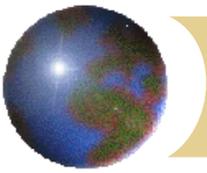


Biobanking and its Role in Research

Jai P. Singh

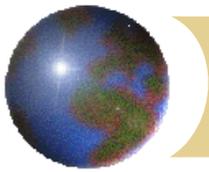
***ASQ Section 0511 Presentation
January 10, 2018***



10 Ideas Changing the World



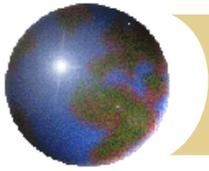
1. Why Your Job is Your Most Valuable Asset
2. Repurposing the Suburbs
3. Survival-Store Shopping
4. Biobanks; Saving Your Parts
5. Need Land? Rent-A-Country
6. The New Calvinism
7. Ecological Intelligence
8. Amortality; Forever Young
9. Africa; Open for Business
10. Reinventing the Highway



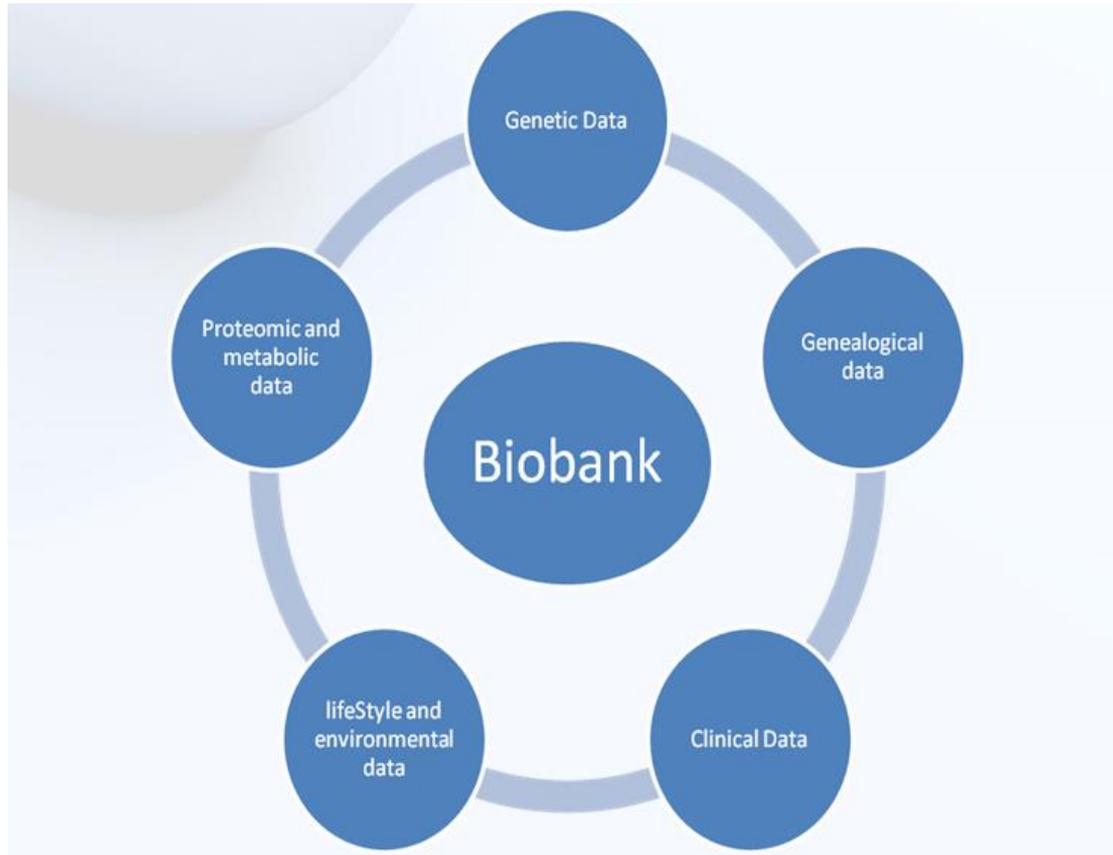
Biobank.....

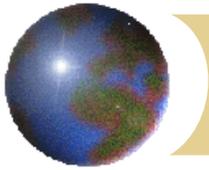
A Biorepository is a biological materials repository that collects, manages, processes, stores, and distributes biospecimens to support scientific investigations.....

A building (conservation facility), room, or container for long term storage for biological specimens either for Clinical or Research purposes.....



