



OBBR

Office of Biorepositories
and Biospecimen Research

**caHUB:
The US National Cancer Institute's
Cancer Human Biobank**

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Office of Biorepositories and Biospecimen Research

Global Biological Resource Centre Network
Joint human and microbial pilot phase meeting
Vienna, 29/30 November 2010



caHUB The Cancer
Human Biobank

NATIONAL
CANCER
INSTITUTE



The NCI Addresses the Challenge

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Consensus of the Broad Scientific Community:

The lack of high-quality, clinically annotated human specimens has become the limiting factor for translational cancer research.

The NCI Moves Stepwise Towards Solutions:

- **Standards**
 - *The NCI's Best Practices for Biospecimen Resources*
- **Science**
 - **The Biospecimen Research Network**
- **Specimens and Service**
 - **The Cancer Human Biobank**



Towards a National Biospecimen Resource: A Step-Wise Process

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2010

- **caHUB Implementation: RFPs and contract awards**

- OBBR begins detailed strategic planning process for caHUB (first working group meeting held June 17, 2009)

2009

- OBBR studies market demands; risk/benefits; organizational and funding models

2008

- NCI Director asks OBBR to explore plans for a national biospecimen resource

2007

- OBBR publishes the NCI Best Practices for Biospecimen Resources

2006

- Biospecimen Research Network (BRN) is formed

2005

- OBBR is formed

2003

- National Biospecimen Network (NBN) Blueprint published

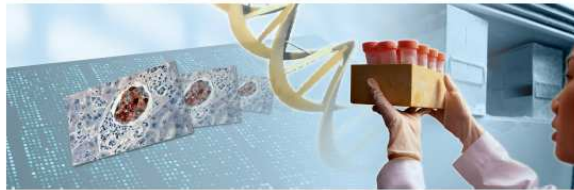
2002

- National Dialogue on Cancer identifies biospecimens as critically important to post-genomic research



Standards: NCI Best Practices for Biospecimen Resources

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National Cancer Institute Best Practices for Biospecimen Resources

June 2007

Prepared by:
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services

Objectives:

- **Unify policies and procedures for NCI-supported biospecimen resources for cancer research**
- **Provide a baseline for operating standards on which to build as the state of the science evolves**
- **Updated in 2010 – open for public comment on US Federal Register**

<http://biospecimens.cancer.gov>



NCI Best Practices Overview

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The NCI Best Practices include recommendations for:

- **Common technical, operational and safety best practices**
 - **New in 2010 version – Management & Operations Section**
- **Quality assurance and quality control programs**
- **Implementation of enabling informatics systems**
- **Establishing reporting mechanisms**
- **Providing administration and management structure**
- **Addressing ethical, legal, and policy issues: informed consent; access; privacy protection; custodianship; intellectual property**
 - **New in 2010 version - Expanded Custodianship & Informed Consent Sections based on workshop results**



Understanding the Problem: The Siloed National Biobanking Landscape

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- **Collection, procession, storage procedures differ**
 - **Degree and type of data annotation varies**
 - **Scope and type of patient consent differs**
 - **Access policies are lacking or unknown to potential users**
 - **Materials transfer agreement conditions differ**
 - **Supporting IT structures differ in capacity and functionality**
- WIDE VARIATION IN QUALITY OF SPECIMENS AND DATA**

Consensus for a Solution: National Biospecimen Network Blueprint (2003)

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Key principles for a national biobank:

- **Standardized** procedures for biospecimen collection and distribution
- **Standardized** data sets and data vocabulary
- **Integrated** information technology system to support all functions
- **Harmonized** approached to ethical and legal issues
 - Standardized consent, MTAs
- **Transparent** governance and business models
 - Transparent access policies
- **Large** well-designed, standardized specimen sets





caHUB Is Founded on NBN Principles

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The Cancer Human Biobank vision:

- **unique, centralized, non-profit public resource**
- **source of adequate and continuous supplies of human biospecimens and associated data of *measurable, high quality* acquired within an ethical framework**
- **source of high-quality biobanking services for the community**



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caHUB: Key Issues

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- **Verification of the need for caHUB**
- **Development planning**
- **Fundamental details**
 - **Who will provide the specimens**
 - **Who will use the specimens**
 - **How data will be collected and handled**
 - **How the specimens will be used (scientific purposes)**
- **Business plans and timelines**
- **Funding: \$60M funds allotted to caHUB in 2009**



