PUBLIC-PRIVATE PARTNERSHIP PROGRAM

PPP ADVISOR

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WINTER 2010

MESSAGE FROM THE DIRECTOR

Dr. Barbara B. Mittleman

Welcome to 2010! We look forward to a New Year full of good will, stimulating opportunities, and great science, as well as fun, health, and happiness for all. This issue allows us a chance to look back as well as to look forward, taking into account the mission of the NationaI Institutes of Health (NIH) and the goals of the NIH Public-Private Partnership (PPP) Program.

In the last months, the PPP Coordinating Committee (PPPCC) has presented a series of talks and discussions related to interactions between industry and NIH. Our December presentation by Joel Cutcher-Gershenfeld, Dean of the School of Labor and Employee Relations at the University of Illinois, was from a perspective not commonly heard in the halls of basic and clinical science—the social scientists' view on stakeholder alignment and how partnerships in other industries may inform PPPs at the NIH. Among the examples quoted were cases in the automotive and aerospace industries, and a framework for considering how to assess and affect the interactions among partners by defining and optimizing their alignment with respect to one another. We are using this approach, in collaboration with our speaker and colleagues, to prepare a case study of The Biomarkers Consortium.

Earlier in the fall we had a presentation by Christine Brennan, Director of Strategic Initiatives for Novartis, who discussed the approach taken by a large pharmaceutical company in thinking about and implementing partnerships with academia, government, and smaller companies. This perspective provided an interesting view of the inner process in one company which has made many diverse partnerships over a period of years.

The spring brings more presentations and discussions at the PPPCC, including perspectives from startup biotechnology companies, the biotech trade organization, U.S. Food and Drug Administration, academics, and more. (Please see the PPPCC article in this newsletter for more details.)

I would also like to welcome a new member of the PPP team. Dr. Audie Atienza began a part-time detail in the PPP Program in January, focusing on mobile health (mHealth). The terrifically successful mHealth Summit in October 2009 has spawned opportunities for another Summit (November 8-10, 2010, at the Washington Convention Center), the advent of an mHealth Inter-

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SPOTLIGHT

The National Institutes of Health Public-Private Partnership (PPP) Program is pleased to include in this issue a guest feature article provided by the NIH Office of Technology Transfer (OTT), Office of the Director. This article, the first of three, provides information about the redesigned OTT Web site that will feature the recent marketing initiatives implemented by the OTT to better public health. These initiatives will help to bring awareness to how NIH is delivering information about product development opportunities based on NIH inventions and new tracking of the latest technologies available for licensing and commercial development.

The PPP Program is also pleased to include in this issue a guest feature authored by Lili Portilla, M.P.A., Senior Advisor for Technology Transfer/National Center for Research Resources, and Kate Marusina, Ph.D., M.B.A., of the University of California, Davis/National Center for Research Resources (NCRR). The article outlines an activity of the Clinical and Translational Science Awards (CTSA) Program, through which NCRR manages and oversees a partnership between academic researchers and pharmaceutical companies for the development of a portal for the exchange of new information for the uses of marketed or pipeline compounds. This novel program represents a unique effort on the part of both pharmaceutical companies and universities to seek solutions for the prolonged, expensive, and inefficient drug development path by short-cutting through the repurposing of existing compounds for new targets or indications.

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Institute Interest Group—to provide a venue for exchanging information and best practices among NIH Institutes and Centers (ICs) with activities related to mHealth as well as an opportunity for technical and research presentations by outside entities to NIHers, and the opportunity to partner with a variety of commercial and nonprofit entities with interests in mHealth, global health, and related topics. Dr. Atienza will also be working closely with the Foundation for the National Institutes of Health to ensure that NIH ICs' interests and scientific agendas are well represented in the mHealth activities on which they are embarking. I would like to take this opportunity to thank the applicants for the detail position on mHealth. This clearly is a topic of interest across many ICs and outside organizations, and the potential to facilitate health and health care research, education and training, care delivery, and policymaking conspires to make working on mHealth compelling to many NIHers and others.

