

Strategic Planning for Biosciences at NIST

and the Role of the October 2008 Biosciences Conference

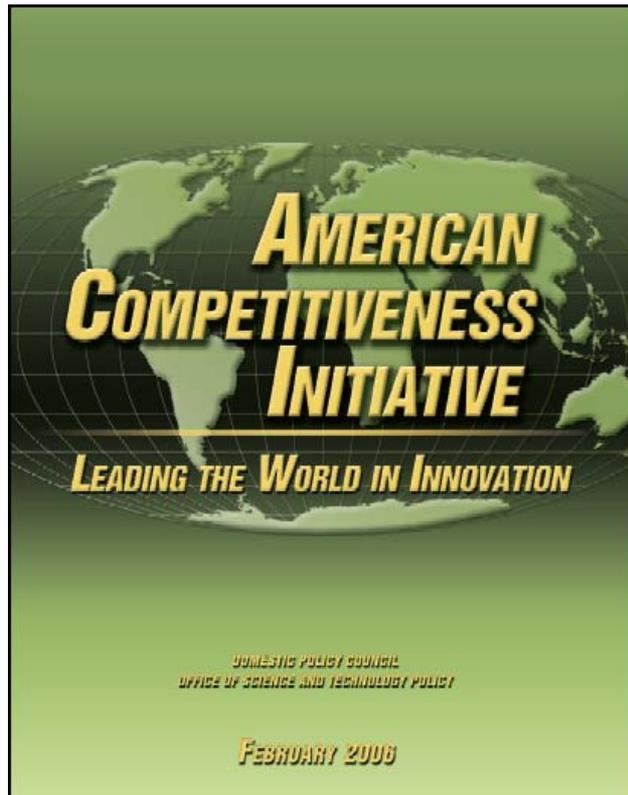
NIST Visiting Committee on Advanced Technology

June 10, 2008

Outline for Briefing

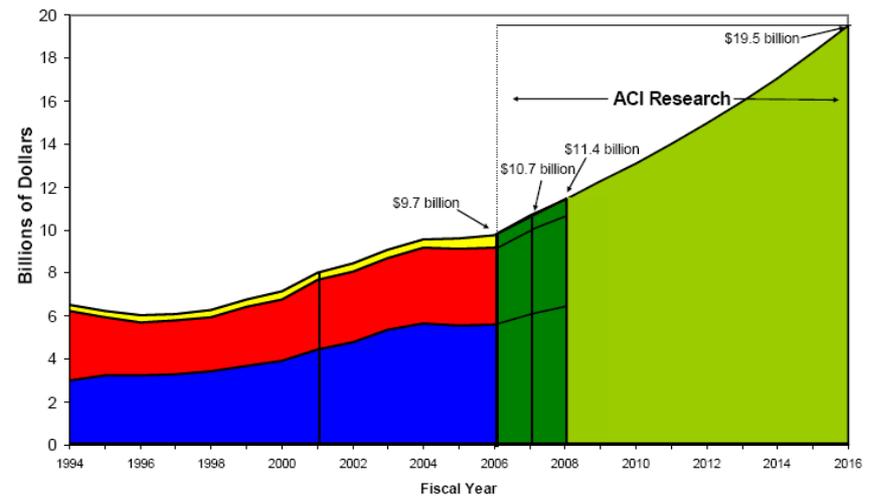
- **NIST's Growing Role in the Biosciences**
- **Current Portfolio of Activities in Bioscience and Health and Need for More Effective NIST-wide Planning**
- **Short Term Plans for Biosciences Program Growth**
 - FY07 Budget Increase
 - FY09 Request
 - Future Plans
- **Developing a Strategic Plan for Longer-Term Biosciences Program Growth**
 - Current and Near-term Activities
 - October 2008 Conference
 - Outline for Strategic Plan
 - Vetting Draft Plan with Stakeholder Community

Both ACI and the America COMPETES Act call for substantially increased funding for NIST core research and facilities

