



**Managing a Successful Core:** Developing business models that best fit your research environment and how to set goals for sustainability

NICL Session

June 18, 2014

# Overview of the Session

- Introduction to the Panelists and the Core Facilities
  - Jeffrey Caplan (University), Carol Barone (Research/Clinical), and Valerie Scott (Independent Research Institute)
- Business plan, rate setting, cost recovery and budgeting
- Financial models or approaches
- Compliance, clinical certifications and quality control
- Marketing: developing and maintaining a user group
- Discussion

# Delaware Biotechnology Institute at the University of Delaware

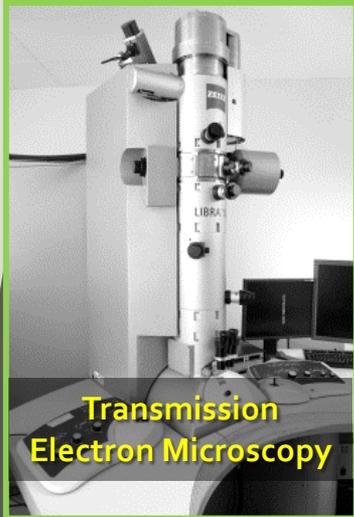
- The DBI mission is to facilitate a biotechnology network of people and facilities to enhance existing academic and private-sector research, catalyze unique cross-disciplinary research and education initiative and to foster the entrepreneurship that creates high-quality jobs.





# BIOIMAGING CENTER

DELAWARE BIOTECHNOLOGY INSTITUTE



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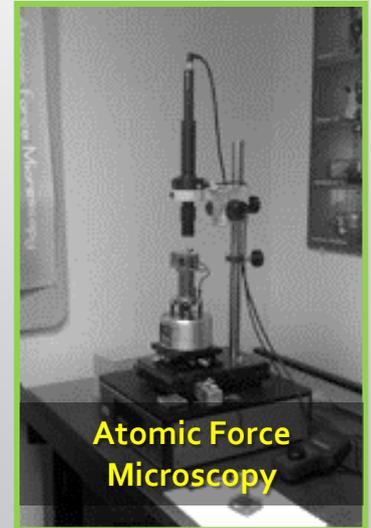
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# NEMOURS



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# *Nemours-Alfred I. duPont*

## *Hospital for Children...*

**Nemours Mission:** To improve the health of children by seeking new approaches to prevention, diagnostic and treatment of childhood diseases and to educate the next generation of leaders in children's health, from bench to bedside. As part of that mission...Nemours has a commitment to scholarly and scientific endeavors directed towards improving the diagnosis and treatment of pediatric medical conditions.

**Research Mission:** To improve the health and care of children by seeking new approaches to the prevention, diagnosis and treatment of childhood diseases...from bench to bedside.

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## *Core Mission Statement...*

**Mission:** To provide basic and complex histology services for diagnostics and biomedical research to Nemours- Alfred I Dupont Hospital for Children, Nemours Biomedical Research, its partners, collaborators and associate scientists in order to aid in the diagnosis and treatment of childhood diseases, as part of an endeavor for continuing *bench to bedside* treatment of the children of Nemours, and children everywhere.

The Core Lab Mission/Vision statement stands in alignment with both the Department of Biomedical Research and Nemours-Alfred I duPont Hospital for Children

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# The Jackson Laboratory

*JAX-West  
Sacramento, CA*

*JAX-Mammalian Genetics  
Bar Harbor, ME*



*JAX-Genomic Medicine  
Farmington, CT*



# JAX Quick Facts

**Mission statement:** *We discover precise genomic solutions for disease and empower the global biomedical community in the shared quest to improve human health.*

**FY12 Operating Revenue:**  
**\$229.6 million**

- Public support, including grants & contracts: \$57.6m
- JAX Mice & Services: \$1158.9m
- Contributions/other - \$13.1m

**1,514 Total Staff :**

- Bar Harbor, ME: 1,282
- Sacramento, CA: 161
- Farmington, CT: 39
- Other locations: 32

**7 Umbrella Cores:**

- Computational Sciences
- Genetic Engineering Technologies
- Genome Technologies
- Phenotyping Technologies
- Library Sciences, Infrastructure Services & Multimedia Services