Biobank





Public Awareness: Patients, Volunteers

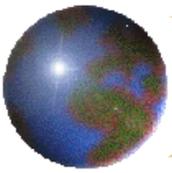
- **Internet Forum, Seminars, Research Presentations**
- **TV/ Radio, Billboards, Public meetings/education**



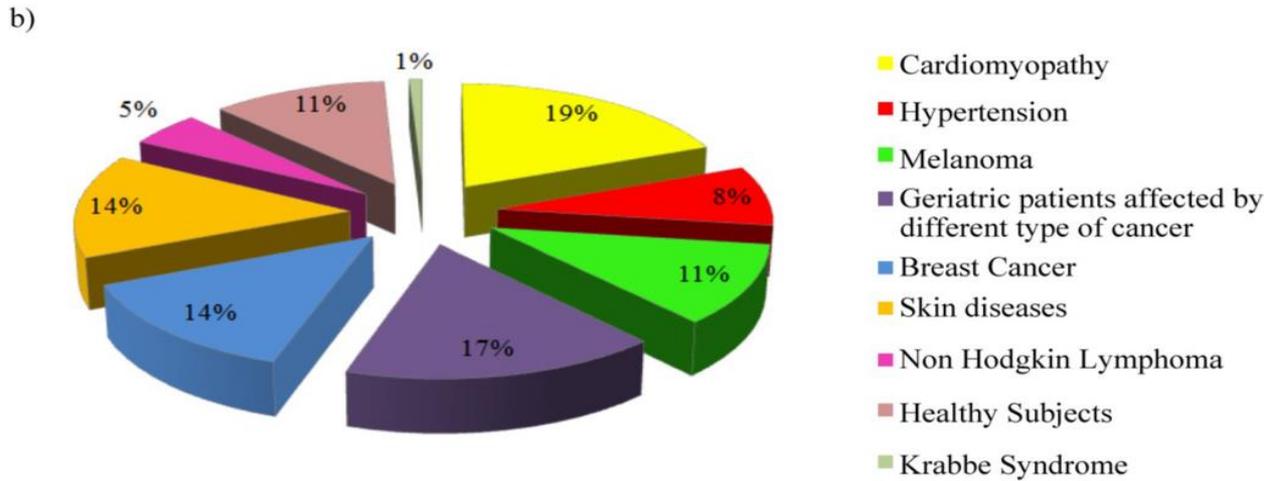
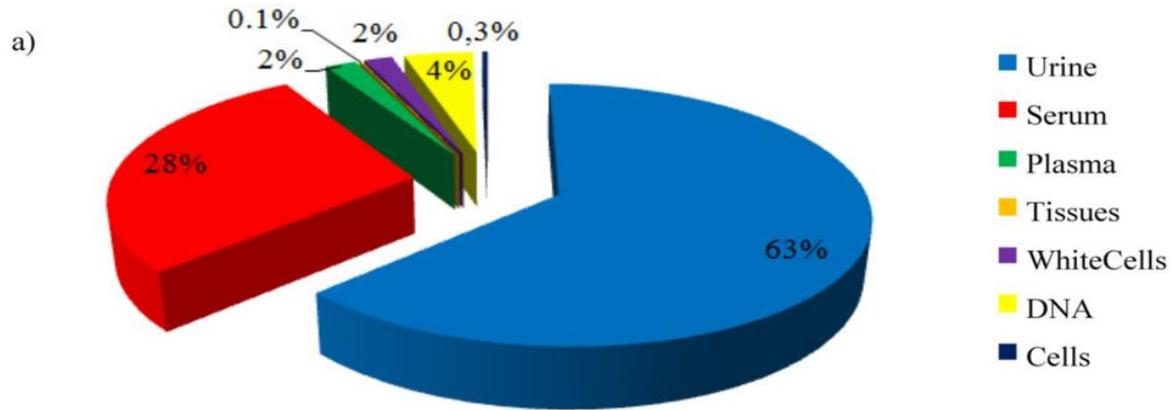
- **Understand the purpose of Biobank**
- **Effective Participation in Biobanking**
- **Fast consenting**
- **No disruption of Clinical Workflow or material**

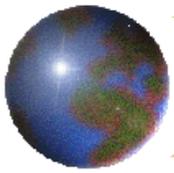


Effective BioBanking



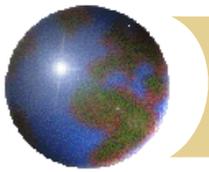
Sample collection Type and Different Diseases



