

SPECIAL STUDY

Biobanks: Collaborating for Cures

Sponsored by: IBM

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INTRODUCTION

Collaborating For Cures: by Brett J. Davis,
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"To wrest from nature the secrets which have perplexed philosophers in all ages, to track to their sources the causes of disease, to correlate the vast stores of knowledge, that they are quickly available for the prevention and cure of disease – these are our ambitions." - Sir William Osler, 1906

Many of the world's most devastating diseases are caused by complex interactions between genes, environment and lifestyle. Advances in genomics and proteomics have begun to enable us to understand the molecular mechanisms of disease, and thus bring closer the promise of a more personalized approach to the diagnosis and treatment of disease. However, to accelerate this paradigm of personalized medicine, researchers and clinicians not only need access to molecular information but also the corresponding phenotypic information often contained in medical records or collected in the course of clinical trials. Biobanks – sometimes called biorepositories or tissue banks – provide both types of critical information, and thus can serve as an important translational bridge between research and clinical practice to accelerate the discovery and development of more personalized medicines.

Leaders in science, medicine and technology have recognized the important role that biobanks can contribute to the understanding of human health and disease, and as a result many private and public biobanking initiatives have been established around the globe. Despite this recognition, many technical, ethical, financial, intellectual property and information technology challenges still face this community. To overcome these obstacles and fully realize the value of these initiatives will require unprecedented collaboration between the public and private sectors. Synergies and connections need to be created between the different stages of scientific endeavor and clinical practice, where historically there has been little collaboration and information sharing, resulting in information "silos" and lack of timely knowledge sharing. Enabling these synergies will not only require investment in interoperable IT systems, but a rethinking of business models, processes and current protocols.

IBM Healthcare and Life Sciences recognized this need for collaboration and hosted two World Wide Biobank Summits in 2004 to bring the global 'biobanking community' together to discuss and address these critical challenges. The community includes leaders from bio-pharmaceutical companies, technology providers, patient advocacy groups, government policy makers, and academic research centers. At the first summit in Nice, France in March 2004 IBM hosted thought leaders and practitioners from around the world to identify the most pressing scientific, technology and policy issues facing the community today. A white paper, *Biobanks: Accelerating Molecular Medicine*, was published detailing the challenges identified at this summit.

World Wide Biobank Summit II, *Collaborating for Cures*, held in Tarrytown, NY in November 2004 was designed to address in depth six high priority challenges identified at the first summit including: *Scientific Quality Assurance, IT Infrastructure, Regulatory and Policy Challenges, Biobanking in Clinical Trials, Data Standards/Semantic Interoperability and Funding*. Once again, IBM has teamed with IDC Life Science Insights to develop this study to share more broadly the challenges, and more importantly the possible resolutions to these challenges, that were discussed and debated at the second summit.

Over the next several decades, personalized medicine is poised to transform medicine. Already, new diagnostic and prognostic tools are increasing our ability to predict the likely outcomes of drug therapy and investment in pharmacogenomics is resulting in more focus on the development of targeted therapeutics. Biobanks are one of the most critical resources required to help accelerate this transformation. They can serve as an engine to enable an understanding of the interaction between genes, environment, lifestyle and disease, and then translate that knowledge into clinical practice quickly through innovative diagnostics, therapeutics and preventative treatment strategies.

Information technology is becoming increasingly important in this transformation, by providing the information infrastructure to seamlessly integrate the requisite genotypic and phenotypic information to reveal the complex underlying causes of disease. IBM Healthcare and Life Sciences is committed to playing a leadership role in accelerating this transformation, and has committed the people, technologies and resources to help make information based medicine a reality.

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EXECUTIVE SUMMARY

With the continued advances in genomic research, information technology, molecular diagnostics and other biotechnologies, it is widely recognized that healthcare in the future will shift towards a more "personalized" paradigm of medicine. To achieve and accelerate this vision requires that our understanding of the genetic and biomolecular mechanisms of healthy and diseased states continues to broaden and improve. "Biobanking" is becoming an essential part of this transformation as evidenced by a growing number of such initiatives and organizations around the globe. Biobanks provide a natural focal point for both molecular and clinical streams of information, thereby serving as a critical bridge to enable translational research. To maximize the value of biobanks for biomedical research, drug development, public health, and healthcare delivery it is advantageous for all interested parties to share their vision, experiences and best practices.

Worldwide Biobank Summit II, *Collaborating for Cures*, organized and hosted by IBM Healthcare and Life Sciences in November 2004, brought together thought leaders and practitioners from around the world to share best practices and discuss possible resolutions to the scientific, technology and policy challenges facing the global biobanking community. This forum continued a discussion initiated at the first biobanking summit in Nice, France in March of 2004. Biobank Summit II was designed to raise the visibility and importance of biobanking and to facilitate and encourage collaboration and cooperation within the biobanking community. Specifically, the participants focused on the following six issues critical to the success of biobanks: Biobank Organization, Management and Governance; Biobank Funding; Biobanking and Clinical Trials; Scientific Quality Assurance; Biobanking IT Infrastructure; and Data Standards and Semantic Interoperability.

These critical topics were considered and debated in detail by all participants at the Summit. Some of the common themes that emerged from the roundtable discussions included:

- ☒ There is an imperative need for ongoing education of the public, governments, regulatory bodies, healthcare providers and payers, biotech and pharmaceutical companies about the needs, benefits and risks of biobanking.
- ☒ Clearly articulated and understood incentives and requirements (e.g. regulatory, privacy, etc.), both government-mandated and other, will be necessary to fully realize the promise of biobank development.
- ☒ Standardization across multiple domains — operating procedures, specimen collection, annotations and ontologies, and IT infrastructures — will be crucial for success and maximizing the value of collected specimens for biomedical research and care.

In addition to the plenary presentations, Biobank Summit II consisted of breakout workshops where a multi-disciplinary set of Summit participants debated the critical scientific, policy and technology challenges facing the biobank community. Highlights of the specific workshops are outlined below. The remainder of this white paper consists of detailed discussions on each topic.

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Biobank Organization, Management and Governance

While local collections of samples for specific clinical research purposes are valuable, centralized national biobanks are needed to maximize the value of specimen collection and can serve as a key resource to accelerate personalized medicine in the post-genomic era. The discussion at this roundtable centered on a vision for a National Biospecimen Network (NBN) specific to the US and focused on cancer, but most of the issues considered apply equally well to any network of biobanks that is national or international in scope. Key conclusions from this workshop included:

- ☒ A successful national biobank requires an organizational structure that creates clear benefits and incentives for participation in biobanking across a range of stakeholders, with particular attention to incentives for Academic Medical Research Centers, the biopharmaceutical industry, healthcare providers and patients. The incentive around which all stakeholder groups can unite is the potential for biobanks to contribute significantly to the development of better diagnostics and therapeutics. The area with the greatest divergence in incentives lies in how to control and manage intellectual property.
- ☒ Determining a structure for granting and managing access to biospecimens found participants coalescing around two major viewpoints. The first is a traditional academic model where access would be granted based on criteria such as scientific merit and clinical significance reviewed by a panel of peers. The other perspective emphasizes applying market-place economics, paying for participation on the donor side, and charging for access within the boundaries of a reasonable cost recovery model.
- ☒ Most participants believe that the creation of a centralized ethics oversight board is necessary to provide successful oversight of the key ethical issues related to the governance and management of a national network of biobanks.

The incentive around which all stakeholder groups can unite is the potential for biobanks to contribute significantly to the development of better diagnostics and therapeutics.

Biobank Funding

It is widely expected that biobanks will eventually become financially self-sufficient, if not profitable. This may be achieved through charging user fees, collecting royalties on intellectual property developed using biobank resources, and potentially through sale of knowledge from biobank data mining. However, in the short-term these banks will require a substantial infusion of capital for the establishment, development and maintenance of the necessary infrastructure. Governments, private foundations and their donors, the biopharmaceutical industry, insurance companies, health care organizations, disease advocacy groups, IT companies, venture capital, and even patients are all potential contributors. While the most appropriate funding source should be considered in the context of a particular biobank (for example, its mission, stage of development, size, geographic location, etc.), it is clear that development of well-reasoned, compelling return-on-investment (ROI) models will be critical for the successful funding and development of large scale biobank initiatives.

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Biobanking and Clinical Trials

Currently, clinical patient care goals always supersede research goals in a trial setting. However, biospecimens from clinical trials represent a highly valuable source of samples for translational research. Therefore, removing the barriers to acquiring the tissues in a course of a clinical trial, controlling the quality of the acquired tissue, and managing the tracking and utilization of such specimens are crucial for ensuring these samples are available for downstream research. Among other stakeholders, regulatory authorities should play a major role both in mandating tissue banking to be an integral part of every clinical trial and in ensuring and enforcing compliance with appropriate standards. These standards include standard operating procedures (SOPs) for collection, annotation and storage, as well as standards for the ethical use of samples and related clinical information. To defray expenses, all parties that stand to benefit from clinical and translational research conducted using specimens collected in the context of a clinical trial should provide funding for such initiatives.

Biospecimens from clinical trials represent a highly valuable source of samples for translational research.

Scientific Quality Assurance

It is well established that results of assays performed on biological material are dependent on the characteristics of the initial specimen. Therefore, the details of specimen acquisition, handling, processing, and storage (the "pre-analytical phase") are particularly relevant to the functionality and integrity of biobanks. Standardization of biobanking procedures, as well as the buy-in and adherence to these practices by all participating organizations are necessary to ensure the scientific quality of data generated downstream. One of the ways to achieve this is through the establishment of biobanking good laboratory practice (GLP) and good clinical practice (GCP) that could be enforceable by regulatory authorities. Development of these GxPs should draw upon current best practices, scientifically validated protocols and relevant existing standards. However, created SOPs should also have the flexibility to incorporate new analytical technologies that will become available in the future. Establishment of a biobank accreditation agency that could take the lead on developing, validating and mandating biobanking specific GxPs was proposed.

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Biobanking IT Infrastructure

A key feature expected of next generation biorepositories is comparability of specimens, in particular the annotated clinical and biomedical data associated with each specimen. Specifically, researchers will require the ability to utilize specimens and the associated annotation collected within a multi-site network to build data sets of sufficient statistical power. Therefore, the informatics infrastructure for biobanking will have to include standardized software supporting the collection, management, clinical annotation, logistics, query tools, distribution and analysis of a biorepository's contents. Implementing these tools is not dependent on the creation of new technology, as most of the information technology (IT) required to support biobanking already exists. However, there currently is a high degree of fragmentation and decentralization of IT infrastructure among various tissue repositories that makes it impossible to effectively share and combine data sets. Clearly, IT centralization and standardization cannot happen in isolation. Standardization of upstream steps and processes, such as experimental procedures, ontologies and semantics, is

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necessary. Ways to "move the dial" (i.e. make incremental changes as opposed to implementing sweeping changes) towards IT centralization and standardization were discussed on the grounds that some centralization is needed for standardization to take hold and be effective. Relatively short-term tactical suggestions focused on identifying best practices and starting small-scale pilots involving multi-site exchanges of data and specimens. These initial efforts could lead to broader efforts, such as the establishment of an open-code repository that would support IT standardization among biobanks.

Data Standards and Semantic Interoperability

Efficient use and sharing of biobank resources among multiple researchers and organizations requires implementing standards regarding a sample — its quality, its handling procedures, associated patient information, etc. — as well as standards regarding the experimental data and data interpretation resulting from sample analysis. Biobank data standards need to address six main categories, each with specific requirements:

1. Clinical – clinical patient information and disease status
2. Sample – acquisition, handling, and pathology
3. Molecular – sample preparation, test type and data
4. Annotations – gene/protein prior knowledge
5. Analysis – process information and results
6. Interpretation – new knowledge, follow-up experiments

Currently, there are no "biobank-specific" standards; however, a large number of standards that could meet the demands of each of the categories are available. These various standards were evaluated for their applicability across the categories with the conclusion that none of them fully meet the needs of the biobanking community. However, instead of developing totally new standards, it is important to build on existing and emerging industry standards and ontologies wherever possible. In evaluating relevant potential standards, workshop participants looked for key characteristics — such as well defined, user-friendly, well governed and adaptable — that would make a standard a good starting point. As a beginning, the workgroup began a specific evaluation of the applicability of using SNOMED in the area of clinical samples for biobanking.

Instead of developing totally new standards, it is important to build on existing and emerging industry standards and ontologies wherever possible.

