



OBRR Office of Biorepositories
and Biospecimen Research

Update: The Cancer HUMAN Biobank (caHUB)

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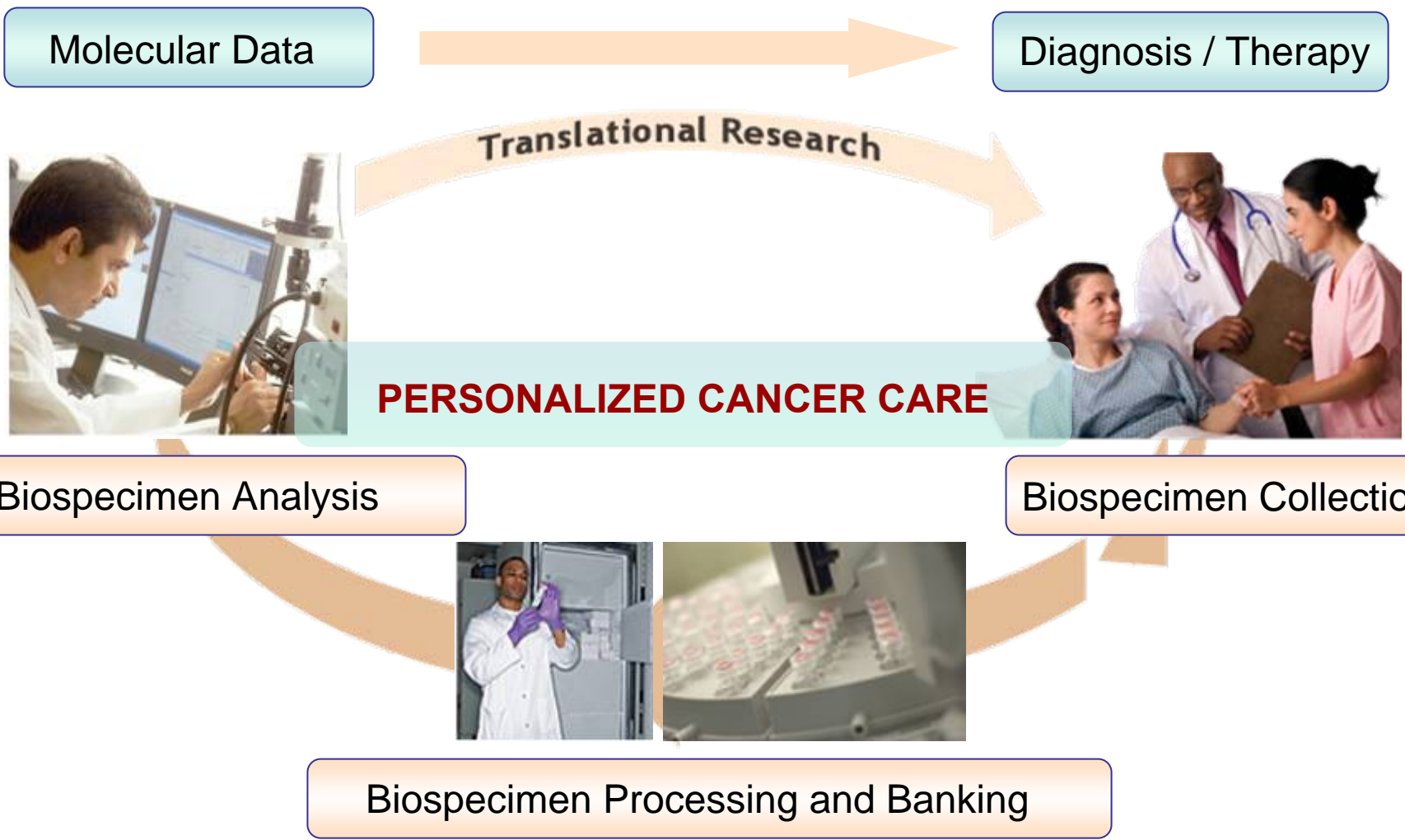
caHUB The Cancer
Human Biobank

NATIONAL
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Getting to Personalized Medicine