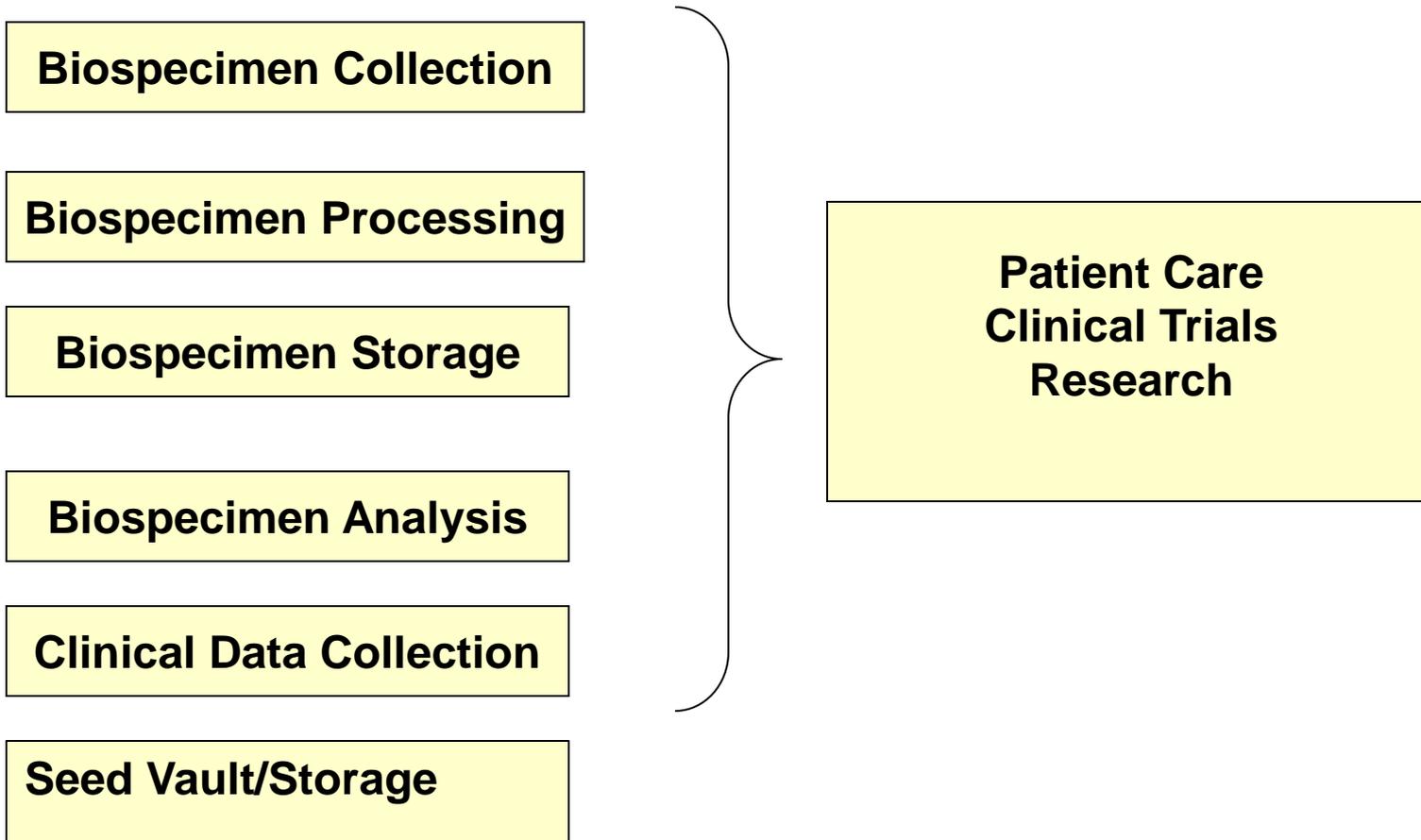


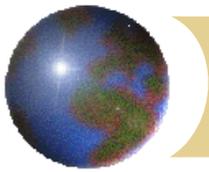
Freezers (-80°C) and Liquid N₂ (-196°C)