**FY14 Operation = \$13.7m**

- Grants: \$1.12m
- Fees: \$6.44m
- JAX: \$6.17m

**Our researchers: 225 Ph.D.s, M.D.s, & D.V.M.s, including:**

40 Profs, Assoc., & Asst. Profs  
46 Research Scientists and Research Associates  
16 Emeritus Scientists  
23 Adjunct Scientists  
5 Visiting Investigators  
5 Affiliated Scientists  
44 Postdoctoral Associates  
9 Predoctoral Associates

**41 Principal Investigator led Research programs: Six major areas:**

- Cancers,
- Computational biology and bioinformatics,
- Developmental and reproductive biology,
- Immunology,
- Metabolic diseases and Neurobiology

**FY11 Genetic resources: 3.0 million JAX® Mice distributed**

- Shipped to ~20,000 investigators / laboratories
- in more than 900 institutions, in 56 countries.
- >7,000 varieties available as breeding mice, frozen embryos, or DNA samples.

# Parts to a Business Plan

- Mission statement
- Organizational structure
- Market analysis
- Products and/or services
- Marketing strategy
- Financial plan and projections

# Developing a business plan

- Develop plan in context - what are your institution's objectives?
  - Research
  - Educational
  - Financial
- Align with—
  - Institutions/departments strategic plan
  - Engage users and stake holders in creating core plan
- It's a plan
  - Measure & be prepared to adjust accordingly



# Business Plan – JAX Cores

- Organization
  - All cores report centrally
  - Serve all three campuses
  - Report through the GM of JAX Mice & Clinical Research Services to the COO
- Market Analysis
  - Internally focused
  - If commercial or other provider delivers capacity, turn-around, price & quality we will not develop a core (unless sample handling is a limiter)
    - Survey peer cores and market annually
- Product & Service Development
  - Aligned with JAX Strategic Research Plan
  - Aim to leverage JAX unique strengths when developing core services

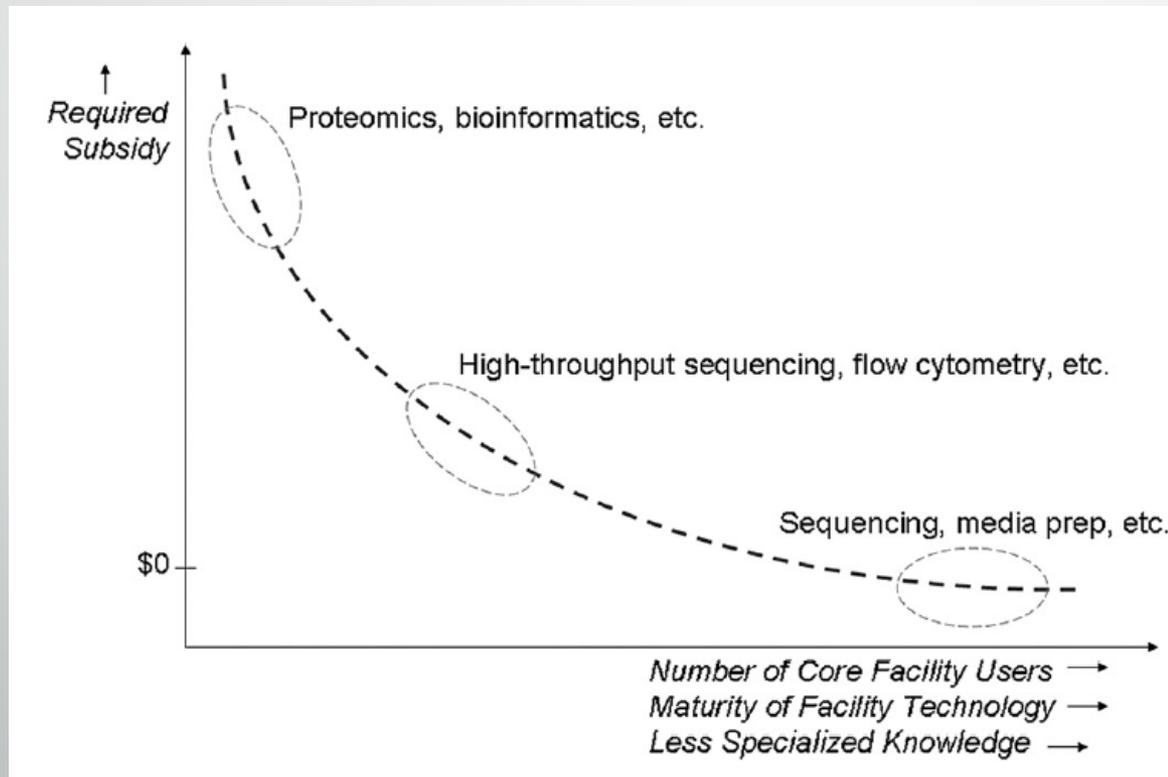


# Business Plan – JAX Cores

- User Base
  - Historically served internal faculty
  - Multi-campus operations
  - Cancer Center renewal – new guide better allows for center to center sharing
  - Supporting some commercial customers adjunct to animal services
- Financial Plan
  - Aim to fully cost recover externally
  - Internally JAX provides strategic subsidy & several cores CCSG supported