Summary

As noted above, the first Biobank Summit brought together thought leaders and practitioners from around the world to identify and discuss some of the most pressing and challenging scientific, technology and policy related issues facing the biobanking community today. Biobank Summit II continued this dialogue by exploring in depth a number of the specific challenges identified at the first summit. The discussions summarized above show how the participants are making progress in solving some of the key issues.

These discussions will be continued and the agenda furthered in Biobank Summit III to be held in Stockholm, Sweden in May 2005. Entitled *Strategies to Address Next Generation Challenges for Biobanking*, Biobank Summit III will pick up some of the earlier themes and explore in detail the need for standardized specimen collection to ensure biological viability as well as emerging technologies to support 21st Century biobanking efforts.

REPORT ON WORLDWIDE BIOBANK SUMMIT II: COLLABORATING FOR CURES

Plenary Sessions

The following summary is a synthesis prepared by Life Science Insights from the plenary session presentations and does not represent precisely or fully any particular presenter's viewpoint, nor should it be taken as representative of the viewpoint of IBM.

The plenary speakers for the Worldwide Biobank Summit II, organized and hosted by IBM Healthcare and Life Sciences, in November of 2004, approached the topic of biobanking from a wide range of perspectives. These perspectives ranged from that of a national health agency devoted to the study of cancer, to leaders of biobank organizations and networks, to scientists and medical researchers from large pharmaceutical companies, to a non-profit organization devoted to accelerating the process of medical research. While all agreed on the crucial importance of biobanking, these unique perspectives led to a broad range of conclusions and discussion including:

- ☒ Financial analysis of the impact of curing cancer
- ☒ Broad visions for the development of personalized medicine
- ☒ Specific pathway and biomarker analyses based on the use of biobanks
- ☒ The role of biobanks in the acceleration of clinical trials
- ☒ The importance of population genomics studies and environmental data.

Woven throughout many of the presentations, see Table 1, were visions of what biobanking should be, goals that define how biobanks should operate and what they should accomplish, obstacles and challenges to implementing such goals, and, ultimately, what the expected benefits will be for patients, industry, and society. In this section IDC's Life Science Insights has synthesized the viewpoints from the plenary presentations and organized them into three broad categories — vision, challenges, and potential benefits.

TABLE 1

Plenary Session Presenters at Worldwide Biobank Summit II: Collaborating for Cures

Speaker	Organization	Title of Presentation
Anna D. Barker, Ph.D. Deputy Director for Advanced Technologies and Strategic Partnerships	National Cancer Institute	Biorepositories for 21 st Century Medicine: Building Momentum
Bartha M. Knoppers, Ph.D. Canada Research Chair in Law and Medicine, Founder PG3	University of Montreal	Public Population Program in Genomics (P3G)
Stephen N. Walker Chief Information Officer	UK Biobank Ltd.	Biobank UK: Improving the Health of Future Generations
Michael Milken Chairman	Faster Cures/ The Center for Accelerating Medical Solutions	Accelerating Medical Solutions
Neil Spector, M.D. Director, Exploratory Medical Sciences	GlaxoSmithKline	New Paradigms in the Development of Targeted Therapies for Oncology
Prof. Monica Nister, M.D., Ph.D. Professor of Pathology	Cancer Center Karolinska Institutet	Karolinska Institutet Biobank
Kenneth W. Culver, M.D. Executive Director	Novartis Oncology	Biobanking for Oncology, Drug Discovery and Development
Kathy Giusti President and Founder	Multiple Myeloma Research Consortium	Multiple Myeloma Research Consortium
Prof. Bruce McManus, M.D., Ph.D., FRSC Professor and Co-Director Scientific Director	The James Hogg iCapture Centre for Cardiovascular and Pulmonary Research, The Institute of Circulatory and Respiratory Health, Canadian Institutes of Health Research	Sharing the Wealth: How Biobanks Do, Could, Must Contribute to Optimal Knowledge Delivery in the Cardiovascular and Respiratory Sciences

Source: IDC, 2005

The Vision for Biobanks

Vital to the success of this emerging network of biobanks is a clear vision of what biobanks should be and how they should interact with each other and a complex set of stakeholders that includes: academia; government agencies; healthcare providers; biopharmaceutical companies; patients; patient advocacy groups; and the general public.

Biobanks can vary widely in type and purpose from national collections focused on broad epidemiological questions to a private company's research on a specific disease. However, they all require collections of biospecimens and associated clinical and molecular data that have been collected, processed and stored under standardized conditions in order to provide statistical power to scientific studies. For greatest value those standards must extend across a network of biobanks, enabling aggregation and collaboration among multiple sites, geographies, and sets of patients. While some may have relatively modest ambitions, such as ensuring that everyone within a particular university system adheres to the same procedures (SOPs) in contributing to an institutional biobank, others are working to create networks that are consistent throughout a particular nation, and yet other leaders are working at the international level on the harmonization of biobank standards.

Regardless of the purpose of the collection, it is typically true that the more data associated with the biospecimens the better, especially for long term clinical research purposes. For greatest value the collections should typically include: pathology reports, clinical annotation, medical history, and lifestyle data. Some biobanks, will also include molecular information, (e.g. genetic sequence, gene expression, protein expression, etc.) as part of the core data that accompany specimens, while others leave molecular testing and annotations for a researcher to add depending on their specific research goals and study design. Depending on the goals of the biobank, additional data such as environmental conditions, family genealogies, and family health histories may also be vital. Many biobanks establish, or plan to establish, relationships with donors that enable them to track clinical outcomes over time obtaining longitudinal information for the better understanding of disease progression and etiology. The value of longitudinal specimen and clinical data was readily agreed to by all, however, how to do so in the varying contexts of the different types of biobanks still needs to be developed.

Whether private or public in ownership, broad or narrow in scope, one of the strongest areas of agreement regarding future requirements is that biobanks must possess an organizational and technology infrastructure that offers a very high level of security with complete protection of privacy for donors. The "chain of trust" must extend from the patient all the way through the institution(s), including any boards with oversight responsibility.

Key to building this trust is the management of informed consent on the part of the patient or individual donor. This is a sensitive area that needs to be managed well since there is the need to balance the scientific desire for broad informed consent to enable the study of yet unasked questions (giving medical researchers latitude to explore a variety of research questions without having to re-contact donors) against the right of donors to determine how their own samples are used. This process should always err on the side of patient privacy and security of information.

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There is broad agreement that the current recognition of the importance of biobanking will require a strong commitment to and investment in information technology. There is an exponential growth in the amount and type of data that are being captured, stored and analyzed within and across institutional boundaries. Phrases such as "cross-institutional informatics platform" and "building *in silico* capability" were used in nearly every vision of the future of biobanking, as well as in descriptions of specific implementations of supporting informatics platforms already underway. Accomplishing this common informatics infrastructure, as detailed in subsequent sections of this report, will require attaining agreement within the community on common nomenclature or ontologies, as well as the data formats and communication protocols to enable access to samples across a network of biobanks, and integration of all the associated data that are required for data mining and analysis.

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While there was much agreement on the importance of biobanks and their social, medical and scientific potential, the diverse perspectives informing the view of the plenary speakers lead to some significant variations on the ideal vision for large-scale biobanking efforts. Some envision biobanks as almost entirely public institutions designed to address national health policy issues, while others involved in drug discovery and development see biobanking first from the perspective of pharmaceutical companies in support of certain research programs or specific pre-clinical and clinical trial studies sponsored by their companies. In addition to the diversity of geographic scope (e.g. institutional, regional, national, international) mentioned earlier, we also see diversity between those biobanks narrowly focused on a particular disease, or family of diseases and those that encompass a much broader range of goals, such as population genomics, and are serving as a very broad-based resource for disease epidemiology. Clearly, this diversity affects the types of specimens collected, the profile of donors, the typical clinical setting for interacting with donors, the type of information (clinical and other) gathered, and the infrastructure needed to operate the institution. This diversity also creates a complexity that will require that groups at this and other meetings continue to work on the issues they can solve in common and those that are particular to their respective institutions.

The Challenges

The road to realizing the vision of networks of interconnected biobanks with seamless sharing of data and specimens that were collected, stored and annotated under a common set of SOPs is fraught with a significant variety of challenges.

One of the most significant challenges to realizing the vision is the legacy of thousands of biospecimen collections worldwide, that today are mostly decentralized, uncoordinated, and lacking standardization on multiple fronts. Those legacy collections have been founded and funded based on specific clinical and scientific goals. Broadening the goals and modifying the SOPs to fit in with a set of standards, not only will be expensive but will meet some organizational resistance from individual clinicians or scientists who believe that the current collections and systems are meeting their needs as is.

One of the most significant challenges to realizing the vision is the legacy of thousands of biospecimen collections worldwide, that today are mostly decentralized, uncoordinated, and lacking standardization.

A second major challenge is the existence of competing ontologies and standards in the scientific and clinical disciplines that are vital to biobanking. A related lack of uniformity among clinicians and researchers in applying those ontologies and

standards complicates matters even further. This problem of standards extends beyond biobanking in that parallel problems exist in each of the scientific disciplines that support biomedical research.

The continuing evolution of societal views and government regulations on biospecimens, privacy, public good, and intellectual property, creates challenges for biobanks in developing policy, administrative procedures and communications with their various stakeholders. For example, the definition of genetic and proteomic data as a "public good" may cause hesitation among biopharmaceutical companies to participate in public biobanks for fear of compromising the intellectual property that they must secure for long-term profitability.

The continuing evolution of societal views and government regulations on biospecimens, privacy, public good, and intellectual property, creates challenges for biobanks in developing policy,

The current fears and concerns within the general population about potential misuse of individual genetic data are another challenge that could easily rise in intensity and dramatically slow the progress of biobanking. That challenge must be met at both the operational level, instituting policies and SOPs that ensure security and privacy, and at the educational level. The general public as well as government officials and legislative bodies need to hear and understand the benefits of biobanking, so that any privacy risks are seen in context.

Securing adequate funding is a key challenge faced by biobank organizations. In addition to supporting specific biobanks there is a clear need for funding that will support the inter-organizational administration tasks that will be essential for a network of biobanks. Lack of funds for migrating existing collections onto current systems is an issue for those already committed to operating biorepositories. Ultimately, a commitment by multiple stakeholders to create long-term funding for biobanking on a grander scale is necessary as it takes time to build biobanks of relevant scale and scope.

Ultimately, a commitment by multiple stakeholders to create long-term funding for biobanking on a grander scale is necessary as it takes time to build biobanks of relevant scale and scope.

This set of challenges is by no means exhaustive, but does capture the major challenges expressed in the plenary presentations.

The Potential Benefits

Given the formidable obstacles facing the formation of successful networks of biobanks, it is important to consider the potential scientific, financial and medical benefits. Why invest? Why endure the challenge of change-over from legacy systems and procedures to an interoperable set of SOPs? Why expose your organization to a practice that will find vocal opposition from some privacy advocates? The following is a synthesis of the reasons that these leaders and their organizations are committed to overcoming the obstacles and moving closer to their ideal of an interoperable network of biobanks.

The reason that such commitment exists is that the estimated value of biobanks is immeasurable. For example, some of the biobanking efforts that the speakers represented have ambitious goals that include eliminating pain and suffering from major diseases such as cancer, or understanding the effects of genetic, environmental and lifestyle factors on human health and disease. Even much more focused efforts, such as using biomarkers to understand an individual's drug response behavior or appropriate drug dosage levels, will ultimately result in more efficient and effective healthcare.

Some of the biobanking efforts that the speakers represented have ambitious goals that include eliminating pain and suffering from major diseases such as cancer, or understanding the effects of genetic, environmental and lifestyle factors on human health and disease.

The plenary speakers discussed the following as the potential benefits for biobanking initiatives. These benefits are interrelated and additive. Biobanks will contribute to the advancement of basic science. Biobanks will enable large correlative studies that will provide a basis for detailed understanding of the interaction of factors (e.g. genetics, lifestyle, and environmental) that cause many complex diseases. Even without additional therapies, a more refined understanding of root causes for diseases will enable patients to take a more intelligent approach to lifestyle changes and other preventative measures. Or, where certain environmental factors are discovered to be among the causes of a disease, that knowledge can provide the impetus to better environmental policy.

Biobanks, through their contribution of well-annotated specimens, will be instrumental in the creation of more sophisticated disease taxonomies based on molecular biomarkers. Understanding of biomarkers will lead to the development of better clinical diagnostic tests. Segmentation of patients into those finer disease categories will provide a foundation for understanding differential response to drugs. This better understanding of causes of diseases, combined with more sophisticated disease taxonomies supported by bio-molecular evidence, will contribute to translational research, which in turn will lead to new diagnostics, therapies and cures for complex diseases.