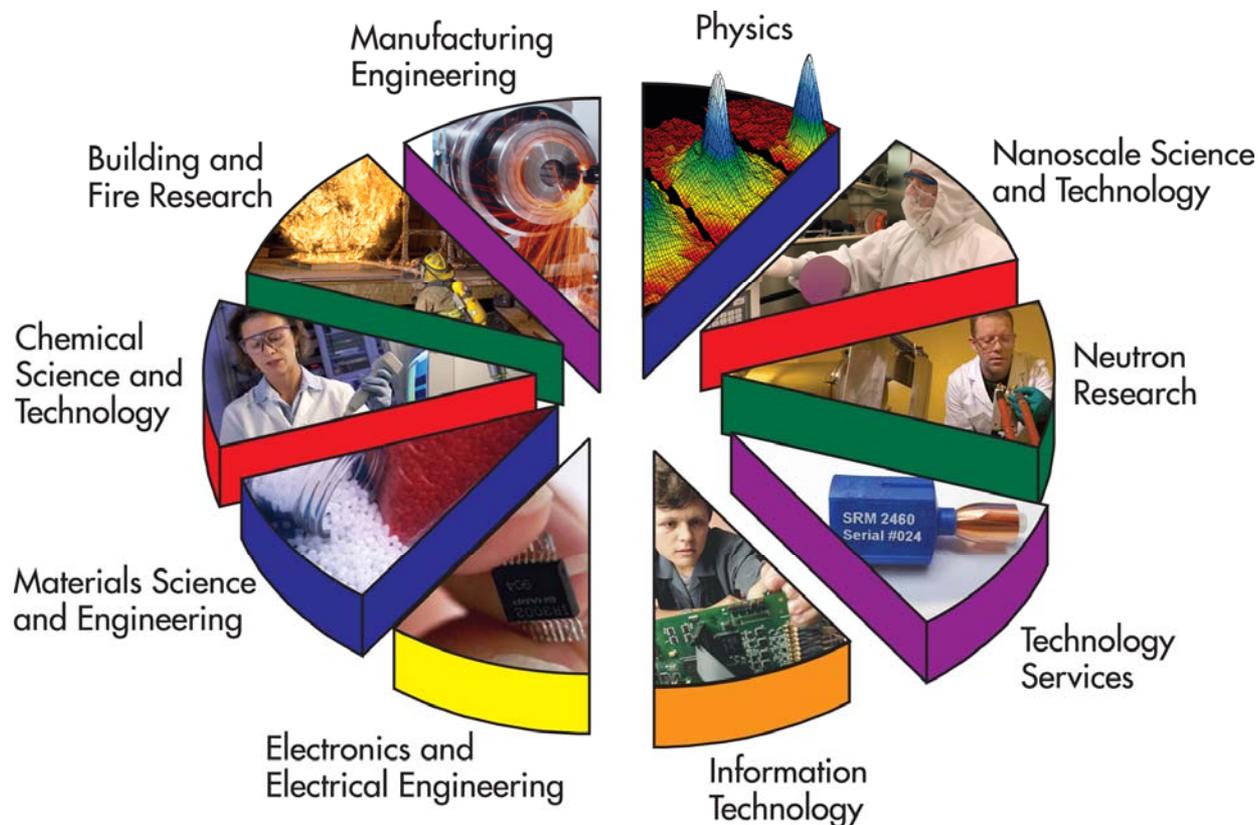


\$50B to be invested over the next 10 years in:

- NIST core (Technical Laboratories and infrastructure)
- National Science Foundation
- DOE Office of Science



NIST has traditionally focused on the physical science and engineering disciplines



Bioscience and Health has been identified as an area for significant growth at NIST

Why NIST and the Biosciences?

