatment.

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Who can participate in Clinical Trials?

Every Clinical Trial has guidelines about who can participate. They are explained in the inclusion/exclusion criteria, which helps to produce accurate results. The inclusion criteria are items that permit someone to participate in the clinical trial. The exclusion criteria are items that would prohibit someone from participating in the clinical trial. Some of the factors in both the inclusion and exclusion are things like age, gender, BMI, medical history, and lab results. Before joining a study the potential participant must qualify for the trial. “It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.” – Clinicaltrials.gov

What is Informed Consent?

Informed Consent is a process that allows the potential participant to learn key facts about the clinical trial before deciding whether or not to join. In addition to the synopsis the patient is told the risk and benefits associated with the study. It is a continual process that allows the participant to receive information through the study. The patient signs the informed consent document to agree to participate in the study, but unlike a contract the patient may withdraw consent at any time.

05 - ebook-4.jpg

What are the Risks and Benefits of participating in a Clinical Trial?

BENEFITS

Clinical trials that are well-designed and well-executed are the best approach for eligible participants to:

- Play an active role in their own health care.
- Gain access to new research treatments before they are widely available.
- Obtain expert medical care at leading health care facilities during the trial.
- Help others by contributing to medical research.

RISKS

There are risks to clinical trials.

- There may be unpleasant, serious or even life-threatening side effects to experimental treatment.
- The experimental treatment may not be effective for the participant.
- The protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

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Prior to participating in any Clinical Trial you should consult your healthcare providers about the details of the trials. In addition to your healthcare providers you should talk with the Researchers who are performing the trial.

WHAT QUESTIONS TO ASK

- What does the trial hope to accomplish?
- What side effects might I experience? Are these worse than those I might experience with standard treatment?
- Who is sponsoring the trial?
- What should I expect if I am in the trial? What should I expect if I am not in the trial?
- What are the possible benefits to me and my family if I go into the trial?
- Will I have to pay for the treatment? Will any of the treatment be free?
- Will joining a trial keep me from being treated with other therapies, either now or later?
- Whom can I call if there are problems while I am in the trial?
- What phone number should I call in the evening or on weekends?
- Is there anything I am not allowed to do while I am in the trial?

Information for the E-Book was gathered from the Following Sources:
Centerwatch.com, Clinicaltrials.gov, Webmd.com, Clinicalconnection.com, Cancer.gov

07 - ebook-6.jpg