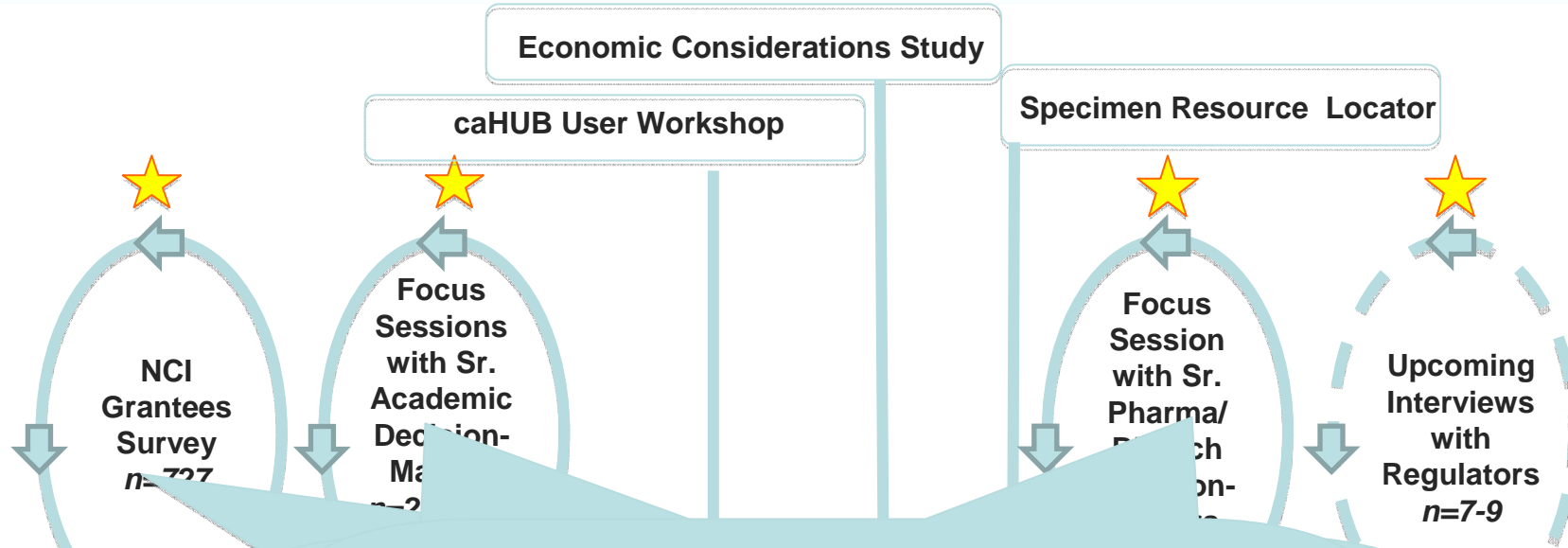
The Need for caHUB

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- **The need for caHUB has been clearly enunciated from all sources:**
 - **Survey of NCI investigators**
 - **Market research using focus group sessions with academia and industry decision-makers (OMB-approved; Strat@com-executed)**
 - **Focus group upcoming for regulators**
 - **Interviews with commercial tissue providers and industry users (economics considerations study by Booz Allen Hamilton)**
 - **caHUB Users Workshop**
 - **Mining of request data from the NCI Tissue Locator: last 7 years**
 - **Direct input to OBBR from potential users: CTEP, NCI Patient Characterization Center (PCC), numerous biomarkers programs**



Stakeholder Feedback



Key Findings:

- Biospecimen collection and storage
- Both the academic and industry sectors
- Researcher interest in a national biobank concept
- Researcher interest in a national biobank concept

Benefits of a National Biobank:

- Inspire confidence in quality of specimens
- Ensure ethical collection standards

Development Challenges:

- IP constraints

Barriers to Contribute:

- IP constraints

Other Findings:

- Strong support for a national biobank concept from all stakeholders
- Infrastructure



Summary: Strat@com Market Research Results

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- **There is clear and universal need for a National, Standardized, Human Biospecimen Resource (NSHBR)**
- **For all audiences, the level of consistency and standardization that could be offered is the most important benefit**
- **An NSHBR has the opportunity to define standard operating procedures (SOPs) for the field/industry**
 - **In fact, stakeholders are counting on it**

caHUB and the Popular Press



8. Biobanks

By ALICE PARK

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Inside Huntsman Cancer Institute's vaults: Pancreatic tumors on ice. Lance W. Clayton for TIME

Folks at the National Cancer Institute (NCI) are heading up an effort to establish the U.S.'s first national biobank — a safe house for tissue samples, tumor cells, DNA and, yes, even blood — that would be used for research into new treatments for diseases.... By fall, the group hopes to have mapped out a plan for a national biobank; the recent stimulus showered on the government by the Obama Administration might even accelerate that timetable.