It is congruent with our mission to support U.S. industry and other stakeholders in overcoming measurement and standards-related challenges in the biosciences

through leveraging our vast multidisciplinary expertise in the quantitative physical and informational sciences to:

- **provide the measurement infrastructure to provide confidence in the results from measurements of complex biological systems and**
- **enable increased innovation**

We do this by:

- **Maintaining world-class research programs and facilities for the physical, chemical and informational sciences**
- **Recruiting staff with new and complementary expertise to work as part of interdisciplinary teams to address strategic needs in the biosciences**
- **Establishing new and strengthening existing external partnerships that complement our facilities, expertise and resources**
- **Working with stakeholders in industry, government, and academia to identify and address measurement and information barriers to innovation**

Bioscience and Health *has been identified as an area for significant growth at NIST*

Administration Input

Understanding Complex Biological Systems

*“Agencies should target investments toward the development of a deeper **understanding of complex biological systems** through collaborations among physical, computational, behavioral, social and biological researchers and engineers, who will, among other things, need to develop the data management tools and platforms necessary to facilitate this research.”*

John H. Marburger III, Director, Office of Science and Technology Policy
Rob Portman, Director, Office of Management and Budget, June 23, 2006

Other Agency Input

Proteomics Today – The Problem

*“In order for proteomics to be accepted as a valid science in clinical medicine, it is vital that the experimental results be reliable and reproducible within the scientific community. **The absence of these standards... is a barrier to innovation...** and ...delays the discovery and transfer of proteomic technologies into clinical applications.”*

Anna Barker, Deputy Director, NCI ₆

Bioscience and Health *has been identified as an area for significant growth at NIST*

VCAT Input

“Consider radical changes to how it (NIST) supports the biotechnology and health care industries”

Dr. Thomas M. Baer, Executive Director,
Stanford Photonics Research Center, Stanford University
NIST VCAT Meeting, June, 2006

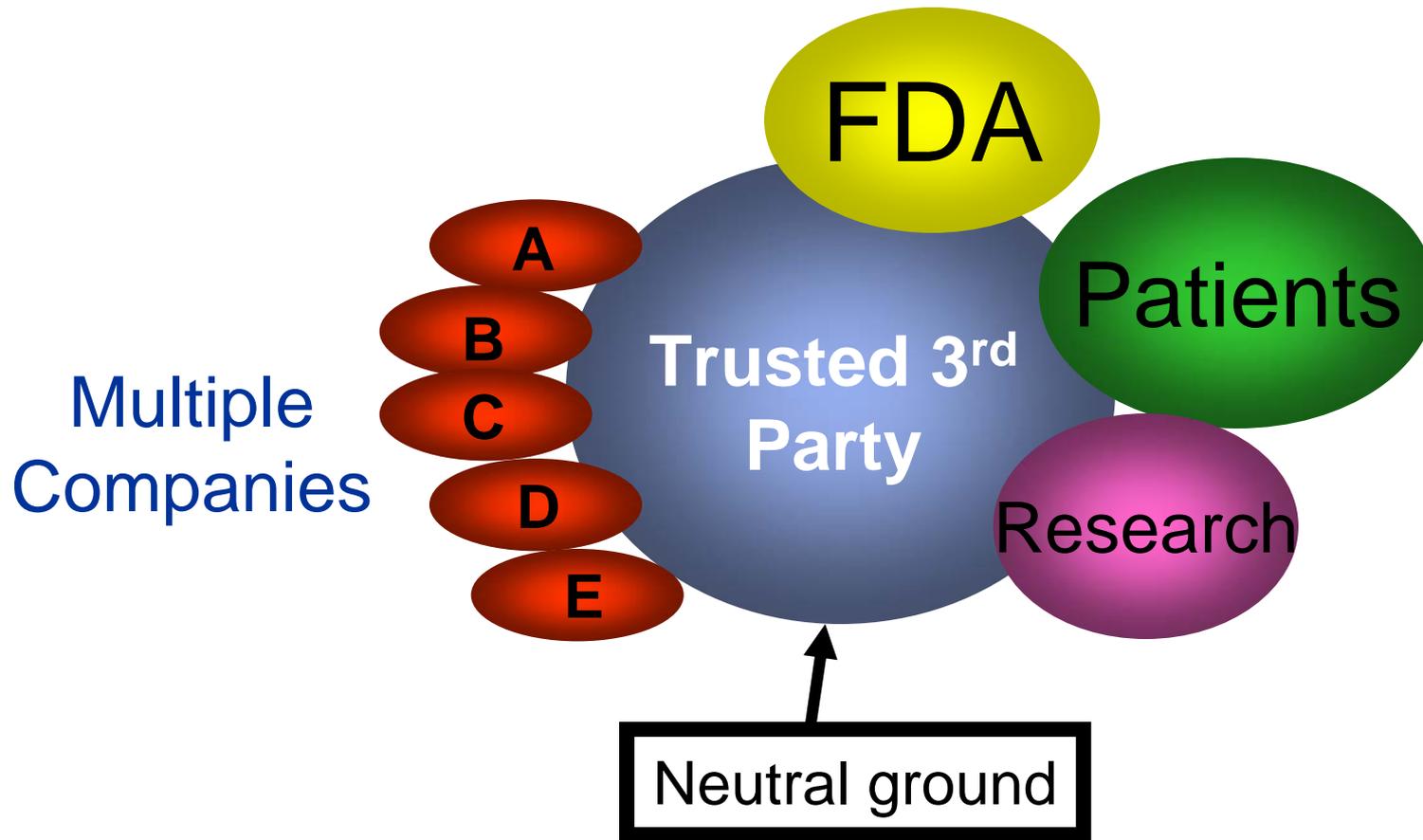
“Provide measurements and standards to support next-generation clinical diagnostics

