Clinical Trials

Clinical trials are essential to bringing life-changing drugs and medical devices to market.

The purpose of clinical trials

Clinical trials research potential new medical treatments and procedures by studying their impact in a controlled environment.

Why are they important?

Clinical trials ensure that new treatments, drugs and devices are safe and effective before they are given to the public.

Trials are carefully designed, reviewed and approved before they begin, and the whole industry is heavily regulated. Understanding the unique, complex threats is vital for all companies.

The phases of a clinical trial

Phase I and First in Human

Usually involving smaller trials of healthy volunteers, Phase I aims to assess the:

- ✔ Safety and tolerability for accurate dosage of the treatment/product
- ✔ Potential side effects of the investigational treatment/product
- ✔ Half-life of the product, and how the body initially reacts with the treatment/product

Phase I studies are often dose escalation studies. This means that the first few patients who take part (called a cohort or group) are given a very small dose of the drug. If all goes well, the next group receives a slightly higher dose, which gradually increases with each group.

Researchers monitor the side effects and how the patients feel until the best dose is found. For pharmaceuticals and therapies treating serious illnesses such as cancer or viral infections, the studies are usually carried out on patients with advanced stages of the illness and whose previous treatment failed.

Phase II

Phase II trials compare the new treatment with another existing treatment in use or a placebo. These tests are carried out on compromised patients with the illness that the investigational product is designed to treat.

Phase II trials aim to:

- ✔ Assess clinical efficacy for the specified illness
- ✔ Develop further understanding on side effects and how to effectively manage them
- ✔ Develop further understanding on safety and efficacy of dosages
- ✔ Determine if the treatment works well enough to be tested in larger Phase III trials

Phase III

Phase III trials compare the new treatment against available standard treatments and aim to discover:

- ✔ Whether the new treatment works better than an existing treatment, if available
- ✔ How the treatment affects the patient's quality of life
- ✔ More about the side effects

Phase III trials typically have a much larger participant size than Phase I or II because the difference in success rates may be small.

Phase IV

Phase IV or post-marketing trials are completed after the drug has been shown to work and has been commercialized or licensed.

Phase IV trials aim to understand:

- ✔ More about the side effects and safety of the drug
- ✔ How well the drug works when it's used more widely
- ✔ The long-term risks and benefits

Medical device trials

Medical device clinical trials are unique because they are typically smaller in scale and require fewer phases. Device studies are difficult to randomize and control because many are dependent on a physician's technique, and device modifications usually happen during the trial. Sometimes it's impossible or unethical to use a placebo in a medical device study.

Observational trials

An observational clinical trial monitors conditions and health over time. The patients in these trials may be receiving treatment but are not assigned to specific interventions. The data collected from these studies advances researchers' understanding of a condition and its treatments. There are two main types of study:

- Cohort studies compare what happens to participants of the cohort that have been exposed to particular variables against members not exposed.
- Case control studies identify people with an existing health problem and a similar group without the problem and then compare them to exposure(s).

Exposures and solutions

The main exposure with clinical trials is bodily injury (including death) to the participants of the trial.

Our clinical trial liability protects against potential injuries to participants arising out of their participation in the trial caused by the study drug or medical device.

CNA has the ability to write clinical trials in multiple territories.

Whether it's bodily injury or property damage stemming from the life sciences product, you need an insurance carrier that understands the challenges facing professionals and organizations dedicated to the creation, distribution or use of life sciences products and services.

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