



Annotated Agenda

Wednesday, May 3

8:30 a.m. Opening and Welcome

The Health Research Alliance: Substantive Collaboration Among Private Funders of Health Research

Speaker: Nancy Sung, Ph.D., HRA Chair and Senior Program Officer, Burroughs Wellcome Fund

9:00—10:30 Plenary Session 1: The Changing Landscape for Medical Research

The Funding Environment for Biomedical and Health Research

A global overview of the impact of federal deficits, investment in bioterrorism research, regional disparities, and other factors on the federal funding environment for biomedical and health research. Where are the opportunities for private sector investment?

Speaker: Gail Cassell, Ph.D., VP, Scientific Affairs, Distinguished Lilly Research Scholar for Infectious Diseases, Eli Lilly and Company

Scientific Frontiers in Medicine

Where are the frontiers in medicine? How is genomics impacting research and practice? What are emerging strategies to spur development of therapies in orphan/neglected disease areas? Where are the innovations in translating clinical discoveries into better health?

Speaker: Jeffrey Trent, Ph.D., President and Scientific Director, Translational Genomics Research Institute (TGen)

10:30—11:00 Break

11:00—12:30 Plenary Session 2: Federal Initiatives in Clinical and Translational Research

An update on NIH's new Clinical and Translational Science Awards, as well as progress on the 're-engineering the clinical research enterprise' aspect of the NIH Roadmap and the FDA's Critical Path Initiative. What is new, what changes are still needed, what is the role of private funders?

Moderator: Gail Cassell, Ph.D., VP, Scientific Affairs, Distinguished Lilly Research Scholar for Infectious Diseases, Eli Lilly and Company

Update on the National Institutes of Health's New Clinical and Translational Science Awards

Speaker: Barbara Alving, M.D., M.A.C.P., Acting Director, National Center for Research Resources, National Institutes of Health

Update on the FDA's Critical Path Initiative

Speaker: Janet Woodcock, M.D., Deputy Commissioner for Operations, and COO, U.S. Food and Drug Administration

12:30—2:00 Lunch

Introduction to the Health Research Alliance and its working groups (Grants in the Health Research Alliance Shared Portfolio [gHRAsp], Program Evaluation, and Grants Administration)

2:00—3:30 Breakout Session #1 on Funding Partnerships

A. Translation: *Models for Developing Translational Infrastructure and Capacity*

Breakthroughs in molecular and genetic bases of disease have opened up vast therapeutic opportunities, underscoring the importance of research that can translate fundamental biological insights into clinical progress. This session will explore three different models that are at the cutting edge of translational research and that represent an evolving approach to building broad-based collaborative infrastructure to enhance the process of clinical research, and increasing the success rate of translating biomedical research into successful patient treatments.

Moderator: Bill Read, Ph.D., VP, Research and Technology, The Flinn Foundation

The Role of Novel Partnerships in the FDA's Critical Path Initiative

Ray Woosley, M.D., Ph.D., President, The Critical Path Institute

Accelerating Med-Tech Innovation: The Role of Foundations

John Linehan, Ph.D., Whitaker Foundation (retired) and Consulting Professor of Bioengineering, Program in BioDesign, Stanford University

Developing a Statewide Translational Research Network

Bill Read, Ph.D. VP, Research and Technology, The Flinn Foundation

B. Human Capital: *Building Research Networks and Funding Teams*

Translational research increasingly requires a diversity of skills and resources, such that the model of the individual investigator is less practical. Yet the culture of individual accomplishment in science is difficult to change. More foundations are moving to a project-based network approach to make progress on well-defined scientific and clinical challenges. Participants will discuss their rationale, experience, and results in building such networks.

Moderator: David Tancredi, M.D., Scientific Director, Fondation Leducq

International Networks in Cardiovascular Research

David Tancredi, M.D., Scientific Director, Fondation Leducq

The Multiple Myeloma Research Consortium: Lessons Learned

Kathy Giusti, M.B.A., CEO and Founder, Multiple Myeloma Research Foundation and Multiple Myeloma Research Consortium

A New Model for an Outcome-Directed Research Collaboration

Rusty Bromley, M.S., COO, Myelin Repair Foundation

The Brain Tumor Funders' Collaborative: A Virtual Organization

Rita D. Berkson, M.P.H., Executive Director, Goldhirsh Foundation, Brain Tumor Funders' Collaborative

C. Community: *Models of Community-Based Participatory Research*

Community-based participatory research (CBPR) is a paradigm of health research that engages community members in the collective analysis of complex problems and has the purpose both to gain knowledge and produce change in public health. Partnerships between communities and academic centers often form the basis, but the traditional distinction of "researcher" and "subject" is blurred as all parties are engaged in the research. The panel will discuss principles of CBPR, provide a case study of a successful project, describe challenges and benefits of CBPR, and explore strategies for the funding and peer review of CBPR proposals. Resources for continued learning about CBPR will also be shared.