- *Technologies for detection organ-specific proteins in blood – e.g., global proteomics, microfluidics, and nanotechnology measurement technologies*
- *Single cell analyses*
- *Technologies for the capture, storage, analysis, integration, and modeling of global data sets”*

Dr. Leroy Hood, President, Institute for Systems Biology
NIST VCAT Meeting, September, 2006

What is needed for Change?

- a partnership



Snapshot of NIST Investment in the Biosciences

Includes: appropriated funds, funding from other agencies, reimbursable funds (from provision of Standard Reference Materials, Calibration and Reference Data services), etc.

	Diagnosics	Drug Development	Therapeutics	Medical Devices	Healthcare IT	Energy	Food Safety and Nutrition	Biomaterials (including tissue engineering)	Forensics	Biometrics	Biohazard detection	Other bio	NIST Bio Subtotal
NIST Total by Category	\$12,145	\$3,491	\$2,726	\$3,448	\$6,691	\$1,452	\$2,198	\$5,137	\$2,943	\$9,055	\$2,780	\$11,944	\$64,009
STRS (appropriated funds)	8,581	2,865	1,309	2,590	3,475	840	167	3,799	200	2,311	1,522	9,529	37,189
SRM Production (reimbursable)	488	89	0	0	0	311	0	0	5	0	0	172	1,065
Other Agency/ Non-Fed Govt/CRADA	1,473	77	971	538	3,012	34	1,134	1,016	1,526	6,744	1,071	1,200	18,797
Other Reimbursable	636	328	445	219	0	206	897	176	1,200	0	25	470	4,603
ITS	475	0	0	100	204	61	0	146	12	0	30	560	1,588
Special Invested Equipment Allocation from Initiative	491	132	0	0	0	0	0	0	0	0	132	125	880

Of the ~ \$37 M STRS, only \$6 M appropriated by the Congress specifically for Bio-related activities

2002: \$2.0 M Standards for *In vitro* Diagnostics and Tissue Engineering

2004: \$1.0 M Marine Bioscience

2007: \$3.0 M Bioimaging

In Response to Stakeholder Needs, NIST's Activities in the Biosciences are Expanding

