PUBLIC-PRIVATE PARTNERSHIP PROGRAM

PPP ADVISOR

VOLUME 1 – ISSUE 6
FALL 2009

MESSAGE FROM THE DIRECTOR

Dr. Barbara B. Mittleman

Another summer has passed, projects as a result of the American Recovery and Reinvestment Act of 2009 are settling down, and partnerships are still moving full steam ahead. We welcome Dr. Francis S. Collins back to the National Institutes of Health (NIH) as the new NIH Director. Developing more public-private partnerships was featured among Dr. Collins' five priorities for his tenure as NIH Director.

We welcome back the Public-Private Partnerships Coordinating Committee (PPPCC) after a summer hiatus and hope this year's series of discussions and speakers will prove useful and informative. We have chosen to connect the 2009-2010 PPPCC speaker series thematically, focusing on "Partnering with Industry." You will find the fall lineup of speakers on the back page of the newsletter in the calendar. We have included speakers from academia with both expertise in studying how partnerships work and specific experience in partnering in other industries such as automotive and aerospace; the perspective from the business/strategic and legal departments of several companies; and discussions by NIH's own Office of the General Counsel and the Foundation for the NIH to provide some information about what can and should (not) be done.

Also coming up this fall is a very exciting and extremely broadly based conference—the mHealth (Mobile Health) Summit, October 29 and 30 at the Ronald Reagan Building in Washington, D.C. The focus of this 2-day conference will be to examine the role of mobile technologies in health-related and health care research and delivery, particularly for underserved populations in the United States and abroad. NIH Institutes and Centers (ICs) involved in planning the Summit include the Fogarty International Center, National Cancer Institute, National Library of Medicine, National Center on Minority Health and Health Disparities, National Institute on Drug Abuse, National Institute of Child Health and Human Development, National Center for Research Resources, National Institute of Biomedical Imaging and Bioengineering, and National Heart, Lung, and Blood Institute. We have a number of very exciting keynote speakers, including Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services; Francis S. Collins, Director, NIH; Thomas Frieden, Director, Centers for Disease Control and Prevention; Dr. Richard Sezibera, Rwandan Minister of Health; Elizabeth Bagley, Ambassador, Special Representative for Global Partnerships, U.S. Department of State; and Eric Goosby, Ambassador, U.S. Global AIDS Coordinator, U.S. Department of State. Participants and speakers are coming from all over the world, and registration is at the full capacity of 650. Late registration will be accepted for a waiting list. On October 28, one day before the Summit, two satellite meetings will be held, one sponsored by The World Bank

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SPOTLIGHT

The National Institutes of Health (NIH) Public-Private Partnership Program is pleased to include in this issue several guest feature articles authored by NIH staff members. Anthony Suffredini, M.D., Senior Investigator, Critical Care Medicine Department, Clinical Center, provides a review of the development of an endotoxin public-private partnership; Mark David Lim, Ph.D., Acting Program Director for the NCI Program for Innovative Molecular Analysis Technologies (IMAT), National Cancer Institute, provides an overview of the IMAT program, which has initiated several partnerships. Also included is an article from Richard Scarfo, Director of Marketing, Communications and Strategic Alliances/Foundation for the NIH (FNIH), featuring information about the upcoming mHealth Summit scheduled for October 29 and 30 in Washington, D.C. The mHealth Summit is a public-private partnership of the FNIH, the NIH, and many others that will bring together researchers, technology experts, and policymakers in the public sector from around the world to exchange and discuss ideas surrounding mobile technologies in the future for health research and health care delivery.

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and another sponsored by the U.S. Department of State/The President's Emergency Plan for AIDS Relief (PEPFAR). Both of these meetings will focus on the use of mobile technologies within their own sponsored programs. Participants from both The World Bank and U.S. Department of State meetings will then join the mHealth Summit, which we expect to result in a number of partnership activities between many of the sponsoring and/or participating organizations.

During the summer months, we launched collaboration with an academic group to develop a case study regarding the partnership model and functioning of The Biomarkers Consortium (BC). The process is expected to take as much as 2 years, involve interviews with many BC stakeholders and participants, and result in scholarly papers to contribute to the peer-reviewed literature. We hope to extend this kind of effort to encompass other activities to contribute to the rigorous assessment of public-private partnerships and the benefits that derive from them.