As always, we continue to discuss partnership opportunities with both NIH IC staff and outside entities including software companies (e.g., 5AM Solutions), nonprofits (e.g., Corporate Council on Africa), non-government organizations (United Nations), and others. Input also comes from NIH Office of the Director Offices and ICs. You will find the Office of Technology Transfer's contribution, the first of three articles, to this newsletter regarding new Web site marketing initiatives plus an article from the National Center for Research Resources about the Clinical and Translational Science Awards Program.

Wishing all a wonderful New Year and many successful partnerships. ❖

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The Biomarkers Consortium: End-of-Year Update

Dr. Shawnmarie Mayrand-Chung

Summer and fall 2009 was a busy time for The Biomarkers Consortium (BC) with the approval of four new projects! I reported back in late spring that two projects were under development by our Neuroscience Steering Committee and I am pleased to report that both of these projects were approved by the Executive Committee at the June 2009 Biomarkers Consortium Executive Committee (BCEC) meeting. As such, funding efforts are presently under way for the *"Use of Targeted Multiplex Proteomic Strategies to Identify Cerebral Spinal Fluid-Based Biomarkers in Alzheimer's Disease"* and *"Placebo Data Analysis in Alzheimer's Disease and Mild Cognitive Impairment Clinical Trials."*

In addition to the two projects in Alzheimer's disease approved in June, two additional projects were approved at the August 2009 BCEC meeting.

- **Positron Emission Tomographic (PET) Radioligand Imaging of Inflammation in Arthritis.** This project will seek to qualify a new, improved translocator protein PET ligand (namely, [18F] PBR06) as a rheumatoid arthritis disease activity biomarker that will be useful in disease-modifying antirheumatic drug clinical trials and clinical practice. The data analysis for this project is anticipated to be completed in approximately 14 months and will cost about $610,000, with $340,000 of this cost to be raised from the private sector. (Inflammation and Immunity Steering Committee)
- **Metabolomics Signatures and Biomarkers for Depression and Its Treatment.** This project involves a comprehensive metabolomic analysis of soluble and lipid metabolites, including neurotransmitter-related metabolites, coupled with statistical analysis and data-mining to identify markers that can predict early and late response to SSRIs (selective serotonin reuptake inhibitors) and SNRIs (serotonin and norepinephrine reuptake inhibitors). Anticipated data from this study are expected to include:
  - Identify biomarkers for drug response phenotypes that, if clinically validated, could directly impact antidepressant drug development.
  - Identify diagnostic and surrogate markers for disease and progression.
  - Develop a method to subclassify depression.

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The Biomarkers Consortium: *End-of-Year Update*

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- Provide candidate pathways for pharmacogenomic followup.
- Inform design and choice of analytical platforms to apply in a larger depression study being contemplated.

It is anticipated that this project will be completed in approximately 2 years (once initiated), and will cost about $1.3 million. (Neuroscience Steering Committee)

Finally, the summer also marked the publication of the first BC project, titled *The Biomarkers Consortium Completes First Project to Show That Adiponectin Is a Predictive Biomarker for Type II Diabetes*. The goal of this project was to determine whether adiponectin has utility as a predictive biomarker of glycemic control in normal non-diabetic subjects and patients with Type II diabetes. The results of this study can be summarized as follows:

- Adiponectin is a robust predictor of glycemic response to Peroxisome-Proliferator-Activated Receptor (PPAR) agonists in both Type II diabetic patients and also in healthy individuals.
- Adiponectin is an accurate predictor of glycemic response to PPAR agonists, but not non-PPAR drugs, in Type II diabetes patients.
- Previous findings about the relationship between adiponectin levels and metabolic parameters (e.g., HbA1C, HDL, hematocrit) have been confirmed by this study.
- The potential utility of adiponectin across the spectrum of glucose tolerance was demonstrated by this study.

These results were presented at the American Society for Clinical Pharmacology and Therapeutics meeting in March 2009 at the American Diabetes Association meeting in June 2009, and are currently in print at the *Clinical Pharmacology and Therapeutics* journal (available online in June and released in the July issue).

Additionally, this project established an approach to cross-company collaboration that embodies a robust, feasible approach to future biomarker qualification, a model that the BC hopes to use and bring to future biomarker projects. The final project team meeting was held on June 15, 2009, to discuss lessons learned from this novel cross-company data-sharing mechanism, and the possibility of a publication that provides guidance and encouragement for future biomarkers projects involving cross-company data-sharing was discussed.