# Setting fees: Cost recovery expectations



(Haley R., J Biomol Tech, 2009)

# Setting Rates: Defining your costs

- **Personnel Costs**
  - Time running an instrument for user samples
  - Time needed to maintain the instrument
- **Instrument Operation Costs**
  - Service contracts
  - Other repairs and maintenance
  - Consumables
  - Depreciation
- **Facilities and Administration Costs**

# Setting Rates: Revenue from usage

- Software for generate usage reports: Attend next session “Tracking metrics: the ABCs of reporting”

5	Usage							
6		<u>Internal</u>		<u>External</u>		<u>Industry</u>		
7	Type of Usage	Previous Year Usage	Projected Usage	Previous Year Usage	Projected Usage	Previous Year Usage	Projected Usage	Total Projected
8	Supervised/Training (working hours)	99	105	0	0	11	10	115
9	Unsupervised (working hours)	1780	1,200	23	0	0	0	1,200
10	Unsupervised (off hours)	no data	200	no data	0	0	0	200
11	<b>Total:</b>	<b>1,879</b>	<b>1,505</b>	<b>23</b>	<b>0</b>	<b>11</b>	<b>10</b>	<b>1,515</b>
12								

# Setting rates for cost recovery

- Type of User
  - Internal Academic
  - External Academic
  - Industry
- Type of Usage
  - Supervised or Training
  - Unsupervised (working hours)
  - Unsupervised (off hours)

Rates						
Type of Usage	Internal (UD)		External Upcharge = 56%		Industry Upcharge = variable	
	Percent Recovery	Chargeback Rate	Percent Recovery	Chargeback Rate	Percent Recovery	Chargeback Rate
Supervised/Training	85.5%	\$ 60.00	85.5%	\$ 93.60	267%	\$ 200.00
Unsupervised	95.0%	\$ 33.50	95.0%	\$ 52.26	565%	\$ 200.00
Unsupervised (off hours)	86.5%	\$ 18.00				

“The costs of providing service are allowable, allocable, consistently applied and reasonable.”

“The rates established to recover these costs are documented and systematically evaluated against actual costs and revised on a regular basis to reflect actual costs (see A-21 J. 47 and A-122 (Attachment B 46.)). ”

“Rates are charged to internal institutional users on a consistent basis, regardless of funding source(s) consistent with the concept of “one service, one rate”.”

# Cost Recovery Level

- Pricing = Strategy
  - Not just covering cost
  - Incentivize use
  - Influence behavior
- What's your objective
  - Full cost recovery – zero bottom line?
  - Partial cost (subsidized) recovery?
  - Surplus generation → earning on the bottom line?
- Whatever you state as policy and implement – PRACTICE CONSISTENTLY!



# JAX – Rate Setting

- Follow federal guidelines / current circulars on costing
  - Internally: Direct cost of labor and materials (minus federal support e.g. CCSG)
  - Externally: Full direct cost of labor and materials plus indirect cost
- Depreciation & maintenance: in indirect cost rate



# Direct & Indirect Costs

- Direct Costs

- Costs for activities or services that benefit specific projects, e.g., salaries for project staff and materials required for a particular project.
- Because these activities are easily traced to projects, their costs are usually charged to projects on an item-by-item basis.

- Indirect Costs (OH)

- Costs for activities or services that benefit more than one project.
- Their precise benefits to a specific project are often difficult or impossible to trace.
- Indirect costs do not vary substantially within certain production volumes or other indicators of activity, and so are considered to be fixed costs.



