

NIH BACKGROUNDER

National Institutes of Health

NIH Roadmap – Themes, Implementation Groups, and Initiatives

Theme: New Pathways to Discovery

Building Blocks, Pathways, and Networks Implementation Group

- National Technology Centers for Networks and Pathways. This network of research Centers will create new tools to describe the dynamics of protein interactions. The Centers will develop instruments, methods, and reagents for quantitative measurements at sub-cellular resolution and very short timescales.
- **Metabolomics Technology Development**. This initiative will promote development of novel technologies to study cellular metabolites, such as lipids, carbohydrates, and amino acids. Knowledge gained from these studies will be used to understand more precisely the role of metabolites in the context of cellular pathways and networks.
- Standards for Proteomics and Metabolomics/Assessment of Critical Reagents for Proteomics. Workshops will be convened to address these two important areas. The "Standards" workshops will engage the scientific community in the establishment of quality and data standards for proteomics and metabolomics. The "Reagents" workshops will seek advice from extramural and intramural scientists and program staff regarding critical reagents required to enhance future research in proteomics.

Molecular Libraries and Imaging Implementation Group

- Creation of NIH Bioactive Small Molecule Library and Screening Centers. These NIH-funded centers will provide: a public collection of chemically diverse small molecules; high-throughput screening (HTS) to identify compounds active in target- and phenotype-based assays; medicinal chemistry to transform hits into chemical probes; implementation of novel technologies, and deposition of screening data into a freely accessible public database.
- Cheminformatics. A database of chemical structures, properties, and activities will be established at the NIH National Center for Biotechnology Information, which will be integrated with other databases and the literature, and will link to data produced by the screening centers. Research-focused cheminformatics tools and funding for the development of improved tools will also be made available.

- **Technology Development**. Bottlenecks in the development of compounds as basic research tools and drugs will be targeted, including improvement of chemical diversity, assay flexibility, screening instrumentation/robotics, and prospective characterization of compounds' metabolism and toxicology properties.
- **Development of High Specificity/High Sensitivity Probes to Improve Detection**. This technology development program seeks to ultimately achieve a 1000-fold improvement in imaging probe detection sensitivity and optimal specificity for basic research and clinical applications.
- **Comprehensive Trans-NIH Imaging Probe Database**. This comprehensive database of imaging probes, with their specificities, activities, and applications will be integrated with the Molecular Libraries Cheminformatics database.
- Core Synthesis Facility to Produce Imaging Probes. This facility will produce known imaging agents for which there is no commercial supply, and generate novel imaging probes, for use in both basic research and clinical applications. The facility will draw from, and contribute to, the Molecular Libraries compound repository and screening activities.

Structural Biology Implementation Group

• **Protein Production Facilities**. This initiative will focus on the long-standing challenge of membrane-bound protein structure through the development of rapid, efficient and dependable methods to produce protein samples that scientists can use to determine the three-dimensional structure, or shape, of a protein.

Bioinformatics and Computational Biology Implementation Group

• National Centers for Biomedical Computing. This initiative will create a national software engineering system in which biologists, chemists, physicists and computer scientists anywhere in the country will be able to tap into a supercomputing network to share and analyze data, using a common set of software tools.

Nanomedicine Implementation Group

• **Planning for Nanomedicine Centers.** In FY 2004, a series of workshops will be held to plan for the launch of Nanomedicine Centers in FY 2005. These centers will focus on quantitative measurement of biological processes at the nanoscale and the engineering of new tools to intervene at the nanoscale or molecular level. This research will help scientists construct synthetic biological devices, such as miniature, implantable pumps for drug delivery or tiny sensors to scan for the presence of infectious agents or metabolic imbalances that could signify disease.

Theme: Research Teams of the Future

High-Risk Research Implementation Group

• **NIH Director's Innovator Awards**. These awards will provide support to a highly select group of individuals who have the potential to make extraordinary contributions to medical research. They will be evaluated in terms of their exceptional creative abilities, potential for ground-breaking discovery, evidence of focused and skillful habits of mind that predict perseverance and thorough exploration of his/her ideas, and prospects for making seminal biomedical research advances.