Ultimately, those improvements in clinical care will lead to additional improvements in human longevity and quality of life, potentially as dramatic as the gains experienced in the previous century. Improved clinical care that is more firmly grounded in data will also contribute to more effective and efficient national healthcare policies and practices. And quite possibly, we will also see improved economic conditions for society through prevention of the premature loss of human capital (e.g. knowledge and skills) and improved living conditions as a result of a better understanding of the impact of environmental causes of disease.

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Workshops

In the course of the Biobank Summit II, there were six workshops, designed to engage Summit participants in discussion on some of the key challenges and to provide a starting place for collaborative work on these issues. The six workshops were:

- Biobank Organization, Management and Governance
- Biobank Funding
- Biobanking and Clinical Trials
- Scientific Quality Assurance
- Biobanking IT Infrastructure
- Data Standards and Semantic Interoperability

The following sections of this white paper provide an account of each of those sessions. Each section summarizes the articulation of key issues or open questions that provided structure for the workshop, the range of discussion and representative viewpoints expressed, and any firm consensus or recommendations coming out of these working sessions. These summaries are a synthesis based on an analysis of the workshop outputs by Life Science Insights, and do not necessarily represent the direct opinions of the workshop moderators, IBM or any particular workshop participant.

A number of core themes that surfaced at the first Biobank Summit, re-emerged in plenary sessions and often wove in and out of the workshops even if they were not the stated topic of the workshop. Table 2 maps the presence of those themes to the workshop sessions.

TABLE 2

Common Themes in Workshops at Worldwide Biobank Summit II

	Workshops					
	Governance	Funding	Clinical Trials	Scientific Quality Assurance	Information Technology Infrastructure	Semantic Interoperability and Data Standards
Standardization	Yes		Yes	Yes	Yes	Yes
Centralization	Yes	Yes			Yes	Yes
Incentives	Yes	Yes	Yes		Yes	
Intellectual Property	Yes	Yes	Yes			
Managing Access	Yes		Yes		Yes	

Source: IDC, 2005

Biobank Organization, Management and Governance

Moderator: Dr. Julie Schneider

Technology Program Manager, National Cancer Institute

When biorepositories consist largely of biospecimens collected, stored and analyzed by the same university or biopharmaceutical lab for the achievement of its own research or clinical goals, the issue of biobank organization and management tends to be encompassed by whatever management structure exists within that university or corporation. However, as soon as labs and hospitals deposit the specimens and data collected at their site into a networked biobank, be it regional, national or international in scope, issues of organization, management of access, and governance become more critical.

As soon as labs and hospitals deposit the specimens and data collected at their site into a networked biobank, be it regional, national or international in scope, issues of organization, management of access, and governance become even critical.

The workshop on "Biobank Organization, Management and Governance" was organized with the following objective: "To brainstorm an ideal framework for the organization, management and governance of a National Biospecimen Network (NBN)."

While the starting context for this discussion was a particular vision specific to a USA-based effort focused on cancer, most of the issues are relevant to any similar national or even international biobank initiative. Other national biobank efforts such as the UK Biobank, the National Cancer Tissue Resource (UK), Biobank Japan, DeCode Genetics (in cooperation with the Icelandic government), and the Estonian Genome Project were highlighted in the discussion to ensure a global perspective was maintained.

For organizational structure and governance to be addressed, the relevant stakeholders, and their interests, must first be identified. These will vary by type of biobank, but typical stakeholders in a national biobank include:

- Academic Medical Research Centers (AMRCs)
- Community Hospitals
- Government Agencies (USA examples include: NIH, FDA, OHRP, NIST)
- Patient Advocates
- Patients
- General Public Pharmaceutical and Biotechnology Companies
- Commercial Biobanking Companies
- Information Technology Companies

This classification of stakeholders, and their relative importance, will vary somewhat from nation to nation. Additionally, it is critical to understand that the relationships among stakeholders and the degree of access granted to a biobank, or biobank network, are even more variable from nation to nation. Some countries, such as the USA, tend to actively court public-private collaborations while others, such as Sweden, have constrained by legislation the ability of for-profit organizations to participate or gain commercial benefit from a biobanking initiative.

The Key Issues

Having set a broad context regarding vision, efforts in multiple nations, and a description of the typical stakeholders, the workshop session focused on the following three issues:

1. What **incentives** would encourage participation of academic medical research centers (AMRCs), biopharmaceutical companies, community hospitals, physicians and patients in a national bio-repository network?
2. How should a national bio-repository network manage **access** to biospecimens, data, and research results?
3. Should a national network establish an overarching **ethics advisory board**? If so, what should be the board's roles & responsibilities?

What Incentives Will Encourage Participation?

The issue of incentives is critical to the success of biobanking efforts. Many efforts to establish collaborative working groups founder because some key class of stakeholders does not have, or perceive itself to have, a clear unequivocal benefit for participation. This discussion directly addressed that issue and set out to articulate clear benefits and potential incentives for participation from within four key stakeholder groups: AMRCs; the biopharma industry; community hospitals; and, associated physicians and patients.

Many efforts to establish collaborative working groups founder because some key class of stakeholders does not have, or perceive itself to have, a clear unequivocal benefit for participation.

AMRCs (Academic Medical Research Centers)

As non-profit educational and research organizations, the AMRCs are motivated by improving the science they can conduct, the care they can deliver, or their standing among their peer groups. Specific incentives would consist of:

- ☒ **Access to resources to advance scientific knowledge** – At the individual level, investigators who contribute sample and data may receive ready access to specimens and associated data that will contribute to their individual research productivity. For the institution as a whole, access to larger biospecimen collections and associated clinical and pathology data collected under standardized procedures, will lead to better science and improve opportunity for publication of research in peer-reviewed journals.

☒ **Contributing to improved medical care** – Ultimately biobanks are aimed at enabling better medical care, a common good that directly fits the mission of most AMRCs. Specifically, this may be delivered through a better understanding of the molecular basis of diseases, particularly rare diseases that require aggregation of samples from many sites in order to have the statistical power to isolate genetic or protein variations. Over time, biobanks will contribute to the development of better diagnostic tests, and provide the basis for the development of more targeted therapeutics.

Ultimately biobanks are aimed at enabling better medical care, a common good that directly fits the mission of most AMRCs.

☒ **Institutional and individual recognition** – Early in the adoption cycle of biobanks, scientists who both use and contribute to biobank resources will improve their ability to publish research and be recognized for their contributions to science. Eventually, that "advantage" will fade with widespread adoption. Since biobanking is an international movement, early contributors and users of biobanks have opportunities for recognition beyond their own national borders. There was a sense that formal recognition of intellectual property (IP) and acknowledgment of origin should remain with data originators, their departments, and their institutions. However, as some of these findings turn into commercial products, IP retention may well be in conflict with the need for commercial firms to purchase access without IP entanglement (see details below).

☒ **Financial rewards** – While AMRCs are not required to be profitable, it is important that in contributing to biobanking efforts they should strive for cost recovery since that will help insulate them from the whims and changing budgetary constraints of funding agencies. Participation in biobanking efforts may also position AMRCs to receive better funding of research through obtaining "in kind" considerations from centralized biobank organizations and finding that improvements in the public image of the AMRC makes it easier to raise funds from corporate sources. Finally, there is the financial benefit that may accrue back to a contributing organization through commercialization of IP that leads to diagnostics or therapeutics. However, that accrual process is much cleaner when all of the sample is collected, stored and analyzed by a single AMRC, but becomes considerably more complex when IP is derived from samples and data donated by a number of distinct organizations. This latter issue is one that will require ongoing work.

While AMRCs are not required to be profitable, it is important that in contributing to biobanking efforts they should strive for cost recovery

☒ **Enhance collaboration among departments and researchers** – Many AMRCs are developing centers, institutes and other organizational forms as a way to break down barriers and increase collaboration across groups within their institutions as a whole. In AMRCs, biobanking activities should be treated similarly as core inter-disciplinary, infrastructure activities that span departmental silos. As a result, biobanks are expected to enable new approaches to problem-solving through access to broader sets of resources, additional perspectives, and facilitation of interactions between researchers.

Pharmaceutical & Biotech Companies

Most biopharmaceutical firms are actively engaged in various types of genomics programs and are collecting biological samples and data as part of their own research programs and clinical trials. However, for such companies to participate more broadly, they will need various incentives:

- ☒ **Speed of access to samples and data** – Pharmaceutical companies are searching for ways to speed up the drug discovery and development process. The expectation is that the centralized collection of a biobank provides quicker access to a more extensive collection (at a potentially lower cost) than building such a resource on their own.
- ☒ **Freedom to direct how samples are used for research** – Pharmaceutical companies, seek arrangements in which broad consent has already been granted, so that they have freedom to investigate the unanticipated questions that will arise in the course of their research.
- ☒ **Access to high quality tissues** – a standardized set of procedures would improve the consistency of sample quality for all researchers including pharmaceutical companies.
- ☒ **Freedom from IP entanglement** – Access to specimens and associated data without long-term entanglement in IP issues and associated fees would be a strong incentive for pharmaceutical companies to participate in centralized biobanking efforts. At the same time, many might seek limited or delayed responsibility for disclosing results in order to develop a competitive advantage in the marketplace.

.Such incentives will have to outweigh the disincentives to participation in public biobanks that include:

- ☒ **A lack of control** – Pharmaceutical companies will lack control over specific patient profiles and conditions of sample collection.
- ☒ **Royalty expectations** – Pharmaceutical companies will be careful about entering into royalty arrangements that may adversely impact profitable operations.
- ☒ **Data returns** – Pharmaceutical companies will be reticent to participate if there is an expectation that all data on additional specimen testing must be returned to the biobank, where it would then be accessible to competitors.

Community Hospitals / Physicians

Community hospitals (i.e. non-AMRCs) and physicians are constantly seeking to raise the level of care they offer their communities. Participation in biobanks has the potential to provide the following benefits:

- ☒ **Improved capabilities** – Community hospitals that participate as regional collection points or nodes in a national network of biobanks, may find that participation raises the bar for both physician-led research and their clinical

Community hospitals that participate ... may find that participation raises the bar for both physician-led research and their clinical capabilities.

capabilities. In turn, this can improve the professional stature of a hospital, its public image, and its consequent ability to attract more patients.

- ☒ **Contributing to the development of better treatments** – Centralized (national) biobanks are a key step in the pathway toward personalized medicine. Since care will be delivered locally tying in to such a system will only help local hospital and MDs.
- ☒ **Specialized community studies** – in communities with unique characteristics (e.g. a strongly homogeneous ethnic community) localized longitudinal studies will benefit the health of the community.
- ☒ **Revenue replacement** – Biobanks cannot rely only on the philanthropic instincts of hospitals and physicians who have a need to cover the loss of revenue for the extra time in collecting and preparing samples and data for submission to a biobank. Options for revenue sources include both direct fee for donation, and indirect financial support through the institution's ability to raise funds based on improved care offerings and its associated public image.

Biobanks cannot rely only on the philanthropic instincts of hospitals and physicians who have a need to cover the loss of revenue for the extra time in collecting and preparing samples and data for submission

Patients

Although it has been shown that on the subject of large-scale biobanks, patients and potential patients have many concerns about privacy, security, information control and access, nonetheless, many biobanks have been created because of patient interest and activism. Key incentives for patients include:

- ☒ **Contribution to medical research** – The most compelling incentive for patients with a disease is to be able to further medical advances in that area. They are often happy to contribute sample and data to the study of the disease from which they suffer in the hope that better knowledge will benefit, if not themselves, then a future generation with the same disease.
- ☒ **Time and attention** – Patients who are donating specimens for a biobanking effort may find that they receive somewhat more time and attention from their physician and nursing staff in fulfillment of the biobanking collection protocols. This benefit is difficult to directly promote because it contains an implicit suggestion that physicians might somehow provide less competent care otherwise.
- ☒ **Discounts on medical services** – Another potential incentive is for biobanks and contributing hospital systems to provide a medical discount to patients willing to donate sample.

The most compelling incentive for patients with a disease is to be able to further medical advances in that area.

These incentives will generally not be sufficient in themselves. As some of the findings in the Biobank Summit II reported, successful engagement of patient groups on a widespread basis requires extensive communication and education. Workgroup participants suggested that educational programs to encourage sample collection (e.g. explain benefits, address concerns about privacy and financial gains, etc.) should be designed. Further, it is believed that it is in the interest of payers (i.e., governments and insurance companies) and pharmaceutical companies to invest in the education of patients on the value of the epidemiology and clinical research which biobanks enable.

