



Heal, Fuel, Feed  
The World.

## **Federal Science & Opportunities**

### **How to Partner with Government**

**Tuesday, May 19: 8:00 AM - 9:30 AM**

**B408**

The Federal Government is a tremendous resource for the new start-up through to big Pharma because federal agencies, such as CDC, FDA and NIH, are able to provide funding, people, materials, technologies, pre-clinical testing and access to clinical sites that would otherwise be difficult, if not impossible, for those on a limited budget to harness. Panel members from Food and Drug Administration (FDA), National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) This panel of NIH, CDC and FDA officials will describe the main avenues of access to the following resources:

Research Funding Opportunities (Grants, Contracts, SBIR/STTR)

The advantages of collaboration with and/or licensing from the Government to tap into federally developed technologies. Research resources (examples):

- Data mining tools
- Clinical trial networks
- In-vitro and in vivo screening programs
- Pharmacokinetic and animal toxicology testing
- Clinical-grade gene vector repositories
- Human organ, tissues and cell repo

Chair:

Anna Amar, Lead Technology Development Associate, National Institute of Allergy & Infectious Diseases

Speakers:

- Greg Evans, PhD, Program Director & Team Leader, Cancer, National Cancer Institute
- Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention
- Chekesha Clingman, PhD, LCDR, United States Public Health Service & Senior Scientific Program Manager, U.S. Food and Drug Administration

## **Regulatory Science and Perspectives: Scientific Priorities at FDA**

**Tuesday, May 19: 8:00 AM - 9:30 AM**

**B409**

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of medical products, our nation's food supply and cosmetics. The FDA is also responsible for advancing the public health by helping to speed scientific innovations that make medicines and foods more effective, safer, and more affordable. In support of the Agency's mission, the FDA has taken steps to enhance its existing regulatory science infrastructure and to prepare for future regulatory challenges through expansion of efforts to address critical gaps in scientific priority areas such as genomics, nanotechnology, rapid detection and regenerative medicine. Panel members from the FDA will discuss agency initiatives and programs in the aforementioned priority areas.

Provide an understanding of the FDA Genomics Initiative and ongoing work in the different Centers at FDA.

Outline the goals of the FDA Nanotechnology Task Force and related efforts dedicated to evaluating and improving the safety of nano-engineered medical products.

Discuss ongoing interagency activities to facilitate the development and implementation of rapid detection methodologies and regenerative medicine products.

Chair:

Jesse Goodman, MPH, Acting Chief Medical Officer, U.S. Food and Drug Administration

Speakers:

Elizabeth Mansfield, PhD, Senior Genomics Advisor to the Chief Scientist, U.S. Food and Drug Administration

Norris Alderson, PhD, Associate Commissioner for Science, U.S. Food and Drug Administration

Steven Musser, PhD, Director, Office of Regulatory Science, U.S. Food and Drug Administration

Keith Wonnacott, PhD, Chief, Cell Therapy Branch, U.S. Food and Drug Administration

## **Hot Federal Biotechnologies Available for Collaboration**

**Tuesday, May 19: 10:00 AM - 11:30 AM**

**B408**

Learn about the innovative, cutting-edge research being conducted at PHS Federal Laboratories in Pharmaceuticals and Biotechnology. The Federal Government partners with industry through collaboration and out-licensing. Federal labs can interact directly with industry to translate research results into commercial products that benefit public health. For example, biological material licenses are used to make research tools available, while non-exclusive and exclusive licensing has been utilized for the commercialization of an array of both Pharmaceuticals (Fludara<sup>®</sup>, Gardasil<sup>®</sup> Taxol<sup>®</sup>, and Velcade<sup>®</sup>) and Diagnostics products (PixCell<sup>®</sup> Laser Capture Microdissection system, AIDS test kits, QuickTox<sup>™</sup> Kit, and West Nile Detect<sup>™</sup>ELISA system), as well as for Vaccines (West Nile-Innovator<sup>®</sup> DNA). This is a great opportunity to capture emerging PHS technologies available for collaborations and licensing.

Highlight several technologies available for collaboration and licensing at the NIH, FDA and CDC.

Demonstrate the breadth of technologies available for collaboration and licensing from the Federal laboratories.

Present early stage, pre- market application, emerging research and clinical applications available at the NIH, FDA, and CDC.