Time Magazine March 23, 2009

Time Magazine November 25, 2009

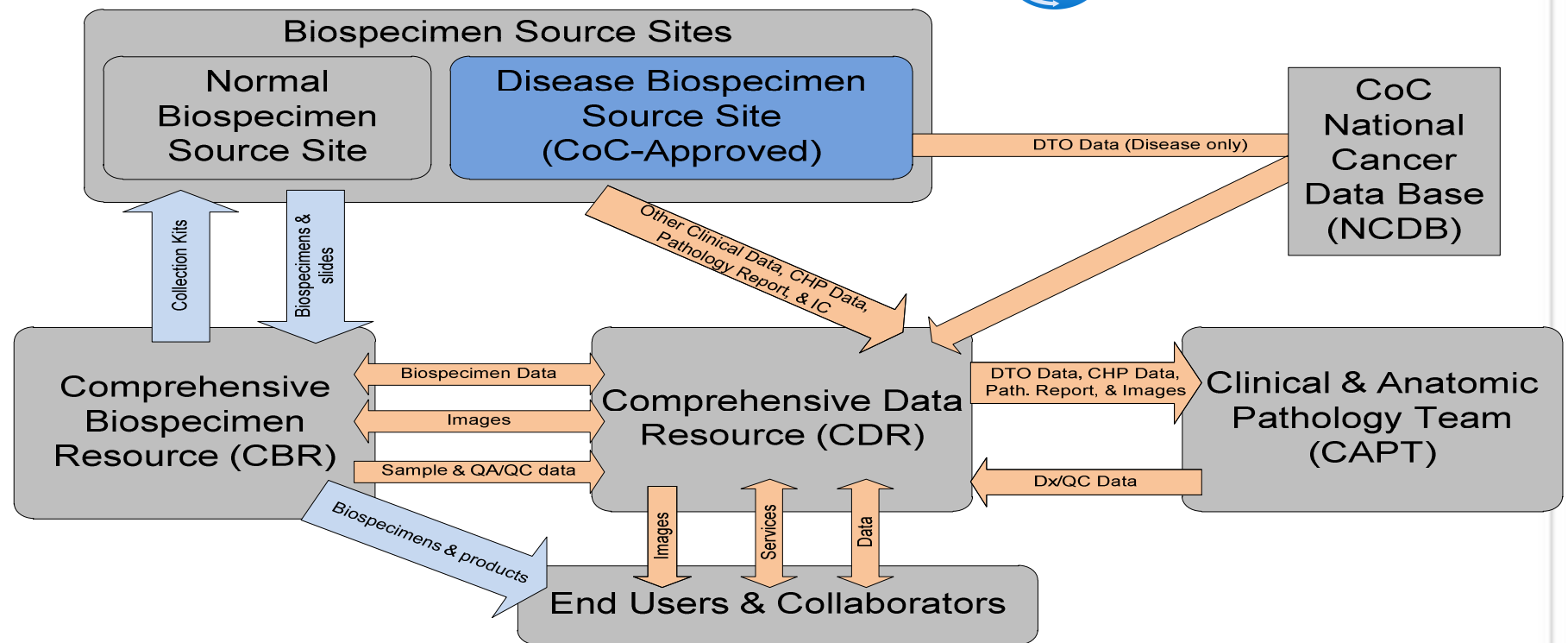
caHUB: Centralized Model

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Centralized Resource: Cost and Quality Control Efficiencies

caHUB Pilot System Overview



CoC – Commission on Cancer
CHP – Collection, Handling, & Processing
DTO – Disease, Treatment, & Outcome (aka clinical)
Dx/QC – Diagnostic (Pathology) & Quality Control
RFP – Request for Proposal
QA/QC – Quality Assurance & Quality Control