This discussion revealed that the most powerful and far-ranging incentive for participation across multiple stakeholders, is the promise that biobanking holds out for making a significant contribution to the improvement of medical research and development of new and more effective treatments. Other benefits are often quite specific to the type of stakeholder, and occasionally, what would provide incentive for one class of stakeholders actually provides a disincentive for another class. It is these differences that require the most attention in future meetings to work out acceptable compromises between diverging goals. Although the discussion of incentives centered on these four highly critical stakeholder groups, there is also a broad recognition that additional stakeholders such as healthy donors, Institutional Review Boards (IRBs), and activist communities focused on research ethics will need to be considered in more detail.

How Should Access to Biospecimens and Data Be Managed?

The second core issue addressed during this governance workshop was how to manage access to biospecimens and associated data. This issue contains some of the most difficult problems to solve. The major questions driving the discussions were the following:

- Should access to the actual biospecimens be treated differently from access to data?
- Should access always require a scientific peer review?
- Should access be based on scientific merit or free market principles?
- Should contributors receive higher access priority than researchers not contributing sample and data?
- Should there be a Steering Committee to govern access?
- Should commercial biopharma researchers be treated differently than academic users?

There was a consensus among the participants that access to biospecimens should be treated differently from access to data. Specimens are, for the most part, finite and perishable. On the other hand, data are non-perishable and reusable. Therefore attention focused on issues of administering access to specimens and little attention was given to data access for the purposes of this debate.

As a step prior to granting any access to specimens, it may make sense to have specimens evaluated to determine their value on the basis of scarcity, medical importance and past demand. This assessment may trigger different criteria and hurdles for access based on specimen value.

Proposals for how to manage access to biospecimens revolved around two major points of view; one that largely followed an academic grant model, and the other that advocated a market model of access. Those workshop participants advocating an academic grant model included variations on peer review with selection criteria based on clinical relevance, ethically sound research, the merit and quality of the proposed

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research, willingness to share research results, and, agreement to limit use. The peer review committees should include representatives from multiple stakeholders, have published criteria and open processes, allowing for no lobbying to reverse decisions. In this view of managing access, there may be some standard payment for samples though pricing for academic and government researchers may well be lower than for commercial research organizations. Another potential factor in this model included granting some type of preferential access based on past contributions of specimens and data into a biobank network.

The other major approach for managing access to biospecimens is to implement a market model that pays donors, AMRCs, physicians and others for providing specimens and data and then sets pricing according to demand within the bounds of reasonable cost recovery models. Western cultural and societal norms reflect that it is inappropriate to sell human specimens, as illustrated by the National Organ Transplant Act (NOTA), which was enacted in 1984. To be consistent with the principles outlined in the NOTA, research-oriented biobanks should only charge specimen users for recovering the costs of collecting, annotating, processing, storing, and distributing biospecimens. However, these costs can become expensive, particularly when specimens are annotated with detailed clinical, biological and longitudinal data.

Hybrid solutions to managing access are also possible, such as using peer review to determine access for academic and government researchers, but include a market pricing element for samples distributed to the private sector. One thread of discussion emphasized the need for simplification of access. This might be done by providing some threshold peer review of ethics, sound scientific methodology and financial ability to complete the study, but beyond that would not layer on additional assessments of the significance of the proposed research or other criteria.

It is widely agreed that donors should have an active role in granting and controlling access to specimens. This can range from "opening the door" for patients and the general public to comment on research projects supported by biobanks, to establishing a clear set of use guidelines and broad informed consent agreements with patients. All of that implies that research projects must be translated for lay people so that donor input is grounded in some understanding of the research. Related to this issue is the right of the individual to know what studies his/her specimens are being used for, and the ability at any time in the future to revoke consents previously given. This sort of control in the donor's hands will require flexibility on the biobank's part and an operating infrastructure that can support it.

It is widely agreed that donors should have an active role in granting and controlling access to specimens.

Determining the conditions of access to biospecimens is sufficiently complex, dependent on the larger cultural and legal settings in which biobanks operate, and also dependent on the purpose and scope of any given biobank, that there will probably never be a single internationally accepted method for determining and managing access. However, all biobanks will benefit if subsequent meetings continue to work the problem to define further the two or three basic access models as templates that biobanks can follow.

There will probably never be a single internationally accepted method for determining and managing access.

Should A National Biorepository System Establish an Overarching Ethics Advisory Board?

One of the key issues for the governance and management of a national system of biorepositories or biobanks is how to handle ethics reviews. Should such reviews remain within the purview of each individual network member, or is there a real need to have a centralized ethics advisory board to examine proposed uses of biospecimens as well as overseeing broad issues such as individual privacy? The workshop participants conducted a quick poll among themselves on this question and arrived at a two thirds majority favoring the establishment of such a centralized ethics board.

Those who voted "yes" to a centralized board noted that the use of human biospecimens involves deep ethical issues and that such a board would be vital in leading a public discussion and in educating lawmakers and the general public on related issues. No one is suggesting that such a board would replace local institutional review boards (IRBs). Rather, it could provide resources and guidance that would lead to standardization of informed consent procedures and a harmonization of interpretation of critical issues. In other words, it would provide some impetus and assistance toward the "standardization" of IRBs. In addition, those voting "yes" also saw a need for a central ethics advisory board to help oversee appropriate use of rare samples (e.g. certain pediatric diseases), where samples might be needed from multiple sites each with their own governing IRB, in order to achieve enough cases for sound analysis.

Even those voting "yes", disagreed over the extent of the authority of a central overarching ethics advisory board. Some participants would invest that board with the authority to "change the system," while others envision a much more constrained role in a federated model only to advise and facilitate, leaving the decision making and control at the local level. Those who voted "no" to a centralized ethics advisory board, believed that too much bureaucracy already existed and that some institutions already exist for this type of oversight. For example, national governments already play a central oversight role in the academic domain, such as the NIH within the US. Others contended that such ethical aspects and competence should be directly integrated into the structure and policies of a national biobank rather than separated from it in an advisory board. And yet others simply believed that the existing IRB structure is sufficient and the decisions should be handled at a lower level where the operating decisions are made.

While not universal, there is a strong majority opinion that a centralized ethics advisory board is a necessary component of a national biobanking system, if only to play a coordinating role in managing the discussions, questions, and disagreements among the various groups that will inevitably arise.

In summary, this workshop on biobanking organization, management and governance articulated key incentives for four major stakeholders that are likely participants in a national network of biobanks. Greatest commonality in incentives exist on the dimensions of enabling better understanding of diseases and ultimately better diagnostics and therapies. The area of incentives that will likely prove most difficult to resolve are those of intellectual property since the various stakeholder groups can

While not universal, there is a strong majority opinion that a centralized ethics advisory board is a necessary component of a national biobanking system

have significantly differing interests. The second major issue addressed was how access to data and specimens should be managed. Viewpoints tended to coalesce around either an academic grant model, emphasizing merit and peer review, or a market-driven model within the bounds of reasonable cost recovery options. Hybrid or differentiated models of access that grant access to public and private sector researchers under separate criteria were also put forward. Finally, this group recommended, though not unanimously, that national networks of biobanks should have a centralized ethics advisory board.

Biobank Funding

Moderator: Prof. Gerd Schmitz, M.D., Ph.D.
Director, Institute for Clinical Chemistry and Laboratory Medicine
University Hospital Regensburg, Germany

One of the fundamental issues related to growth and ongoing development of biobanks is funding for these institutions. In addition to private or governmental organizations other sources of funding should be seriously considered. These include funding by diagnostic and biopharmaceutical companies, health insurance agencies and health care providers. Even patients can be viewed as a potential source for research funding.

The Key Issues

The main goal of the workshop on Biobank Funding was to brainstorm options and potential solutions to key issues in the funding of biobank projects. Participants of this workshop discussed three main issues:

1. What are the **potential sources** of biobank funding?
2. What are the **benefits/possible ROI** for funding organizations?
3. How can biobanks **meet the funding requirements** of the various stakeholders?

What are the Potential Sources of Biobank Funding?

From the funding perspective, a primary goal for biobanks is to ensure that they become self-sufficient. In the long-term this could be achieved through establishing cost recovery policies such as: charging user fees; collecting royalties on intellectual property developed using biobank resources; and, potentially, selling information based on biobank data mining. However, it is clear that in the short-term tissue banks require a substantial infusion of capital for the establishment, development and maintenance of the infrastructure. Such funding could come from the government, private foundations and donors, biopharmaceutical industry, insurance companies, health care organizations, disease advocacy groups, IT companies, venture capital, patients, etc.

These funding sources should be considered in the context of the mission of each biobank (public vs. private, general vs. disease-specific), their stage of development, as well as their geographic location. For example, there is a general perception that public non-profit biobanks are more likely to attract funding than private ones, as there is more "trust" in the former than in the latter. This notion is particularly strong in Europe and in Asia-Pacific. In the US, much of the funding will also come from public sources, but funding may also be available from venture capital firms, provided that the biobank business model fits into venture capital ROI expectations.

Government

If biobanks are to realize their potential in improving healthcare delivery, governments must become engaged and provide the necessary support. Currently, public funding is difficult to obtain for biobank infrastructure development, however, large agencies like National Institutes of Health (NIH), National Cancer Institute (NCI), National Center for

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Research Resources (NCRR), and Department of Defense (DOD) in the US, European Union Framework Funding in Europe, and National Cancer Center (NCC) in Japan should be asked to contribute. Local communities could be expected to get involved in regional network development. In future grant submissions to government agencies, operational banking requirements have to be explicitly stated. It was also suggested that whenever a research grant is given by a funding agency for biomedical research a certain proportion should be set aside for tissue banking. In soliciting government funding, biobanks have to evaluate the potential for creating hurdles to the potential private/commercial use of the biospecimens and any limitations on flow of data to the private sector. Government funding may also restrict rights to inventions derived from the use of biobanks financed in this manner. Such barriers may well prohibit biobanks from generating revenue from the biopharmaceutical industry.

Private foundations

Private foundations should be considered primarily as short-term solutions for biobank funding. Many disease-specific foundations and patient advocacy groups may be too small to sustain funding for a biobank over the long run, but may be able to participate in raising seed money to cover initial capital expenditures. Private philanthropic foundations could play a larger role in cooperation with the government through creation of private-public partnerships to fund well-defined projects.

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Health Insurance, Healthcare Providers

Hospital R&D budgets could be used to get biobanks started. To sustain biobank development, involvement from the health insurance agencies might be necessary. However, funding of biobanks by private payers could be problematic due to concerns about data privacy and patient rights. Additionally, in the US, health insurance companies (including HMO plans) have little incentive to invest in biobanks due to the lack of customer/patient loyalty – typically a member stays with a given health plan for less than five years. For payers, providers and employers to become sources of funding they will have to be educated and convinced about the long-term money-saving merits of biobanks. However, if persuaded and if they can receive some of the long-term benefits, they should be able to provide sustainable funding.

Biopharmaceutical Companies

In the short-term, pharmaceutical and biotechnology companies should be asked to fund tissue collections at academic medical centers. Development of a comprehensive infrastructure for biobanks is of great interest to the industry and, as such, should make them active financial supporters of these projects. In the long run, biopharma will be expected to pay user fees for access to samples and related information. It could also be expected (and thus, worked into appropriate agreements) that biopharma will pay biobanks royalties on IP generated from biobank use. However, caution must be exercised because if the licensing arrangements become too complex or onerous, since biopharmaceutical companies may choose to go their own way rather than participate in academic or public biobanks.

In the long run, biopharma will be expected to pay user fees for access to samples and related information.

Patients

Patients should be considered as sources for biobank funding as well. After having established the initial infrastructure, biobanks could use a portion of patient medical fees to fund operations. In general, patients stand to benefit from the therapeutic discoveries that will result from biobank-supported research. But, patients could also turn to these organizations for their own needs, such as access to their family history of disease, for prenatal and newborn screening, as well for ongoing evaluation of their own medical condition. Furthermore, patients might pay for access to biobank e-health portals that would provide them with comprehensive medical information of interest.

Funding Challenges

Regardless of the funding source, ethical, legal, and privacy issues will have to be addressed clearly and convincingly to generate financial support. The willingness of government authorities to fund biobanks remains unproven. For government-funded biobanks, issues related to use of the biospecimens, including generation of intellectual property by the biopharmaceutical industry remain to be addressed. In the US, a fragmented healthcare environment inhibits investments in the infrastructure needed to build biobanks.