Moderator: Marc Hurlbert, Ph.D., Senior Consultant, Grants and Partnerships, Avon Foundation

Community-Based Participatory Research: A Partnership Approach for Conducting Health Research

Barbara Israel, Dr.P.H., Professor, University of Michigan School of Public Health

Donele Wilkins, Executive Director, Detroiters Working for Environmental Justice

Community-Based Participatory Research: Moving the Field Forward

Sarena D. Seifer, M.D., Executive Director, Community-Campus Partnerships for Health

4:00—5:30 Breakout Session #2 on Funding Partnerships

D. Translation: Disease-oriented Models of Drug/Vaccine Development

Therapies and vaccines for the so-called orphan and neglected diseases often remain undeveloped because they afflict a small or impoverished population and thus do not guarantee a revenue stream to the developer. In response some funders have moved into the gap, absorbing the risk of funding drug discovery and development with the goal of adding new drugs or vaccines to the pipeline for these diseases. Participants will discuss their experiences, results, and remaining challenges.

Moderator: Michael Katz, M.D., Senior VP for Research and Global Programs, March of Dimes

The Medicines for Malaria Venture: A Public/Private Partnership for Drug Development

Queta Bond, Ph.D., President, Burroughs Wellcome Fund

Creating Drugs for People with Cystic Fibrosis

Suzanne R. Pattee, J.D., VP of Public Policy and Patient Affairs, Cystic Fibrosis Foundation

JDRF Experiences with "Cure Therapeutics"

Robert Goldstein, M.D., Ph.D., CSO, Juvenile Diabetes Research Foundation International

E. Human Capital: Career Development of Clinical Investigators

Individual academic investigators are the lifeblood of the clinical research enterprise, yet there are many disincentives to establishing a career in academic medicine, no matter what disease area is of interest. This panel will describe recent recommendations from the Association of American Medical Colleges to reform training and structures for clinical research within institutions. It will also highlight outcomes and plans for training coming from the National Institutes of Health, as well as a new Howard Hughes Medical Institute program to provide clinical research training to basic scientists.

Moderator: Scott Campbell, Ph.D., National VP, Research Programs, American Diabetes Association

A Private Funder's Approach to Developing Biomedical Researchers

William Galey, Ph.D., Director, Graduate & Medical Education Programs, Howard Hughes Medical Institute

NIH Career Development Awards ("K" Awards)

James F. Hyde, Ph.D., Senior Advisor, Research Training Programs, NIDDK

The Role of Academic Medicine in Nurturing Translational and Clinical Research

David Korn, M.D., Senior VP for Biomedical and Health Sciences Research, Association of American Medical Colleges

F. Community: Regional Models for Influencing State Policy

This panel will review state funding of health research and highlight recent models/case studies for influencing state policy and involvement in health research. State support of health research is substantial, estimated to be about \$2.0-\$2.4 billion annually; however, data on support is limited and is not collected by any single national organization. Over the past 10 years, increased state support for health research has resulted from, among other issues: (i) the tobacco settlement of 1998; (ii) policy discrepancies between federal and state governments; particularly related to research involving stem cells; and (iii) an increase in community members desire to be involved with health research issues related to their communities.

Moderator: John Murphy, M.S., President, The Flinn Foundation

State/Regional Partnerships in the Biosciences

Walter H. Plosila, Ph.D., VP, Technology Partnership Practice, Battelle Memorial Institute

California's Stem Cell Research Initiative: Science, Advocacy, Politics and the Public Trust

Philip A. Pizzo, M.D., Dean, Stanford University School of Medicine

Building Strategic Partnerships to Advance Health Research

John Murphy, M.S., President, The Flinn Foundation

Show Me Partnerships! Founding the Missouri Bio-Belt

Susan M. Fitzpatrick, Ph.D., VP, James S. McDonnell Foundation

6:00 Reception and Dinner

The Importance of Science from the Perspective of a Patient Advocate

Speaker: Margery Perry, Chair of Research Emeritus, Juvenile Diabetes Research Foundation Intl.

Thursday, May 4

7:00—8:00 Breakfast Roundtables: A list of topics is posted at the Registration Desk. Table topics will be identified by tent cards on the tables on topics of interest (electronic grantmaking, program evaluation, patient advocacy, reviewer conflicts of interest, and other topics)

8:15—9:00 Plenary Session 3: Translating Research into Practice

Where are the emerging opportunities for private funders to improve the evidence base for and dissemination of good clinical practice?

