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What is a PI? A PI (principal investigator) holds a doctoral-level degree (PhD, PharmD, DNP, DO, MD, DDS or equivalent degree). He/she serves as the principal investigator and accepts responsibility for the safe and ethical conduct of a clinical trial.

PI Certification - ACRP - acrpnet.org

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Adverse Event (or Adverse Experience) Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease ...

Adverse Event Collection: When to Start and When to Stop?

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Pharmaceutical Regulatory Affairs glossary & taxonomy

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