To address some of these challenges in gaining financial support the following were proposed as immediate next steps to further progress:

- Generate health economics arguments for biobanking and develop well-reasoned ROI models
- Using such tools, convince funding sources of the benefits of biobanks
- Educate the public on the benefits of biobanking with a primary focus on patient care benefits

What are the Benefits for Funding Organizations? What is a Potential ROI?

There may not be an obvious financial return in the short-term, but eventually biobanking will serve the "greater public good" through improving healthcare delivery. Clearly, the establishment of biobanks will stimulate biomedical research that could lead to breakthrough therapeutic discoveries. Biopharma companies capitalizing on the use of biobanks could become more competitive as they could potentially lower developmental costs of new medicines. Some of the long-term benefits of biobanking, as discussed by the participants, are listed below:

There may not be an obvious financial return in the short-term, but eventually biobanking will serve the "greater public good" through improving healthcare delivery.

- Biobanking will enable lower cost and higher quality of healthcare
- Biobanking will generate the basis for preventive measures that will reduce the cost of healthcare for payers
- Biobanks can create a competitive advantage for the geographic region that invests in biobanking infrastructure

- ☒ Underserved populations will benefit from targeted, personalized approaches to patient care that will be more economical
- ☒ Biobanks provide a high quality inexpensive source of clinical trial resources for the bio-pharmaceutical industry resulting in lower costs and accelerated development times

One of the main issues related to the clear establishment of an ROI for biobanking is that the payers and users of tissue banks are often not the same organizations. As a result, the true costs are often buried and the ROI can be distorted. For example, pathology departments of hospital that collect and store biospecimens are burdened with all associated costs. Researchers from other departments view these samples as a free resource and expect pathology departments to continue to provide their services without passing along the costs. Until such distortions are rectified, the incentives for funding agencies and stakeholders will be misaligned and ROI arguments potentially misleading.

One of the main issues related to the clear establishment of an ROI for biobanking is that the payers and users of tissue banks are often not the same organizations.

Government

Large investments of public money into any venue/project often become highly politicized and therefore, government agencies may show cautious backing because of concerns about political liability. However, such investments can generate much positive momentum as well. For example, in the UK, the Department of Health together with the Medical Research Council are considered to have assisted the public good through investments in biobanking by meeting the demands of both researchers and users. In addition, they were able to attract additional funding from charities, such as Cancer Research UK. Government organizations are also in the position to address public concerns over ethical and efficient use of sample material and associated information. Furthermore, through investing in IT infrastructure for biobank development, governments can avoid redundancies and obtain more efficient use of resources for translational medicine than biobanks could do on their own.

Private foundations

By providing support for biobanks, disease advocacy groups could significantly accelerate research for diagnosis, treatment and prevention of the disease in question, thereby fulfilling their mission of providing better healthcare, access to relevant information and faster access to improved diagnostics and therapeutics for that particular indication.

Healthcare Providers

- ☒ Hospitals can decrease their operating costs by supporting biobanks and implementing standardized procedures for sample collection, processing and storage. Money will be saved in the long run since sample collection is very expensive. Improved data access and data quality will lead to cost savings and quality improvements.
- ☒ Standardization and automation of biobanking procedures will also improve the use of physicians' time, as they will have to spend less time on manual tasks.

- ☒ Properly preserved samples accompanied by well-documented clinical information and clear patient consent will foster academic scientific collaboration and will serve as a resource for R&D for years to come.
- ☒ These assets will also be of high interest to the biopharma industry and, thus, could be turned into a source of revenue in return for access to the specimens and information.
- ☒ Properly managed tissue collections should improve diagnostics, thereby reducing the medical costs of misdiagnosis.
- ☒ Properly managed tissue collections may also reduce the risk of legal liability stemming from improper handling of samples and associated information, therefore, avoiding potentially expensive litigation and settlement costs.

A possible model discussed was the funding and creation of a "pre-competitive" biobank initiative for biomarker identification and validation supported by a consortium from the pharmaceutical community.

Biopharmaceutical Companies

Through biobanks the biopharmaceutical industry will gain access to a valuable R&D resource that could enable development of effective and safe medicines in a more efficient way. One of the immediate benefits to the industry is that biobanks could provide cheaper support for clinical trial-associated tissue collection and management over current solutions, wherein most companies are managing their own. A possible model discussed was the funding and creation of a "pre-competitive" biobank initiative for biomarker identification and validation supported by a consortium from the pharmaceutical community.

How can Biobanks Meet the Funding Requirements of the Various Stakeholders?

Without the time to undertake a discussion of this entire issue, participants of the roundtable considered the issue of the integration of biobanks into the existing healthcare models in various regions of the world as an initial point of discussion to answer this question. Well-established healthcare networks, such as those in the Western European countries, require stepwise integration of the existing biobanking capabilities (e.g., as in Sweden). Such integration requires much higher levels of funding compared to the introduction of biobanking into the newly developed healthcare infrastructures. Thus, the newest members of the EU (Eastern Europe), as well as the Asia-Pacific

The Integration of Biobanking and E-Health Towards Personalized Medicine

Contributed by Prof. Gerd Schmitz, M.D., Ph.D. Director, Institute for Clinical Chemistry and Laboratory Medicine, University Hospital Regensburg, Germany

Today, specimens and associated information stored in biobanks are used for multiple purposes, such as basic scientific research, pharmaceutical development, diagnostics and epidemiological investigations. Current medical research seeks to identify and validate novel biomarkers and therapeutic targets that will serve as the basis for the development of innovative drugs and personalized medicine. This process would benefit from a strategic alliance of medical research, the diagnostic and pharmaceutical industries, and healthcare providers. While such collaborations are already taking place, their connection to practical medicine is often poorly developed. Integration of medical research findings, derived from the biobanking initiatives, into E-Health portals will provide value for both medical professionals and patients by giving them access to the most current information from a wide variety of clinical research. A closer integration of medical research and education will also lead to quality improvement in a dialogue between "informed patients" and "lifelong learning physicians". Later, creation of highly networked national healthcare systems (that would include biobanks) will promote the communication between all stakeholders, facilitate drug and biomarker development, allow for rapid organization of multi-centric clinical trials, shorten the distance between bench and bedside, and finally help reduce rapidly rising healthcare costs.

countries, might have a logistical and financial advantage when considering integration of biobanks into their healthcare systems. Collectively, the countries and funding providers need to work closely together to develop funding models in parallel with the organizational structures and operations so that finance and function are aligned.

In summary, funding for biobanks initially will require substantial investments by government agencies, disease focused philanthropic foundations and pharmaceutical companies. Over the long-term it is anticipated that biobanks will become self-funding through user-fees and participation in royalties from drugs and diagnostics developed out of research enabled by specimens and data from biobanks. Funding challenges, range from covering the cost of step-wise integration of existing biorepositories, to sorting out intellectual property rights, and establishing well-reasoned ROI models based on health economics that support investments from multiple stakeholders.

Biobanking and Clinical Trials

Moderator: Carolyn Compton, M.D., Ph.D.

Chair, CALGB Pathology Committee

Chair, NCIC CTG Tumor Banking and Correlative Science, Member Subcommittee H

Biospecimens from clinical trials represent a highly valuable source of samples for translational research. However, in most trials, specimen collection is done for clinical, that is diagnostic, purposes. Therefore, clinical patient care goals always supersede research goals in a trial setting. Collected specimens most often end up in pathology departments of participating institutions and not in biobanks. The processes of sample collection and handling differ not only among various organizations conducting clinical trials, but may also be highly variable within a given institution. Relevant clinical information associated with the samples is often poorly captured. Furthermore, due to cost cutting pressures, clinical investigators are encouraged to collect a minimal number of samples, just enough to make an adequate diagnosis, and that limits specimen availability for research purposes. Additional impediments come from regulatory and legal standards that further complicate access to samples and relevant clinical information. Collectively, these issues create fundamental problems for the down-stream use of clinical trial specimens for translational research.

In most trials, specimen collection is done for clinical, that is diagnostic, purposes. Therefore, clinical patient care goals always supersede research goals in a trial setting.

The Key Issues

Participants in the workshop on biobanking and clinical trials discussed three major questions:

1. How to **remove the barriers** to acquiring the tissues in a course of a clinical trial?
2. How to **control the quality** of the tissue acquired (especially given the situation of adding a scientific goal onto a clinical activity at the institutional level)?
3. How to **manage the tracking and utilization** of specimens?

It was suggested that each of these questions should be addressed from four different angles:

- Legislation/Public Education/Outreach
- Funding/Resource Allocation
- Standard operating procedures (SOP) development and standardization
- Data management

How to Remove Barriers to Tissue Acquisition?

Legislation/Public Outreach

Regulatory authorities, such as the FDA, should play a major role both in mandating tissue banking to be an integral part of every clinical trial and in ensuring and enforcing compliance with standards for ethical use of samples and related clinical information. Clear legislative guidance for the use of data from specimens by third

parties must also be established. Patients require protection from potential discrimination by insurers and employers. This is particularly important for countries that do not have a national healthcare system, such as the US. Tissues need to be established as the property of the patient, this would guarantee that tissue collection and access are driven by the patient mandate. Obtaining a "blanket" consent from a patient for sample use for current and future research purposes would be ideal from the perspective of a biopharmaceutical company. However, current legislative requirements, such as those dictated by HIPAA, do not allow for such practices. Educating the public about the benefits of biobanking could possibly result in pressure on the department of Health and Human Services (HHS) and the FDA, and related organizations in other nations, to amend the guidelines in a way that would encourage tissue collection and access. In general, keeping in mind that biobanking could significantly improve healthcare delivery, the legislature could and should provide adequate financial, human, IT, and legal resources for these initiatives.

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Funding

Tissue collection, handling and storage are expensive, therefore, the real cost of biobanking at an institutional level should be included in the cost of a clinical trial. In addition to an impact statement providing the rationale for biobanking, clinical trial grant applications should include a budget line item specifically dedicated to sample acquisition, processing, etc. Since it has been established that clinical trials performed at accredited medical institutions actually reduce healthcare costs, with the appropriate education, insurance companies could be incented to reimburse clinical trial banking. Overall, a call was made for the creation of a broad-based coalition of the FDA, Centers for Medicare & Medicaid Services (CMS), National Cancer Institute (NCI), the private sector, and other interested parties to re-engineer incentives for physicians and pathologists to participate in biobanking. In addition to funding, such incentives could include access to better infrastructure, broader scientific recognition, and further publication opportunities.

Since it has been established that clinical trials performed at accredited medical institutions actually reduce healthcare costs, with the appropriate education, insurance companies could be incented to reimburse clinical trial banking.

SOPs/Standards and Data Management

Appropriate regulatory bodies, such as the FDA and NIH, have to recognize and mandate biobanking of samples from all patients as a new standard of care. With the exception of tissues collected for diagnostic purposes, specimens should go straight to the biobank and not to a pathology department. Due to the non-renewable nature of the trial-linked biospecimens it is necessary to guarantee that biobanks do not get depleted of these valuable resources, therefore, samples must be managed properly, including the return of unused samples.

Government agencies should also set aside funding to develop and enforce standards for tissue handling. Adherence to the developed SOPs will be crucial for the success of biobanks. As a starting point, harmonization of the practices of cooperative groups and other organizations conducting clinical trials was proposed. Clearly, obtaining the buy-in of all stakeholders will be necessary therefore, people from all aspects of the work-flow process related to biobanking will have to be involved in the development of these SOPs. Re-engineering the role of the pathologists and/or adding technical support staff might be necessary to make the process more reproducible. Interconnection of clinical sites participating in multi-site trials will be essential as well. Otherwise, variations in

logistical operations and governance of biorepositories in different trial groups will compromise inter-group investigative science.

How to Control the Quality of Acquired Tissue?

Legislation/Public Outreach

First of all, a fundamental change in the perception of tissue collection in a clinical trial setting is necessary. Public outreach initiatives have to emphasize the value of translational research for the improvement of patient care, as well as its potential to decrease healthcare costs. Translation research should be an integral part of every trial. The FDA and NIH should set new procedures for trials that will incorporate biobanking into patient care and, thus, will require standardization. Participating sites should be validated/certified according to best practices by a regulatory body.

The FDA and NIH should set new procedures for trials that will incorporate biobanking into patient care and, thus, will require standardization.

