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