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Glossary of Clinical Trial terms

This glossary provides definitions for common terms used in the realm of clinical research and trials. Whether you're a participant, caregiver, researcher, or simply interested in understanding the language of clinical trials, this resource aims to demystify key terminology. As you explore our glossary, we hope you find clarity and insight into the terminology commonly encountered in clinical trials. Should you have any questions or need further clarification, don't hesitate to reach out to our team.

Clinical Research:
Clinical research is a vital aspect of medical exploration, focusing on understanding diseases and how the human body functions. It often involves human participation and plays a crucial role in advancing medical knowledge and treatments.

Clinical Trials:
Clinical trials are a fundamental component of clinical research. These studies involve human participants and aim to test new treatment drugs, evaluate management techniques, or explore the mechanisms of diseases. Clinical trials are essential for developing and improving medical interventions. There are many types of clinical trials including Diagnostic trials, Prevention trials, Screening trials, or Diagnostic trials.

Huntington's Disease Clinical Trials:
Huntington's disease clinical trials specifically target this neurodegenerative disorder. Researchers investigate new medications to alleviate symptoms, reduce the levels of the Huntingtin protein, or slow down the disease's progression.

Healthy Volunteer:
A Healthy volunteer is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention.

Trial participant:
Any individual who has been diagnosed with some health problem and consents to participate in a clinical trial to better understand, diagnose, treat, or cure that disease or condition.

Informed Consent:
Consent given by any individual after someone explains risks and potential benefits about a clinical trial in a language or manner that is comprehensible for the individual who is participating in the clinical trials.

Inclusion/Exclusion Criteria:
These criteria are factors that allow someone to either participate or to be excluded from participating in a clinical trial. As the name suggests, exclusion criteria allow the researchers to exclude an individual from participating in clinical trials, while, someone who fulfills the inclusion criteria will be part of the clinical trials.

Principal Investigator (PI):
A Principal Investigator is a clinician leading the clinical research. Working alongside a team of other researchers, a PI is responsible for regular monitoring of study participants' health to determine the study's safety and effectiveness.

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Study protocol:
A Protocol is a carefully designed trial document, which contains the study question, study methodology, inclusion and exclusion criteria and more information on the study to safeguard participant health and run the clinical trials smoothly over multiple centres across the globe.

Randomisation:
Randomisation is the process by which two or more alternative treatments are assigned to volunteers by chance rather than by choice. Most often, the study participants are grouped into sub-groups and are given either different doses of the study drug or sometimes get either placebo or the trial drug, sometimes without the knowledge of the participant.

Cohort:
A group of people in a clinical trial who receive the same treatment.

Baseline:
A starting point used in clinical trials to mark the participant's condition before any intervention occurs. Measurements taken at baseline serve as a reference for comparison over time to identify changes.

Placebo:
A placebo is a substance with no therapeutic effect, used to eliminate psychological biases during clinical trials.

Placebo effect:
A phenomenon where individuals exhibit improvement or feel better after receiving a treatment, even if it is inactive (placebo). Researchers aim to minimize the placebo effect in clinical trials to ensure accurate assessment of treatment efficacy.

Bias:
Factors that could influence the outcomes of a clinical trial, aside from the intervention being studied. Measures such as blinding and randomization are implemented to minimize bias and ensure the reliability of trial results.

Blinding:
A method employed in clinical trials to prevent bias. In a single-blinded study, participants are unaware of the treatment they receive, while in a double-blinded study, both participants and researchers are unaware of the treatment allocation.

Double-blinded study:
A double-blinded study is a clinical trial where neither the doctor nor the participant knows which treatment the participant is having. These trials are designed to prevent bias from affecting the results of the trial.

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Single-blinded study:
A single-blinded study is a clinical trial in which the doctor and the research team know which treatment the participant is being given, but the participant doesn't know.

Control group:
The group of participants in a clinical trial that receives the control treatment, typically the best standard treatment available. This group is compared with another group receiving the experimental treatment.

Dose escalation:
The gradual increase in the dosage of a new drug to determine the optimal dose. Often conducted in Phase I clinical trials with a small number of patients, followed by dose expansion to gather more data in larger groups.

Human Research Ethics Committee (HREC):
A committee tasked with safeguarding the rights and well-being of clinical trial participants by reviewing and approving trial protocols. Comprised of diverse professionals, they ensure the ethical conduct and safety of clinical trials.

Intervention:
A treatment, procedure, or action administered to prevent or treat disease or enhance health. In clinical trials, interventions are tested to evaluate their efficacy and safety.

Intravenous (IV):
Administration directly into a vein. Intravenous drips deliver fluids and/or medications directly into the bloodstream.

Intramuscular injection:
Administration into a muscle via injection

Orally:
Refers to medications taken by mouth, such as tablets, capsules, or liquids swallowed.

Topical administration:
Any drug that is applied on a surface, such as the skin.

Inhalation:
Any medicine that can be introduced into the body by inhalation.