Speaker: Carolyn M. Clancy, M.D., Director, Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services

9:00—9:30 gHRAsp: The Online Searchable Database “Grants in the Health Research Alliance Shared Portfolio”

gHRAsp is a collaborative resource under development that will consolidate award information among non-governmental funders of health research, to provide information useful for strategic planning and decisionmaking.

Speaker: T.J. Koerner, Ph.D., Director of Research Information Management, American Cancer Society, and members of the gHRAsp Working Group

9:30—10:30 Breakout Session #1 on Operational Issues

G. Encouraging the Mentoring of Early-Career Clinical Investigators and Scientists

This session, through a series of presentations, a group discussion, and a time for questions, will seek to address: What are some of the existing mechanisms for mentoring researchers who are beginning their careers? What are their goals and results? Is mentoring essentially the same across the career spectrum, or are there mentoring needs that are specific to each “population” of mentees? How do you measure mentoring to determine if it has an impact? (See full description included in packet.)

Moderator: Virginia Krawiec, M.P.A., Director, Health Professional Training Grants, American Cancer Society

The Health Research Alliance Mentoring Projects

Virginia Krawiec, M.P.A., Director, Health Professional Training Grants, American Cancer Society

History and Analysis of a Mentored Clinical Investigator Award for Cancer Research

Jennifer McCafferty-Cepero, Ph.D., Scientific Director, Damon Runyon Cancer Research Foundation

Mentoring: Insights Into the Satisfied Trainee

Victoria McGovern, Ph.D., Senior Program Officer, Burroughs Wellcome Fund

Mentoring Via a Consortium

Lori Conlan, Ph.D. Program Manager, Science Alliance, New York Academy of Sciences

H. Managing Donor Activism in the Peer-Reviewed Science Process

This interactive session is designed to provide participants with a common understanding of the concept of “donor activism;” exposure to a range of policies from a variety of funders on sponsoring research; examples of strategies for managing donor expectations; and examples of strategies for leveraging donations to move an organization’s science agenda forward. (See full description included in packet.)

Session Organizer and Speaker:

Maria Carrillo, Ph.D., Director, Medical and Scientific Affairs, Alzheimer’s Association National Office

10:30—11:00 Break

11:00—12:00 Breakout Session #2 on Operational Issues

I. Starting from Scratch: A Biomedical Funding Tutorial for New or Small Foundations

This session, through presentations, handouts, and response to audience questions, is designed to help participants understand NIH definitions of basic, translational and clinical research; be aware of issues to consider when creating a grants program; learn how to write a Conflict of Interest Policy for Scientific Review Committee members; and become familiar with the necessary steps in managing a grants program. (See full description included in packet.)

Session Organizer and Speaker:

Sally McNagny, M.D., M.P.H., VP, The Medical Foundation

J. Intellectual Property and Royalty Issues: Preclinical Drug Discovery and Development

Through a series of presentations, a group discussion, and a time for questions, this session will examine how funding agencies can protect access to IP rights or licenses to technology that are critical for drug development; when it is appropriate or desirable for funding agencies to ask for royalties on IP developed with their grant support; and how IP and royalty issues should differ when grants are made to academic or industry grantees. (See full description included in packet.)

Moderator: Michelle Cissell, Ph.D., Associate Director for Strategic Planning, Juvenile Diabetes Research Foundation International

NIH Policies on Intellectual Property Protection, Licensing, and Royalties

Susan Rucker, Esq., Senior Technology Licensing Specialist, NIH Office of Technology Transfer

How Funders Can Drive the Therapeutics Pipeline and Manage IP: The CFF Experience

Suzanne R. Pattee, J.D., VP of Public Policy and Patient Affairs, Cystic Fibrosis Foundation

Acquiring Patent Rights To Gene Sequences: Adding to the Portfolio of Tools to Accelerate Drug Discovery

Cynthia Joyce, M.S., Executive Director, Spinal Muscular Atrophy Foundation

12:15—1:30 Lunch and Closing Plenary: *Mechanisms for Accelerating Drug Development for Orphan Diseases*

How is the financing of drug development changing? Where are the opportunities for non-profit funders to partner with venture capital firms and biotech companies? What do academic scientists need to know if they aim to develop their discoveries into approved therapies?

Speaker: Tom Caskey, M.D., F.A.C.P., Executive VP for Molecular Medicine & Genetics, The University of Texas Health Science Center at Houston

1:30 Adjourn