In closing, I will note that in the next issue of the *PPP Advisor*, I will report on the various working groups that the BC has established and the emerging strategies for increasing the visibility of the BC. ❖

CTSA Portal Project Seeks to Marry Pharmaceutical Companies and Academic Resources

Ms. Lili M. Portilla, National Center for Research Resources, and
Dr. Kate Marusina, University of California, Davis

The National Institutes of Health (NIH) National Center for Research Resources Public-Private Partnerships Key Function Committee of the Clinical and Translational Science Awards (CTSA) Program, administered by the National Center for Research Resources (NCRR), is overseeing the development of a portal for exchanging information on novel uses of marketed or pipeline compounds between academic researchers and pharmaceutical companies. The Pharmaceutical Assets Portal Project (www.ctsapharmaportal.org), funded by an NCRR supplemental grant, marries academic objectives with the goals of the pharmaceutical industry. Because of the high cost of drug research and development, pharmaceutical companies have focused on "drug repositioning," that is, finding new uses for drugs already marketed or in the pipeline, typically by identifying a new disease indication, new delivery method, or new combination with other drugs. About 14,000 compounds have reached Phase II and III clinical trials, but the U.S. Food and Drug Administration has approved only about 2,800 compounds over the past 60 years. The rest are referred to as "shelved" assets.

Few academic investigators have the opportunity to develop drugs de novo in the academic setting; thus, a better access to the thousands of drugs with an established clinical safety profile presents an attractive opportunity for translational research, satisfying both academic and commercial goals. As a

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CTSA Portal Project Seeks to Marry Pharmaceutical Companies and Academic Resources *(CONTINUED FROM PAGE 3)*

result, it is likely that more drugs would be approved for new indications.

The project is a team effort led by Dr. Kate Marusina of University of California, Davis, and includes CTSA representatives from the University of Washington, Oregon Health & Science University, University of Pennsylvania, and University of Chicago. The project team has already established relationships with several major pharmaceutical companies interested in exploring drug repositioning such as Pfizer's Global Indication Discovery Unit. The project leaders envision that the information exchange would take place on several levels. Because the information about "shelved" assets is not directly available, the portal would establish a way to obtain this information using two indirect routes. First, the portal participants would be able to submit a mini-Request for Applications (RFA) to participating pharmaceutical companies, seeking a drug for their particular research. Second, the portal would cluster the CTSA researchers via their interests in particular targets or diseases. This clustering would enable researchers to form project teams and to match these project teams with companies' repositioning candidates.

The project team is also evaluating the use of existing material transfer agreements (MTA) to assess the key principles of drug transfer. So far, there has been a successful match made between pharma and the NIH Chemical Genomics Center. On December 4, the NCRR, National Cancer Institute, and NIH Clinical Center hosted a drug repositioning symposium in the NIH Clinical Center Lipsett Auditorium. Approximately 200 representatives from academia, pharmaceutical companies, and NIH participated in the event. The event is currently archived on the NIH videocast website and can be accessed by going to videocast.nih.gov/PastEvents.asp and searching for December 4, 2009, "CTSA Pharmaceutical Assets Portal: Matching Academia and Industry for Drug Repositioning". ❖

Coordinating and Integrating mHealth Activities at the National Institutes of Health in 2010

Dr. Audie A. Atienza

2009 mHealth Summit Spurs on NIH activities

The inaugural mHealth Summit (October 29-30, 2009), sponsored by the Foundation for the National Institutes of Health (FNIH) in partnership with the National Institutes of Health (NIH) and other non-NIH partners, has stimulated synergistic mHealth research activities at the NIH. The use of mobile technologies in health research represents a cross-cutting topic area relevant to numerous NIH Institutes (ICs) and Offices, as evidenced during the 2009 mHealth Summit. The rapid proliferation of mobile phones, sensors, and integrated mobile devices (for example, smart phones with global positioning systems, accelerometers, and Bluetooth connectivity) among the U.S. and international populations offers unique and unprecedented opportunities to assess and improve health both domestically and globally. Yet, distinct challenges and barriers have also arisen as researchers increasingly adopt the use of mobile technologies, and there has been limited dialogue among the NIH ICs on this topic. A small but rapidly emerging portfolio of NIH grants using mobile technologies has emerged across the various NIH ICs, creating opportunities to explore shared interests within NIH and further development of public-private partnerships.