As the summer closed, the NIH Program on Public-Private Partnerships (PPPP) staff finished a 2-year review of PPPP activities. The information is available for your review on request, but, in short, we have seen a steep rise in the number and type of outside organizations with which we have interacted as time has gone on. We have interacted with all of the NIH ICs and with many components within some of the ICs, have spoken and presented at a variety of scientific and organizing meetings, and have helped by providing advice, reviewing documents, and making connections between NIH-ers and outside entities. We represent the NIH in a number of settings, provide advice to the Canadian Government as it tries to formulate how to do PPPs for biomedical research and to translate scientific discovery to improvements in health and economic growth, and interact with our counterparts in the European Union.

Looking forward to a full and active year, and as always, we are here to help you! ❖

Best regards,
Barbara

PPP Program Staff
Barbara B. Mittleman, M.D., Director
Shawnmarie Mayrand-Chung, Ph.D., J.D., NIH Program Director for The Biomarkers Consortium
Wendy B. Smith, M.A., Ph.D., BCIAC, NIH Program Director for Clinical Research Partnerships
Marjorie A. Bonorden, Program Analyst

Catalyzing Innovation by Supporting Risk-Taking: *The National Cancer Institute's Program for Innovative Molecular Analysis Technologies (IMAT)*

Dr. Mark David Lim, Acting Program Director, NCI IMAT Program

DNA microarrays and polymerase chain reaction are examples of a concept that at its inception was highly innovative but whose translation from theory to application was considered to be extremely risky. Fortunately, innovators pursued the development of these powerful tools, which have been essential for increasing our scientific knowledge base and advancing our understanding of the underlying forces behind disease progression. Such technologies are now commonplace in research and training laboratories, so it is easy to forget that the pipeline for their dissemination is full of bottlenecks that require a high level of technical expertise and financial support.

In 1998 the National Cancer Institute (NCI) recognized the importance of out-of-the-box approaches for cancer technologies and created the program for Innovative Molecular Analysis Technologies (IMAT, http://innovation.cancer.gov) as an investment in the potential of innovation to revolutionize its mission for reducing the burden associated with cancer.

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Catalyzing Innovation by Supporting Risk-Taking: *The National Cancer Institute's Program for Innovative Molecular Analysis Technologies (IMAT)* *(continued from page 2)*

The emphasis is on supporting high-risk and high-payoff innovations, which, if successful, would revolutionize cancer research and medicine. As an investigator-initiated program, its intent is to catalyze the development of a technology that at the time of its inception may have few to no data demonstrating its feasibility. By focusing on the scientific development of a technology, the investigator has the support to obtain the pretechnology transfer feasibility data regardless of whether its end goal is widespread dissemination via licensing/intellectual property protection or through publication of the methodology to advance hypothesis-based research. The IMAT is a transdivisional program, allowing individual investigators to access the resources at the NCI and direct the application of their technologies in the areas of cancer biology, prevention, therapy and detection, and control and epidemiology or as tools for the reduction of cancer-associated disparities.

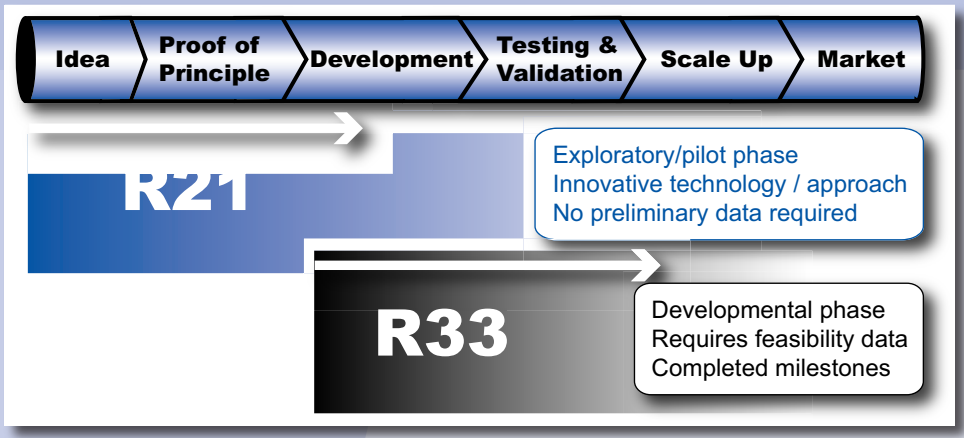

Figure 1. The IMAT's funding mechanisms to support the pipeline for innovation.

