

KNOWLEDGEBASE: STUDY

GENERAL

RegenMed defines a “Study” as an organized approach to collecting and analyzing data to help determine the safety, efficacy or other parameters of a particular healthcare intervention.

All Studies supported by RegenMed involve an Observational Protocol, a Principal Investigator, Cases, Patients, Reports, Consent Forms, Basic Circle Settings, Data Review/Verification and HIPAA/GDPR compliance. Most Studies involve many other elements as well, including Team Members, Advanced Circle Settings and Publication.

The minimum criteria for a Study comprise 100 Cases created within a six-month time period, a single Investigator and Basic Circle Settings. From there, a Study can scale to virtually any level of complexity and size.

TYPES OF STUDIES

A Study may be:

- Designed for human, animal or ex-vivo data.
- Observational, retrospective, prospective, clinical, single- or multi-center.
- Conducted privately, or with the intent to publish.
- Designed, funded and controlled by the same or different persons.
- Open-ended or limited in terms of duration and/or population.
- Designed with one or more control arms, or none.
- Double, partial or non-blinded.
- A Case Series, or subject to oversight by an Institutional Review Board or Medical Ethics Committee.

ILLUSTRATIVE STUDY OBJECTIVES

Study objectives include:

- Traditional medical research, including grant submissions and execution.
- Private clinical investigations.
- Regulatory submissions (e.g., IND's, IDE's, post-market surveillance).
- Development or improvement of medical products.
- Medical education or training.
- Reimbursement support.
- Legal/regulatory compliance.
- Patient education, engagement.
- Developing public awareness, or supporting policy initiatives.
- Journal articles, conference presentations, social media posts.
- Verification of competing products, alternative clinical interventions.

STUDY ECONOMICS

Traditionally, healthcare studies have been expensive, time-consuming and therefore beyond the capabilities of all but well-funded organizations. Today, however, the strong demand among regulators, payers and patients for real-world evidence has put a premium on studies which are clinically and cost efficient. "Pragmatic" and "n of 1" studies and trials are examples. In addition, a properly structured study should generate financial and/or professional value.

RegenMed provides turkey solutions for Studies which are scientifically rigorous, clinically-efficient, low-cost and designed for demonstrable return on investment.

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