Formation of the National Institutes of Health mHealth Research Inter-Institute Interest Group

In efforts to increase coordination of NIH mHealth research activities, the NIH Public-Private Partnership Program has spearheaded the formation of an mHealth Research Inter-Institute Interest Group (IIG) at the NIH. The aims of the NIH mHealth IIG will be to (1) share information on mHealth across NIH ICs and offices, (2) coordinate mHealth research activities across NIH ICs and offices, (3) interface with other NIH IIGs with relevant interests (e.g., biomedical informatics, etc.), (4) invite speakers to give presentations on topics pertinent to mHealth research, and (5) identify areas of shared work across NIH ICs/Offices and

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Coordinating and Integrating mHealth Activities at the National Institutes of Health in 2010 (CONTINUED FROM PAGE 4)

possibly with outside partners. We anticipate that the NIH mHealth IIG will serve as a central venue for discussion of collaborative activities across NIH. Subcommittees from the NIH mHealth IIG will assist with specific Public-Private Partnership Program office activities (e.g., mHealth Summit 2010).

The Foundation for the National Institutes of Health and the National Institutes of Health Continue Partnership in mHealth in 2010

The FNIH, in partnership with the NIH, will sponsor the 2010 mHealth Summit November 8-10, 2010, in Washington, D.C. The 2010 mHealth Summit will expand upon the activities and ideas generated during the inaugural mHealth Summit, focusing on research issues in both domestic and international settings. The 2010 Summit will further explore how mobile information technology, research methodology, and policy can intersect to improve clinical care, population health, public health surveillance, global health disparities, and delivery of health care to high-risk and underserved populations.

In 2010, NIH will partner with the FNIH to explore and further develop other public-private partnerships in mHealth research. Dialogue continues with non-Federal partners, including the United Nations Foundation, Vodafone Foundation, Rockefeller Foundation, Microsoft Research, and Qualcomm. Additional collaborations/partnership with other industry (e.g., AT&T, Verizon, Nokia, T-Mobile, Sprint/Nextel, etc.), Federal government (e.g., Federal Communications Commission, U.S. Food and Drug Administration, National Institute of Standards and Technology, Health Resources and Services Administration), and nonprofit (e.g., Robert Wood Johnson Foundation, Bill & Melinda Gates Foundation, etc.) entities will be explored in 2010. This collaborative cross-sectorial and cross-disciplinary approach to mHealth research, involving public-private partnerships, offers much promise in addressing current and future health and health care issues in the United States and globally. ❖

Speeding Up Commercialization of Scientific Discoveries: New Marketing Initiatives to Attract Private Enterprise in Product Development (1 of 3)

Marketing Operations, Office of Technology Transfer,
National Institutes of Health

The Web site of the Office of Technology Transfer (OTT) at the National Institutes of Health (NIH) was recently redesigned in order to showcase the recent marketing-related initiatives undertaken at the OTT. The site provides new helpful features including Really Simple Syndication (RSS) feeds, a customizable product showcase, a product development pipeline, a "marketplace" of small companies that have already developed technologies based on NIH discoveries, and many others that will be described in more detail in this and subsequent articles. Over the next three articles, we will attempt to highlight some of OTT's major marketing initiatives to enhance awareness of the contribution of NIH toward greater public health and the opportunities for product development based on NIH inventions.

Use RSS Feeds to Keep Track of Inventive Technological Developments

Do you find yourself going through pages and pages of technologies on the NIH OTT site to find the technology that interests you? Do you already subscribe to the NIH OTT Listserv® but find the updates too infrequent, irrelevant, or broad? By implementing RSS technology, OTT has made it easier to keep track of the latest technologies available for licensing and commercial development. In a matter of seconds, you can sign up for RSS feeds, and then, at no cost, the latest available technologies are delivered directly to your inbox in your e-mail program or a feed reader program, such as Google Reader. RSS allows users to stay up to date on content that changes frequently and eliminates the need to search multiple Web sites to find the information you are looking