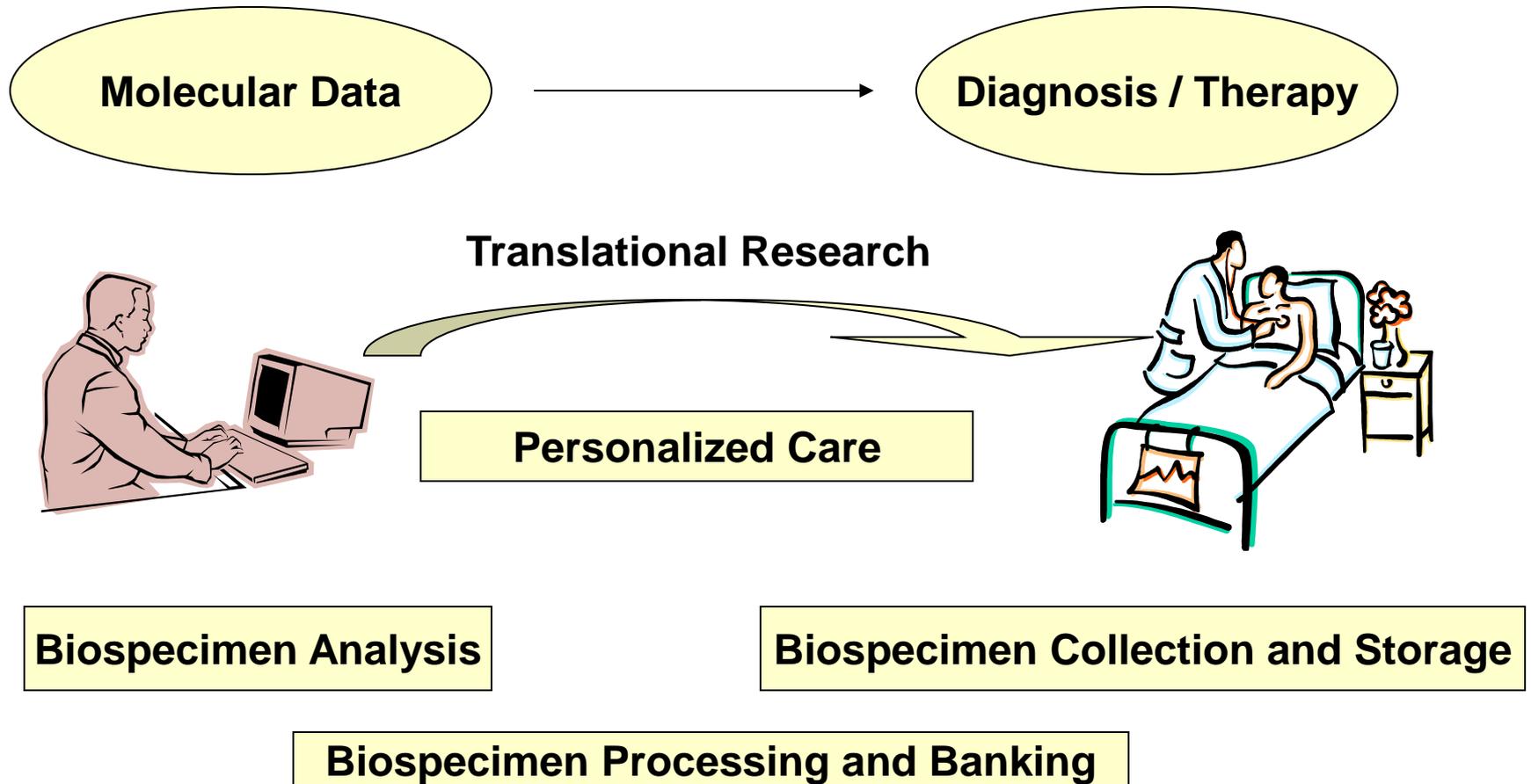


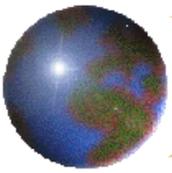
Biospecimen are collected for Patient Care and for Research