Funding

Making biobanking part of the standard of care will require increases in funding. It would be unrealistic to expect volunteerism to sustain the system; hence, financial support for banking will need to be managed differently than it is now. Additional public-private incentives will have to be created (e.g., funding, training, clinical trial access, etc.) to make it worthwhile for all stakeholders.

SOPs/Standards and Data Management

Variations in inter- and intra-institutional processing methods negatively affect analytical results in correlative science studies. Therefore, scientifically validated SOPs for all aspects of tissue acquisition, handling and storage need to be created and broadly agreed upon. This should start with re-engineering the trial process to allow the incorporation of the research that could be done on the samples, instead of acquiring tissue simply for diagnostic purposes. Often trial eligibility is determined based on pathology diagnosis. A proposed change would ensure that all patients are treated upfront as if they were in a clinical trial, making collected specimens a precious commodity. Education of surgeons and pathologists about best practices of biobanking is necessary. The creation of a dedicated clinical staff position responsible for samples collection and processing could reduce the process to minutes per specimen. Finally, consistent quality control measures will have to be employed to ensure adherence to the SOPs including a robust sample tracking and analysis infrastructure (e.g., applications, barcoding, RFID, middleware, etc.).

How to Manage the Tracking and Utilization of Specimens?

Legislation/Public Outreach

Monitoring sample use is important for patient privacy and maintaining ethical standards. Investigators therefore, should be required to sign a contract with a biobank to use samples only for approved purposes and to return any unused specimens. Financial or even criminal penalties for tissue misuse could be instituted.

Funding

As sample tracking is largely an informatics matter, IT companies clearly view this as a new market opportunity for them. In return, the biobanking community is expecting IT companies to share the cost burden of developing appropriate tools.

SOPs/Standards

Standards not only for annotating tissue samples, but also for the experimental data are necessary. Adoption of such standards will result in tool development and data mining techniques that could be deployed uniformly. Standardization will also improve collaboration, as data will become shareable.

Data Management

A robust, flexible, and cost-effective system that would create a unique tracking identifier for each sample and associate it with all relevant information (e.g., clinical record, IRB, contracts, uses, returned scientific data) is necessary. Ideally, such a system will be able to track specimen utilization in real time. Creation of a central bank to handle the logistics, manage unique identifiers, etc., was proposed. A web-based interface with smart query capabilities to access and mine the database will be essential for access and the productive use of stored information.

In summary, the workshop on biobanking and clinical trials discussed potential ways to encourage and stimulate biospecimen collection during the process of clinical research. Many of the issues that were discussed, such as public education on the benefits of biobanking, funding methods, development of SOPs, data and sample management, are also relevant and applicable to the general biobanking initiatives. However, aspects unique to clinical trial settings, such as the non-renewable nature of trial specimens, issues related to obtaining broad consents, and a deeper focus on ethical standards were brought to light.

A robust, flexible, and cost-effective system that would create a unique tracking identifier for each sample and associate it with all relevant information (e.g., clinical record, IRB, contracts, uses, returned scientific data) is necessary.

NCI's Funding for Biobanking in The Context of Clinical Trials and The Development of Standard Operating Procedures

Kishor Bhatia, Ph.D., MRCPATH.
Cancer Diagnosis Program
National Cancer Institute

Future advances in the clinical management of cancer are likely to come from correlating molecular characteristics of tumors to clinical phenotypes. The value of human specimen banking particularly in the context of clinical studies cannot be overestimated. Historically however, the primary goal of specimen collection in clinical trials has been diagnostic. Banking of the tissues and other related specimens while being accomplished in the existing clinical trial infrastructure has nonetheless remained a secondary goal.

The critical need for well annotated human cancer biospecimens has paralleled the increasing recognition that one of the major benefits of randomized clinical trials is the opportunity to collect biological samples from patients whose diagnostic, clinical and outcome history is known. Such a collection of extensively annotated samples empowers investigators to go back retrospectively to evaluate and validate newer clinically relevant tests, significantly shortening the time required for the translation from bench to bedside.

In order to ensure the collection of, storage of, and access to high-quality, well annotated human specimens accrued from and representative of the patient populations entered into NCI-funded, clinical treatment trials, NCI has entered into cooperative agreements with nine clinical trials groups. NCI will support the further development of the existing specimen repositories of the clinical groups, so as to position them to be effective resources for molecular studies of prognosis, response and pharmacogenomics. As a part of the agreement, NCI and the clinical groups will work through a group banking committee with representation from each of the clinical trial groups to achieve coordination of banking activities. The objective of the agreement is to implement, as far as possible, common collection and storage practices, common data structures for banking and data exchange, and clear and common principles for access to and utilization of banked specimen and data. The groups will incorporate mechanisms to meet the emerging needs of the cancer investigator community for access to high quality specimens to rapidly translate information from bench to bedside.

The key purpose of the Group Banking Committee is to move the clinical trials banking activities forward to facilitate the interactions between the bankers, the trialists, and the tissue users, such that the necessary changes and revisions are rapidly implemented. NCI's recognition of the need for coordinated efforts among the clinical trial groups for tissue collection will impact the identification and the resolution of other barriers to efficient and investigator friendly specimen banking. Thus, the support provided by NCI to clinical cooperative group banking will contribute to the enhancement of tissue repository practices in general. Issues such as establishment of common frameworks for the use of data from specimens by third parties, providing clarification and/or recommendations for the development of regulatory guidelines that both meet the privacy needs of the patient and the requirements of the tissue users are more likely to be addressed in a coordinated fashion.

Scientific Quality Assurance

Moderator: Richard G. Hegele, M.D., FRCPC, Ph.D.
Professor, Department of Pathology and Laboratory Medicine
University of British Columbia
James Hogg iCAPTURE Centre for Cardiovascular and Pulmonary Research

There is an old adage in computing that states "garbage in = garbage out". It is likewise true, but at times surprisingly under-appreciated, that the results of assays performed on biological material are dependent on the characteristics of the initial specimen. Seemingly mundane issues — details of specimen acquisition, handling, processing, and storage ("pre-analytical phase") — are particularly relevant to the functionality and integrity of biobanks. Clearly, biospecimen sets must be comparable across collection protocols and sites to ensure that histological and molecular changes reflect biological differences and not process variability. However, at present, there is a plethora of "home-made" methods for sample collection, storage and processing, and even if these are designed with good intentions, there is severe risk for undermining quality and reproducibility of analysis. In particular, these protocols vary not only among the different institutions contributing samples to biobanks, but could also be quite dissimilar within a given organization. Therefore, standardization of biobanking sample collection and handling procedures, as well as buy-in and adherence to these practices by all participating organizations are necessary to ensure scientific quality of data generated downstream.

Clearly, biospecimen sets must be comparable across collection protocols and sites to ensure that histological and molecular changes reflect biological differences and not process variability.

The Key Issues

Participants of the workshop on Scientific Quality Assurance discussed how to facilitate maximum functionality and flexibility of biobank material while maintaining adequate scientific quality assurance.

Standard Operating Procedures

First and foremost, participants called for an environmental scan of standard operating procedures (SOPs) for biobanking, to critically evaluate and identify evidence-based best practices and note "gaps" for which development of new procedures are warranted. Challenges of defining who should drive the process and who should be involved were considered. It was emphasized that well-established and validated protocols are available; therefore, it would be important not to re-invent the wheel. Sharing existing protocols and drawing upon best practices established in other disciplines, such as forensic medicine, should help in the development of SOPs. While peer groups could be instrumental in this process, the involvement of an external regulatory body was deemed critical to provide the necessary oversight and reference base.

So far, funding agencies, such as governments, private foundations and industry, have been slow to recognize that standardization of biobanking procedures is a critical issue for the success of these organizations. The time has come to change this practice. Moreover, to facilitate buy-in and compliance with SOPs by various banks and contributing institutions, development of biobanking GLPs might be necessary. Establishment of a biobank accreditation agency that could take the lead on developing, validating and mandating biobanking GLPs was proposed. Compliance with biobanking GLPs will be required for accreditation of biobanks in the future.

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In spite of the emphasis on standardization, protocols have to be flexible enough to incorporate new analytical technologies that will become available in the future. Thus, adaptability of SOPs has to be built-in from the very beginning. To ensure that in the future samples are on hand for analysis by novel methods, longitudinal data and multiple samples should be collected whenever possible.

Clinical Content Data Quality and Common Nomenclature

Clinical data associated with specimens, collected from patients and healthy volunteers, need to be standardized to ensure maximal usefulness of the samples. As a starting point, it will be necessary to establish a standardized disease nomenclature. The nomenclature has to be relatively simple, as physicians are not likely to spend much time entering complex diagnostic categories. ICD-10 and SNOMED standardize certain clinical nomenclatures; however, neither of these ontologies was developed for biobanking purposes. Furthermore, there are significant differences in the scope (and agendas) between ICD-10 and SNOMED.

In the theme of avoidance of "reinventing the wheel", additional developmental efforts are necessary to address ontology issues that are specific to tissue banking. IT approaches could play a central role in this process, by identifying and establishing commonalities between ICD-10 and SNOMED. Then, relying on the unified information, there is a potential common basis for development of additional standards for biobanking ontology. Physicians and sample collectors will have to be trained in using new standardized nomenclatures through vehicles such as integrating biobanking into continuing medical education.

Just as with adherence to SOPs, compliance with common nomenclature will be crucial for success of biobanks. To ensure compliance, panelists proposed introducing biobanking GCPs that again can be enforced by a biobank accreditation agency.

Establishing and Sharing Best Practices in an International Environment

While various biobanks across the globe have different goals and priorities, it is clear that establishing and sharing best practices will benefit all. One approach for knowledge exchange is through establishing a biobanking journal. Publication of the methodologies backed by scientific data will help to confirm best practices. Latest developments could also be shared on the Internet. Creation of a biobanking portal could be a compelling step in this direction. IT companies, such as IBM, could take a lead on developing and maintaining this portal. Costs associated with both a journal and a portal could be paid for by the parties standing to benefit from their use.

While various biobanks across the globe have different goals and priorities, it is clear that establishing and sharing best practices will benefit all.

In summary, scientific quality assurance is a vital issue for the advancement of biobanking. Though often under-appreciated as a confounding factor in studies, consistency in sample collection, preparation and storage are a critical base for all testing and analysis that follows. Biobanking must commit to standardization and wide adoption of current best clinical and laboratory practices. In addition, data associated with biospecimens need a matching commitment to standardization. These issues will receive additional focus and attention in upcoming Biobank Summits.

Biobanking IT Infrastructure

Moderator: Martin L. Ferguson
Sr. VP Bioinformatics
Ardais Corporation

The need for statistically sized and comparable tissue biorepositories to support modern translational medicine research is well established. This need in turn drives a requirement for broad, sophisticated information technology systems that can support all facets of operating such repositories, such as: connecting multi-site networked collections; enabling highly structured clinical annotation; enforcing donor confidentiality and privacy; managing the logistics of biospecimen collection and tracking; and, support of key functionality such as query tools, data integration with molecular profiling results, etc.

Two key interlocking assumptions were made at the start of this workshop:

- Examples of widely deployed IT supporting the above needs do not yet exist, however
- Most of the IT required to support modern biobanking does already exist.

Evidence of this can be seen in an examination of the current biobanking situation, where many repositories do exist. In fact, the current situation is so decentralized that there are thousands of principal investigators (PIs) with small (or sometimes not so small) collections, each with its own processes for collecting and storing samples, and each with its own set of data requirements, data formats and software tools. These systems have typically been purchased, implemented or custom-built with little or no regard to communicating the data or sharing the samples beyond the confines of the lab for which the annotated specimens were collected. The resultant level of decentralization is such that even the same lab may have several, completely different, non-compatible systems for multiple projects. Solutions to these issues for biobanking support are only rarely dependent on future advances in information technology. For the most part, this workshop focused on the need to make choices among existing technologies and on putting the necessary "carrots" (benefits and incentives) and "sticks" (regulations and penalties) in place to move technology adoption along in preferred directions.

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In an effort to solve this problem, the working group made a further assumption: that a synergistic pathway to greater adoption of standards was through encouraging more centralization of biobank data and biobank samples.

The Key Issues

Two issues were then posed as questions for this workshop.

1. How do we "**move the dial**" on (i.e. incrementally move) biobanking IT to be more centralized than decentralized, for biospecimen collection, standardization, annotation and access?
2. How does the community **make decisions** on more broadly accepting existing IT standards and start moving forward?

How do we move toward centralization?

