MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Clinical Research GLOSSARY

Version 3.0 September 2025

Summary of Updates and Changes

Introduction:

This is the third version of the MRCT Center Clinical Research Glossary: Version 3.0 September 2025. The MRCT Center is committed to full transparency in the creation of the Clinical Research Glossary. This Summary of Updates and Changes outlines how the resource has been modified since the last edition.

Version 3.0 September 2025

- 29 additions
- 0 removals
- 6 changes to existing terms and content

The details of these modifications follow below.

You can access the updated Clinical Research Glossary online and as downloadable Excel and PDF documents here: at www.mrctcenter.org/glossary/

Clinical Research Glossary Additions:

The following terms, along with their plain language definitions, and additional information, were added to the Clinical Research Glossary:

- approval (IRB/ethics)
- biobanking (research)
- blinding
- case-control study
- crossover trial
- decentralized clinical trial
- eSignature
- human subject
- investigational device
- Investigational Device Exemption (IDE)
- long-term follow-up (research)
- masking (study treatment)
- medical device
- opt-in
- opt-out
- participant code
- personal data
- principal investigator
- recruiting (status)
- sample (study)
- screen failure
- Serious Adverse Drug Reaction (SADR)
- sham (procedure)
- study doctor
- study identifier
- study monitor
- study site
- termination (of a research study)
- vaccine

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Clinical Research Glossary Removals

There were no terms removed from the Clinical Research Glossary.

Clinical Research Glossary Changes

The following existing terms were assigned new c-codes and NCI thesaurus links:

- placebo-controlled trial
  https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncit/C203925

The following existing terms had changes to the plain language definitions or other content elements.

- **adverse event**
  The plain language definition changed to refer to "a study" instead of "the study."
- **adverse reaction**
  The plain language definition changed to refer to "a study" instead of "the study."
- **Institutional Review Board**
  "More information" changed to include additional details about the purpose of IRBs.
- **phase**
  The plain language definition changed to remove the reference to devices since phases do not apply to device research. The additional supportive information was also updated.
- **serious adverse event**
  The plain language definition changed to remove the word "can" to indicate that an SAE is anything that leads to hospital care, lasting medical problems, life-threatening conditions, or death.