Recognizing that most innovative ideas cannot be anticipated, the IMAT's philosophy is to allow the investigator to identify the unmet need in cancer research and medicine and define how the use of the proposed technology will address that need. To jumpstart and advance innovation, the IMAT utilizes the NIH R21 and R33 funding mechanisms to support the inception, development, and validation of an innovative or emerging cancer technology (Figure 1). Innovative technologies are those that promise to be better, faster, and/or cheaper than the current state of the science and that have not yet been fabricated; the latter are innovative platform technologies that have not yet demonstrated feasibility in an intended use. The only targeted and solicited need is in the area of "sample preparation" technologies. This theme addresses those technologies that can maximize the utility and value of a human specimen (biospecimen) or the analytes derived from a biospecimen. For example, it would provide the ability to assess or minimize the introduction of preanalytical variations that occur with biospecimen collection, handling, processing, and/or storage or those technologies that can better preserve isolated analytes such as RNA for downstream research. More information about the biospecimen sciences can be obtained from the NCI Office of Biorepositories and Biospecimen Research (http://biospecimens.cancer.gov).

The environment that encourages and nurtures risk-taking innovation is constantly in flux and depends on at least a couple of universal factors that directly impact the investigator. The financial climate is an obvious one, especially as private and public sources of capital become increasingly competitive. The IMAT's scope supports the establishment of technical metrics that still may not be adequate in this increasingly competitive environment. To address this concern, which is not limited to IMAT investigators, technology incubators have emerged and have become essential precommercialization entities at the university, regional, and State levels. This tier of support allows a technology with a minimal level of feasibility data to further mature and become more competitive for Small Business Innovation Research (SBIR) opportunities or private equity. The infrastructure that they provide to the investigator has become an important component of the pipeline to commercialization as they provide the essential mentorship, infrastructure, physical resources, and exposure needed for an investigator to address the business and market concerns expressed by those who can offer larger financial capital support. The IMAT has initiated several partnerships with established technology incubators to explore the possibility of providing opportunities for mentorship/resources to IMAT investigators who may not have access to their knowledge base and network. As part of the partnership, these incubators are encouraged to advise their local investigators about appropriate opportunities available from the IMAT, as well as serve as a gauge to the innovation environment.

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Catalyzing Innovation by Supporting Risk-Taking: *The National Cancer Institute's Program for Innovative Molecular Analysis Technologies (IMAT)* *(continued from page 3)*

Another factor that is a bottleneck for innovation and translational science is the difficulty in identifying the unmet needs for novel technologies. For example, a molecular biologist with a scientific breakthrough may realize that it is just the start of a series of additional hypothesis-based research but may not realize that there is a direct application that can be engineered from this finding and that this technology could be used to further the scientist's hypothesis. Conversely, an engineer who develops a novel tool that pushes the limits of detection may not be able to identify an application in the biomedical sciences. Bridging these two groups together lies at the heart of the IMAT's mission. Since unmet needs are not limited to the United States, the IMAT has begun partnerships with various international bodies that are similarly focused on advancing biomedical innovation. For example, the Quebec Consortium for Drug Discovery (CQDM) is a public-private partnership focused on developing technologies that can advance the drug discovery process. Its first pilot grants awarded for 2008-2009 include supporting the development of technologies that have the potential to accelerate research into diabetes and Alzheimer's disease, and the development of novel vaccines. The IMAT has formed a partnership with the CQDM as a way for both programs to evaluate how they support open innovation, address and reduce deficiencies, and explore methods of generating "technology wish-lists" that could be disseminated to its investigators and the general public. Similar partnerships are also being explored with other international groups.

In addition to international and domestic partnerships, the IMAT seeks partners at other NIH Institutes since a majority of its investigators have created technologies that have broader implications beyond cancer. Envisioned in these partnerships are academic exercises that would identify bottlenecks to innovation from the perspective of the different institutions, using the power of collective brainstorming to address those barriers. ❖

2009 mHealth Summit Launched by the Foundation for the National Institutes of Health

Mr. Richard Scarfo, Director of Marketing, Communications and Strategic Alliances, Foundation for the National Institutes of Health

Keynote Addresses From Secretary Sebelius and Dr. Francis S. Collins To Open Summit

The Foundation for the National Institutes of Health (FNIH) has launched the 2009 mHealth Summit, scheduled for October 29 and 30, 2009, at the Ronald Reagan Building in downtown Washington, D.C.