Legend

- Data Flow
- Biospecimen Flow
- Modules solicited under this RFP
- Other caHUB components

Related to data sent to or retrieved from Information systems of the CDR
 Related to tissues, blood, slides, images, & analytes



caHUB Planning

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- **Planning committees operating for one year:**
 - **Administration**
 - **Strategic planning:** mission, vision, scope, organizational structure, evaluation, milestones and success factors
 - **Normal tissue acquisition:** rapid autopsy (also metastatic tumor, premalignant disease)
 - **Biospecimens:** SOPs, prioritization strategies, collection design, quality control monitors, and qualifying metrics
 - **ELSI:** Ethical, legal and social issues
 - **Facilities** requirements and design
 - **Informatics** requirements, design, and implementation
 - **Partnerships** and business models
- **210 expert contributors to the process and products**
- **Delivery of final products (white papers, SOPs, other manuscripts): future publication and/or availability through OBBR website**
 - Independent value to broader biobanking community



caHUB Collection Prioritization: Process Design

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- **Process goal: Objective, realistic, quantitative**
 - **A quantitative prioritization matrix was developed using 9 criteria and a 3-tiered scoring system of importance for each**
 - **9 criteria:**
 - Ease of collection
 - Size of tumor at diagnosis
 - Treatment by surgery
 - Pre-resection treatment
 - Need for new clinical tools for diagnosis and treatment
 - Prevalence
 - Increasing incidence
 - Survival rates
 - Cost to society
 - **60 cancers selected (of 850) using NLM/SEER data**
 - **Weighting against scientific demand during launch phase**



caHUB Collection Strategies and Standard Operating Procedures (SOPs)

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- **Completed:**
 - **Tissue collection SOPs developed for 19 organs and 23 cancers**
 - **Specimen qualification SOPs: Morphologic, morphometric, and molecular qualification metrics**
 - **Blood collection SOP: Collection and processing**
 - **Quality monitoring: Key quality criteria for all steps of process flow**
- **In progress:**
 - **Identification of critical process steps that require continuous, detailed monitoring**
 - **Integration into the caHUB Quality Management Plan**



caHUB Collection Design: Informed by User Need

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In high demand and short supply:

- **Benchmark samples:** biospecimens collected through standardized collection, handling, storage, processing and distribution procedures, with strict quality control and associated metrics
 - Data associated with process variables
- **Cases with multiple aliquots:** Confirmation of prior studies or the opportunity to contribute information to prior studies based on new technologies
- **Statistically valid numbers of biospecimen sets**
- **Fully defined “patient case sets”**
 - Tumor
 - Adjacent normal tissue
 - Tumor periphery (invasive border)
 - Pre- and post operative blood samples
 - Urine
 - Rich clinical data and outcome information for patients



The caHUB Comprehensive Data Resource: Functionalities

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- **Provide user access to caHUB**
- **Ensure patient privacy and confidentiality**
- **Integrate patient and specimen data from multiple sources:**
- **Allow submission of data on caHUB specimens**
- **Perform QA/QC on all data**
- **Allow researchers to query specimen inventory based on data types**
- **Allow requesting of specimens**
- **Allow requesting, analysis, and download of datasets**



caHUB Data: Principles, Procedures and Systems

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- **CaBIG is leading the planning/development of all informatics systems for caHUB**
- **Informatics strategies embody caBIG principles (interoperability; open source; standardized data vocabularies)**
- **caHUB Notional Informatics Architecture has been developed, reviewed, refined**
- **“Use Case” titles for the caHUB Comprehensive Data Resource are developed**
- **Data types include:**
 - Clinical data on patient including future follow-up
 - Specimen “life cycle” data: intra-operative, procurement and processing data
 - caHUB pathology review, digital imaging, and quality control data
 - Overall quality management data
 - Specimen inventory and tracking data
 - Molecular analysis data



The caHUB Business Model: A Commodities and Services Model

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COMMODITIES: Cost Recovery

Distribution of specimens and data

Increasing value of aliquots over time with increasing data richness: Time-dependent maturity

SERVICES: Revenue Generation

Build on existing infrastructure and improve return on investment: Not time-dependent