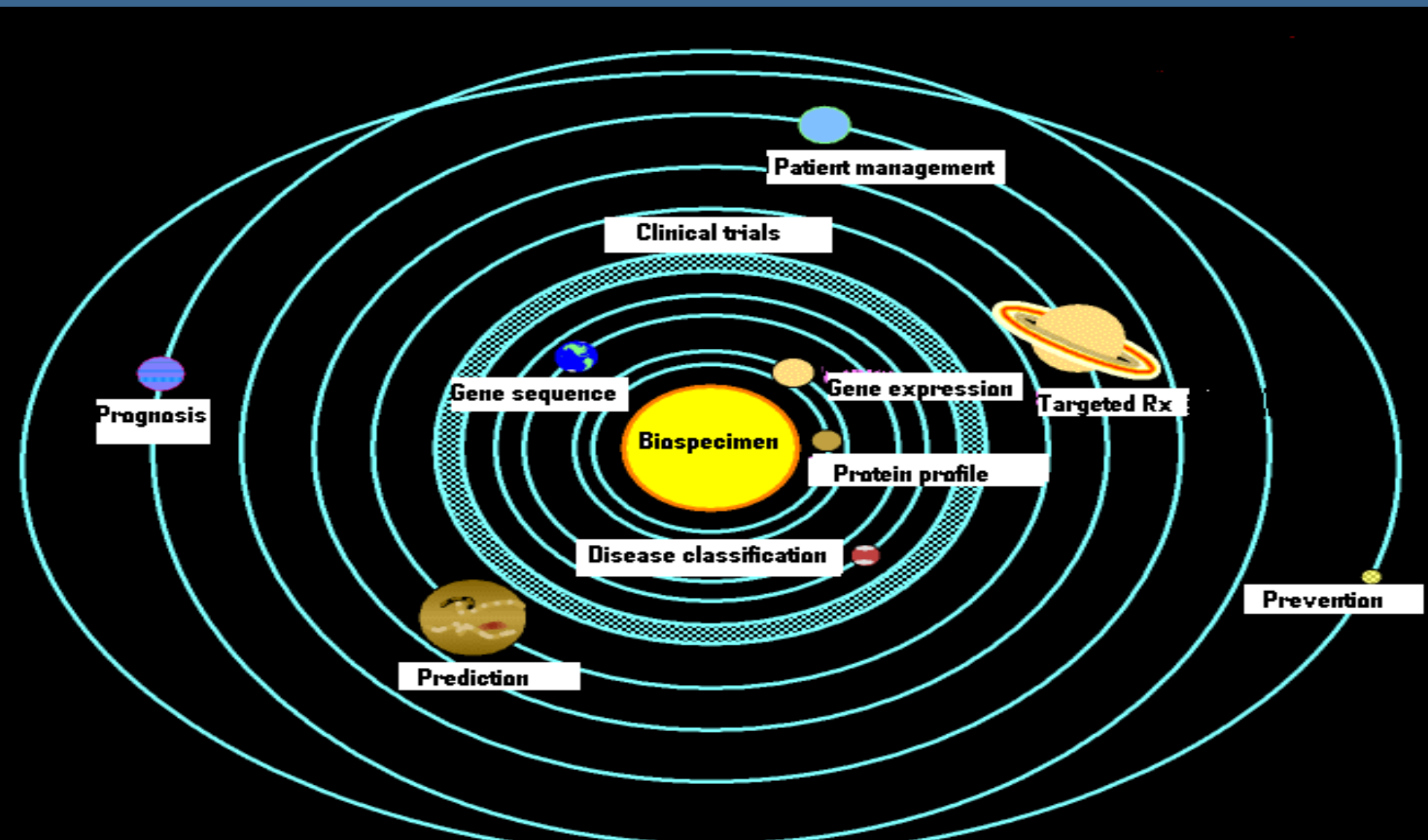
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The Personalized Medicine Universe

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Why Is It Difficult to Acquire High-Quality Specimens and Data?

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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**

The NCI Addresses the Challenge

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**



Consensus for a Solution: The 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





National Biospecimen Resource: caHUB

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A unique, centralized, non-profit public resource that will ensure the adequate and continuous supply of **human biospecimens and associated data** of measurable, high quality acquired within an ethical framework and provide high-quality biobanking **services** to the community.