# Financial Model: Primary Research Support

- Fairly large, diverse personnel group that is challenging to support with usage fees alone.
- Add personnel effort support on large projects to cover the cost of additional data analysis, writing, scientific guidance etc.
- Work directly with principle investigators to ensure that core facility usage fees are included in the budget.
  - Budget office now flags grants with unlimited usage fee in budget
  - Estimate real cost of usage

# Financial Model: Internal Core Facility Research Program

- The Bioimaging Center has staff with primary research grants.
  - Principle Investigator on NIH Ro1 and NASA research grants
  - Co-PI on two NSF grants
  - Four post doctoral associates, one graduate student, and multiple undergraduates
- Indirect support of the Bio-Imaging Center

# Financial Model: Industrial usage support

- Up to 25% of usage on NIH funded instruments can be industrial
- Rate can be significantly higher than internal rates
- Can be used to subsidize academic usage
- Higher flexibility with setting rates

# Financial Model: Funding instrumentation purchases

- Shared instrumentation grants: NIH SIG S10 and NSF major research instrumentation (MRI)
- University or state funds (Unidel)
- Departmental or college
- Leasing equipment
- Rallying support from major users

# Financial Models: JAX Cores

- What types of financial models do you implement?
  - Two core financial models in place
    - Transactional/fee recovery
      - Majority of JAX Cores
    - Direct effort recovery – Computational Sciences
      - Target 65% total effort recovered through direct project specific grant support
      - 35% institutionally supported & available for nominal analysis, pilot projects, grant application development etc.
- How do your financial models fit together into your overall financial plan?
  - Both methods have institutionally defined target recovery



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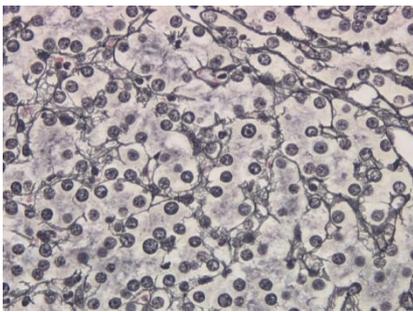
## *Developing a Financial Model...*

.... *“In this time of economic restraint and increasing research costs, organized and efficient core facilities are essential to research”*(1)... **Designing a model to maximize the return on investment was our goal ?**

Academic services needed to remain the #1 focus for core ...however, the Core was designed with a few diagnostic specialties to provide support revenue for research, without additional investment.

- A *simple* business agreement, later, allowed us to provide service to external users, without overwhelming the primary academic core service
  - Direct facility to facility payment, protected us against cumbersome billing practices required by insurance companies and/or medicaid/medi-care providers for diagnostics
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# A Starting Perspective...a quick history



• *Pathology labs* were by no doubt the backbone of day-to-day operations of every hospital histology service. They also supported many *research* labs by providing parallel services to investigators.

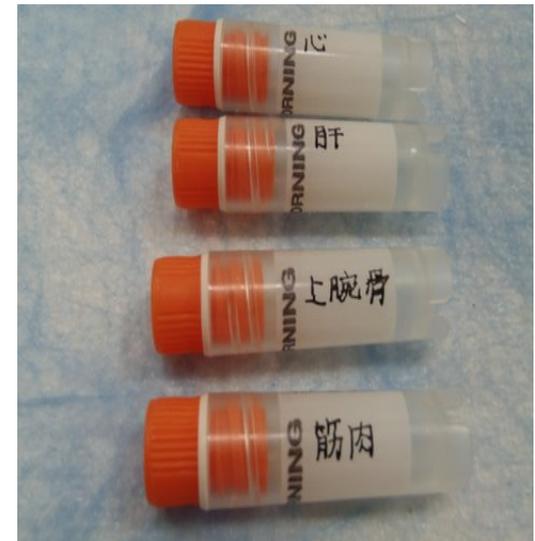
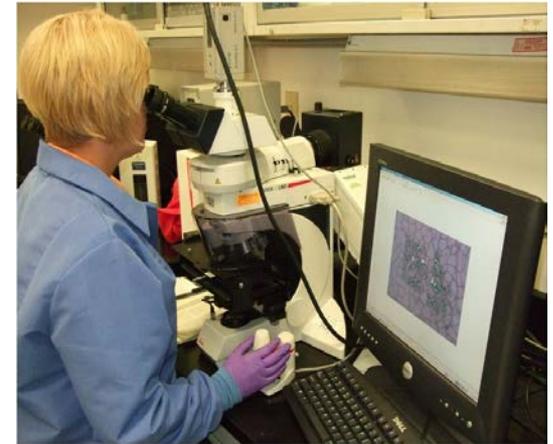
• However, over time many of these laboratories became pressured from higher volume workloads and requests for shorter and shorter turn-around-times (TAT) for diagnostics.

• The development of core labs as a “shared resource” to support the more *specialized needs* of research, reversed that paradigm. Core labs were developed as a useful tool for supporting research.

