

## **KnoPro | Glossary Health Equity Challenge**

**Business Concept** – A way to serve individuals, other businesses, or communities by delivering services or selling products.

**Clinical trial phase** – The stage of a clinical trial, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics.

**Clinical trial phase 1** - The purpose of Phase 1 is to ensure that the treatment is safe in humans and to determine how and where it distributes within the body. This testing normally takes place with a small group of healthy volunteers.

**Clinical trial phase 2** – To determine the right dosage and effectiveness in treating that particular disease. This testing normally takes place with a larger number of volunteers who have the disease, and uses different doses and a placebo treatment.

**Clinical trial phase 3** – A Phase 3 Clinical Trial involves a much larger group of volunteers and primarily focuses on determining whether the treatment would be safe and effective for a wide variety of people.

**Clinical trial phase 4** – After approval by the FDA and manufacturing of the drug on a large scale by the sponsor, the process enters what is called Phase 4 Clinical Trial. For at least the entire time a treatment is on the market, the FDA monitors for public safety and potentially serious adverse events. (<u>Source</u>)

**Cohort** – A group or subgroup of participants in an observational study that is assessed for biomedical or health outcomes. (<u>Source</u>)

**Competitive Analysis** – a strategy that involves researching major competitors to gain insight into their products, sales, and marketing tactics. (<u>Source</u>)





Concept Map - Concept maps are visual representations of information. (Source)

**Diseases** – A disordered or incorrectly functioning organ, part, structure, or system of the body resulting from the effect of genetic or developmental errors, infection, poisons, nutritional deficiency or imbalance, toxicity, or unfavorable environmental factors; illness; sickness; ailment.

**Disparity** - lack of similarity or equality; inequality; difference.

**Diversity** - A collection of individual attributes that together help agencies pursue organizational objectives efficiently and effectively.

**Eligibility Criteria** – The key requirements that people who want to participate in a clinical study must meet or the characteristics they must have. Eligibility criteria consist of both inclusion criteria and exclusion criteria.

Enrollment – The number of participants in a clinical study.

Ethics - Moral principles that govern a person's behavior or the conducting of an activity

**Equity** - The quality of being fair and impartial.

**Exclusion Criteria** – A type of eligibility criteria. These are reasons that a person is not allowed to participate in a clinical study.

**Food and Drug Administration (FDA)** – Responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. The FDA also has the responsibility in maintaining the safety of our nation's food supply (human and animal), cosmetics, and products that emit radiation. (<u>Source</u>)

**Immunotherapy** – Treatment designed to produce immunity to a disease or enhance the resistance of the immune system to an active disease process.

**Inclusion** - The practice or policy of including and integrating all people and groups in activities, organizations, political processes, etc., especially those who are disadvantaged, have suffered discrimination, or are living with disabilities.

**Inclusion Criteria** – A type of eligibility criteria which are required for a person to participate in the study.

**Informed Consent** – A process used by researchers to communicate to potential and enrolled participants the risks and potential benefits of participating in a clinical study.





**Insight Statement** – A discovery of understanding and the identification of unmet needs to explain why something is happening the way it is. (<u>Source</u>)

**Intervention** – A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise.

**Interventional study** – A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes.

Iterating - To do (something) over again or repeatedly.

**Marketing Campaign** - An effort to have an impact on a lot of people or a specific group of people to persuade them to change something about themselves or their behaviors by developing awareness.

**Medical Research** – Involves research in a wide range of fields, such as biology, chemistry, pharmacology and toxicology with the goal of developing new medicines or medical procedures or improving the application of those already available. (<u>Source</u>)

Medical Treatment – The management and care of a patient to combat disease or disorder.

**Observational study** – A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific intervention/treatment.

**Pitch** - A short presentation that is given with the intention of persuading someone of your ideas.

**Placebo** – An inactive substance or treatment that looks the same as, and is given in the same way as, an active drug or intervention/treatment being studied.

**Proof of Concept** – Evidence, typically derived from an experiment or pilot project, which demonstrates that a design concept, business proposal, etc., is feasible. (Proof of concept vs prototype)

**Protocol** – The written description of a clinical study. It includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information.





**Problem Statement** – Identifies the issue that is a concern and focuses in a way that allows it to be studied in a systematic way.

**Product Design** - Something that people will use that could be marketed, has value on its own.

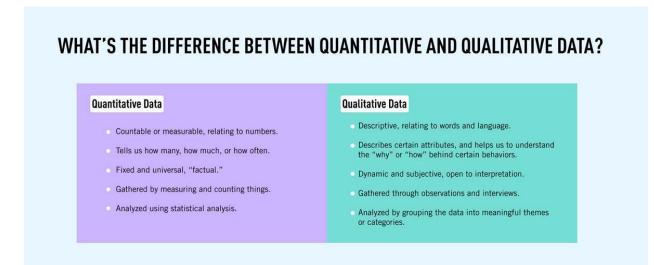
**Prototype** - Prototyping is a process of developing a new product through the physical representation of an idea. (<u>Proof of concept vs prototype</u>)

**Research** - Diligent and systematic inquiry or investigation into a subject in order to discover or revise facts, theories, applications, etc.

**Quality control** – A system for verifying and maintaining a desired level of quality in an existing product or service by careful planning, use of proper equipment, continued inspection, and corrective action as required. (<u>Source</u>)

**Qualitative Data** – Descriptive and regards phenomenon which can be observed but not measured, such as language. (describes attributes to understand the "why" or "how".) (<u>Qualitative vs Quantitative</u>)

**Quantitative Data** – Measurable, related to numbers and nswers the questions what or how many. (<u>Qualitative vs Quantitative</u>)



**Randomized** – To order or select in a random manner, as in a sample or experiment, especially in order to reduce bias and interference caused by irrelevant variables; make random.

**Social Determinants of Health (SDOH)** – The conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks





The 5 Domains are:

- 1) Economic Stability,
- 2) Education Access and Quality,
- 3) Health Care Access and Quality,
- 4) Neighborhood and Built Environment,
- 5) Social and Community Context

**Sponsor** – The organization or person who initiates the study and who has authority and control over the study.

**Trial** - A type of research study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes.