- **Bio-related activities have expanded throughout NIST**
 - Through reprogramming of existing base funds within individual Operating Units
 - However, not done in a coherent and coordinated manner at NIST level and consequently
 - Some gaps exist
 - There is some unnecessary duplication of efforts
 - More effective needs assessment and program coordination is called for at NIST level
- **NIST Biovision Team established in 2006 with broad NIST representation to provide input to NIST leadership for development of:**
 - Vision for biosciences program growth at NIST
 - Allocation plan for FY07 Bioimaging Initiative funds
 - Coherent set of new initiatives to support program expansion
- **Increased NIST-level coordination of bioscience programs to be implemented to assure more strategic focus and better internal and external communications**

Current Plan for NIST Biosciences Program Growth

- FY07 Budget Increase Calibration and IT standards for MRI, CT, PET and cellular imaging
- FY09 Budget Request Technology and standards for individual and multiplex measurements of biochemical health status markers
- Under Discussion Support for development of advanced tools for visualization of structural and biochemical changes associated with disease

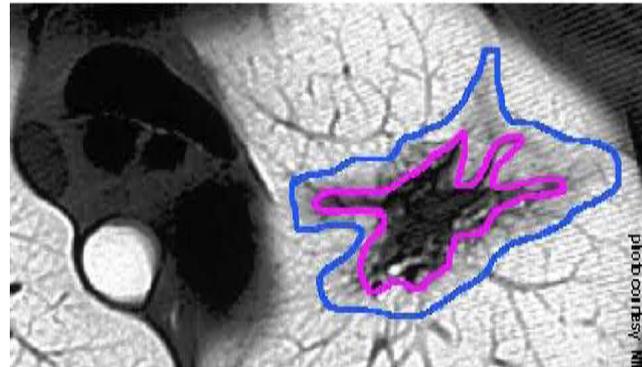
	FY07 + \$3M	FY09 + \$10M	Under Discussion
Medical Imaging	<ul style="list-style-type: none"> ➤ Standards for MRI contrast agents ➤ Phantoms for PET/CT 		<ul style="list-style-type: none"> ➤ Standards tools to enable enhanced image analysis, data comparison and feature extraction
Cellular and Biomolecular Measurements	<ul style="list-style-type: none"> ➤ Standards and techniques to enable quantitative fluorescence microscopy and cellular imaging. 	<ul style="list-style-type: none"> ➤ Quantifiable measurements of individual biomolecules and biomarkers ➤ Development of multiplexed measurement platforms 	<ul style="list-style-type: none"> ➤ Technologies and standards for quantitative protein measurements, ➤ structure function analysis, ➤ manufacturing and process monitoring
Computational Tools	<ul style="list-style-type: none"> ➤ Software validation for image analysis and extraction 	<ul style="list-style-type: none"> ➤ Uncertainty analysis ➤ Collection and exchange of data ➤ Validation of modeling tools 	

Bioimaging: A 21st Century Toolbox for Medical Technology

FY07 Increase: + \$3 million

Macroscopic imaging (MRI, CT, PET)

The problem with MRI and the exciting new imaging modality combination of PET/CT, is that radiologists and oncologists **must rely on visual comparisons** to determine if a tumor is shrinking and/or if medically-relevant topographical features have changed with treatment.



Microscopic imaging (Fluorescence, quantum dots, label-free methods)

Pathologists and drug discovery scientists use fluorescent antibody and DNA probes, as well as various label-free spectroscopic imaging techniques to look at cells and tissues

but, **results are almost impossible to compare** from one lab to another.

Standards for Bioimaging Program

Examples of Year 1 Activities

A. Quantitative Medical Imaging

NIST's work will enable digitization of the images to allow for accurate size quantitation and understanding of changes to topological features.

- Metrology for MRI contrast agents over a broad range of field and frequency
- Establish MRI standards such as NIST-traceable T1, T2 relaxation time standards.
- 3D phantom models for CT/PET

B. Quantitative Imaging of Cells and Tissues

NIST's work will develop ways to standardize these microscopic imaging modalities.

- First reference materials for intensity standardization of fluorescence microscopy
- Determine mass detection limits of broadband CARS

C. Standards and Validation for Software

NIST's work will establish software validation methods that will enable more accurate, quantitative and comparable image feature measurement and detection.