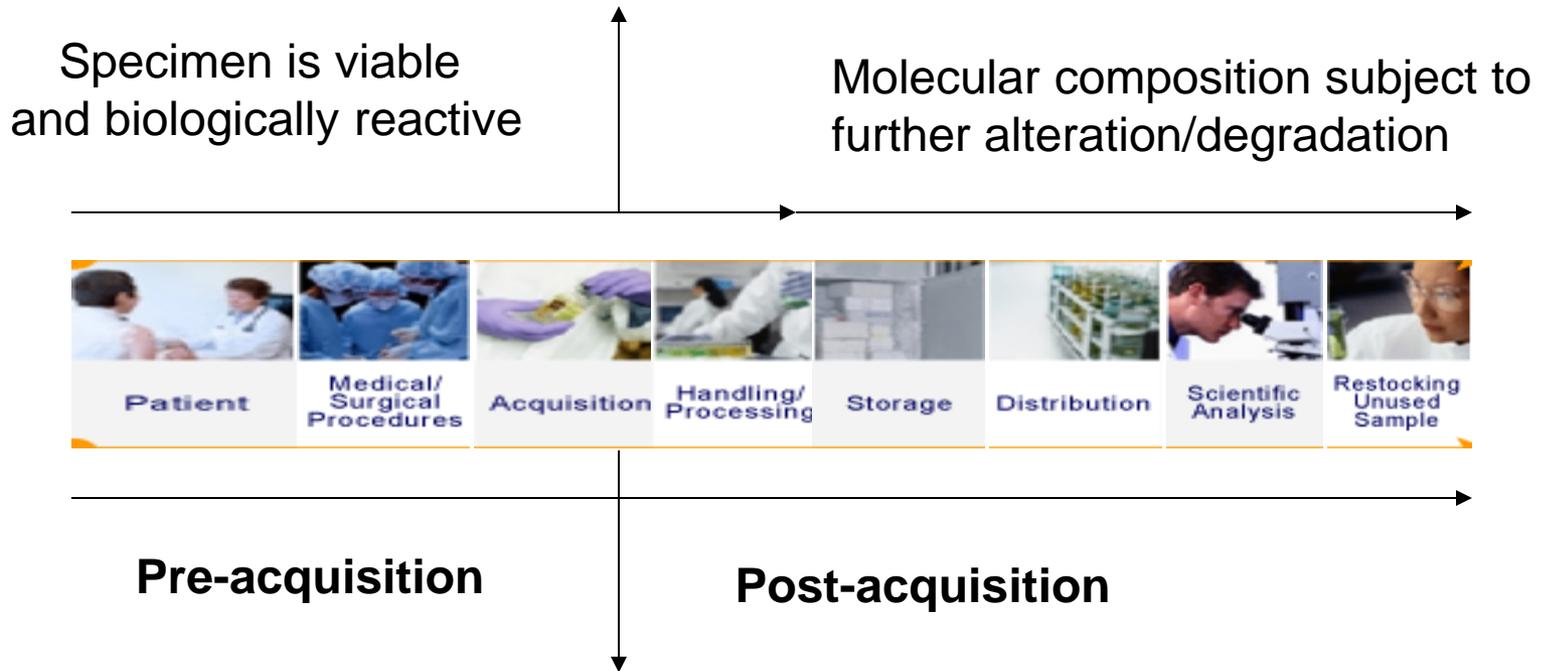


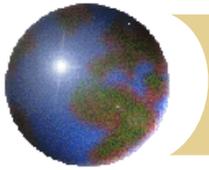
Translational Research Will Lead the Way to Personalized Medicine





Lifecycle of the Biospecimen



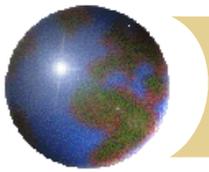


Biospecimen Availability and Quality: Major Challenge for Research

The **lack of high quality**, appropriately collected, stored and annotated specimen is the limiting factor for translational research or basic research

High quality specimen enables:

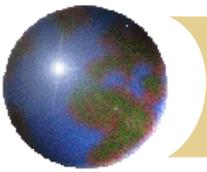
- Drug discovery
- Translational Research and basic research
- Clinical development
- Assay variability
- Specimen variability
- Diagnostic development
- Personalized medicine
- Targeted therapies



The Difficulty in Acquiring High Quality Specimens and Data?

- **Collection, processing, storage procedures differ**
- **Degree and type of data annotations 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**
- **Funding sources varies**

Leads to Wide Variation in Quality of Specimen and Data



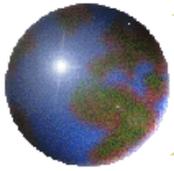
Pre-analytical Variables

Pre-acquisition variables:

- **Antibiotics**
- **Other drugs**
- **Type of Anesthesia**
- **Duration of Anesthesia**
- **Arterial Clamp time**
- **Blood pressure variations**
- **Intra-op blood loss**
- **Intra-op blood administration**
- **Intra-op fluid administration**
- **Pre-existing medical conditions**
- **Patient gender**
- **Ethnicity**

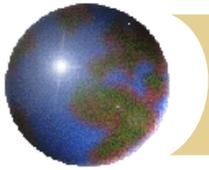
Post-acquisition variables:

- **Time at room temperature**
- **Temperature of room**
- **Type of fixative**
- **Time of fixative**
- **Rate of freezing**
- **Processing method**
- **Size of aliquots**
- **Type of collection container**
- **Biomolecule extraction method**
- **Storage temperature**
- **Storage duration**
- **Storage in vacuum**



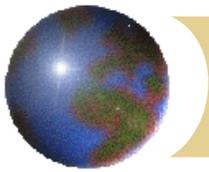
Strategic Approach to Problem

- **STANDARDS:** Develop guidance for biobanking to harmonize procedures for collection, processing, storage and distribution of biospecimens (**The Best Practices for Biospecimen Resources: ISBER**).
- **SCIENCE:** research to better understand how pre-analytical factors affect the integrity of the biospecimen (**Biospecimen Research Network**).
- **Synergies:** Collaboration to share resources and develop community-wide and international standards (**CAP, FDA, NIST, National and International Partners**).



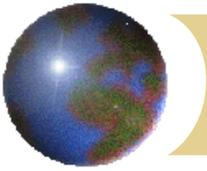
Biorepository Services

- Manage and Support functions
- Managing Contracts for Storage
- International Collaboration for Biorepository: Establish and Educate on Best Practices for Collection, Processing, Storage and Distribution of Biospecimen.
- Maintain Compliance.
- Work with European Partners
- cGMP Biospecimen Storage Services: Government and Commercial partners.
- Develop relationship with International and Domestic Biorepositories.
- Clinical Trials Support Services



