

# PSG Introduction to Clinical Trials

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# Course Outline

- Three one-hour seminars at PSG annual meeting
  1. Seminar 1: Introduction to PSG Clinical Trials
  2. Seminar 2: Trial Implementation
  3. Seminar 3: Ethics, Regulatory Concerns, and Investigator Responsibilities

# Seminar I 2011

## Seminar I Goals:

1. Provide a brief introduction to clinical trial conduct and methodology
2. Introduce new members to PSG trial development and member participation
3. Guidance for data mining projects from completed PSG trials



# Sequence of clinical trial phases

traditional sequence

# FDA General Considerations for Clinical Trials

- Cardinal logic of clinical trials, in serially conducted studies the results of prior studies should influence the plan of later studies
- Phase concept is a description, not a set of requirements, phases do not imply a fixed order, many types of studies occur across multiple phases

# Phase I trials

- Typical study: human pharmacology
- Starts with initial administration of new drug into humans
- Usually have non-therapeutic objectives; initial safety and tolerability, pharmacokinetics, and pharmacodynamics

# Phase II trials

- Typical study: therapeutic exploratory
- Initial exploration of therapeutic efficacy
- Determine the dose and regimen for phase III
- Additional endpoints e.g. potential study endpoints, target populations (e.g. mild vs. severe dementia), concomitant medications

# Phase III trials

- Typical study: Therapeutic Confirmatory
- Demonstrate or confirm therapeutic benefit
- Intended to provide a basis for marketing approval

# Phase IV trials

- Typical study: varies, but focused on therapeutic use
- Begins *after* drug approval
- Studies to optimize the drug's use
- Examples include, additional drug-drug interaction, dose-response, mortality/morbidity studies, epidemiologic studies

# Questions?

- Please hold them until the end of the program for the expert panel.