- Develop statistical methodology for annotating lung cancer CT images
- Develop standard methods and technologies for combining, interpreting, registration, and visualizing data from various imaging techniques for RIDER, LIDC, and other related image data sets

Measurement and Standards to Accelerate Innovation in the Biosciences

FY09 Request: \$10M

1. Improve measurements for *individual* biological molecules

- Improve quality, accuracy, and comparability for detection of biomarkers in blood and tissues

2. Develop *simultaneous* measurement capabilities for *large numbers* of different biological molecules

- Provide the measurement tools necessary to measure 100s-1000s of biomolecules simultaneously

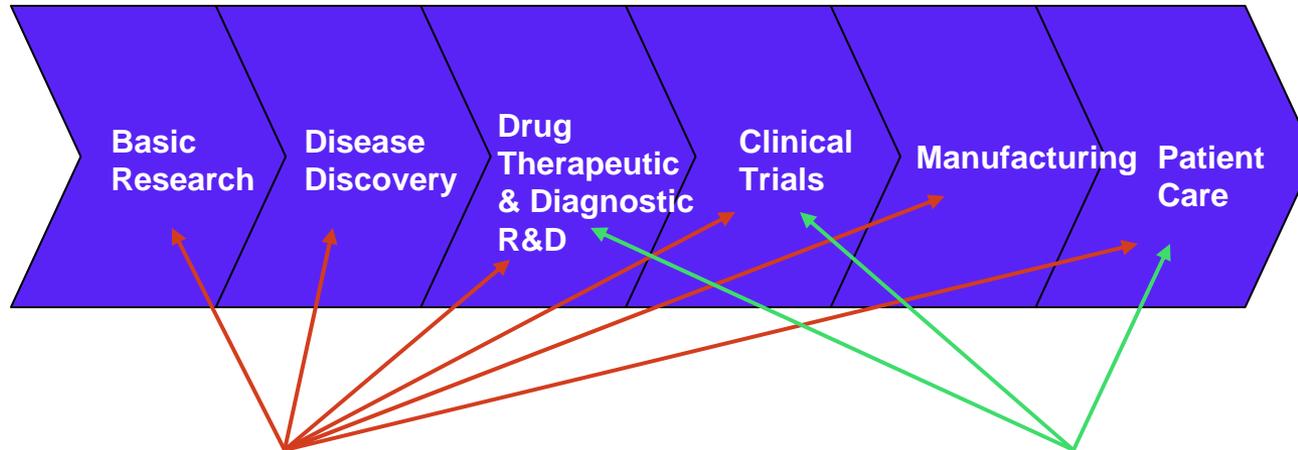
3. Provide computational tools to “make sense” of the data

- Standards for the classification and exchange of data
- Mathematical methods for validation and assessment of uncertainty



Beyond the FY2009 Request

NIST proposes to support development of advanced tools for visualization of structural and biochemical changes associated with disease processes to support innovation in health care.



Protein Measurement Science

- Enable a more sophisticated and accurate understanding of living systems
- Facilitate the development of more effective drugs, therapeutics, and diagnostics
- Reduce the time and costs associated with drug and therapeutic approval
- Enable the transition of medicine from treatment oriented to preventative, and from a one-size-fits-all approach to a more personalized model

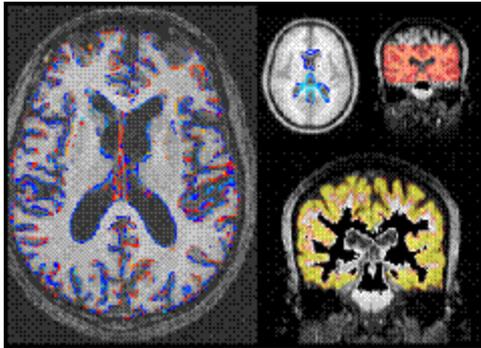
Quantitative Medical Imaging

- Allow physicians to accurately monitor disease progression and therapeutic response
- Allow for earlier detection of disease and enable more effective treatment decisions
- Improve the reliability and accuracy of clinical trial data