- **Biobanking services to other initiatives**
 - Other NCI/NIH
 - Rare diseases
 - Advocacy
- **Education and training**
 - Pathology and laboratory functions
 - Operating room functions
 - IT and data management
 - Biostatistical and analytic methods
- **Consulting services**
 - Biobanking methods and best practices
- **Biobanking support service to industry**
 - Assay development
 - Clinical trials
- **Laboratory space and services**
 - Research incubator functions
 - Longer term in-house research contracts



caHUB Business Model

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Commodities and Service-Based Model



Sample Orders
Data Orders

Customized Processing Services

Managed Collections
"Front Door" Concept

Center of Excellence
Training



The caHUB Business Model: Economic Considerations

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- **A detailed 15-year Total Life Cycle Cost of Ownership (TLCO) planning model for building and operating caHUB developed based on:**
 - **Comprehensive caHUB supply chain/value chain framework**
 - **Encompasses all costs for (1) collection; (2) processing; (3) storage; (4) distribution; (5) infrastructure; and (6) administration**
 - **Data derived from an analysis of the current biobanking landscape**
 - **Interviews with >75 commercial and academic biobanking experts**
 - **“Risk-based” approaches to changing business parameters and impacts on costs**
 - **An iteratively refined approach to estimated costs**
 - **Cost baseline was revised and narrowed through numerous working sessions with key experts to inject realism into estimated costs**
 - **Continuous refinement of case flow accrual projections and processing protocols.**



3 Fundamental Factors That Drive Pricing

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Fit for Purpose – Relationship to Pricing

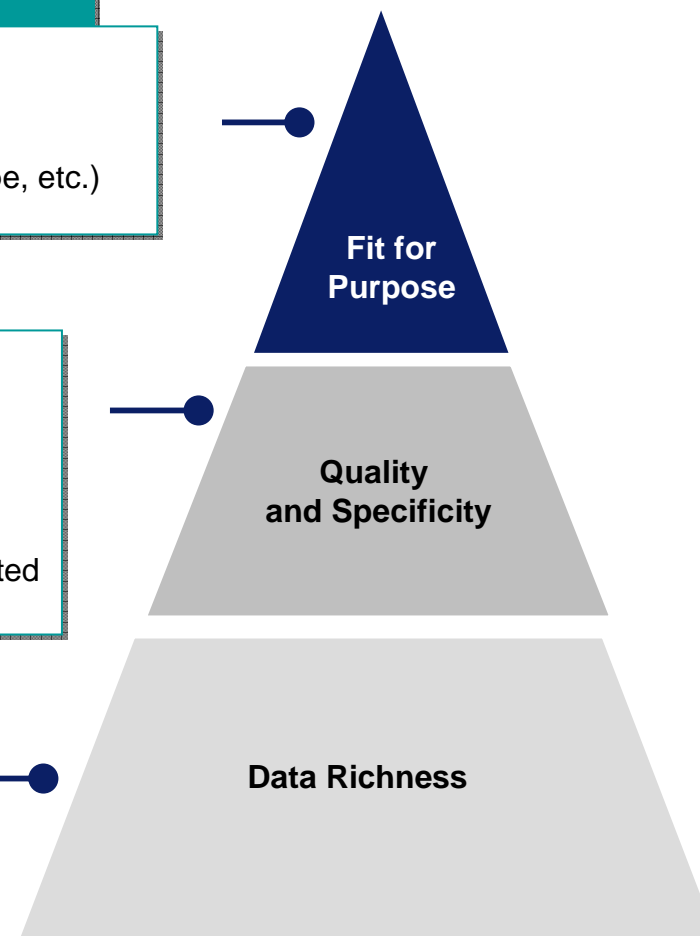
- ▶ The research application and scientific question being addressed
- ▶ Specifics of the collection protocol
- ▶ Specific project needs (e.g. normal, diseased, tissue origin, specimen type, etc.)

