

IRBMED Seminar Series

Phase I Clinical Trials and Safety:
Consideration of a Subject's Death in France

October 4, 2016

Fall Installment

Welcome

- Circumstances for subjects participating in the Bial trial are true with one exception:
- For purposes of the Mock IRB review, the study stopping rules were modified ->

Segue to U-M procedures involving reportable events

Phase I Clinical Trials - Generally

- Testing of a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- Determine the "maximum tolerated dose" of a drug that does not produce unacceptable side effects.

Phase I – Patient Volunteers

- Patient volunteers (such as cancer patients) are followed primarily for side effects, not for how the drug affects their disease.
- The first few volunteer subjects receive low doses of the trial drug to see how the drug is tolerated and to learn how it acts in the body
- The next group of volunteer subjects receives larger amounts (dose escalation)
- Phase 1 studies typically offer little or no benefit to the volunteer subjects

Phase I – Healthy Volunteers

- Testing and dosing parameters are the same as Patient Volunteers but:
- Volunteers have no known significant health problems
- Provide crucial data because their health information can be used as a comparison to individuals who have a specific disease or condition
- Research with healthy volunteers is designed to develop new knowledge, not to provide direct benefit to study participants

Phase I - Safety

- Preclinical research
- Protocol design/documentation
 - Other drugs in the same class
 - Dose escalation
 - Staggered dosing in a cohort
 - Safety labs
- Stopping rules
- Adverse event reporting plans
- Communication between volunteer and study team
- Communication within the study team

Three Video Presentations

Background information about actual events:

- 1) CNN / Clinician interview about Phase 1 clinical trials
- 2) BBC News clip
- 3) US Fox News clip