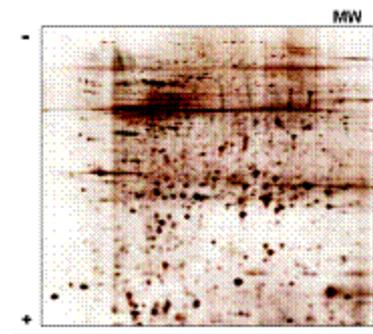
Beyond the FY09 Request

Tools to Support Visualization of “Disease Signatures”

unique patterns can be used as more definitive indicators of health status



**Abnormal Anatomical
Features**



**Abnormal Protein
Patterns**

A shift from measurement of individual biomarkers to “analysis of disease signatures” would help to enable

- a new comprehensive and integrated approach to wellness that includes prevention of disease, early detection of disease risk and individualized treatment plans for individual patients.
- predictive toxicology for new drug candidates -- ability to predict which individuals will benefit and those who might be most at risk for experiencing serious side-effects

Developing NIST Plan for Strategic Biosciences Program Growth

Current Activities

- Summarizing relevant input from past needs assessments
- Updating inventory of current NIST activities in the biosciences
- Completing plans for October 2008 Conference being convened to identify measurement, standards, and technological needs to inform and guide research and biosciences program growth at NIST



Planned Activities

- Summarize needs identified during October 2008 Conference
- Perform gap analysis
- Develop implementation plan with timelines for addressing identified gaps
- Develop and implement longer-term plan for continuing to assess and validate needs



NIST
Strategic Plan
for
Biosciences
Program
Growth

Refining Our Process for Bioscience Inventory Assessment

- to establish baseline for conducting gap analysis

Major Biosciences Healthcare Industry Sectors (March 07 VCAT)

- **Health Care**
 - Diagnostics
 - Drug Development
 - Medical Devices
 - Services
- **Biotechnology**
 - Energy
 - Food products
 - Materials
- **Life Science Research**
 - Instrumentation, devices,
and reagents for research
- **Homeland Security**
 - Forensics
 - Biometrics
 - Biohazard detection

Categories for NIST FY07 Biosciences Inventory

- Diagnostics
- Drug Development
- Therapeutics
- Medical Devices
- Healthcare IT

- Energy
- Food Safety / Nutrition
- Biomaterials

- Forensics
- Biometrics
- Biohazard detection

- Other bio

Categories for NIST FY08 Biosciences Inventory

- Diagnostics
- Drugs
- Non Drug Therapeutics
- Medical devices (non-diagnostic)
- Bioenergy
- Biomanufacturing (non-medical)
- Food Safety/
Nutrition/Cosmetics
- Environmental
- Homeland Security/ Forensics/
Human Identity Testing
- Life Sciences Research
- Bioinformatics
- Nano EHS

- Other bio

International Conference: October 20-22, 2008

“Accelerating Innovation in 21st Century Biosciences: Identifying the Measurement, Standards, and Technological Challenges”

Objective:

- To identify and prioritize measurement, standards and technology barriers to realize optimal economic and broad societal benefit from new discoveries in the following focus areas:
 - **Medicine** ➡ improving health through measurement of complex biological signatures
 - **Energy** ➡ obtaining sustainable energy from biological sources
 - **Manufacturing** ➡ obtaining higher quality products through better bioprocess measurements
 - **Agriculture** ➡ increasing yield, quality, & safety in the world’s food supply
 - **Environment** ➡ understanding our planet through linking molecules to ecosystems

Expected Outcome:

A listing of measurement, standards, and technology needs to inform and guide research at NIST and the measurement and standards community worldwide

Format:

- **Plenary Symposium** with lectures from visionary bioscience thought-leaders discussing future trends and measurement, standards and technology needs in the Conference focus areas
- **Workshops** to identify & prioritize measurement and standards challenges impeding innovation in the five focus areas plus a sixth workshop to capture broader needs within the biosciences

Participants:

