Regulatory Science Career Paths in Academia

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Regulatory Science

• Translational Science with a Regulatory Twist

• Multidisciplinary
  – Basic Science/Biomedical Engineering
  – Clinical Trial Methodology
  – Epidemiology
  – Biostatistics
  – Bioinformatics
  – Medical Informatics
  – Regulations, guidelines, policies
  – ………
Gaps in “Biostatistics” for Regulatory Science

- Non-Inferiority Trial Design
- Response Adaptive Trial Design
- Composite & Surrogate Outcomes
- Missing Data
- Multiple Outcomes
- Meta-analysis of completed trials
- Post approval surveillance
- Comparative Effectiveness Research
- Mining of data warehouses
Administrative vs Faculty Role / Career in Academia

- No single individual
- Administrative: related to rules, policies, guidelines, practices
  - Greatly needed
  - Academia not always tuned in to regulatory requirements
- Faculty Career
  - Research
  - Training
  - Academic Home?
Academic Values for Promotion & Advancement

• Scholarship
• Excellence in Novel Research
• Prestigious publications
• Impact
• Funding success
• Teaching & Mentoring
• Team Science?
• Regulatory Science??
• Need success in a component discipline
Clinical Translational Science Award (CTSA) Centers

• 60 Academic Centers
• Natural academic home
• Most developing training programs in translational science / adjunct degrees
  – Type I, II, …..
• Multidisciplinary already
• Add regulatory knowledge
• Still need to develop expertise in your individual field
FDA-NIH-Academia

• Bring together necessary expertise to advance regulatory science

• Most of academia not familiar with regulatory process or regulatory science
  – E.g. Reward academic statisticians to focus on regulatory concerns/gaps
  – E.g. Encourage / facilitate FDA biostatisticians to collaborate with academia

• A rich field for research
Challenges

- COI Issues
- IP Issues
- Sharing of data, not typically accessible to academics
- Getting academia to better support team research
- Getting academia to value regulatory science research