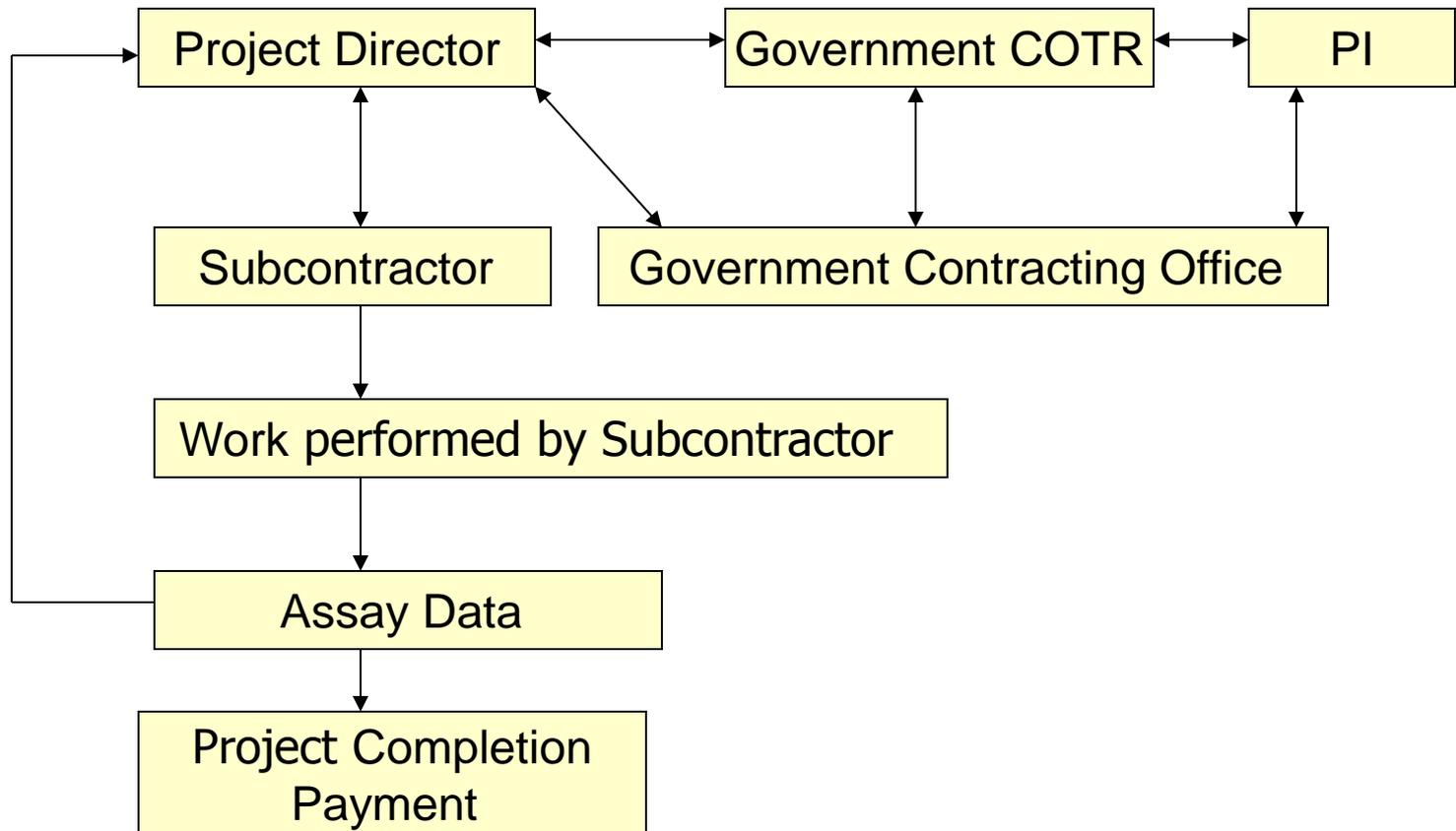
Contract Services and Management

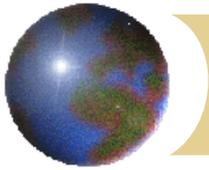
- **Work with Government researchers or Private Translational Institutes and collaborate on Specimen Collection and Storage and Research.**
- **Identify laboratories for specialized assay for research. Select laboratory and determine the process of procurement for their services.**
- **Develop specimen processing scheme in collaboration with researchers/investigators and support the specimen collection, processing, storage and retrieval of specimen (Domestic and International).**
- **Process specimen based on the requirement set in study protocol.**
- **Develop protocol for initial collection of specimen at field sites. Select collection sites and collect specimen, process materials, schedule procurement of materials and shipment of materials to designated field sites.**
- **Store specimen and manage inventory.**
- **Shipping and receiving of specimen to and from laboratory.**
- **Maintain laboratory under compliance.**
- **Automation in specimen processing**



Contract Process Flow

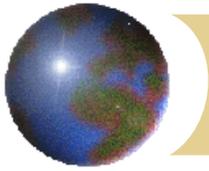
Project Process Flow





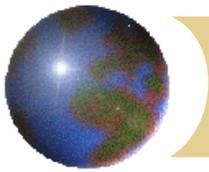
Challenges in Contracting Process and Solutions

- **Education and Awareness at all Levels of Government and Internal Management Team (Department, Legal and Finance)**
- **Statement of Work**
- **Finding Laboratory to Work on the Project (Competitive Pricing)**
- **Develop Subcontract in Conjunction with Contracting Office, Internal Legal Office**
- **Material Transfer Agreements**
- **Shipment of Specimen and Manage Inventory**
- **Receipt of Specimen and Maintain Inventory**
- **Manage Subcontract and Subcontractor Performance**
- **Automation**
- **Communication**
- **Decision making**



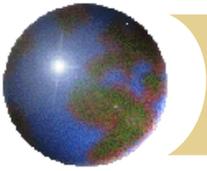
Challenges in Contracting Process and Solutions.....