The 2009 mHealth Summit, a public-private partnership of the FNIH, is an unprecedented event that will bring together researchers, policymakers, collaborators, and visionaries from around the world to exchange ideas, novel approaches, research, and findings surrounding mHealth issues in both the United States and developing countries.

The Mission

The mission of the Summit is to explore the use of mobile technologies to improve public health, particularly for underserved populations; to expand health research, training, and education applications; and to enhance delivery systems in the United States and around the world.

This 2-day Summit is an example of how the FNIH and the National Institutes of Health (NIH) can lead and work together to identify and address complex scientific and health issues and bring together diverse stakeholders to leverage their wide-ranging strengths and resources.

The Partners

The FNIH has partnered with the NIH and a host of leaders at the forefront of the search to find global health solutions. Supporting partners include the Robert Wood Johnson Foundation, Rockefeller Foundation, United Nations Foundation/The Vodafone Foundation Technology Partnership, President's Emergency Plan for AIDS Relief, U.S. Agency for International Development, and The World Bank.

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2009 mHealth Summit Launched by the Foundation for the National Institutes of Health (CONTINUED FROM PAGE 6)

The Summit also includes industry support in the form of sponsorships. Partnering sponsor Microsoft Research will join other sponsors: Abbott Fund, Battelle Memorial Institute, Becton Dickinson and Company, Johnson & Johnson, and Pfizer, Inc.

The Goals

This Summit will bring together domestic and international researchers and policymakers with mobile technology experts and visionaries. Within this context, the goals are:

- to assess current policies regarding mobile health technologies and their use in reducing or eliminating domestic and global health disparities
- to build a bridge between clinical and biomedical researchers and mobile technology experts
- to foster integration of mobile and medical technologies to improve the delivery of health care to underserved populations

At the conclusion of the Summit, leaders from the FNIH, NIH, government, industry, and the nonprofit sector will gather for a private session. This executive-level group will explore and craft a vision for the integration of biomedical research with mHealth technologies and a plan to move forward on a collaborative basis. Ongoing working groups are expected to result from these deliberations.

The Genesis and the Gap

Although biomedical researchers are entrenched in the science of public health and although, concurrently, mobile technologies offer the potential for complementing and extending the clinical ability of researchers to reduce health disparities around the world, until this Summit, there has been limited dialogue between scientists and technologists. Similarly, there has been limited research to assess the efficacy and potential of a cross-disciplinary approach for accelerating service to meet the needs of underserved populations, domestically as well as internationally. The mHealth Summit will help fill these gaps.

Keynote Presenters and Summit Program

A number of leaders will deliver keynote addresses over the 2-day Summit: Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services; Dr. Francis S. Collins, Director, National Institutes of Health; Dr. Thomas R. Frieden, Director, Centers for Disease Control and Prevention; Ambassador Elizabeth Frawley Bagley, U.S. Department of State Special Representative for Global Partnerships; and Ambassador Eric Goosby, U.S. Global AIDS Coordinator.

These leaders will set the tone for generating unprecedented insights, and their participation underscores the roles of current policies and ongoing initiatives relevant to the ability of mobile health technologies to deliver on the promise of reducing or eliminating domestic and global health disparities.

The 2-day Summit is unique in its multidisciplinary approach. This is the first event to explore the role of biomedical research as the driver for the development of compelling applications based on mobile technology. The program will comprise a series of case studies and panel discussions that will be complemented by small exhibits and posters.

Case Study Presentations

- Point-of-Care Diagnostics and Remote Patient Monitoring
- Remote Data Collection and Surveillance
- Public Health Education
- Healthy Behavior Change and Well-Being Promotion

Panel Discussions

- Security, Ethics, and Privacy
- Capacity
- Visionaries

The mHealth Summit will be preceded by a related program sponsored by The World Bank and focused more specifically on policy issues surrounding mHealth. This pre-Summit event, "From Policy to Implementation," will take place at The World Bank headquarters in Washington, D.C. This meeting is by invitation only but will complement the content of the mHealth Summit.

For additional information about the mHealth Summit or the FNIH, please contact Richard Scarfo at 301-496-9921.