Sample Quality and Specificity– Relationship to Pricing

- ▶ Quality and specificity price drivers:
 - ▶ Specimen rarity and size requirements
 - ▶ Extent of customized processing requested
 - ▶ Clinical parameters (e.g. treatments, etc.), and pathology parameters (e.g. tumor subtype, positive tissue markers) requested

Data Richness – Relationship to Pricing

- ▶ Outcomes data are in high demand
- ▶ Comprehensive data sets may double sample price
- ▶ Customized data increases the sample price

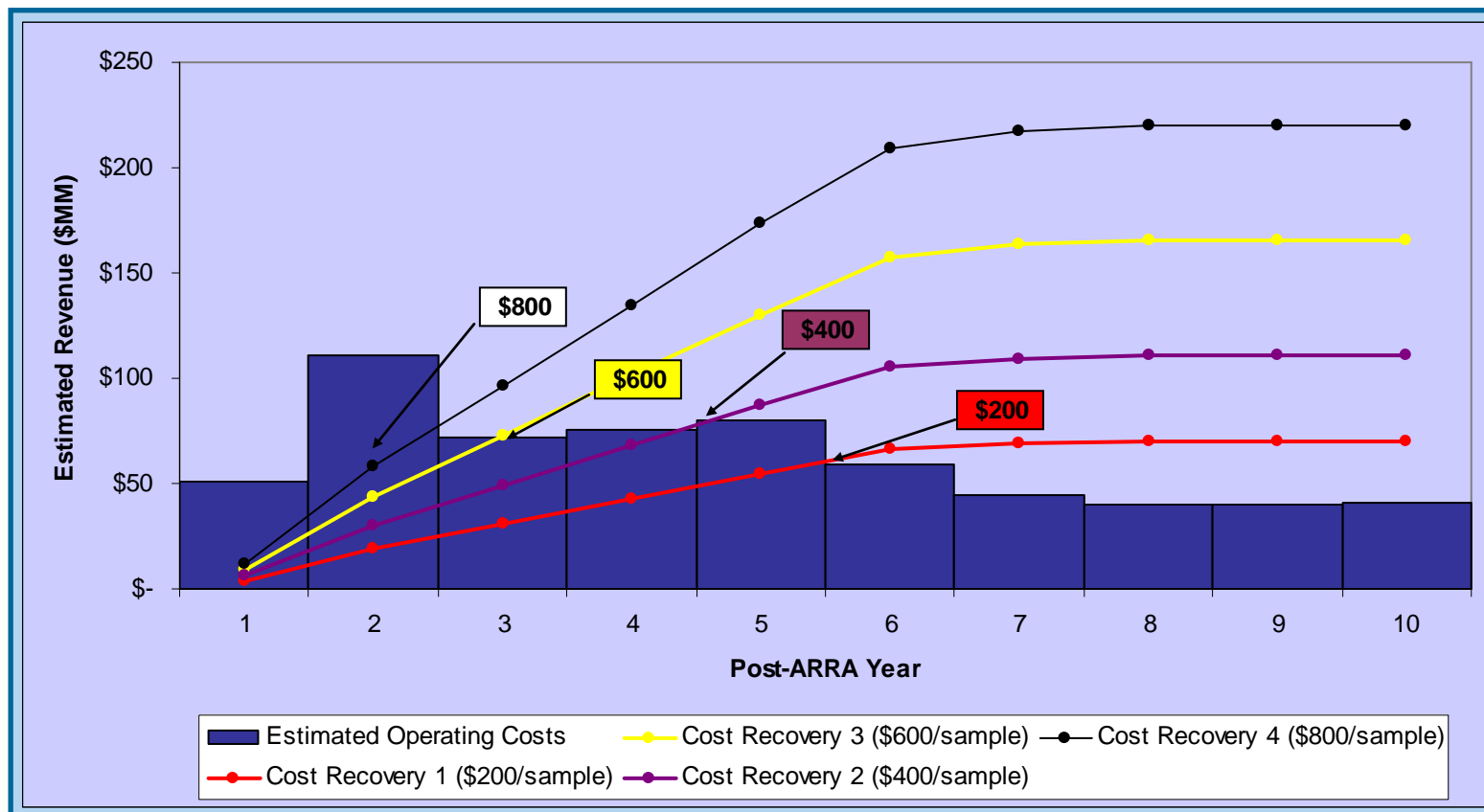




