Demystifying Cancer Clinical Trials

Project with the Cancer Center at Tufts Medical Center

Dates: Five Fridays: October 14, November 18, December 16, February 10, March 10
Time: 1:00-5:00PM EST; 20 hours of instruction

Location: TBD

Audience: Fellows, Junior Faculty, Senior Faculty; any other interested party (PhDs, Neely Research Center, Cummings School of Veterinary Medicine, Friedman School of Nutrition, etc.)

Sessions will be filmed and videos posted on Tufts CTSI I LEARN

Goals of Series: (Participants will be able to…)

1. Explain how to navigate investigator-initiated clinical trial processes in cancer.
2. Discuss how to work with pharmaceutical industries and other for-profit entities.
3. Identify what are investigational new drug (IND) and investigational device exemption (IDE) studies and explain how IND/IDE clinical trials are conducted.
4. State the Principal Investigator's responsibilities for leading a clinical trial as well as the responsibilities of the research team.

Pre-work
I LEARN (http://ilearn.tuftsctsi.org/courses/courseCatalog.aspx)

Draft Content Outline

I. **Getting Started: Introduction to the Clinical Research Life Cycle (October 14, 2016)**
   a. **Welcome and Introduction to the Training**
      Presenters: Andreas Klein, Susan Parsons, Andy Evens and Rachel Buchsbaum
      i. Overview of the training and series' expectations
      ii. Overview of goals, anticipated outcomes and how this series fits in with overall training
   b. **Differences between Industry-Sponsored, Industry-supported, and PI-initiated Studies**
      Presenter: Fred Frankhauser
      i. Funding: what is covered and what is not
      ii. Intellectual property: Who owns the idea? What are the restrictions, if any, to publications?
      iii. Conflict of interest
   b. **Clinical Research Lifecycle**
      Presenters: Bob Martell and Andy Evens
      i. Phase I and Phase I/II
      ii. Phase II
      iii. Randomized Phase II/III

II. PI Initiated Clinical Trials – Study Design (November 18, 2016)

a. **Developing a Research Study Protocol**

Presenters: Andreas Klein

- i. Stating your rationale and hypotheses
- ii. Defining outcomes
    1. What do you measure?
- iii. Inclusion-Exclusion Criteria
    1. Reviewing protocol
    2. Research Process Improvement
- iv. Adverse events
    1. Recording and reporting requirements

b. **Collaboration with Statisticians**

Presenter: Lori Lyn Price

- i. When and how to optimize collaboration with statisticians (Process)

c. **Introduction to Study Design**

Presenter: Jess Paulus

- i. Experimental vs. Observational Study Design
- ii. Research Utilizing Existing Data
- iii. Pilot Studies versus Full Studies

d. **Statistical Analysis**

Presenters: Angie Rodday and Farzad Noubary

- i. Sample Size estimates and determination of power
- ii. Stopping Rules
    1. What they mean
    2. When to use them
- iii. Futility Analyses
    1. What they mean
    2. When to use them
- iv. Interim Analyses:
    1. What they mean
    2. When to use them

III. Clinical Trials (December 16, 2016)

a. **Institutional Regulatory Review**

Presenters: Andreas Klein and Jack Erban

- i. Protocol Review and Monitoring Committee
    1. Roles and Responsibilities
    2. Preparation prior to PRMC review
- ii. Scientific Review Committee
    1. Roles and Responsibilities of the SRC
    2. Preparing for peer scientific review
- iii. IRB
    1. What is the IRB and what do they do
    2. Statutory basis in the Common Rule
        a. Reliance agreements, cooperative agreements and central IRB's: Models and relative merits (including cost)
- iv. IBC
    1. Biosafety considerations

b. **Investigator Responsibilities**
   Presenter: Susan Parsons
   i. Ethics of Clinical Research
   ii. How to Lead Studies as PI
   iii. Responsibilities as co-PI
   iv. Team Science
c. **Biorepository: Use of tissue specimens for research**
   Proposed Presenter: Sandra Gaston
d. **Data and Safety Monitoring Board (DSMB)**
   Presenter: Tamsin Knox
e. **Study Budgets**
   Presenter: Doug Reichgott
   i. What does it really cost to run a clinical study?
   ii. Big picture considerations (Study Specific)
   iii. Details needed to construct an appropriate budget for Investigator Initiated, Industry, and NIH or Foundation

IV. Clinical Trials—From PI-initiated to Collaborative Research (February 10, 2017)

a. **Team Science**
   Presenters: Bob Martell and Andy Evens
   i. Finding and working as a collaborator: Cooperative groups, NIH
b. **Engaging with Industry**
   Presenters: Bob Martell and Andy Evens
   i. How to engage with Industry
      1. Know your Medical Science Liaison
      2. The letter of intent – crafting for success
   ii. How to work with Industry
      1. Conflict of interest
      2. Industry Standards
   iii. Case Studies about collaborations
c. **Food and Drug Administration (FDA)**
   Presenters: Andreas Klein & Bob Martell
   i. Investigational New Drug Applications
      1. When an investigator is also a sponsor?
      2. When are they required
      3. Application basics
      4. Reporting/follow up requirements
   ii. Investigational Device Exemptions
      1. When are they required
b. **Centers for Medicare and Medicaid Services (CMS)**
   Presenter: Doug Reichgott
   i. Coverage rules
   ii. Conflict of Interest

V. Clinical Trial Oversight (March 10, 2017)

a. **Local/Institutional Clinical Trials Office**
   Presenters: Doug Reichgott and Elizabeth Grimm
   i. Interactions and work flow regarding regulatory documents

ii. Regulatory, coordination, recruitment, data collection and management roles

b. **Multi-center Clinical Trials**

Presenters: Karen Freund & Susan Parsons

i. Oversight (site selection, initiation, closeout)
ii. Data management (collection, online tools)
iii. Safety reporting and compliance

c. **Data Management Tools**

Proposed Presenter: Alejandro Moreno-Koehler

i. Using online tools (REDCap and others) for data management

d. **Cooperative Group Studies**

Presenters: Jack Erban & Susan Parsons

i. Major study/protocol process at the NCI
    1. Disease committee
    2. Scientific Steering Committee
    3. DCP
    4. CTEP
ii. Correlative studies

e. **Panel Discussion**

Proposed Panelists: Andy Evens, Bob Martell, Wasif Saif, Susan Parsons, Andreas Klein

i. Balancing Research and Clinical Demands
ii. Investigator Quality of Life: What drives it? What wrecks it?
iii. Goals, deadlines, balancing uncertainty

f. **Conclusion of Training**

Presenter: Andy Evens

i. Summary of training and next steps
ii. Other available trainings, additional educational opportunities (TU CTS MS and PhD programs)
iii. Current available grants
iv. Evaluation