

Academic Careers in
Research and Innovation:

The Echocardiography Core Laboratory

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Relationships With Industry

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>

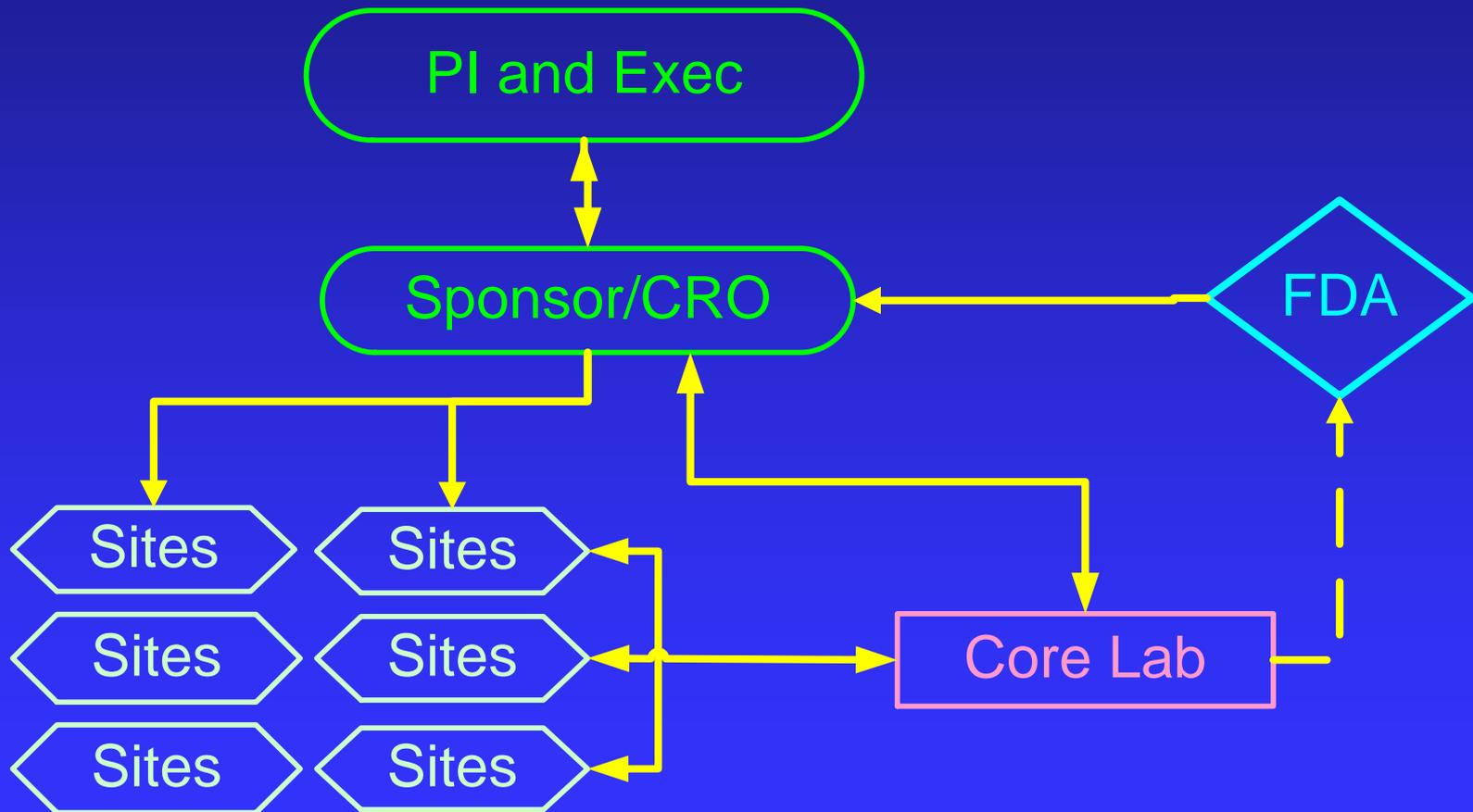
How Does Core Lab Work Fit Into an Academic Career?

- 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

Organization of a Clinical Trial



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 1^o or 2^o 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!!

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