GLOSSARY OF RESEARCH TERMINOLOGY:

Standard & plain language versions, for patient advocates

Standard language version:

Research & Study Design

- **Clinical Research** – Studies involving people to learn about diseases, treatments, or health outcomes.
- **Clinical Trial** – A type of clinical research that tests a medical intervention (drug, device, procedure, behaviour).
- **Observational Study** – Researchers observe outcomes without assigning treatments.
- **Interventional Study** – Researchers actively assign a treatment or action to participants.
- **Protocol** – The study's rulebook describing objectives, methods, eligibility, and analysis plans.
- **Control Group** – The comparison group (placebo, standard care, or no treatment).
- **Randomization** – Participants are assigned to groups by chance to reduce bias.
- **Blinding / Masking** – Keeping participants and/or researchers unaware of treatment assignment to prevent bias.
- **Placebo** – An inactive treatment used for comparison.

Participants & Eligibility

- **Inclusion Criteria** – Characteristics required to participate in a study. (Who *can* participate in a study).
- **Exclusion Criteria** – Characteristics that prevent participation, usually for safety or scientific reasons. (Who *cannot* participate).
- **Informed Consent** – The process of explaining the study, including risks, benefits, and participant rights.
- **Enrolment** – The process of joining and being accepted into a study.
- **Retention** – Keeping participants involved in a study until completion.
- **Withdrawal** – When a participant leaves a study (voluntary or because it is required).

Outcomes & Measurements

- **Outcome Measure** – What the study is designed to assess.
- **Primary Outcome** – The main question the study is designed to answer.
- **Secondary Outcomes** – Additional effects or questions the study examines.
- **Endpoint** – A specific event or result used to measure outcomes.
- **Biomarker** – A biological sign (such as a blood test, imaging result, or gene) indicating disease or response to treatment.
- **Surrogate Endpoint** – A substitute measure used instead of a direct clinical outcome (e.g., lab value instead of survival).

Patient-Centred Research Terms

- **Patient-Reported Outcomes (PROs)** – Information reported directly by patients (such as symptoms or quality of life).
- **Quality of Life (QoL)** – How a disease or treatment affects daily living and overall well-being.
- **Patient Experience Data** – Information about what it is like to live with a condition and its treatments.

- **Patient Engagement** – Meaningful involvement of patients in research planning, conduct and decision-making.
- **Co-creation / Co-design** – Patients and researchers working together to shape studies.
- **Health Equity** – Fair access to research participation and healthcare across populations.
- **Underrepresented Populations** – Groups historically excluded or insufficiently included in research.

Safety & Ethics

- **Adverse Event (AE)** – Any negative health event during a study.
- **Serious Adverse Event (SAE)** – Life-threatening, disabling, or fatal events.
- **Risk–Benefit Ratio** – Comparison of potential harm versus potential benefits.
- **Ethics Committee / Institutional Review Board (IRB**)– Independent group that reviews studies to protect participants.
- **Data Safety Monitoring Board (DSMB)** – An independent group that monitors safety during a trial.
- **Confidentiality** – Protecting participants' personal health information.

Data, Analysis & Results

- **Statistical Significance** – The likelihood that results are not due to chance.
- **Clinical Significance** – Whether results make a meaningful difference for patients.
- **Sample Size** – Number of participants in a study.
- **Power** – The ability of a study to detect a meaningful effect if one exists.
- **Bias** – Systematic errors that can affect results.
- **Real-World Evidence (RWE)** – Data from routine care, registries, or patient reports.
- **Generalizability** – How well study results apply to the broader patient population.

Regulation & Access

- **Regulatory Agency** – A government body that reviews and approves treatments (e.g., FDA, EMA).
- **Investigational Product** – A treatment that is still being tested and not yet approved.
- **Approval** – Authorization for public use after review of evidence.
- **Expanded Access / Compassionate Use** – Access to investigational treatments outside clinical trials.
- **Post-Marketing Study** – Research conducted after approval to monitor long-term safety and effectiveness.