Chair:

Vio Conley, MS, Technology Transfer Specialist, National Institutes of Health

Speakers:

Melissa Maderia, Technology Transfer Specialist, National Institutes of Health

Rosemary Walsh, Technology Development Associate, National Institutes of Health

John Hewes, Technology Transfer Specialist, National Institutes of Health

Suzanne Seavello Shope, Technology Licensing & Marketing Specialist, Centers for Disease Control and Prevention

## **Use of Products during Public Health Crisis: Focus on Emergency Use Authorization (EUA)**

**Tuesday, May 19: 10:00 AM - 11:30 AM**

**B409**

Blood products, and biologic therapeutics), and devices (e.g., in vitro diagnostics) that did not have FDA approval or FDA approval for their intended use could only be used under an Investigational New Drug (IND) protocol during a public health emergency. An Emergency Use Authorization (EUA) is a mechanism that can be used to enable the large-scale and timely deployment of medical countermeasures during emergencies. Panel members from Biomedical Advanced Research and Development Authority (BARDA), Food and Drug Administration (FDA), National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) will discuss the will discuss the regulatory and research implications of EUA on countermeasure R&D. Session format will include robust and interactive question and answer opportunities.

To understand the early development of the medical countermeasure pipeline at NIH and the potential handoff to BARDA for advanced development.

To understand the statutory framework and how the EUA mechanism facilitates the use of promising medical countermeasures that do not have FDA approval or FDA approval for the intended use.

Factors FDA considers during the review of a pre-EUA or EUA request.

Chair:

Tanja Popovic, PhD, MD, Chief Science Officer, US Department of Health & Human Services

Speakers:

Debra Yeskey, Director, Regulatory and Quality Affairs Division, US Department of Health & Human Services

Carmen Maher, Commander/Senior Nurse Officer & Policy Analyst, U.S. Food and Drug Administration

Michael Kurilla, Director, Office of Biodefense Research Affairs; Associate D, National Institutes of Health

## **Federal Laboratory Consortium**

**Tuesday, May 19: 2:00 PM - 3:30 PM**

**B408**

More than 250 U.S. federal laboratories and research centers – representing almost all U.S. federal departments and agencies - conduct over \$100 billion in research and development annually and employ more than 100,000 scientists and engineers. To capitalize on this investment, the knowledge and technologies created in these facilities must be brought to the marketplace. The Federal Lab Consortium for Technology Transfer (FLC) is the U.S. government-wide forum for developing strategies to link U.S. federal lab technologies and expertise with the marketplace. Our members are responsible for implementing technology transfer efforts at their respective U.S. federal labs. This session highlights U.S. federal lab capabilities, means for identifying federal lab partners and mechanisms to facilitate collaboration with those partners; with several case studies highlighting collaborative efforts between federal labs and their partners to bring assistive technologies to market. These assets will be highlighted at the National, Regional, Agency and lab levels.

Learn how FLC can be a resource to the biotechnology industry.

Discover the Technology Locator and how to use it.

Discover the benefits of and how to get involved with the FLC in your respective Regions.

Chair:

Mojdeh Bahar, CLP Chief, Cancer Branch, NIH Office of Technology Transfer

Speakers:

Gary Jones, MBA, Washington DC Representative, Federal Laboratory Consortium for Technology Transfer

Clara Asmail, SBIR Program Manager, National Institute of Standards & Technology (NIST)

Don Nordlund, Technology Transfer Coordinator, US Department of Agriculture

## **Biomedical Computing and Improved Health Care**

**Tuesday, May 19: 2:00 PM - 3:30 PM**

**B409**

Organizing the volume and complexity of biomedical data is a challenge we all need to address in order to more effectively make the bench to bedside translation. There are challenges in data generation, collection, organization, analysis, and security. This session will present the audience with current work at federal agencies addressing the handling and computing of biomedical data. Building of BioGrids and their applications toward improving public health and intelligent biomedical computing will also be discussed.

To learn how handle high throughput and high content biomedical data is handled at different Government agencies.

To discover current thinking in FDA regarding e-regulatory environment, including challenges and issues related to data submission.

To increase awareness of current federal science directed toward use of biomedical computing to improve bench to bedside translation.

Chair:

Jonathan Levine, PhD, Senior Scientific Policy Analyst, U.S. Food and Drug Administration

Speakers:

Weida Tong, PhD, Director, Center for Toxicoinformatics, US Department of Health & Human Services

Elizabeth Neuhaus, PhD, Computational Science Specialist & Team Lead, US Department of Health & Human Services

James Sorace, MD, Medical Officer, US Department of Health & Human Services

Tom Savel, MD, Director, Informatics R&D Laboratory, US Department of Health & Human Services