- **Working with International Subcontractor**
 - **Communication (develop understanding)**
 - **Education on subcontracting process**
 - **Education on best practices**
 - **SOP development: specimen collection, processing and storage**
 - **Specimen collection, processing and inventory management**
 - **Specimen Storage and distribution**
 - **Temperature monitoring and record keeping**
 - **Inventory management (system, support and record keeping)**
 - **Payment structure (currency and price fluctuations issues)**



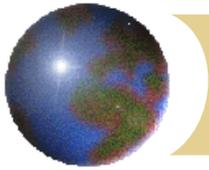
Government Contract Activities and Report

Subcontract #	MEP #	Study/Res.	NCI- PIs	Status	Study Value \$\$
BRC-55502-23 (COA # 31) Johns Hopkins Univ.	264	Rakai Circumcision HPV/ Genotype	Charles Rabkin	Completed	\$39,520.00
BRC-55502-17 (COA # 18): USC		Melatonin Assay	Ann Hsing Lisa Chu	Open	\$63,294.00
BRC-55502-17 (COA # 18): USC	266	Prostate Tissue Study Hormones	Ann Hsing	Open	\$181,623.00
BRC-55502-17 (COA # 18): US	250	Hormone Assay	Rebecca Troisi	Open	\$44,400.00
BRC-55502-17 (COA # 18): USC	287	Hormone Analysis NIT study	Neal Freedman	Open	\$87,296.00
BRC-55502-17 (COA # 18): USC		Ghrelin Assay	Neal Freedman	In-Process	\$23,568.00
Subcontract with USC (NEW)		Hormone Assay: Mongolia	Rebecca Troisi	In-Process	\$163,000.00
BRC-55502-22 (COA # 30): RAND	237	BioSpecimen	Jim Vaught	completed	\$103,999.00
BRC-55502-28 (COA #40): Hershey Medical	263	Vit E; Smoking and Prostate cancer	Demetrius Albanes	Open	\$97,096.00
BRC-55502-29 (COA #41): BioServe/Sandor (India)		DNA Extraction, SNP and storage	Rashmi Sinha	Open	\$59,192.00
BRC-55502-31 (COA #44): Children's Hospital Boston		Hormone Analysis	Katherine McGlynn	Open	\$178,699.00
BRC-55502-30 (COA #42): Lady Davis Institute, Montreal, Canada		Adipokines analysis	Roni Falk	Open	\$49,755.00
Non-subcontract Work					
Tecan Robot		Processing specimen			\$250,000.00
Subcontract 17 & 27	202	Dartmouth Twins	Troisi	Open	
Non-subcontract	228	Lung Cancer in Women in China	Qing Lan Nat Rothman	Open	



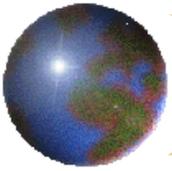
Commercial Storage and Management

- **Type of Biomaterial and its requirement for storage: temperature, how long? How much?**
- **Biomaterials are stored in vapor phase of liquid nitrogen. Cell banks are split (50:50) in two freezers**
- **Bacterial cell banks stored in vapor phase of liquid nitrogen**
- **Distribute biomaterials as requested ensuring proper temperature condition and maintain inventory**
- **Provide Clinical Trial Support Services: Collection Kits, labeling, storage and inventory**
- **Monitor freezer condition 24 hours a day by automated system and maintain records**
- **Access to Biorepository is tightly controlled. Security is a high priority**
- **Strategic development and grow commercial business**
- **Redundant Systems (Generators, monitoring services)**
- **Compliance (cGMP, EMA, FDA)**