Given the current, some might say "extreme", state of non-standardization, the workshop participants focused on the modest goal of "moving the dial" toward more centralization as opposed to incorporating great sweeping changes. One of the drivers for standardization – on multiple levels of tissue collection, processes, informatics and data formats — is the desire to compare data sets collected in multiple labs in order to increase statistical power. Without some movement toward standards and the ability to share data, those experiments requiring uniformity and comparability will not happen, or be so filled with error that their utility will be severely limited.

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In this context, IT standardization does not address hardware but focuses at the software level. These software standards and data schema in turn are dependent on standardization at a higher level of abstraction, namely on standards for tissue collection workflow, experimental procedures, ontologies and semantics. As those higher level standards are set, it then becomes important to implement standards on database schemas, on API's (Application Programming Interfaces) in analytical applications, on integration and communication protocols (such as CORBA, web services, etc.). Although significant work is required to attain this level of standardization, the greater adherence there is to such standards the fewer layers of middleware "glue" and custom programming are needed to make all the components work together. That said, there are both pros and cons to a move toward standardization and centralization outlined in Table 3.

TABLE 3

Pros and Cons of Centralization for Biobanks

Pros	Cons
Consistency in implementation	Lack of Flexibility
Operational efficiency	Too general (brittle)
Cheaper	Politically unattainable
Control	Single point of failure
Ability to audit	Higher up-front costs (integration and security layers)
Validation	Slowness of decision-making
Ownership	Scalability
Internationalization	

Source: IDC, 2005

In addition to the general merits and drawbacks of centralization, the group also identified some key hurdles to the practicality of achieving greater centralization. These centered on hurdles placed by government regulations, the lack of a governing regulatory committee and the difficulty of achieving consensus, in particular across national boundaries. Key to the discussion was the assumption that although standardization is theoretically possible without centralization, in practice some centralization is needed for standardization to take effect.

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As a result, the group thought about the following incentives and disincentives that could help accelerate progress toward centralization and how to organize in a way that could start to implement progress:

"Carrots":

- Contributing data provides an improved path to publication for scientists.
- Inform and motivate patients to provide specimens and influence their healthcare provider to participate — this parallels the direct to consumer advertising that pharmaceutical companies use to create demand for their drugs.
- Create critical mass – consensus and a rising roster of participating organizations, a core of high credibility sponsors, and rising data volumes at central biobanks will help create momentum.
- Provide incentives – suggested incentives included: preferential access to samples based on record of contributions; access to collaborations; and, monetary rewards.
- Create and validate an ROI model for centralized vs. de-centralized approaches to biobanking.
- Pilot a proof-of-concept.

"Sticks":

- Obtain regulatory approval for biobanking.
- Lobby funding bodies to pay for, and require registration of samples.
- Make grants conditional on contribution to a centralized (registered) biobank.
- Have journals require registration of samples as a condition for publication.

In particular, the workshop participants believe that in order to trigger a significant move toward centralization, the NIH and large pharmaceutical companies must come to agreement and require that the research funded by their respective organizations contribute samples and data in accord with specific standards. No matter how alluring, "carrots" in and of themselves will not be sufficient.

Both a "carrot" and a "stick", publicity and education were also seen as critical elements to help change behavior by creating both a pull and a push. Suggestions included:

- Conduct contribution campaigns targeted at the general populace
- Deliberately seek media coverage
- Develop a campaign targeting physicians asking them to encourage patients to register with a central repository
- Reach out to enlist support from the patient advocacy community
- Get a celebrity to endorse biospecimen donation
- Establish a peer review journal for biobanking

Since technology decisions ultimately cannot stand apart from people and process decisions, the issues of organization and governance arose as these structures will enable or hinder the willingness and ability to move to a more centralized operation. Specific recommendations on governance overlap with some of the findings of the governance workshop, but include suggestions such as:

- Convene a MIAME-like work group to determine minimal dataset of variables/components; create a centralized "Meta Data Structure"; develop a worldwide method of providing ID to donors and samples; and define a method of exchanging information and processes.
- Glean lessons and benefits from other international collaborations that have demonstrated success (e.g. projects like SARS).
- Establish cross-disease working groups sponsored by the NIH or similar organizations.
- Build on existing EHR (electronic health record) and PHR (personal health record) efforts, since eventually EHR efforts will provide solid longitudinal clinical data for association with biospecimens. Of course, this tends to be easier in a centralized healthcare system.
- Establish government based projects predicated on centralized access, like BioShield or the National Biospecimen Network.
- Create public-private partnerships to define and manage biobanking efforts

In the spirit of "moving the dial" toward centralization, workshop participants indicated a desire to start small with a defined infrastructure, create an open-code repository architecture and a generic data model. These should enable easy adoption and become an incentive for each biobank to avoid creating its own version. It should be noted that while there was general agreement that there are some areas that are pre-competitive and shareable, there was disagreement as to how "shareable" the IT platform should be, whether, for example, the entire informatics framework should be based on open-code repositories.

In the spirit of "moving the dial" toward centralization, workshop participants indicated a desire to start small with a defined infrastructure, create an open-code repository architecture and a generic data model.

This set of recommendations touches on both the very specific tasks of establishing data standards as well as the importance of reaching out across numerous boundaries (national, disease, public/private, and science/healthcare) to learn, cooperate and ultimately integrate. This level of integration and cooperation is at the very heart of the promise of what biobanking can contribute to science and health.

How Does the Community Make Decisions on Existing IT, and Start Moving Forward?

While it is beneficial to have discussions about IT standards, there is widespread recognition that first steps need to be taken not just discussed. Specific questions the group addressed included:

- Who governs (the IT standards) and to what extent?
- How many sponsors is fair?
- What will be the role of government in making these choices?
- What are the relevant parts of IT?

The primary hurdles to making decisions on IT infrastructure are focusing and actually getting agreement on the exact IT components. The second hurdle identified was how to create an equitable and credible governing body for the informatics side of biobanking.

Two options were put forward for the governance of an informatics infrastructure. The first is to have a public agency, such as the NIH, fund and manage the development of a domain-specific middleware and informatics infrastructure, and use its clout to encourage, or force, compliance. The second option is to follow a model such as ISO 9000 and establish an industry supported governing body to make decisions on standards, provide guidance and certification of compliance.

Two options were put forward for the governance of an informatics infrastructure ... a public agency... or an industry supported governing body.

Whatever the governance model, the workshop participants indicate a need to have some form of evaluation to determine the "best" model for scalability, performance and reliability. It is envisioned that this evaluation would be based on a competition between several pilot implementations of standards and associated IT architecture. The outcome of this would be a clearly defined set of IT specifications that biobanks could confidently support and implement on a wider basis.

As the group translated these goals into tactical and practical next steps, the following emerged as recommendations:

- Conduct a proof-of-concept. For example, coordinate systems so that one can demonstrate and validate the ability to securely run queries on specimen databases, transmit data between organizations, merge specimens and data from two biobank organizations for a single study and provide it to a researcher at a third organization, without compromising privacy requirements.
- Evaluate existing biobanks and establish *Best Practices*.
- Establish technology benchmarking on a national level.
- Create a reference implementation (test bed) of hybrid systems.

- ☒ Persuade technology vendors (e.g. IBM, Affymetrix, SAS, etc.) to make tools freely available for a pilot study.
- ☒ Use the Veterans Administration or Department of Defense (USA) as pilot environments.
- ☒ Create the one-stop-shop (at a pilot level to start) across academia, patient, medical community and private-public sector.
- ☒ Forge linkages with major middleware and infrastructure working groups (e.g., NMI, GGF, etc.).
- ☒ Define the "benefits" for various constituent groups such as academia, pharma, government, and healthcare. (See earlier workshop section on biobank organization, management and governance).
- ☒ Define high-level generic SOPs by consensus committee and force implementation to lead to pre-approved regulatory standards.

This discussion of the various elements needed to start, surfaced additional issues and questions that subsequent working groups will need to address, such as:

- ☒ How do biobanks effectively make decisions across such a disparate set of IT choices?
- ☒ What are the best approaches to meet stringent security requirements?
- ☒ How involved should governments become in creating, enforcing and adopting these standards?
- ☒ How should biobanks manage coordinating bio-specimen identification numbers with the push toward MPI (Master Patient Index) identifiers?
- ☒ Continue to push for improvement in key enabling technologies, such as NLP (Natural Language Processing), that are needed to mine existing legacy bio-repositories and collections.

In summary, the workshop on IT standards clearly recognized that IT standardization cannot happen in isolation. It will only occur in the context of a broad move to create more centralization of the registration and management of bio-specimens and associated patient data. Initial steps can happen most directly within organizations or departments. For example, biospecimen banking across an entire academic medical center could be provided as a "core" services operation by the pathology department. As a smaller step, even within a single department, steps could be taken to ensure harmonization of IRB protocols, common data elements, and tissue processing protocols. Whatever can be done to "move the dial" toward centralization will also assist in the IT standardization process. On a tactical level, the group concluded that it is time to start pilot studies and work toward defining IT and informatics best practices among biobanks. This, in turn, will possibly lead to the establishment of an open code repository that would further accelerate IT standardization among biobanks.

Toward 21st Century Biobanks, Moves are Afoot!

Martin L. Ferguson, Sr. VP Bioinformatics, Ardaís Corporation

One of the key theses of the IT Infrastructure working group (November, 2004, IBM Biobanking Summit, Tarrytown NY) is that most, if not all, of the technologies and standards needed to launch biobanking networks already exist. It is not until such networks form that large biospecimen repositories (replete with the necessary characteristics of being comparable, containing high quality tissue, structured clinical and logistics data, and implementing standardized protocols) will truly support statistically powerful translational clinical research studies. The main hurdle remains getting enough entities and programs to actually agree upon and adopt a common set of systems for deployment, and thus become a sort of "nucleation point" for a functioning biospecimen collection system. That first network could act as a pilot or proof-of-concept, and would accrete others to its fold. 2005 marks the year that many are sensing some real movement.

Recently, a cluster of efforts has come together, as the result of encouragement by the cancer research community along many different vectors, to overcome what can best be described as an "activation energy barrier." It should not come as a surprise that early interest happens in oncology, since the clinical procedures can commonly yield tissues and have historically created large, but sometimes less than useful, biobanks. The effort started several years ago, when the NCI and C-Change (formerly known as the "National Dialog on Cancer") brought together many interested parties in the field of cancer research to develop a blueprint for a "National Biospecimen Network (NBN)." Since then, many committees, thought leaders, and others have weighed in and worked to find the best place to prototype a biospecimen network. In March, the NCI published an RFP soliciting proposals to establish an informatically intense, multi-site biospecimen coordination system and repository to support a collaborative prostate biomarker study between 11 academic medical centers that have Specialized Programs in Research Excellence (SPORE) grants. The RFP calls for the successful proposal to implement three main objectives:

Deploy an prostate biospecimen collection, annotation, processing, and distribution system robust enough to support the Inter-SPORE Prostate Biomarker Study (IPBS).

Pilot a program demonstrating the viability of an NBN-like system on the framework of the multi-site collections supporting the IPBS.

Utilize caBIG (an NCI Center for Bioinformatics program) developed software, and data and communication standards to enable the interoperability of information generated within the NCI designated cancer centers and other entities participating in the study.

While it may seem like an "everything but the kitchen sink" approach to conglomerating deliverables within a pilot program, this system, when launched, will provide that nucleation point for the NBN. The benefits to other NCI programs, such as cancer signature studies, comparative genome sequence projects, and other cooperative or organ-site efforts, are also clear. With efforts reaching into other diagnostic areas, it will fully validate the critical infrastructure status of multi-site collection networks designed for delivering personalized medicine in the 21st century.

Data Standards and Semantic Interoperability

Moderator: Steven Lincoln
VP of Bioinformatics
Affymetrix

"The beautiful thing about standards is that there are so many to choose from"

Scott Clarke
Former CIO, Syntex, Roche Bioscience
Former CIO/COO, Incyte Pharmaceuticals
CEO, Discovery Innovations

This ironic quote set the stage for the discussion in the workshop devoted to data standards and semantic interoperability.

The Key Issues

The session's objectives were posed in the form of three questions:

1. What is the **state of data standards** which are relevant to or needed by biobanks and/or biobank users?
2. What are the **fits and gaps** with actual long-term needs?
3. What are we doing, or **what can we do** about items 1 and 2?

Six domains were identified as major elements of an organizing framework each with its own need for data standards. A key assumption is that the ultimate benefit of biobanking, resulting from the ability to combine data from several domains for analysis, will be realized by consistency within and across these domains.