caHUB Cost Recovery Modeling

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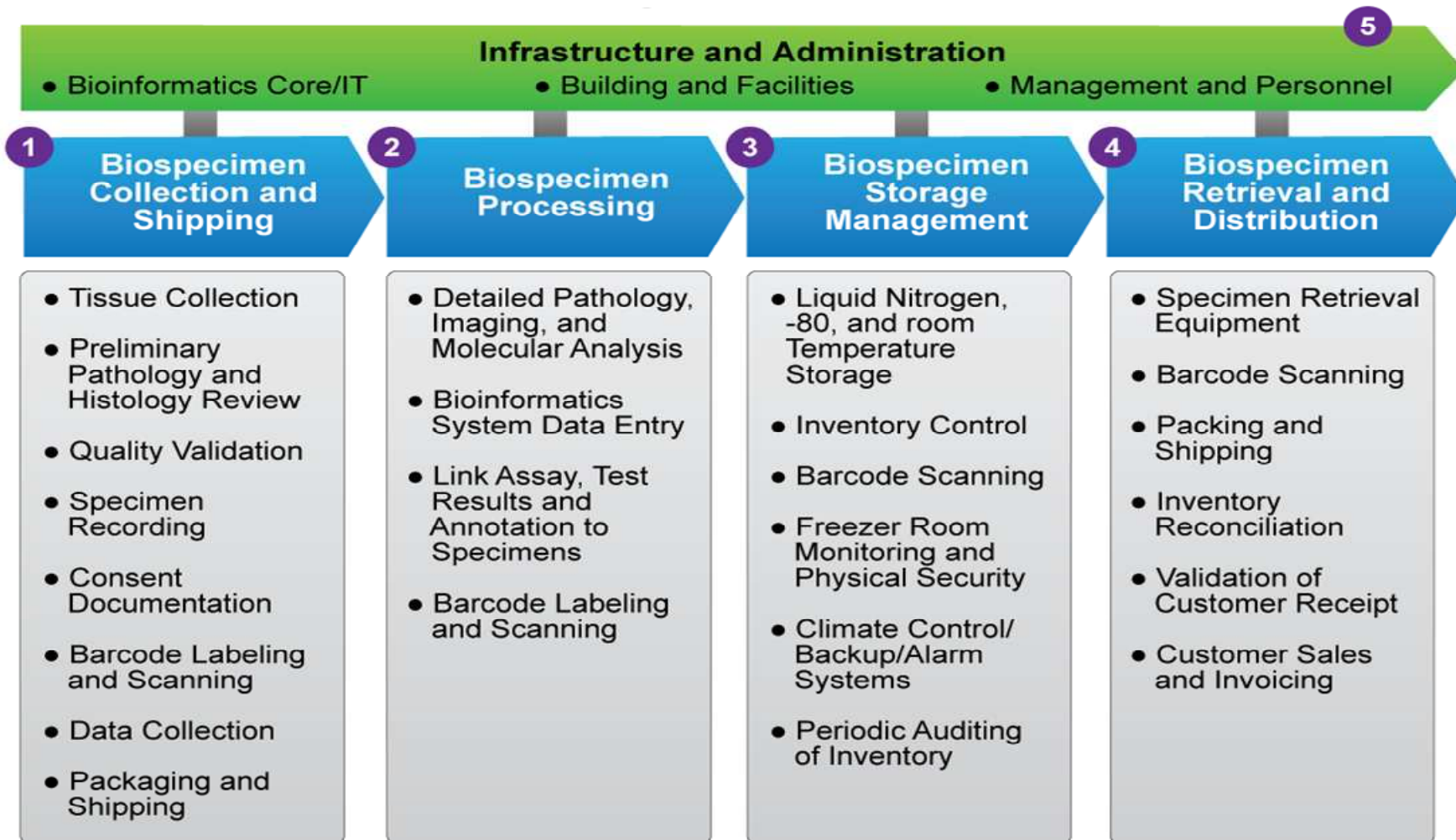
caHUB Cost Recovery Breakeven Point Given Various Average Prices Per Sample





CaHUB Infrastructure & Administration

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caHUB Timeline

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Planning

- Pathology Resource Center
- Working Groups
- Cost Recovery
- Market Research

Phase 1

- caHUB pilot
 - procurement
 - operations
 - data coordination
 - R&D
- PPP Development