To register for the mHealth Summit, please visit www.fnih.org. ❖

Developing and Sharing a Unique Clinical Research Tool: *Endotoxin and the Public-Private Partnership*

Dr. Anthony F. Suffredini, Critical Care Medicine Department, Clinical Center, National Institutes of Health

Endotoxin as a Tool To Study Innate Immunity

Integrating human physiology with inflammatory mechanisms discovered in vitro is an essential step to defining the relevance of these mechanisms in health and disease. Although nonhuman animal models often provide insight into their significance, there are multiple differences in human host immunity that require further refinement with clinical investigation.[1] The availability of reagents to study inflammation in humans in vivo is an essential part of this process.

Innate immunity is the highly conserved defense strategy that protects multicellular organisms from infection. It is composed of cell-associated and circulating proteins that recognize molecular structures associated with microbes. Within minutes of ligand-receptor binding, myeloid and lymphoid cells as well as humoral proteins are activated.[2] The resultant cascade of inflammatory events recruits inflammatory cells and proteins to the nidus of infection, killing the microbe and initiating repair of damaged tissue. Adaptive immune responses are facilitated by these responses, resulting in long-term, highly specific immunity to the microbe.

Endotoxin is a major structural component of the wall of gram-negative bacteria and is the archetypical microbial factor that mediates inflammation associated with these infections. It is both a mediator of shock when present during serious infections and under other circumstances a potent immunostimulant.

The administration of endotoxin or lipopolysaccharide to humans has occurred over the past century as both a tool to understand human inflammatory responses to microbes and a novel therapy for malignancies.[3-5] When administered intravenously in small doses to humans, endotoxin elicits a series of events similar to the initial phases of a true infection (i.e., fever, increases in heart and respiratory rates and leukocyte count, and decrease in blood pressure as well as the induction of a wide spectrum of host inflammatory genes and proteins). When directly instilled or inhaled into the lungs, endotoxin elicits brisk local inflammatory responses in the pulmonary tissue, with minimal systemic inflammatory responses. With the discovery of novel cytokines and chemokines beginning in the 1980s, human endotoxin challenges provided a convenient and safe approach to assessing the relevance of these mediators in vivo.

During the past three decades, over 2,000 healthy volunteers have participated in studies based on endotoxin administration.[3,6] In addition to providing basic information regarding mechanisms of human inflammation and proof of principle for the effects of inflammatory-modulating therapies, endotoxin has been rediscovered as a potent stimulus to enhance immune responses in trials of immunotherapy for cancer. This latter approach is based on the ex vivo stimulation of dendritic cells by endotoxin, exposure to a specific tumor antigen, and then reinfusion of the activated cells into the patient to enhance antigen presentation to cytotoxic lymphocytes and thus provide targeted immunotherapy to the tumor.[5]

The Development of an Endotoxin Standard for Clinical Investigation and Drug Development

The current batch of endotoxin used in human studies was originally synthesized in the Rocky Mountain Laboratories of the National Institute of Allergy and Infectious Diseases (NIAID) in 1976.[7] This source material has been used by the U.S. Food and Drug Administration (FDA) as a reference standard for assays of endotoxin in fluids or materials that are used clinically. For over two decades, this material was made available to investigators and was used in a wide variety of human challenge studies.

In 1997 the FDA reassessed its regulatory requirements regarding endotoxin use in humans. The original source material was not produced under good manufacturing practice (GMP) conditions, and to meet new standards, the FDA mandated that any endotoxin used in human studies be vialed under GMP conditions. Because of the narrow niche market for endotoxin, no commercial source of endotoxin for human use was available to investigators. The NIH Clinical Center (CC) has had a long tradition with NIAID in the conduct of human endotoxin studies. It reached an agreement with the FDA to take some of the bulk endotoxin and fund the vialing of this material under GMP conditions to meet regulatory requirements for Phase I human trials. This was done as a service to the greater research community to maintain the availability of the material for human studies.

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Developing and Sharing a Unique Clinical Research Tool: *Endotoxin and the Public-Private Partnership*

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The CC currently holds the sole FDA master file for this preparation and provides the endotoxin at no cost to both academic and pharmaceutical industry investigators. The recipients are required to have an institutional review board-approved protocol and an investigational new drug number and to complete a material transfer agreement with the CC. The CC reference endotoxin has been given to over 40 different investigators and centers worldwide, representing biopharmaceutical firms, clinical research facilities, and academic centers for three major areas of research: understanding mechanisms of inflammation, proof of principle for evaluation of novel pharmaceutical or biologic agents, and most recently as an immunoadjuvant for immunotherapy trials of cancer.