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Speeding Up Commercialization of Scientific Discoveries: *New Marketing Initiatives to Attract Private Enterprise in Product Development (1 of 3)* *(continued from page 5)*

for. The OTT RSS feeds provide a title, brief abstract, and link to the complete technology description. Subscribers can opt to receive all National Institutes of Health (NIH)/U.S. Food and Drug Administration (FDA) technologies available for licensing or on a specific topic such as cancer, infectious diseases, etc. These RSS feeds accelerate access to new scientific information for the general public and companies (for commercial development) and yet allow for complete privacy of your information, including the keywords you are using in your search. At present, RSS feeds are available in two general categories: "NIH/FDA Technologies Available for Licensing" and "NIH CRADA Opportunities." To pick either of the feeds, please visit http://www.ott.nih.gov/rss. If you would prefer to have the available technologies delivered via the traditional route to your mailbox (e-mail), sign up for our e-mail subscription service at http://www.ott.nih.gov/subscribe.

NIH/FDA Products Showcase and Related Widget Opens Window Into NIH Public Health Impacts

Are you eager to get up to speed on the latest products resulting from inventions developed in the laboratories of the NIH and the FDA? The OTT website offers a useful application, the Product Showcase (http://www.ott.nih.gov/productshowcase), to exhibit products that have moved from the laboratory bench to the marketplace. You can use this tool to learn about vaccines, therapeutics, diagnostic kits, veterinary treatments, research reagents, and devices developed by companies after licensing scientific breakthroughs at the NIH and FDA. These breakthrough inventions were licensed to companies for commercial development and marketing (including those that are no longer in the market). Products showcased on this site are utilized every day to detect, treat, or prevent disease or assist researchers as they continue to explore ways to develop newer and more effective health care products and procedures. Some of these products are FDA-approved and many do not necessitate FDA approval. The purpose of the Showcase is to highlight the contributions of NIH and the FDA and to serve as an inspiration to companies to step forward and further develop technologies based on NIH/FDA inventions. OTT has developed a companion "widget" that allows anyone to download the Showcase onto their own Web site. This widget is completely free and requires no maintenance, yet it automatically updates the list of products when NIH OTT adds new information to its database. This widget can be downloaded at http://www.ott.nih.gov/widgets. ❖

NIH Public-Private Partnership Program and the Foundation for the NIH: *News from FNIH!*

NIH PPP Program Office

We at the National Institutes of Health (NIH) Public-Private Partnership Program are very sad to say goodbye to Amy McGuire Porter, who is leaving the Foundation for the NIH (FNIH) after serving as its Executive Director since 2002. Previously Amy had a long career, with extensive experience in the nonprofit sector, in communications, and in development. Amy has been a great friend and colleague of the NIH and has tirelessly worked to broaden the vision and activities of the FNIH to its current size and scope of 42 employees and 97 programs and a fundraising total of $426 million. She is moving on to a position as Executive Director and Chief Executive Officer of the National Osteoporosis Foundation (NOF) beginning February 1, 2010. We will miss her and wish her great success at the NOF. ❖

NIH Public-Private Partnership Coordinating Committee: *January-June 2010 Speaker Series: Partnering With Industry*

Ms. Marjorie A. Bonorden

The 2009-2010 NIH Public-Private Partnership Coordinating Committee (PPPCC) Speaker Series started in September 2009 focusing on *Partnering With Industry* to provide insight into how partnerships work and provide specific partnership examples and experience from guest speakers from the areas of academia, Federal government agencies including NIH's Office of Technology Transfer and the National Cancer Institute's Innovative Molecular Analysis Technologies Program, and industry such as pharmaceutical and biotechnology companies. If there is a speaker with whom you would like to meet on the day they are scheduled to speak, please let me know and I will be happy to arrange for a time that is convenient for all. Please feel free to distribute any of these opportunities within your IC; we invite all interested NIHers to join us. (Please note: The schedule for the speakers and topics of the talks are subject to change.) Here is the schedule for *Partnering With Industry* from January through June 2010:

