SURA TECHNOLOGY RISKS

Clinical trials

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

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?

Experimenting and testing has always been at the heart of medical advancements. Clinical trials ensure that the 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 Phase I First in Human

Usually smaller trials of healthy volunteers. The main aims of Phase I trials are to assess the:

- Safety, 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.

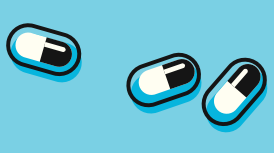
Phase I studies are often dose escalation studies. This means that the first few patients that take part (called a cohort or group) are given a very small dose of the drug. If all goes well, the next group have a slightly higher dose, and then gradually increases with each group.

The researchers monitor the side effects and how the patients feel, until they find the best dose. For pharmaceuticals and therapies that are for serious illnesses, such as cancer or viral infections, the studies are usually carried out on patients with advanced stages of the illness due to previous treatment failing.

Phase II

Phase II trials are typically bigger than Phase I trials, with the new treatment compared to another existing treatment in use, or with a placebo. These tests are carried out on compromised patients with the illness that the investigational product is designed to treat. The main aims of a phase II trial are 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
- Learn if the treatment works well enough to be tested in larger Phase III trials.

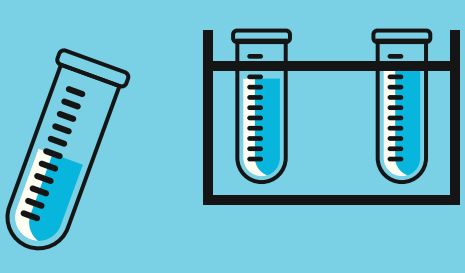


Phase III

This phase of the trial compares the new treatment against available, standard treatments. Its main aims are to discover:

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

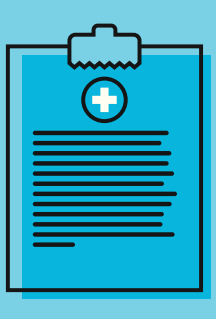
Phase III trials typically have much larger participant size than Phase I or II because the differences in success rates may be small.



Phase IV

Phase IV or post marketing trials are completed after the drug has been shown to work and has been commercialised or licensed. The main aims of a Phase IV trial are to understand:

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



Medical device trials

Medical device clinical trials are unique, typically because they are smaller in scale overall and require less phases. Device studies are difficult to randomise, and control. Many are dependent on physician's technique, and device modifications usually happen during the trial. It is sometimes impossible or unethical to use a placebo in a medical device study.

Observation trials

An observational clinical trial monitors conditions and health over time. The patients in these trials may be receiving treatment, but they 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 study drug or medical device.

Find out about our specialist life science solutions by contacting your SURA Technology Risks underwriter

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

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