The bulk endotoxin material has been vialed under GMP conditions for the CC on two occasions (1997 and 2006). This work has been done in collaboration with the National Cancer Institute (NCI)-Frederick, Biological Resources Branch (BRB), Division of Cancer Treatment and Diagnosis (DCTD), which has helped coordinate the contracting and quality review process for the endotoxin. The cost for this processing of the bulk material in 1997 was originally covered by the CC. These costs rose over sixfold with the 2006 vialing and were supported by an unrestricted research gift from a pharmaceutical sponsor and the NCI.

A Public-Private Partnership To Develop and Share a Unique Clinical Research Tool

The FDA has now recommended that new sources of endotoxin be found to replace the current preparation and to meet the continuing needs for human clinical research. The new endotoxin preparation would need to be developed in a manner that meets current regulatory requirements for a biologic and thus would need to be manufactured and vialed under GMP conditions. As the scope of this new project process is much greater, the cost has substantially increased to over thirtyfold more than the costs of the original GMP vialing 12 years ago. In this period of relative budget austerity, it is not feasible for any single research entity to bear the substantial expense required for this new formulation. Thus, academic and pharmaceutical investigators are at risk of losing access to this unique resource.

As an advocate for clinical investigation, the CC sees this as an opportunity to address an important unmet need for the research community. Several groups are working together at this critical juncture to address a mutually beneficial solution. These include biopharmaceutical sponsors, which are willing to help underwrite the costs associated with this new initiative; the Foundation for the National Institutes of Health, which helps identify and develop opportunities for the partnership of industry and academia for this project; and within the intramural program, the CC and NCI-Frederick (BRB, DCTD), which are directing the development and will be responsible for the final distribution of this product. Pilot projects to manufacture the GMP endotoxin are currently under way, and despite the challenges that remain in achieving the total required funding, this public-private partnership has the potential to aid the clinical investigations of multiple academic and pharmaceutical researchers worldwide. ❖

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Program on Public-Private Partnerships
Office of Science Policy Analysis
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1, Room 209
1 Center Drive, MSC 0170
Bethesda, Maryland 20892

301.443.YPPP (9777)
301.402.0280 fax
pppartnerships@od.nih.gov

Please send your ideas and comments for future *PPP Advisor* articles/ publications to:

Marjorie Bonorden, Editor
PPP Program
Building 1, Room 209
Bethesda, Maryland 20892
or email: bonordenm@od.nih.gov

CALENDAR

DATE	MEETING	TIME	LOCATION	SPEAKER	SUBJECT
10.15.09	PPP Coordinating Committee	1 - 3 pm	NIH Campus	**Alan Goldhammer, Ph.D., Vice President, Scientific and Regulatory Affairs, Pharmaceutical Research and Manufacturers of America	The Pharmaceutical Trade Organization's View of PPPs
10.28.09	mHealth: From Policy to Implementation* *(This meeting is by invitation only but will complement the content of the mHealth Summit.)*		The World Bank, Washingon, DC	Host: The World Bank	Meeting will focus on the policy aspects of mHealth
10.29.09-10.30.09	mHealth Summit: The Mobile Phone as a Health Care Platform*	10.29.09 7 am-7 pm 10.30.09 8 am-2:30 pm	Ronald Reagan Building, Washington, DC	Host: Foundation for the NIH	The Mobile Phone as a Health Care Platform
11.19.09	PPP Coordinating Committee	1 - 3 pm	NIH Campus	**Christine Brennan, Director of Strategic Alliances, Novartis Institutes for BioMedical Research, Inc.	One company's view of PPPs
12.17.09	PPP Coordinating Committee	1 - 3 pm	NIH Campus	**Joel Cutcher-Gershenfeld, Dean and Professor, School of Labor and Relations, University of Illinois	PPP views from industries other than biomedical and pharmaceutical

Please check the PPP Web site for updates and additions.

**For more information on the mHealth Summit, visit www.fnih.org.*

*** If there is a speaker with whom you would like to meet on the day he or she is scheduled to speak, please contact the NIH Program on Public-Private Partnerships (Marjorie A. Bonorden, bonordenm@od.nih.gov) so that a meeting time can be arranged.*

NIH Publications
No. 08-6531
Printed October 2009