- **January 21:** Perspectives on partnering from a startup company and from a large biotechnology company point of view
  - **O. Prem Das, Das Advisors**
    Dr. Das's perspectives on the business aspects of partnering, from a viewpoint of a small company or a startup company and focusing on how industry and NIH can forge unique opportunities in medical research and drug discovery.
  - **Lila Feisee, Biotechnology Industry Organization**
    Ms. Feisee will provide her views on what goes into developing PPPs from the biotech industry's perspective and how/why NIH can develop partnerships with the biotech industry
- **February 18:** IP and Strategic Partnerships: Partnership perspectives from small and midsized pharmaceutical companies
  - **Wendy Petka, Boehringer Ingelheim Pharmaceuticals, Inc.**
    Dr. Petka will discuss strategic partnerships from an international, midsized pharmaceutical industry standpoint, IP concerns that PPPs generate, and feasible solutions.
  - **Karen Brown, Ironwood Pharmaceuticals, Inc.**
    Dr. Brown will provide her view of partnerships, what goes into selecting partners, and "go/no go decisions" from a small pharmaceutical company's perspective.
- **March 18:** Regulatory issues and partnering
  - **Vicki Seyfert-Margolis, U.S. Food and Drug Administration**
    Dr. Seyfert-Margolis will discuss the role of the FDA and partnerships.
- **April 15:** Innovation
  - **Mark Rohrbaugh, Office of Technology Transfer, Office of the Director, National Institutes of Health**
    Dr. Rohrbaugh's presentation will be on innovation and NIH plus practical tips for successful partnerships between NIH and industry.
  - **Mark Lim, IMAT Program, National Cancer Institute, National Institutes of Health**
    Dr. Lim's presentation will be on an innovative public-private partnership, Innovative Molecular Analysis Technologies (IMAT) Program.
- **May 20:** Perspectives on partnering from a small biotechnology company and a small entity
  - **Norman Garceau, Blue Sky Biotech**
    Dr. Garceau will provide his view on partnerships, what goes into selecting partners, and "go/no go decisions" from the perspective of a small biotechnology company.
  - **Anne Wojcicki, 23andMe, Inc.**
    Ms. Wojcicki's presentation will be on partnerships, what goes into selecting partners, and "go/no go decisions" from the perspective of a small entity such as 23andMe, Inc.
- **June 17:** Regulatory, academia, industry, etc.
  - Speaker panel (speakers and topics to be announced) ❖

Visit us at **http://ppp.od.nih.gov**

LOOKING FOR PPP INFORMATION?

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CALENDAR

DATE	MEETING	LOCATION & TIME	SPEAKER
10.15.09	PPP Coordinating Committee Presentation: Biotechnology and Partnering	NIH Campus 1 - 3 pm	O. Prem Das, Das Advisors Lila Feisee, Biotechnology Organization
2.17.10-2.18.10	The CTSA Public-Private Partnership (PPP) Key Function Committee: CTSA Industry Forum - Collaborative Drug Discovery and Development Event	Natcher Conference Center, NIH Campus Starts at 8 am both days	Hosted by NIH NCRR and the CTSA Consortium Registration is free. Register now at http://www.palladianpartners.com/CTSAIndustryForum
2.18.10	PPP Coordinating Committee Presentation: Strategic Partnerships and IP	NIH Campus 1 - 3 pm	Wendy Petka, Boehringer-Ingelheim Karen Brown, Ironwood Pharmaceuticals, Inc.
3.18.10	PPP Coordinating Committee Presentation: Partnerships and FDA	NIH Campus 1 - 3 pm	Vicki Seyfert-Margolis, U.S. Food and Drug Administration
4.15.10	PPP Coordinating Committee Presentation: Innovation	NIH Campus 1 - 3 pm	Mark Rohrbaugh, OTT, OD, NIH Mark Lim, IMAT Program, NCI, NIH
5.2.10-5.6.10	BIO Conference	McCormick Place, Chicago, IL	http://convention.bio.org/default.aspx
5.20.10	PPP Coordinating Committee Presentation: Partnerships—Small Company's Perspective	NIH Campus 1 - 3 pm	Norman Garceau, Blue Sky Biotech Anne Wojcicki, 23andMe
6.17.10	PPP Coordinating Committee Presentation: Panel Discussion	NIH Campus 1 - 3 pm	TBA
11.8.10-11.9.10	mHealth Summit	Washington Convention Center, Washington, DC	

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