- **High-quality** samples and associated data
- **Prospective** scientific design of collection strategies
- **Standardized** processing and annotation of all specimens
- **Centralized** operations for QC, pathology analysis, storage
- **Publicly available** resource for human specimens and specimen-related services serving academia, industry, advocacy, government
- **Transparent** access policies
- **Cutting-edge:** leadership for biospecimen resources (biobanking tools, biospecimen science, training and education)



The Need for caHUB

- **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

Economic Considerations Study

caHUB User Workshop

Specimen Resource Locator



Benefits of a National Biobank:

- Inspire confidence in quality of specimens
- Standardize practices between labs
- Ensure ethical collection standards
- Unite the community around shared sense of mission

Development Challenges:

- IP constraints

Strong support for a national biobank concept from all stakeholders

Barriers to Contribute:

- IP constraints

Key Findings:

- Biospecimen Development Challenges:
- Both the quality and quantity of specimens
- Researcher barriers to contribute
- Researcher support for a national biobank





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**



Importance of Standardized Specimens and the Requirement for a National Biospecimen Resource

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- **Genomics and Personalized Medicine Act of 2007**
- **Institute Of Medicine Report: *Cancer Biomarkers*, 2007**
- **Dept. of Health and Human Services, *Personalized Health Care Report*, Sept. 2007**
- **President's Council of Advisors on Science and Technology: *Priorities for Personalized Medicine*, Sept. 2008**
- **President's Cancer Panel Report, *Maximizing Our Nation's Investment in Cancer*, Sept. 2008**
- **Kennedy-Hutchison Cancer Bill (ALERT Bill: "War on Cancer, Part II"), 2009**
- **The NCI By-Pass Budget for FY2010**



8. Biobanks By ALICE PARK

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

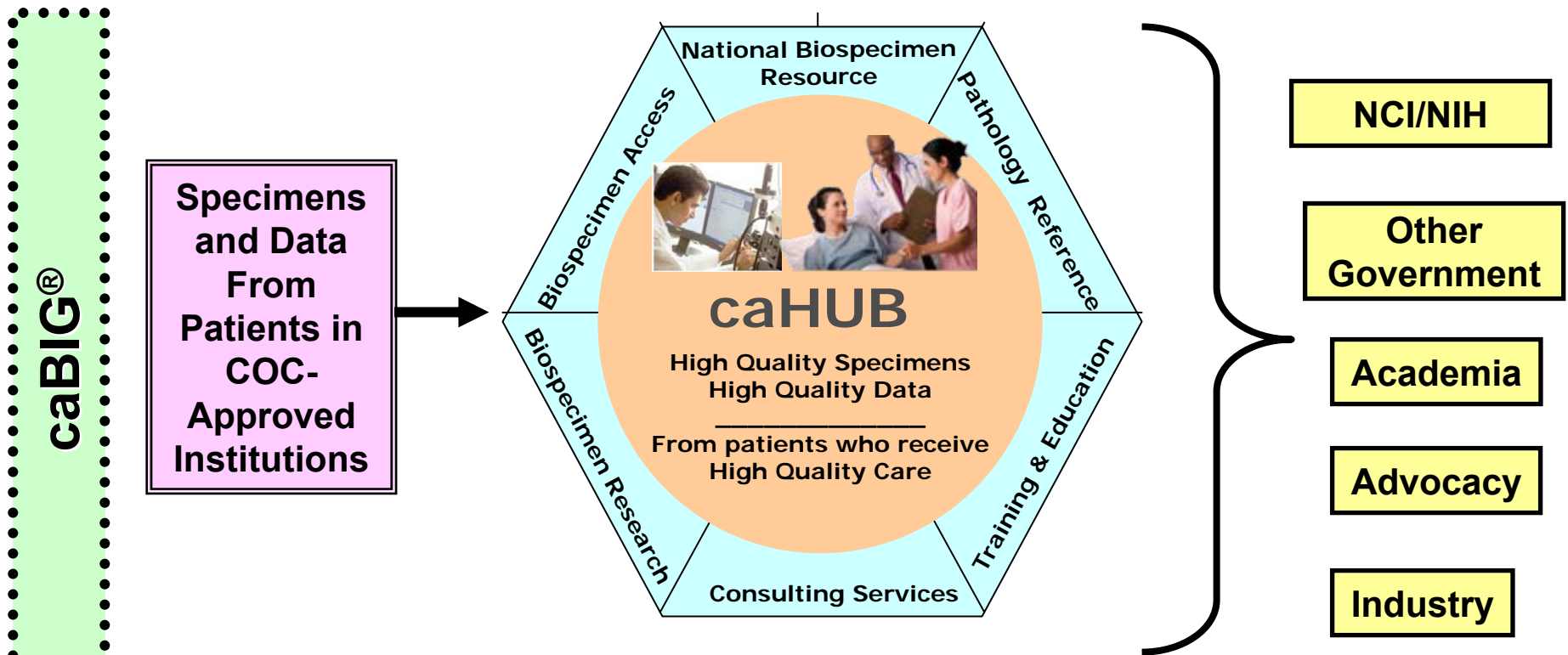
Folks at the National Cancer Institute (NCI) are heading up an effort to establish the U.S.'s first national biobank — a safe house for tissue samples, tumor cells, DNA and, yes, even blood — that would be used for research into new treatments for diseases.... By fall, the group hopes to have mapped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