• Our Core was originally designed with clinical testing as part of the matrix of the *Core*, to support hospital dx services, while adding an alternate revenue stream for the core, from other external sources.

## *Shared resources save money \$\$\$\$ - Clinical and Research*

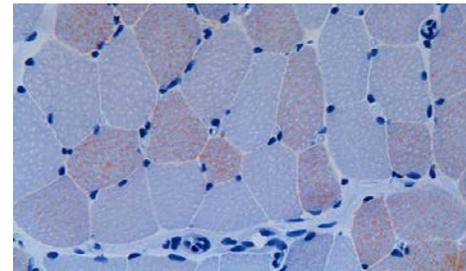
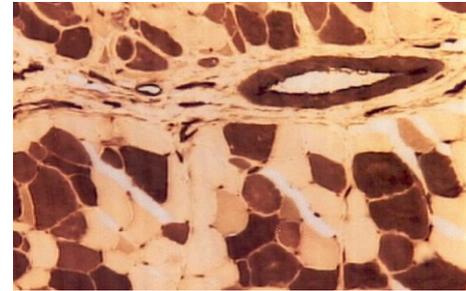
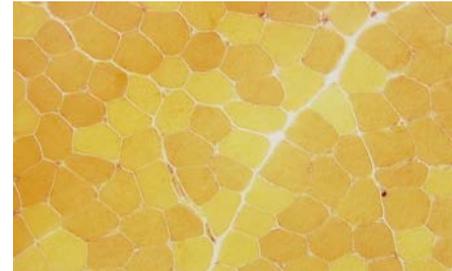
- We know rapid development of new complex technologies start in research... and are carried over to clinical services...in the bench to bedside paradigm of translational research
- Time consuming and intricate protocols for these new technologies often fall outside the objectives and constraints of our *clinical* laboratory.
- The Core lab can bridge that gap...
- Though cores are fundamentally different than clinical services...in protocols, technologies, and/or instrumentation...they are similar in design and often have similar goals which align. Tying our Cores to some clinical services as a revenue stream *seemed to make perfect sense...* in our original Core model.



*Clinical services add revenue and also reflected our labs skill and competency, as well as support specialized services with short TAT (CLIA certified).*



*Frozen Sectioning*



*Muscle Enzyme Histochemistry*

## *Our evolving model....*

Over time our financial model has evolved to include other revenue sources, including academic collaborators and partners, non NIH external academic users and a few small corporate users. This has allowed us to implement a tiered pricing structure.

### *•Pricing and revenue...*

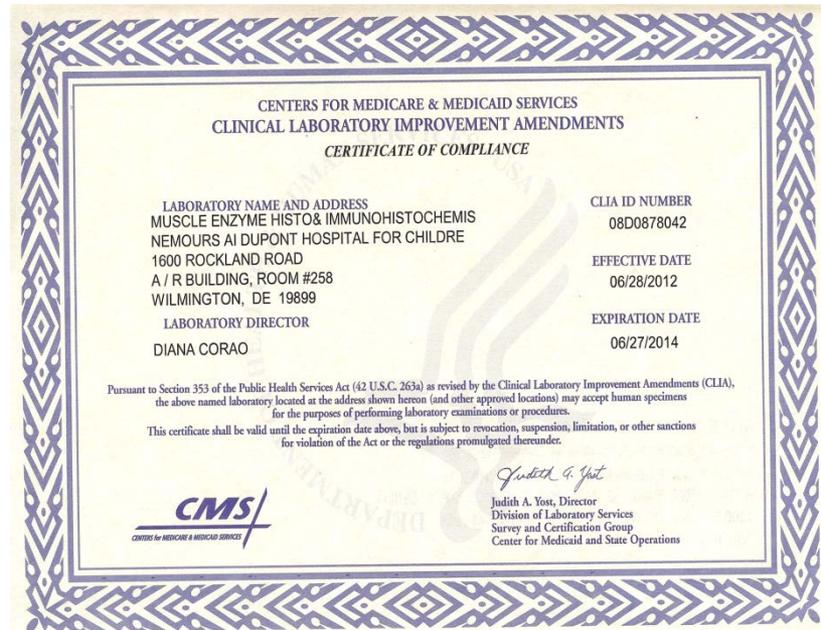
- Our diagnostic services easily blend with a tiered, cost + pricing structure, for non NIH external academic users or corporate users.*
- Internal academic users (academic partners, collaborators and other federal or state funded users) rates were discounted (set at materials and tech time only at the fully burdened rate) providing a substantial discount over general service rate, which are placed at mid-market level.*
- Presently about 1/3-1/2 of our Core revenue comes from about 10% of the workload...provided by our diagnostic services; 1/3-1/2 comes from external services and other revenue sources; and the Nemours Foundation covers any short-fall.*