1. Clinical – clinical patient information and disease status
2. Sample – acquisition, handling, and pathology
3. Molecular – sample preparation, test type and data
4. Annotations – gene/protein prior knowledge
5. Analysis – process information and results
6. Interpretation – new knowledge, follow-up experiments

What is the State of Data Standards Relevant to Biobanks?

It should be noted that many standards lack "tight" definition, that is, terms or fields that match in format but don't have the same meaning, and others that match in meaning but have different formats. In addition, data collection practices often rely too heavily on unstructured text entered in notes fields. These among other difficulties create significant interoperability issues among biobanks and the scientific and medical disciplines on which biobanking depends.

Many standards lack "tight" definition, that is, terms or fields that match in format but don't have the same meaning, and others that match in meaning but have different formats.

A starting assumption was, "We do not want to invent new biobank standards or reinvent any standards if we can at all avoid it." While almost universally agreed upon as a starting assumption, the actual level of patience for working with existing standards committees to accommodate the needs of biobanks will certainly vary. Some organizations will have great patience in working with existing standards bodies whereas others will have only minimal patience and soon take off on their own path creating and/or adopting data standards and ontologies that fit the needs of their particular biobank.

The following were identified as characteristics of a good standard:

- ☒ **Well-defined** – A standard should remain focused and not try to solve all problems. Within its assigned boundaries, it should work with a defined ontology that provides necessary and sufficient coverage of the field. Structurally, it should use clear syntax and semantics to provide consistent meaning to all users. Finally, it should be simple to understand and support unambiguous exchange of information.
- ☒ **Is Used** – A standard should be widely deployed and used, preferably in multiple nations.
- ☒ **User Friendly** – A standard should be efficient to implement, clear to users and simple or straightforward to learn. Governed – A standard should be governed responsively and have a structure and members that keep issues from becoming committee bound and stalled. Ideally, the governance should include representatives from multiple disciplines including linguistics, computer science, biology, and medicine.
- ☒ **Cost efficient** – A standard should be efficient to create and to implement.
- ☒ **Adaptable and flexible** — A standard should be based upon the current best state of knowledge, have a well defined process for modification and be adaptable to change with minimal maintenance costs.

By common consent it is believed that very few, if any, standards fit all these ideals, but nonetheless the ideal characteristics provide a basis for comparing and choosing among standards when they are partially or entirely overlapping in the field that they cover.

What are the Fits and Gaps With Long-Term Needs?

While the general state of affairs in standards is not ideal, the applicability of existing standards to the needs of biobanks can be thought of in two steps. One, how do existing standards map and provide coverage to the six domains? Two, overall how well do the standards meet the needs of biobanking in each domain? The following table and figure summarize the views of workshop participants.

Table 4 shows the result of a mapping exercise of existing ontologies and data standards against the six domains identified earlier.

TABLE 4

Mapping of Existing Standards and Ontologies To Biobank Functional Needs

	Functional Domains for Biobanks					
	Clinical	Sample	Molecular	Annotation	Analysis	Interpretation
NCI-TOX	X					
ICD (9,10,03)	X					
ISH LT	X					
HL7	X					
HL7 CG	X		X			
CDISC	X					
BETHESDA II		X				
SNOMED	X			X		
SNOMED CT	X	X				
MEDRA	X					
ISO (all)		X	X	X		
CAP/CLIA			X			
MESH				X	X	
GO				X		
EC				X		
MAGE-ML			X	X	X	
MEDLINE						X
GENBANK (format)				X	X	X
SEND	X	X				
HUPO			X			
HISA	X					
AHFS	X					
EVOKE		X				
GPIC	X				X	X
UICC	X	X	X	X	X	X
TNM	X	X				
ICMS	X	X	X	X	X	X
LOINC		X	X			
DICOM	X	X	X	X	X	X

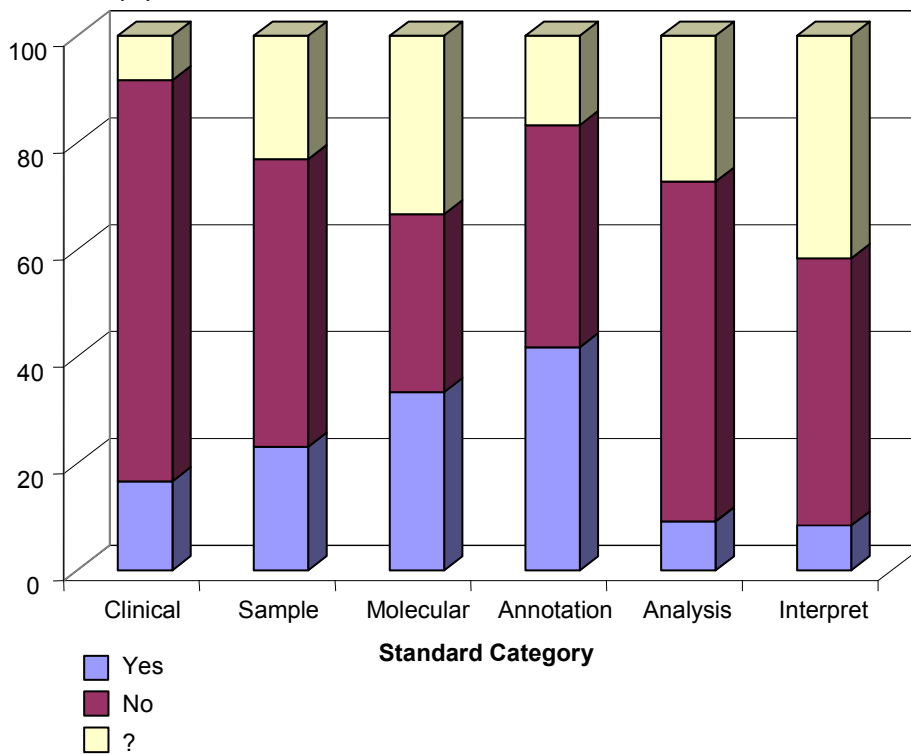
Source: IDC, 2005

Once the standards were mapped against the relevant domain areas, participants assessed whether they met the needs in each of the six domains. As seen in Figure 1 below, the Annotation and Molecular categories were the domains with the highest percent indicating for a positive fit, but even then, less than 40% believed that the fit was good. The domains with seemingly the least fit between existing standards and needs of biobanks are in the areas of Analysis and Interpretation.

FIGURE 1

Do Standards Meet the Needs of Biobanks?

Distribution (%)



Source: IDC, 2005

What Are We, or Can We Do About the Fit of Standards to Biobanking?

In order to think more clearly and plan more concretely about what can be actually done to improve the fit of standards to the needs of biobanking, the workshop participants chose to focus on the area of clinical samples, specifically evaluating the applicability of SNOMED (The Systematized Nomenclature of Medicine) as a standard for use in biobanking. A SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis was performed in the workshop with the following group consensus.

TABLE 5**SWOT Analysis of SNOMED as a Clinical Standard for Biobanks**

Strengths	Weaknesses
<ul style="list-style-type: none"> • Vendors of imaging systems and software • Standards both general and specific • Have lab operations standards, although not always followed – non Dx • Many different specialist standards • Government (USA) embraced it • Well governed 	<ul style="list-style-type: none"> • Subjective • Lab data handling not addressed • No computable consent • Broad standards, not detailed enough (e.g. SNOMED CT) • Slow adaptation of SNOMED by CAP, process is not transparent
Opportunities	Threats
<ul style="list-style-type: none"> • Reporting standards • Establish best practice • Mapping detailed standards into general ones • Could work with CAP (College of American Pathologists) 	<ul style="list-style-type: none"> • CAP might not be as cooperative as we need • SNOMED not globally available or translatable

Source: IDC, 2005

Building on the SWOT analysis of SNOMED as an appropriate standard, the following actions were suggested. First, a proof of concept project based on SNOMED should be developed. Second, there should be an effort to establish a working relationship with CAP. Third, specific work should proceed on developing data interchange standards as well as standards for sample handling. In addition, educational materials such as glossaries, meta-data matrices and e-learning web portals should be created to support deployment in biobanks.

There is not yet widespread agreement on what standards fit best. For example, some contend that a combination of HL7, CDISC and ICDN has the best promise. Others point out difficulties in the internationalization of CDISC. There may also need to be a significant effort to reconcile several smaller, more focused standards. Finally, as might be expected, there are open questions about who will drive the standards decisions and efforts. Should it be driven by an accreditation body or should they look for de facto emergence of the most useful standards? Will those organizations providing funds get a voice in standards decisions? Should the use case and scenarios method be used to drive the decisions?

In summary, this workshop on data standards and semantic interoperability concurred that one of the significant challenges for biobanks is the plethora of competing ontologies and data standards. Many of the standards that do exist lack tight definition and disciplined adherence to rules of use. By the assessment of this workgroup all relevant domain areas have available standards, and some standards have relevance across multiple domains. Nevertheless, the collective opinion of the group is that the needs of biobanks are not particularly well covered by the existing set of standards. More assessments such as the one started in this workshop on SNOMED need to take place with input from multiple biobank organizations, and individuals with deep experience from a variety of scientific and medical disciplines.

Conclusion

We have seen that the development of biobanking is continuing to gain momentum around the world. As new biobanks are being developed and existing ones are built upon, there is a strong movement to consolidate biorepositories into larger collections and enable better access and analytical capabilities through aggressive use of information technology. Centralized visions of biobanking are strongest in Europe where they fit into the centralized public healthcare system. However, even in the US with its decentralized approach to healthcare, there is significant interest and new initiatives to organize existing biorepositories into networks that share common SOPs and interoperable informatics systems. Events such as the Biobank Summits, organized and hosted by IBM, are bringing together diverse sets of thought leaders and encouraging dialogue and cooperation across national boundaries.

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Visions of biobanking focus on building high-quality collections of biospecimens, that are annotated with several of the following types of data: clinical diagnosis and record of treatments; pathology reports; patient medical history; anatomical measurements; lifestyle assessments; biomolecular test results; family genealogy and health history; and, environmental conditions. Biobank collections will attain greatest value when specimen collection, processing and storage are consistently conducted in accordance with widely agreed upon standard operating procedures based on best practices. Also critical to the value of biobank collections are the acceptance and use of common ontologies and data standards for encoding the annotations. Widespread adherence to standards will enable interoperability between biobanks and the aggregation of sample and data will provide better statistical power for scientific and medical research.

Biobank collections will attain greatest value when specimen collection, processing and storage are consistently conducted in accordance with widely agreed upon standard operating procedures based on best practices.

There are numerous challenges to overcome in achieving this vision. Challenges include:

- Finding ways to cooperate rather than compete with the administrators and researchers who maintain thousands of legacy biospecimen collections.
- Forging agreement on standards for both specimens and data, that will enable interoperability, when so many of the scientific and medical fields on which biobanks rely struggle with standards in their own more narrow domain.
- Creating equitable and effective organizations and governance particularly in the context of national networks of biobanks.
- Securing long-term funding for biobanks that give them time to achieve scale and demonstrate their impact on research and clinical care.
- Working through issues of intellectual property and remuneration so that all stakeholders are motivated to participate.
- Working with the general public to diminish fears of misuse of consolidated personal, medical and genetic data.
- Persuading government agencies and legislative bodies to assist in the development of biobanking through regulation.

The potential benefits for achieving the vision of large networks of interoperable biobanks are enormous. Leading biomedical researchers believe that biobanking is a vital component in the move toward personalized paradigms of medicine. That move will not occur, however, without access to large collections of high-quality biospecimens that are well managed and well annotated on multiple dimensions. With such resources at hand, it is anticipated that healthcare as a whole will be more effective on both the individual and the societal levels as a result of having:

- ☒ A deeper understanding of the root causes of complex diseases.
- ☒ More sophisticated disease taxonomies and associated diagnostic tests
- ☒ More effective targeted therapies with fewer side-effects
- ☒ Potential cures for complex diseases.

To arrive at this goal, it is important for leaders of biobanks and key stakeholders to continue to cooperate to advance and refine the vision, to work together to overcome the challenges and create networks of biobanks that will effectively serve the needs of biomedical research and clinical care in the years to come. Biobank Summits I and II started the group down this path by describing what biobanks must accomplish and how they should operate, discussing the various challenges, and recommending specific actions. Biobank Summit III and other future summits will continue to work on that agenda and help make this vision a reality.

Leading biomedical researchers believe that biobanking is a vital component in the move toward personalized paradigms of medicine. That move will not occur, however, without access to large collections of high-quality biospecimens

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