caHUB: Centralized Model

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- HIGH QUALITY SPECIMENS • HIGH QUALITY DATA • FROM PTS RECEIVING HIGH QUALITY CARE



Centralized Resource: Cost and Quality Control Efficiencies



Biospecimen Science: Moving Towards Evidence-Based SOPs

Time 0

Specimen is viable
and biologically reactive

Molecular composition subject to
further alteration/degradation



Patient

Medical/
Surgical
Procedures

Acquisition

Handling/
Processing

Storage

Distribution

Scientific
Analysis

Knowledge
Base

Pre-acquisition

Post-acquisition





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
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 - **Rich clinical data and outcome information for patients**



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) scheduled for March 2010; for publication and/or availability through OBRR website**
 - Independent value to broader biobanking community



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

caHUB, A Transformative Initiative



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)**



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CaHUB Public Information Meeting
March 1, 2010



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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





Update on Key Issues

- **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 ARRA funds allotted to caHUB in 2009**



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Importance of a National Biospecimen Resource Cited on Many Levels

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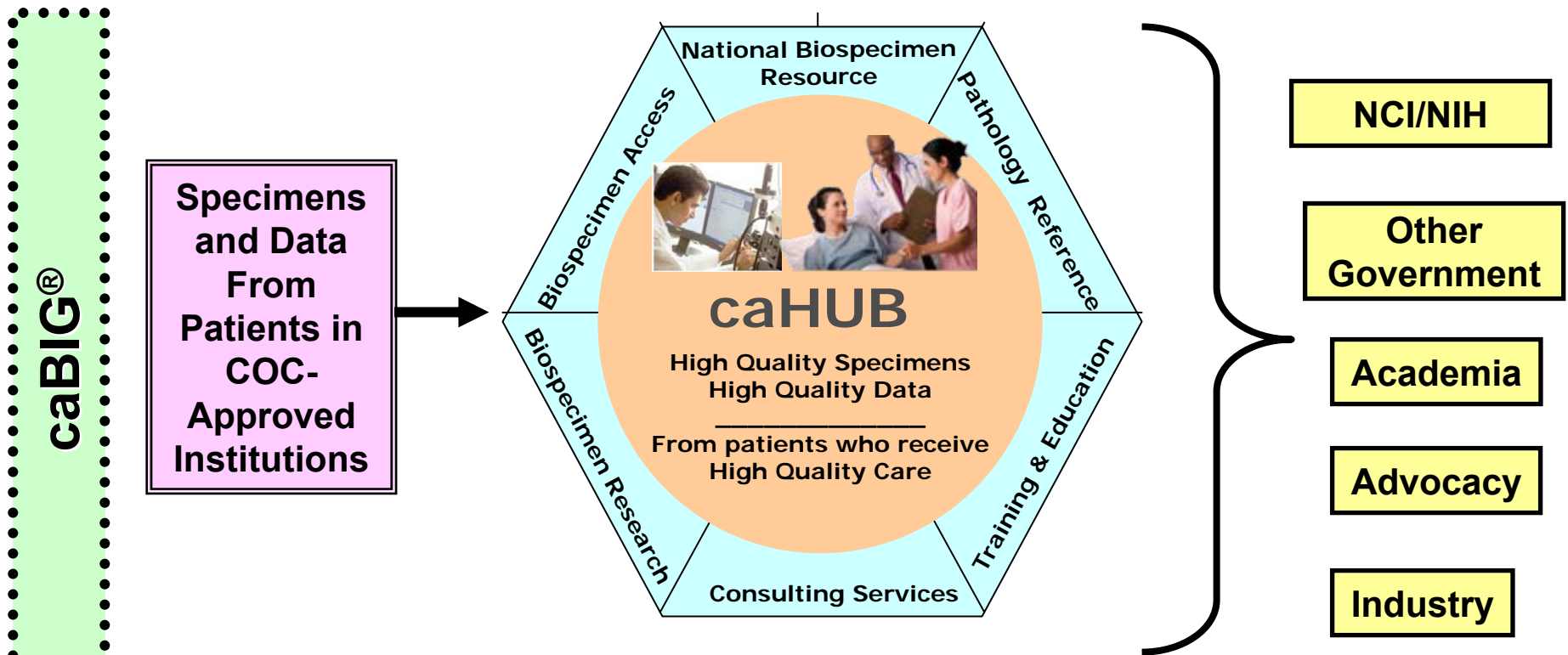
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caHUB Collection Prioritization: Process Design

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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**



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.