- National and international experts from industry, academia, and government focused on the broad spectrum of measurement and standards needs in the biosciences



“Accelerating Innovation in 21st Century Biosciences: Identifying the Measurement, Standards, and Technological Challenges”

Opening Plenary Session: Morning (Day 1)

Science Policy Roundtable

Moderator: Linda Miller, Executive Editor of Nature Journals

Panelists:

John Marburger, US OSTP

Timothy Hall, EC Directorate General for Research

Sergio Rezende, Brazilian Ministry for Science and Technology

Patricia Kelly, Australian Dept. of Innovation, Industry, Science and Research

NMI Directors' Roundtable

Moderator: Robert Kaarls, President CIPM CCQM

Panelists:

James Turner, Deputy Director, NIST

Alejandro Herrero, Director, EC JRC-IRMM

João Jornada, INMETRO, Brazil

Laurie Besley, NMIA, Australia

James McLaren, NRC-INMS, Canada

Kwang Hwa Chung, KRISS, Korea

“Accelerating Innovation in 21st Century Biosciences: Identifying the Measurement, Standards, and Technological Challenges”

Plenary Session: Afternoon (Day 1)

- **Leroy Hood**, Institute for Systems Biology
- *[to be confirmed]*
- **Steve Weisberg**, So. Calif. Coastal Water Research Proj. Auth.
- **James Thomas**, Amgen
- **Pam Ronald / Raoul Adamchak**, Authors, “*Tomorrow’s Table*”

Medicine

Energy

Environment

Manufacturing

Agriculture

Outline of Plenary Talks:

- Sector overview
- Importance to society and the economy
- Vision for sector potential
- Major technological impediments to innovation
- Consequences of failure

“Accelerating Innovation in 21st Century Biosciences: Identifying the Measurement, Standards, and Technological Challenges”

Workshops and Expected Outcomes (Days 2 & 3)

- **2-day facilitated breakout session in each of the five focus areas to identify and prioritize measurement and standards challenges that significantly impede innovation.**
 - Co-chaired by Steering Committee member + outside subject matter expert
 - Facilitated discussions to identify measurement barriers – not propose solutions
 - 3-5 measurement and standards barriers expected from each Breakout Session
- **A sixth session to include short talks from industry, government, and academic experts in strategically important bioscience areas, followed by facilitated discussions to identify major measurement and standards barriers in topical areas such as:**
 - Stem cell therapy
 - Emerging microbiological threats
 - Gene therapy
 - Antibiotic and antiviral drug resistance
 - Transgenic plants and animals as biopharmaceutical sources

NIST Strategic Plan for Biosciences Program Growth: Four Publications Planned

- **Executive Summary of Draft Strategic Plan**

- Can be used as stand-alone document, tri-fold, or brochure for broad distribution including Executive Branch transition staffers and legislators
- Will also be included in the expanded reports for internal and external audiences

- **Draft Strategic Plan for External Audiences**

- Glossy document of approximately 30 pages (available in digital and hard copy formats)
- Suitable for public, but with enough details to satisfy decision-makers
- Forward-looking document

- **Draft Strategic Plan for Internal Audiences**

- Will expand on the external report and include additional details about needs assessment activities, current activities and initiative plans
- To be used to inform future decisions regarding priorities, growth and coordination of activities within and among NIST Operating Units

- **October Conference Report**

- To inform NIST leadership and the worldwide measurement and standards community of the highest priority barriers to innovation in the biosciences

Timeline for Post-Conference Activities

- Complete Executive Summary **December 08**
- Complete first draft of Strategic Plan and share draft with stakeholders **January 09**
- Complete draft Conference Report **January 09**
- Complete final Conference Report **April 09**
- Commence meetings with bioscience industry leaders and OA stakeholders to discuss: **March-August 09**
 - current NIST activities in the biosciences
 - draft plan for NIST biosciences program growth
 - measurement and standards needs not being addressed
- Complete Strategic Plan version.1 **October 09**



Thanks for Your Attention

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