AST-CST Clinical Trials Symposium: Taking a Study from Start to Finish

Friday, April 29, 2011
1:00 pm – 7:15 pm
Philadelphia, PA

A "How-To" Course on the Design, Implementation, and Reporting of Clinical Trials

Organizers/Chairs:	Milagros D. Samaniego, MD, *AST Education Committee Chair* Patricia E. Birk, MD, *CST Education Committee Chair*
12:30 pm	Lunch
1:00 pm	**Welcome Remarks** *Robert S. Gaston, MD, AST President Elect*
1:10 pm	**State-of-the-Art Lecture** Ethical and Legal Principles of Clinical Research *Daniel C. Brennan, MD* This presentation will discuss the issues associated with performing research on humans. A brief history of the ethics and legal principles will be followed by controversies in the general field of clinical investigation and finally an exploration of risk versus benefit and the investigator's responsibilities.
1:40 pm	**Science of Clinical Trial Design I** Principals of Study Design *Greg A. Knoll, MD* • What makes a good study? • Types of study designs and the RCT • The research hypothesis • Defining the study population • Interventions • Outcome measures including use of surrogates
2:10 pm	**Science of Clinical Trial Design II** Statistical Considerations *Joseph Kim, MD, PhD, MHS* • Sample size, power • Recruitment, retention and trial feasibility from a statistical perspective
2:40 pm	**Science of Clinical Trial Design III** Avoiding Pitfalls: Lessons from the Literature *Jesse D. Schold, PhD* *"Those who forget the past are doomed to repeat it"*
3:10 pm – 3:30 pm	Break

3:30 pm **Clinical Study Implementation and Management I**
Clinical Trial Conduct: Planning for Success
Roy D. Bloom, MD

- Recruitment and retention strategies
- Research compliance/investigator responsibilities
- Monitoring of clinical trials, including regulatory requirements
- Setting up a data system
- Privacy/HIPPA
- DSMB

4:00 pm **Clinical Study Implementation and Management II**
Operational Issues
Rita R. Alloway, PharmD

This presentation will explore the role of the research pharmacist, drug dispensing, adverse event reporting, design of CRFs, and working with a CRO.

4:30 pm **Innovations in Clinical Studies I**
Introducing Mechanistic and Translational Studies into Clinical Trials
Minnie M. Sarwal, MD, PhD

5:00 pm **Innovations in Clinical Studies II**
Beyond the Primary Study Question: Lessons from the Alert Study
Edward H. Cole, MD

5:30 pm **Innovations in Clinical Studies III**
Research in Deceased Organ Donors: Ethical and Practical Challenges
Scott D. Halpern, MD, PhD

6:00 pm – 6:15 pm Break

6:15 pm **Clinical Research Consortia: The Future of Clinical Research in Transplantation**
Arthur J. Matas, MD

6:45 pm **How Do I Get My Paper into AJT?**
Allan D. Kirk, MD, PhD, Editor, American Journal of Transplantation

This presentation will focus on:

- What editors look for in a paper: including the concepts of innovation, citation index, relevance, scientific integrity and internal logic
- What readers are looking for: news, clinical relevance, and education
- The role of publications in the academic career of transplant professionals

7:05 pm **Final Comments**
Milagros D. Samaniego, MD and Patricia E. Birk, MD

7:15 pm Conclude