Academic Careers in Research and Innovation:
The Echocardiography Core Laboratory

Pamela S Douglas, MD, MACC, FASE, FAHA
Ursula Geller Professor of Research in Cardiovascular Diseases
Duke University
Past President, American College of Cardiology
Past President, American Society of Echocardiography
I direct the DCRI Imaging Program and which has core lab contracts with:

- Abiomed
- AngelMed
- Atritech/Boston Scientific
- Boehringer Ingelheim
- BMS
- Edwards
- GSK
- Ikaria
- Lilly
- Pharmacyclics

All my relationships with industry may be found online at: http://www.dcri.duke.edu/research/coi.jsp
How Does Core Lab Work Fit Into an Academic Career?

• What a core lab does (and would you want to do it)
• Balancing service and innovation
• Ensuring academic value
• Financial and other benefits
• *Is core lab work right for you?*
Why Do Trials Need Core Labs?

- Expertise in imaging trial design and operations
- Quality control of site image acquisition
- Manage image transfer and archiving
- More accurate analysis of images
- More reliable/reproducible data
- Interpretation of results
- Reduces sample size to yield net profit
- FDA may require central image analysis
What Does an Echo Core Lab Do?

**Start up**
- Trial and substudy design
- Case Report Form
- Image Review Charter or Site manual
- Site selection, training and qualification
- Image analysis protocol
- Reader training and reproducibility testing

**Enrollment & F/U**
- Image transfer, processing and storage
- Image review and analysis
- Data quality management
- Ongoing assurance of site image quality and evaluability
- Ongoing assurance of image analysis quality

**Close out**
- Data cleaning, analysis
- Transfer to sponsor
- Data interpretation
- Results dissemination
- Regulatory submission support

Good Clinical Practices and Regulatory Compliance
Optimal Core Lab Use Matches Trial Requirements

- **Category A**
  - FDA or other regulatory body oversight
  - Performed for device or drug registration/approval
  - Highest level of ‘best practices’ and compliance required

- **Category B**
  - No FDA or other regulatory body oversight
  - May require complex imaging
  - Echo measures are 1º or 2º efficacy or safety endpoints

- **Category C**
  - No regulatory oversight, no complex imaging, no echo endpoints
Key Core Lab Roles

• Medical director/Principal investigator
• Technical manager/Project leader
• Lead sonographer
• Clinical trial coordinator
• Data quality management
• Statistician
• Information technology
• Quality assurance officer
• Echo readers (MD, sonographer, etc)
Balancing Service and Innovation

Service
• Innovation and creativity largely reside in trial design and results interpretation, not echo reading
• ECL requires a robust and compliant infrastructure
• Attention to detail and process are important

Innovation
• Clinical trials can have an immense impact on care
• Part of the team evaluating new drugs and devices
• Opportunity for using new imaging techniques and/or additional novel analyses; Echo substudies
Ensuring Academic Value

• Discuss this before you commit to doing the work
• Echo generally does not get drugs/devices approved
• Ex officio role on Steering Committee not a given
• Publications
  – Service to the trial should count for authorship
  – Echo-driven ms vs those that include echo data
• Image repositories
  – Sponsor ‘owns’ images
  – Access to clinical dataset, unblinding may be limited
• Regulatory science
Financial and Other Rewards

- Leverage Core lab for other projects
  - Revenue
  - Research fellow salary
  - Stats relationships
  - Core lab infrastructure

- ‘Moonlighting’ income without RWI
  - Professional expenses (meetings, journals, etc)

- Meticulousness demanded by core lab work can inform and improve clinical echocardiography

- Entrée into clinical trials world; Build relationships
Is Core Lab Work Right For You?

• Do you like doing Team Science?
• Is the required infrastructure, etc available?
• Are you a ‘process person’?
• Are you likely to get interesting projects?
• If academic value is important to you, can you ensure that you will get it?
• Does the ‘collateral gain’ make it worthwhile?
• There is no right answer!!
How Does Core Lab Work Fit Into an Academic Career?

• What a core lab does
• Balancing service and innovation
• Ensuring academic value
• Financial and other benefits
• Is core lab work right for you?