Glossary of Research Terms

AE: Adverse Event
Any undesirable patient experience.

CDA: Confidentiality Disclosure Agreement
Must be signed before trial protocol can be viewed.

Con Meds: Concominant Medications
Any drug that a patient takes during a trial other than the study drug.

COV: Close-Out Visit
Final monitor visit occurs after patients are no longer being dosed, all data has been collected, and all queries resolved.

CRA: Clinical Research Associate
Commonly known as a "Monitor".

CRC: Clinical Research Coordinator
Responsible for conducting clinical research trial.

CRO: Contract Research Organization
Provides support to pharmaceutical and biotechnology companies.

CV: Curriculum Vitae
Required for every investigator. Documents staff qualifications for the conduct of the trial.

Delegation Log:
List of all qualified research staff who can perform trial-related duties.

EDC: Electronic Data Capture
All clinical trial data must be entered into this computerized system.

Enrollment
Enrollment period begins after all pre-study visits and procedures are completed, study drug is received, and Sponsor opens the trial.

FDF: Financial Disclosure Form
Certifies the absence of financial interest or discloses financial interest of PI. Must be signed by PI before trial opens and again one year after COV.

Forms FDA 1572
Contract between PI and Federal government. Informs PI of obligation to comply with FDA regulations and to personally supervise all aspects of the trial.

GCP: Good Clinical Practice
Must be adhered to for all clinical trials. Ensures credible and accurate data and protects patient's rights. Online training must be completed by all research staff.

IATA Training
International Air Transport Association training ensures the safe and efficient transportation of biological specimens. Completed by site staff.

ICF: Informed Consent Form
Outlines specific trial details for the patient. No research procedure may begin until patient has signed this form.

IE Criteria
Inclusion/Exclusion criteria to help researchers determine who is qualified to participate in trial. Examples are age, gender, medical history.

IMV: Interim Monitor Visits
Meeting takes place between Site and monitor to ensure the trial is being conducted properly.

IP: Investigational Product
Treatment that is being researched. Also known as investigational drug or study drug.

IM: Investigator's Meeting
Most trials begin with protocol training at an IM. A remote IM is typically 1-2 days. Alternatively, an online IM may be 1-2 hours.

IRB: Institutional Review Board
Primary purpose is to ensure that the rights and welfare of the study participants are being protected. Most affiliate sites use the Central IRB chosen by the trial's Sponsor.

Monitor
Also knowns as a CRA. Works for the Sponsor or CRO and is in charge of ensuring compliance with clinical trial protocol, checking Site activity, making onsite visits, and communicating with research staff.

PI: Principal Investigator
Partners with the research site to be responsible for the conduct and oversight of the trial.

PSV: Pre-Selection Visit
The monitor visits the research site to assess site's ability to successfully conduct the trial.

Query
Also known as "Data Clarification Form" or "DCF". Used by trial Sponsor or CRO to clarify data discrepancies or ask for data clarification.

Randomization
A randomized patient is an official participant and will be placed into a specific treatment arm of the study. A patient can only be randomized into a trial after meeting all IE criteria.

SAE: Serious Adverse Event
Must be reported to the Sponsor and IRB within 24 hours of occurrence. Examples are death, hospitalization, and permanent damage.

Signature Page
A protocol's signature page must be signed by the PI to indicate that he/she has read the protocol and agrees to conduct the study per the protocol.

SIV: Site Initiation Visits
The monitor visits the research Site to train the PI and other research staff before enrollment opens.

Sponsor
A pharmaceutical, biotechnology, or medical device company that develops and investigational treatment and designs the clinical research trial.

Sub-I
A sub-investigator is typically a physician, NP, PA or clinician who performs critical trial-related procedures and/or makes important trial-related decisions.

V1, V2, …
Indicates a patient's study visit. A specific schedule of patient visits is outlined for each trial.

iact HEALTH
People • Promise • Progress