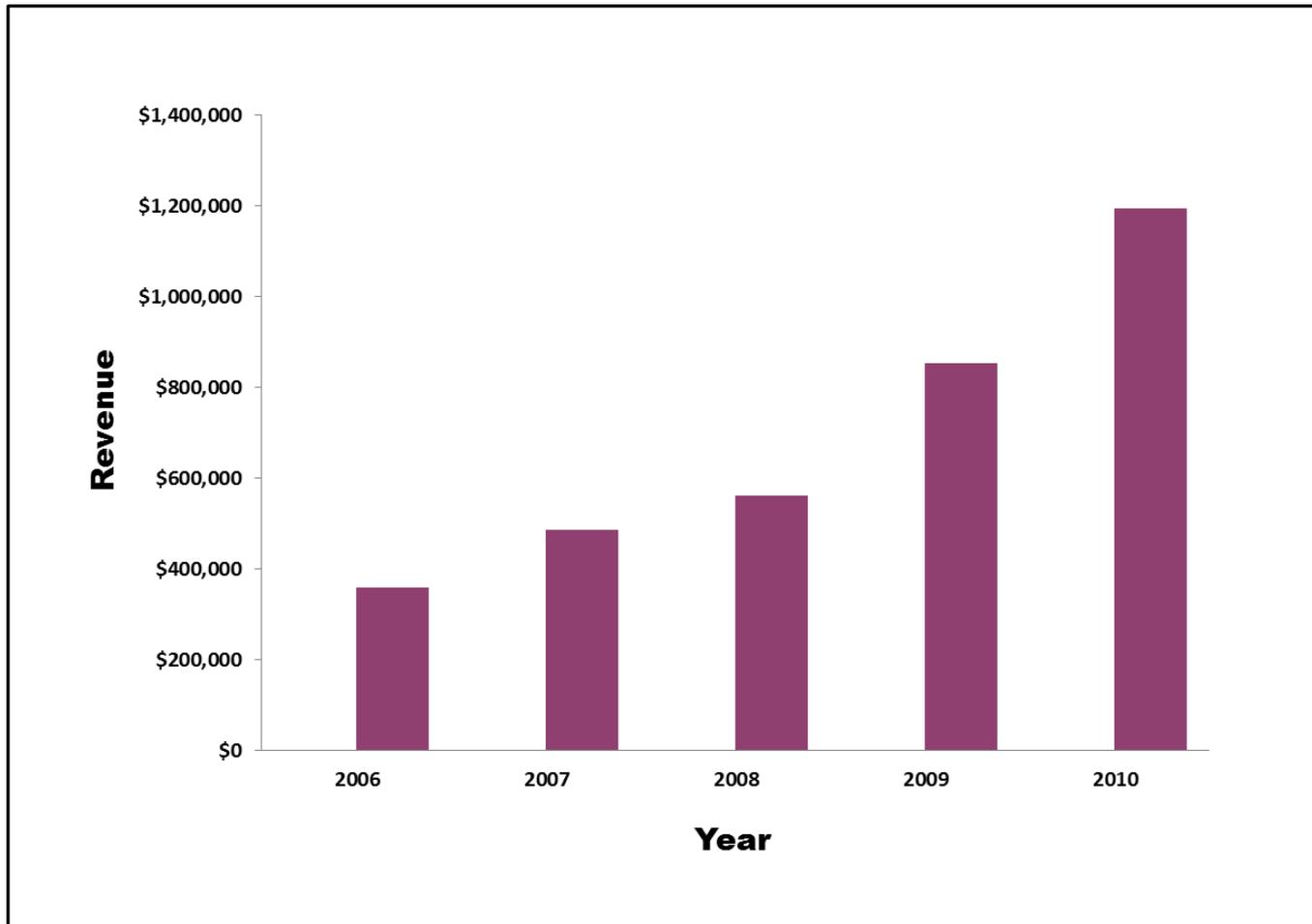
Streamlining the Process: Changes

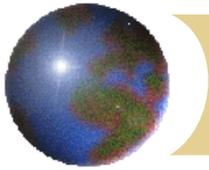
- **Review process and incorporate changes:**
 - **Develop interdepartmental communication (team based approach)**
 - **Renewals and transfers**
 - **Work with account managers (sales team)**
 - **Added checks and balances in cell banking process flow: Cell bank directed by the end of production**
 - **Work with order management (weekly meeting): Generate quotes and send to account managers**
 - **Streamline cell storage paperwork acceptable to all accounts meeting quality and compliance**
 - **Add Project managers into the process for support**



Commercial Cell Storage

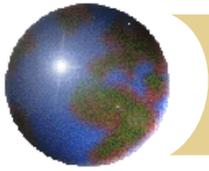
Revenue by Year





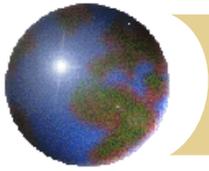
Cell Storage Improvements

- **Changes for future Improvements**
 - **Developed cost models**
 - **Auto renewal process (eRoom)**
 - **Standardized terms and conditions (Domestic, International)**
 - **Developed questionnaire regarding storage**
 - **Developed SOPs (Domestic International)**
 - **Developed global product offering (Domestic, International)**
 - **Expansion on LN2 storage**
 - **Expansion on Pharmaceutical storage capabilities**
 - **Bring new technologies for assay development**
 - **Automation in sample processing**



Summary

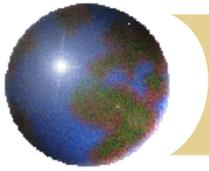
- Perspective on Biobanking
- Importance of High Quality Specimen Collection, Storage and Distribution
- Government Contracting Process
- Commercial Storage Process



How Accomplished.....?



- **Personal touch**
- **Dedication to service**
- **Customer Education**
- **Meeting and Exceeding customer expectations**



Thank you for Your Attention

Questions??