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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

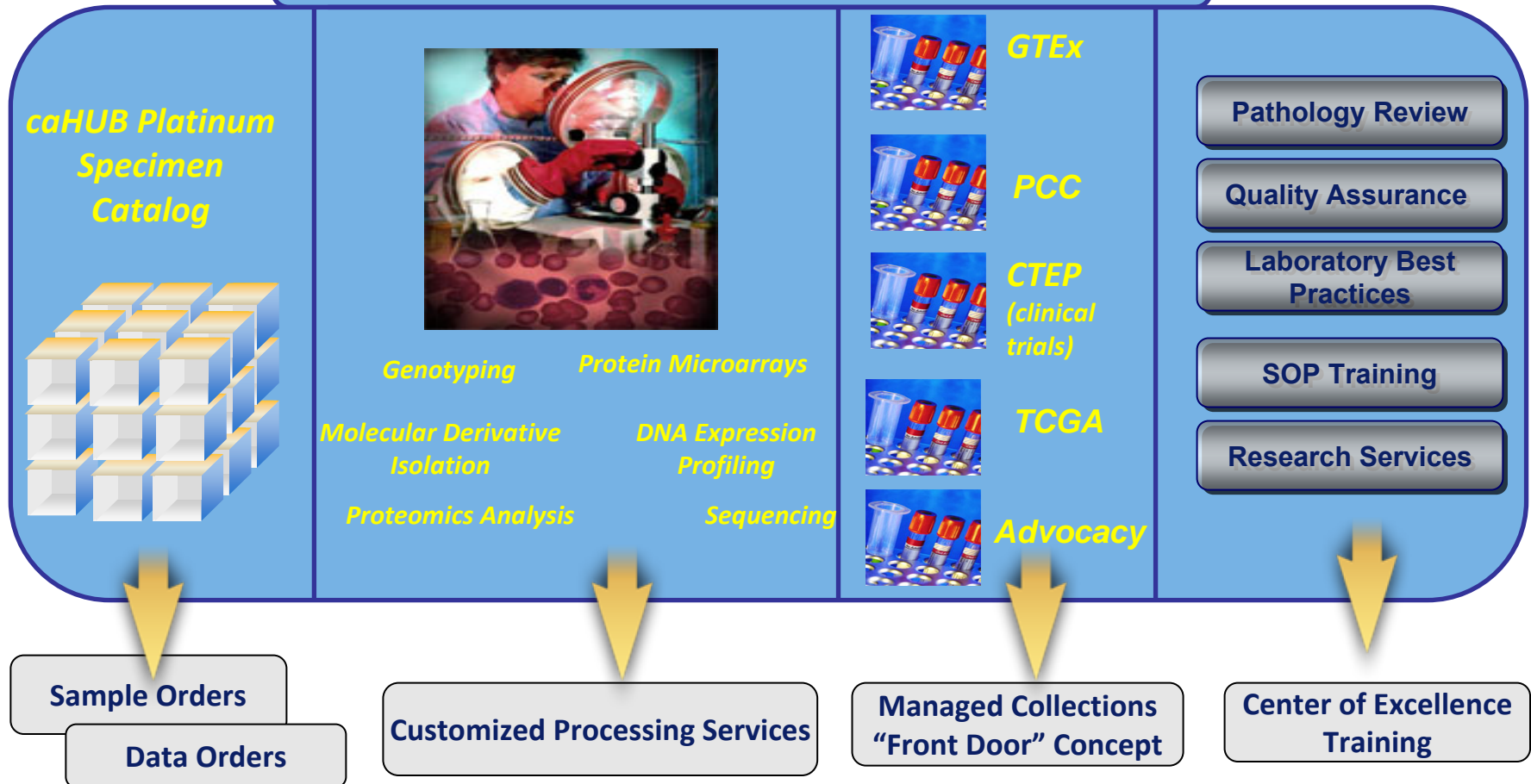
- **Biobanking services to other initiatives**
 - Other NCI/NIH
 - Rare diseases
 - Advocacy
- **Education and training**
 - Pathology and laboratory functions
 - Operating room functions
 - IT and data management
 - Biostatistical and analytic methods
- **Consulting services**
 - Biobanking methods 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