# Compliance: NIH Circular A21 and new Omni Circular

- Circular A21 guidelines: See link for full document ([http://www.whitehouse.gov/omb/circulars\\_a021\\_2004/](http://www.whitehouse.gov/omb/circulars_a021_2004/))
- Determine your institutions interpretation of the guidelines
- FAQs of guidelines are easier to understand
  - Circular A21 FAQ (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-053.html>)
  - NIH shared Instrumentation FAQ ([http://dpcpsi.nih.gov/orip/diic/shared\\_instru\\_faqs](http://dpcpsi.nih.gov/orip/diic/shared_instru_faqs))

# *The Regulatory Requirements - Achieving Certifications*

- *Do we need Certification?*
- *Choosing the best fit*
- *The value in certification*
- *CAP*
- *CLIA*
- *CLASS (ASQ)*
- *Audit preparedness*
- *Manuals and documentation*



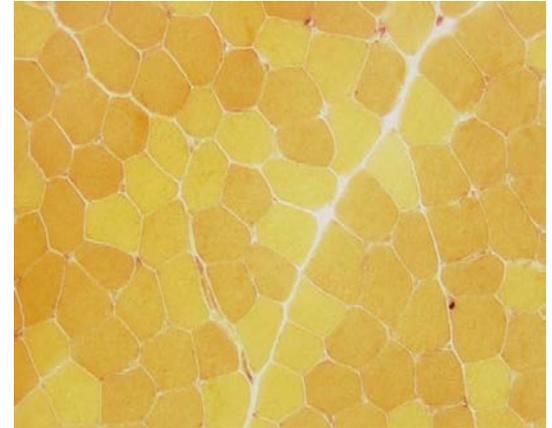
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## *Acquiring a Certification...*

### *What do I need?*

#### **CAP/ CLIA/ CLASS Certifications?**

- **College of American Pathologists – CAP**
  - The “Gold” Standard for accreditation regulatory compliance and standards



#### **Clinical Laboratory Improvement Act – CLIA**

- Established testing standards, for accuracy, reliability and timeliness for diagnostic testing regardless of facility, for moderate and high complexity testing
  - **CLASS Laboratories also participate /IOS-ASQ**
-

## *Certification: C.L.I.A.*

The Centers for Medicare and Medicaid Services (CMS), formerly known as HCFA - Health Care Financing Administration, governs CLIA certification. CMS / HCFA establishes standards for medical providers that require compliance to meet certification.

The Clinical Laboratory Improvement Act '88 is Federal legislation to oversee quality assurance practices for non-CAP laboratories, requiring them to establish and document testing protocols and to meet accepted benchmark standards for clinical testing performed in their labs. Under CLIA Histology is considered "High Complexity Testing" which requires proficiency testing for these labs every 6 months. Cores with clinical services must be CLIA certified, and certification renewed every 2 years . (7)

## CLIA Certification:

- Is not as stringent as CAP
- Aligns with CAP
- Is not required if you have CAP certification
- Requires a CLIA application
- Requires an on-site inspection
- Requires proficiency testing (6 months)
- Cost: \$100 for the application
- Cost: \$400 for the site visit
- Protocol Manuals, continuing ed for staff
- Manuals for instrumentation maintenance
- *Required for clinical testing in cores*

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## *What is required to maintain a clinical component?*

### *Total Quality Management (TQM) or CI*

- Proficiency and competency testing
  - Variance reporting
  - Metric tracking
  - Professional staffing to support the technical core
  - Continuing education for staff
  - Professional associations
  - *Organization...*
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## *Maintaining Standards...a requirement*

*What will be required to meet regulatory standards*

**Total Quality Management (TQM)** is the best over-all way to maintain standards in a Core.

**Proficiency testing:** Assessing the laboratory's ability to followed approved protocols to meet the benchmark standard...(our PT testing is outsourced and recorded)

**Competency testing:** The ability of the staff to follow protocols and meet the laboratory standard...(Technical Director)

**QC/Variance Report:** An analysis report of any change from the standard benchmarked protocols for the laboratory (Reporter/Director)

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## *Meeting Regulatory Requirements*

Know what they are...