Interdisciplinary Research Implementation Group

- Interdisciplinary Research (IR) Centers. Planning grants will be awarded to begin IR programs that will address significant and complex biomedical problems, particularly those that have been resistant to more traditional approaches. Planning activities will include approaches to overcoming traditional institutional barriers to IR, which are intended to lay the foundation and prepare investigators for submitting a subsequent application for support through an IR Consortium.
- **Interdisciplinary Research Training Initiative**. This new model of funding will address-key issues critical to IR team science. Also, as IR will likely cross the borders of two or more NIH institutes and centers, the new model of support will allow each institute and center to support wholly components of a consortium that are relevant to its mission, even when the preponderance of research in a given consortial effort does not.
- **Innovations in Interdisciplinary Technology and Methods (Meetings)**. The goal of these initiatives is to facilitate interdisciplinary research, which includes the behavioral, and social sciences, by developing and improving methods and measurement.
- **Removing Structural Barriers to Interdisciplinary Research**. This initiative will help NIH remove business practice barriers that impede IR. For example, NIH only recognizes one principal investigator, and this minimizes the contributions of co-investigators. NIH program officials run focused programs within their area of scientific expertise, and this may not serve IR grant applications and grants well when the research involves areas outside of a single program official's area of specialized expertise.
- NIH Intramural Program as a Model for Interdisciplinary Research. As a corollary to the extramural IR Centers, this initiative will utilize the NIH Intramural Research Program (IRP) as a laboratory to demonstrate the feasibility, benefits and successes to establishing IR teams. Specifically, the IRP will serve as an excellent model for (1) providing Ph.D.'s with training and education in interdisciplinary translational research, and (2) building programs that bring interdisciplinary research teams together.
- Interagency Conference on the Interface of Life Sciences and Physical Sciences (See *NIH House Appropriations Report* 108-188, p. 94). In response to FY 2004 House

Appropriations report language for NIH and for the National Science Foundation, an interagency conference will be convened "to discuss what needs to be done to encourage progress in the physical sciences that will provide support and underpinning in the future for advances in the life sciences."

Public Private Partnerships Implementation Group

- **Designation of a Public-Private Sector Liaison**. Public-Private Partnerships enhance NIH research, training, and information activities. To expand such collaborations, the Public-Private Sector Liaison will serve as a resource to NIH staff on such partnerships, share best practices across the NIH by developing training and policies and procedures and chair an internal Public-Private Partnerships Coordinating Committee.
- **High-level Science-driven Partnership Meetings**. The Public-Private Sector Liaison, working with the Public-Private Partnerships Coordinating Committee, will identify scientific initiatives that could be accelerated, improved upon, or facilitated by public-private partnerships and that warrant a high-level meeting. The NIH Director will meet with senior officials in potential partner organizations to explore partnership opportunities.

Theme: Re-engineering the Clinical Research Enterprise

Clinical Research Implementation Group

- Harmonization of Clinical Research Regulatory Requirements. This initiative is intended to enhance the leadership and coordination of efforts to harmonize, standardize, and streamline Federal policies and requirements pertaining to clinical research, while emphasizing the integrity and effectiveness of Federal and institutional systems of oversight. As part of its stewardship responsibilities, NIH is responsible for taking steps to foster the responsible conduct of high-quality clinical research.
- **Integration of Clinical Research Networks**. The efficiency and productivity of the Nation's clinical research enterprise will be enhanced by promoting clinical research networks capable of rapidly conducting high-quality clinical studies and trials where multiple research questions can be addressed.
- Enhance Clinical Research Workforce Training. The early career development of clinical researchers engaged in all types of clinical research will be supported. These individuals would be expected to achieve excellence in their ability to design and oversee research in multi-disciplinary team research settings, as well as have a high potential to become leaders of various fields of clinical research critical to the overall mission of the NIH and research needs of the nation. In addition, a cadre of NIH National Clinical Research Associates will be established. This group will be composed of community-based practitioners who will receive specialized training in clinical research. These

Research Associates will play a critical role both in advancing the discovery process and in disseminating research findings to the community.

- Clinical Research Informatics: National Electronic Clinical Trials and Research Network (NECTAR). A standardized data system, the National Electronic Clinical Trials and Research Network (NECTAR), will be developed through a phased planning and development process. The network will allow community-based clinicians from the NIH Clinical Research Associates to participate in important national studies, facilitate the sharing of data and resources, and augment clinical research performance and analysis.
- **Translational Research Core Services**. This effort will facilitate the translation of basic discoveries to early phase clinical testing. It will provide bench and clinical investigators with cost-effective core services, including the expertise needed to move projects through complex logistical and regulatory barriers, and the technical services to synthesize chemical and biological agents for early phase clinical studies.
- **Regional Translational Research Centers**. These centers will increase interactions between basic and clinical scientists and accelerate the translational development of new drugs, biomarkers, and treatment strategies from the laboratory bench to clinical testing. New centers will provide essential core infrastructure and support, including specialized cores that provide expertise in biostatistics, clinical pharmacology, pharmacogenetics, and genetics.
- Enabling Technologies for Improved Assessment of Clinical Outcomes. There is a pressing need to better quantify clinically important symptoms and outcomes, including pain, fatigue, and quality of life that are now difficult to measure. Through this effort, new technologies will be developed and tested to measure these self-reported health states and outcomes across a wide range of illnesses and disease severities.