Advocacy-Relevant Concepts

- **Meaningful Benefit** – Improvement that patients consider important.
- **Treatment Burden** – The effort, side effects, and life impact of treatment.
- **Unmet Medical Need** – Conditions where effective treatments are lacking.
- **Shared Decision-Making** – Patients and clinicians making healthcare decisions together.
- **Transparency** – Open sharing of study goals, risks, and results.

Plain language version:

What Research Is

- **Medical Research** – Studies that help us learn about diseases and treatments.
- **Clinical Study** – Research that involves people.
- **Clinical Trial** – A study that tests a new treatment or a new way to use a treatment.
- **Study Plan (Protocol)** – The written plan for how the study will be done.

Who Can Join a Study

- **Participant** – A person who takes part in a study.
- **Inclusion Rules** – Who is allowed to join the study.
- **Exclusion Rules** – Who is not allowed to join (often for safety reasons).
- **Informed Consent** – A form and conversation explaining the study before someone joins.

Study Groups

- **Treatment Group** – People who receive the study treatment.
- **Control Group** – People who get usual care or a "dummy" treatment.
- **Placebo** – A dummy treatment with no medicine in it.
- **Random** – People are put into groups by chance (like flipping a coin).

What the Study Measures

- **Outcome** – What the study is trying to learn or measure.
- **Main Outcome** – The most important result the study looks at.
- **Side Effects** – Unwanted effects from a treatment.
- **Biomarker** – A lab test or scan that shows what is happening in the body.

Patient Voice

- **Patient-Reported Outcome** – Information patients report themselves (such as pain, fatigue, or daily functioning).
- **Quality of Life** – How health affects everyday living and well-being.
- **Patient Experience** – What it is really like to live with a condition or treatment.
- **Patient Engagement** – When patients help shape research, not just take part in it.

Safety & Rights

- **Risk** – What could go wrong in a study.
- **Benefit** – What could help participants or future patients.
- **Ethics Board** – A group that checks studies to protect participants.
- **Privacy** – Keeping personal health information safe.
- **Leaving a Study** – Participants can stop taking part at any time.

Results & Meaning

- **Results** – What the study found.
- **Works Better** – The treatment helps more than current options.
- **Works About the Same** – No clear difference compared to existing treatment.
- **Works Less Well** – The treatment is not better that what is already used.
- **Real-Life Benefit** – Whether results truly matter to patients' lives.

After the Study

- **Approval** – When a government agency allows a treatment to be used.
- **Access** – Whether patients can get the treatment.
- **Follow-Up Study** – Studies done after approval to track long-term safety and effects.

Key Ideas for Advocates

- **Patient-Centred Research**– Research focused on what matters most to patients.
- **Fair Access** – Making sure different communities can take part in research.
- **Clear Language** – Information written so people can understand it.
- **Shared Decision-making** – Patients and doctors deciding together.

References

Clinical Research Basics

- **ClinicalTrials.gov — Glossary of Terms**
  https://clinicaltrials.gov/study-basics/glossary?utm_source=chatgpt.com
- **ClinicalTrials.gov — Learn About Studies**
  https://clinicaltrials.gov/study-basics/learn-about-studies?utm_source=chatgpt.com
- **NIH Glossary of Common Clinical Research Terms**
  https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms?utm_source=chatgpt.com

Patient Voice & Engagement

- **FDA Patient-Focused Drug Development Guidance Series**
  https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical?utm_source=chatgpt.com
- **FDA Patient-Focused Drug Development Program Overview**
  https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development?utm_source=chatgpt.com

Patient-Friendly Language

- **FDA Patient-Friendly Language for Clinical Trials**
  https://www.fda.gov/about-fda/oncology-center-excellence/patient-friendly-language-cancer-clinical-trials?utm_source=chatgpt.com
- **NCI Dictionary of Cancer Terms – Clinical Trial**
  https://www.cancer.gov/publications/dictionaries/cancer-terms/def/clinical-trial?utm_source=chatgpt.com

Optional Overview Resources

- **Wikipedia — Clinical Trial**
  https://en.wikipedia.org/wiki/Clinical_trial?utm_source=chatgpt.com
- **Wikipedia — Inclusion and Exclusion Criteria**
  https://en.wikipedia.org/wiki/Inclusion_and_exclusion_criteria?utm_source=chatgpt.com