Phase 2

- Centralization
- Expansion
- Special Collections
- Training Services

From caHUB Project Charter September 2010

6.2 Key Project Risks

Risk	Risk Mitigation Plan
Funding for providing a sustainable resource	Investigate NIH authority for cost recovery; raise additional funds through the FNIH
Integration of informatics systems	Maximize use of existing resources; maintain a dedicated IT support team
Competing with existing resources for tissue	Select BSSs based on ability to prioritize the caHUB collection; coordinate with other programs, like TCGA, to collect matched samples; prioritize caHUB collections based on unmet needs
Having too few qualified specimens to meet the demand	Select BSSs based on case volumes for different cancers; routinely reassess collection strategies; maximize use of each qualifying case
Biospecimens collected do not meet quality metrics	Provide SOPs to BSSs; engage in hands-on training and education; maintain a dedicated team for managing BSS relationships
Maintaining competitiveness	Remain apprised of trends and advances in technology
Lack of end user confidence	Communicate proof of concept (and results); engage in strategic communications and outreach
Lack of public support	Engage with patient advocacy groups; communicate benefits of the caHUB to medical research and patient populations

6.3 Project Constraints

- Time: Initiated in 2009, funds awarded must be spent by 2015; however, the subcontract period of performance will be for 2 to 3 years with option years.
- Funding: Funding is limited to \$60 million in ARRA funds.
- Human resources/staffing: There are a finite number of OBRR Federal employees and NCI contractors; most staffing will be SAIC-F contractors.
- Governance: The project will be co-led by NCI-OBRR as the project sponsor and SAIC-F as the prime contractor. Oversight committees and working groups will be established.
- Requirements: Biospecimen quality and data requirements will be stringent.



caHUB, A Transformative Initiative

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More Efficient Research



- Reduction in re-experimentation due to higher quality samples
- Avoided cost of incremental labor from PIs and lab technicians, researchers
- Avoided cost of replacing failed samples because of higher sample quality
- Avoided time delays and labor costs for recontact and recontact of patients for new studies

More Efficient Use of Resources



- User leverage of caHUB's systems infrastructure, reducing the need to purchase and maintain requisite infrastructure
- User leverage of caHUB goods and services, decreasing labor costs to process samples in order to meet research requirements

Ensured Implementation of Best Practices



- Increased comparability (quality and uniformity) of specimen and data sets
- Ensures compliance reducing implementation and monitoring costs

Stronger Clinical Correlation



- Quality and uniformity of data promotes more accurate modeling
- Avoided re-collection of data, saving time and cost



caHUB, A Transformative Initiative

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More Efficient Product Development and Regulatory Approval



- Higher quality samples helps advance biomarker research
- Higher quality specimens helps reduce clinical trials timeframes and costs
- FDA recognition of “platinum” status specimens may lead to more rapid approvals for new drugs and diagnostics

More Efficient Technology Development and Clinical Implementation



- Standardized biospecimens allows direct performance comparisons
- Benchmark biospecimens allows calibration, performance monitoring and operator proficiency testing

Added Clinical Value: Improved Standards of Care



- Speed the transition from research standards to standards of care
- More rapid implementation and standardization of diagnostic assays in clinical laboratories

Improved Outcomes for Cancer Patients



- **Increase in lives saved**
- **Improvements in quality of life**
- **Positive impact on personal economics**
- **Savings to healthcare systems**
- **Positive impact on national economics (GDP, tax revenues)**



New Biospecimen Resource Website

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- **New website for OBBR's cancer Human Biobank (caHUB) initiative includes:**



- Videos from thought leaders in the field
- Funding and partnership opportunities
 - Reports for scientific, policy, and advocacy communities
 - Other resources for:
 - general public
 - professionals who work with biospecimens
 - potential partners
 - healthcare professionals
 - patients
- <http://cahub.cancer.gov>



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Launch NCI Best Practices

Launch caHUB

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caHUB

News and Events

Resources

2011 BRN Symposium

Overview

Agenda

Hotel and Travel Information

Abstract Submission

Event Registration

Live Webcast Information and Registration

BRN Forum

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Overview

The National Cancer Institute Office of Biorepositories and Biospecimen Research (OBBR) presents the

4th Annual Biospecimen Research Network (BRN) Symposium: Advancing Cancer Research Through Biospecimen Science

March 28-29, 2011

Bethesda North Marriott Hotel & Conference Center
Bethesda, Maryland

Register today!

Important dates to remember:

- * Registration closes on February 28, 2011
- * Abstract Submissions are due by January 31, 2011
- * Hotel cutoff date is March 7, 2011

Symposium Goal:

Human biospecimens are the foundation of the translational research that will transform patient care. The primary goal of the symposium is to address the:





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