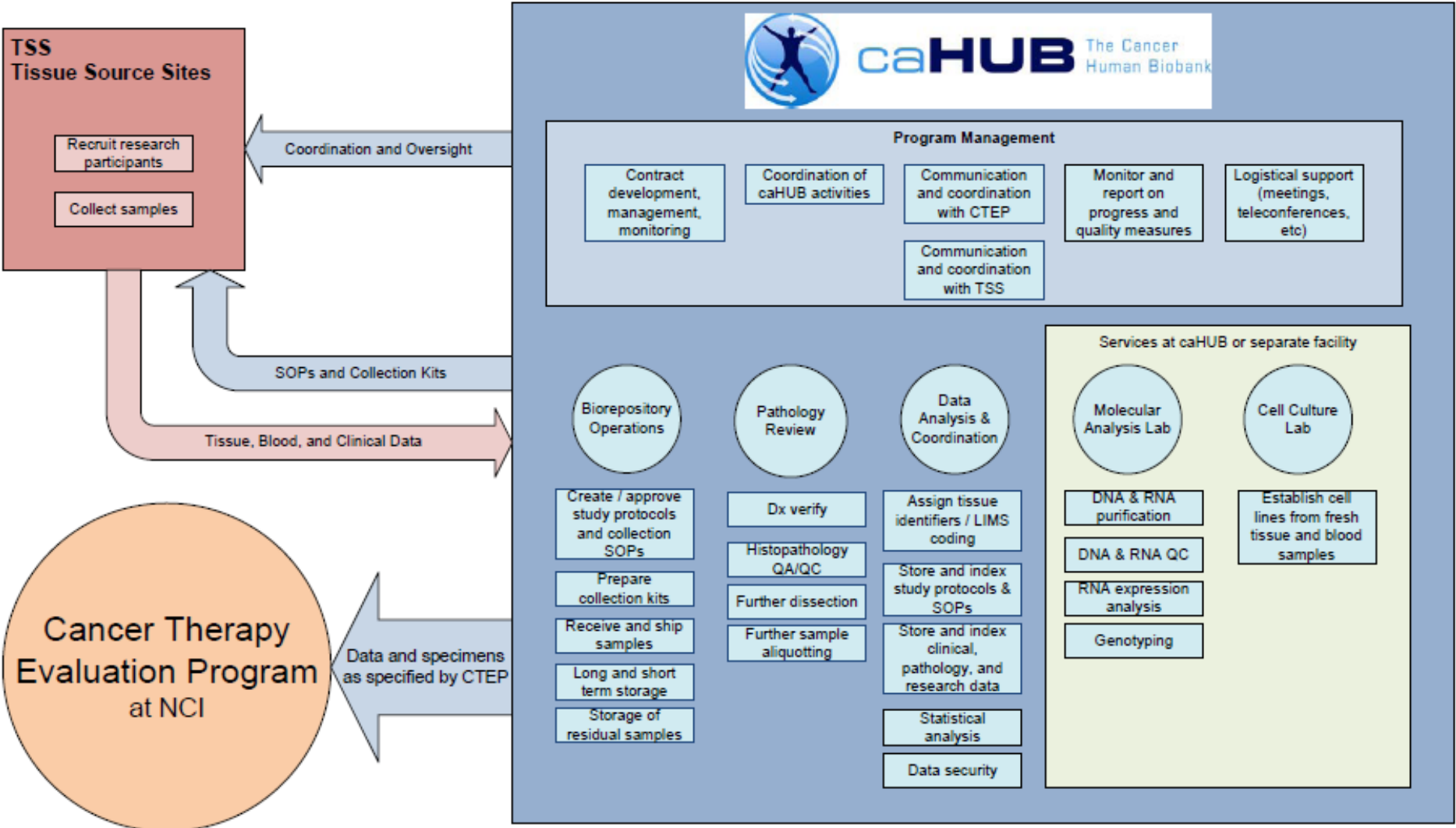
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Commodities and Service-Based Model



caHUB as Service Provider: CTEP Example





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