Clinical...CLIA (42CFR-493.00), ....

- Keep up-to-date, organized, well maintained data / manuals
  - Have examples of forms/reports available for the auditors
  - Operate an organized and well maintained laboratory
  - Retain proof of proficiency for lab, competency testing for staff, chain of custody for samples
  - Document continuing education of staff *and the Director*
  - Provide quality control for pre-analytical, analytical and post analytical testing (and new test development/clinical services)
-

# Marketing and Attracting New Users

- Many core facilities are driven by the needs of primary research groups.
- Use marketing to ensure that you are visible and accessible to those groups.
- Accessibility and user friendliness is important.
- The goal is to maximize the positive impact of your core facility on research (See next session for tracking that impact).
- A strong, stable user base is essential for sustainability and success.
- Projects/users often come and go with funding, so there is a constant need for maintaining visibility and accessibility.

# Marketing: the broad approach

- Modern website
- Network! Join core facility databases (VGN/ABRF and local) and attend core facility centered meetings
- Brochures for different target audiences
- Tours for new faculty, graduate students and undergraduates
- Workshops
- Open house or open forum

# Marketing: the targeted approach

- Determine the needs of individual projects by participating in the research community: Attend talks, poster sessions, committee meetings, symposium etc.
- Invite new investigators or PIs with new projects to group meeting
  - Understand the scientific question
  - Evaluate the current and future needs of the project
    - Do we have the capabilities?
    - If we don't, will we have it in the future? Do others need it as well?

# Marketing & attracting users: JAX

- Core operate almost fully subscribed ( $\geq 85\%$  capacity)
- How do you develop a stable user base for sustainability?
  - \$64,000 question –
  - Deliver what your customers need: quality, turn-around, cost
- How do you maintain visibility so that researcher are aware of your services?
  - Web presence
  - Poster Sessions
  - Newsletter
  - Face-time
  - Presentations/Interest Groups
  - Participate in PI Recruiting
  - New PI & Post Doc orientation



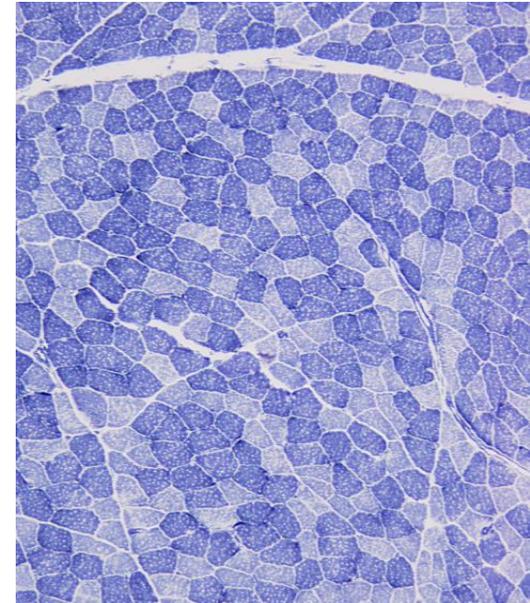
# *Marketing the Service to Customers*

## The Best Marketing Strategies...

- *“Quality Results” and “TAT”*
  - *Well designed websites*
  - *Tri-fold brochure/Handbook*
  - *Networking events*
  - *Posters and open house events*
  - *Web-list servers*
  - *Core associations*
  - *Clinical Certification*

*and...offer what no one else does*

**Biggest Mistake:** Core labs cannot compete with commercial laboratories or clinical labs ...remember *this is not an objective of a core service*



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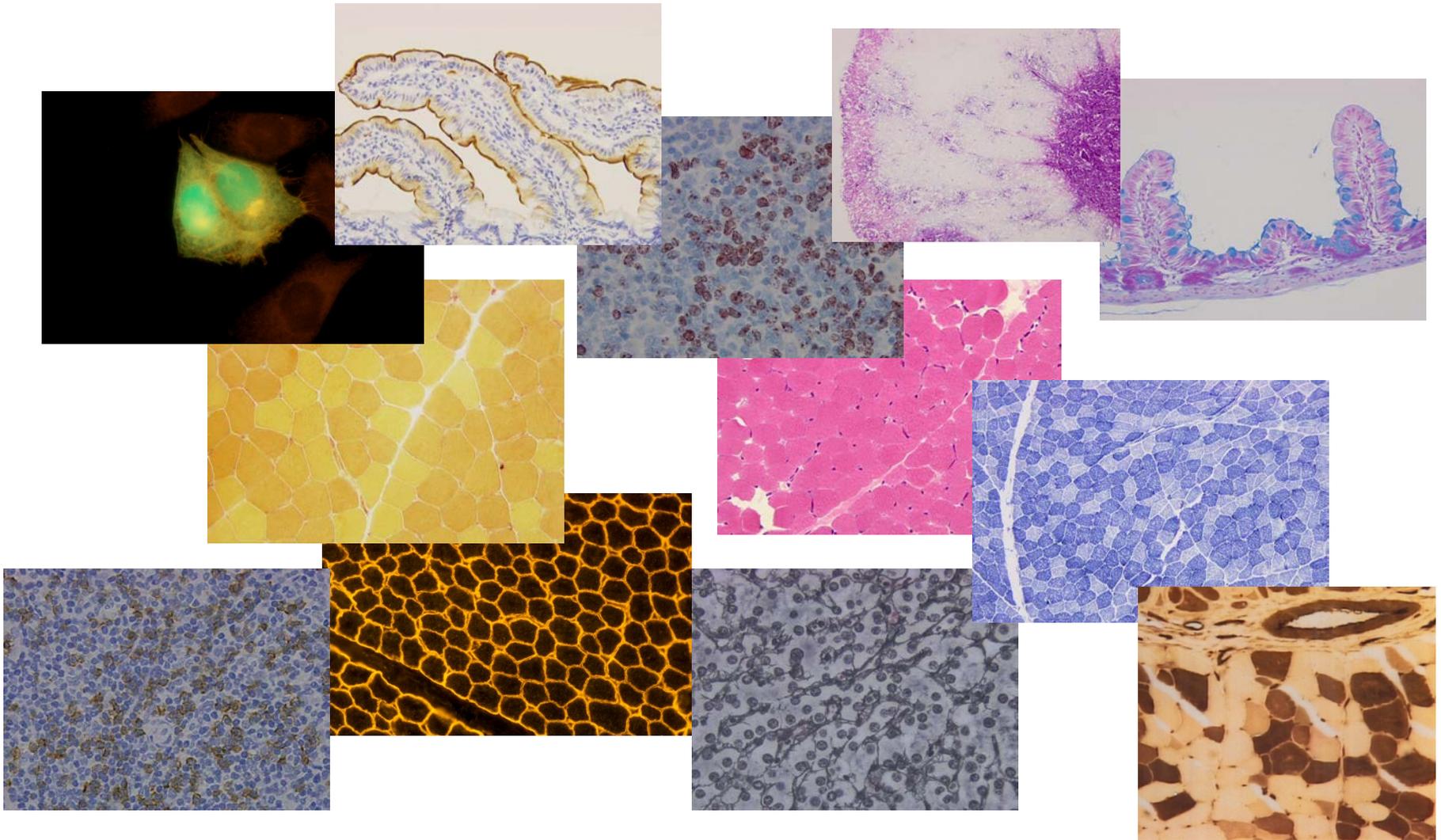
## *In Summary*

*Consider a clinical/other component to provide additional revenue*

- **Create an Action List:**

- ❑ Select services you are comfortable with - stay in your comfort zone
  - ❑ Create a functional, user friendly environment for users
  - ❑ Focus on a unique service you can offer – and one you do well
  - ❑ Be realistic about the demands of a core service when selecting venues you might serve
  - ❑ Work with existing instrumentation to restrain costs
  - ❑ Provide a regulatory framework for excellence
  - ❑ Limit your scope to start - build gradually
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# *Successful Core?... You can do it!*



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# Questions?

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# Other Nuggets

- Equipment Maintenance
  - Maintenance –vs- Replacement
    - Monitoring performance against manufacturer lifespan
    - Planned replacement often cheaper than continuous resuscitation
- Data is king
  - Data collection & management key (eLIMS)
  - You really can't manage what you don't measure
  - Metrics are Essential
  - Use strategically for continuous improvement
  - Developing performance metrics :

- Establishing critical processes/customer requirements
- Identifying specific, quantifiable outputs of work

# Multi-campus Operations

## ■ New challenges

- ❑ Developing individual character while maintaining culture
- ❑ Financial practices consistent
- ❑ Navigating State & University processes require advanced planning – still doable
- ❑ New collaborations are a great opportunity
- ❑ Operating cores effectively in 5 temporary locations
- ❑ Communications
  - Constant
  - SKYPE, VTC, Phone, e-mail, web, F-2-F
  - All methods essential