ADVISOR VOLUME 2

VOLUME 2 - e ISSUE 2

MESSAGE FROM THE DIRECTOR

Dr. Barbara B. Mittleman, Director, NIH Public-Private Partnership Program, National Institutes of Health

It has been a busy spring in the land of public-private partnerships (PPPs), and we have a lot of exciting news to share with you.

The National Institutes of Health (NIH) Public-Private Partnership Coordinating Committee (PPPCC) meetings have featured very interesting and informative speakers, all focusing on intellectual property (IP) in a variety of guises and from diverse perspectives. The series has covered a wide range of points of view, from that of venture capitalists representing several industries (pharmaceutical and telecommunications technology) to that of a corporate/pharma chief IP counsel, matched with feedback from the NIH staff regarding the Federal Government's and the public's interests in protecting and sharing valuable inventions and insights. We have shared several of these meetings with the NIH mHealth Inter-Institute Interest Group, recognizing our shared interests and challenges.

PPP scholarly activities have resulted in manuscripts under development and in review regarding the alignment of stakeholders and the mechanics and principles of constructing robust and successful PPPs (watch this space for citations and references in upcoming issues of the *PPP Advisor*). Ongoing research engagements in this arena include the completion of a case study focusing on The Biomarkers Consortium. A new and a collaborative effort funded by the National Science Foundation (NSF)—EarthCube—will examine a multistakeholder, interdisciplinary effort to connect the earth science and cyberinsfrastructure communities in an effort to promote more collaborative and interdisciplinary science. More information about the EarthCube project and its very ambitious

goals are in the article by Clifford Jacobs and Almadena Y. Chtchelkanova of the NSF. This project is relevant to many NIH initiatives in its interdisciplinarity, scale, and need for the management and analysis of big and diverse data sets. Our expectation is that better understanding of the mechanics and principles of consortium structure, relationships, and functioning will provide

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SPOTLIGHT

In this issue of the National Institutes of Health (NIH) *PPP Advisor*, we bring you news of several exciting public-private partnerships currently under way here at the NIH and elsewhere:

- Alzheimer's Disease Research Summit. Suzana Petanceska Ph.D., Laurie Ryan, Ph.D., and Lorenzo Refolo, Ph.D., Program Directors, Division of Neuroscience, National Institute on Aging, offer information about the Alzheimer's Disease Research Summit, which was organized and held at the NIH as part of the National Alzheimer's Project Act (NAPA) in May 2012. Partnerships are anticipated to result from the shared objectives of the stakeholders committed to improving the lives of people affected by Alzheimer's disease.
- In June 2012 the National Science Foundation (NSF) hosted the second EarthCube Charrette, an open public meeting encompassing the diverse disciplines studying the Earth system and dedicated to developing a shared vision and roadmap for a combined information management system, including transdisciplinary data. Clifford Jacobs, Ph.D., Senior Advisor, Geosciences Directorate, and Almadena Y. Chtchelkanova, Ph.D., Program Director, Computing and Communication

Foundations, National Science Foundation, provide an overview of what EarthCube is and the work being done in this area.

 Exciting news comes from Jonelle K. Drugan, Ph.D., M.P.H., Office of Science Policy and Planning, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH, regarding the NIH Osteoarthritis Initiative and the new Biomarkers Consortium PPP project, which is managed by the Foundation for the NIH.

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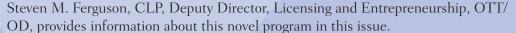
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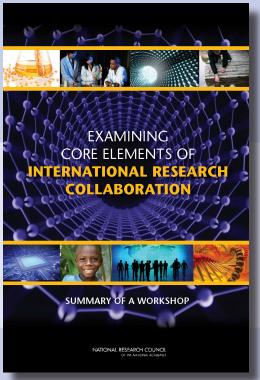
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both useful and actionable feedback to the EarthCube community and usable insights to inform future efforts to engineer "big science" activities in other fields as well.

The NIH has a new member of our community: The Office of Technology Transfer/Office of the Director (OTT/OD) and BioHealth Innovation, Inc. (BHI) have collaborated to house an entrepreneur-in-residence at the NIH. BHI's goals are to accelerate technology transfer and research in central Maryland to license and develop new startup companies by providing financial, managerial, and scientific support in the areas of drugs, vaccines, therapeutics, diagnostics, and medical devices at the NIH and at the U.S. Food and Drug Administration (FDA). This is an exciting opportunity for cross-cultural communication and education between government and business, information-sharing about the NIH's resources and accomplishments with the business sector, and perhaps the development of new ways to more broadly disseminate the NIH's insights and inventions.





Report available for free download at http://www.nap.edu/catalog.php?record_id=13192

Within the NIH there are broad and deep interests in a variety of aspects of mobile health (mHealth), and many of the previous issues of this newsletter have included information on this topic. Current activities related to PPPs include the following. The 2012 mHealth Summit will be held at the Gaylord National Resort and Convention Center, at the Washington, DC, National Harbor on December 3-5. This year's summit will be sponsored for the first time by the Healthcare Information and Management Systems Society (HIMSS), and efforts are under way to craft a solicitation for abstracts, define the agenda, and plan for opportunities for NIH involvement (please see the mHealth Summit article, submitted by Richard Scarfo, in this issue for more details). Interest in the evidence needed for both data-driven decisionmaking and the interoperability of devices and data is shared by the NIH and the FDA, along with many others, and is leading to the development of a large, multistakeholder PPP around mHealth. NIH Institutes, Centers, and Offices (ICOs) continue to support clinical, behavioral, and technological research and training in the field. A cross-sectoral meeting was held in April 2012 to discuss the possibility of developing an mHealth PPP, with enthusiastic interest expressed across the board; an organizing committee is meeting regularly to develop a timeline and operating principles. This activity represents the best of PPPs—spanning many Federal Government agencies and departments and many stakeholder groups and organizations and providing for synergies and coordination/reduction in redundancy. Watch this space for news about the mHealth PPP as it unfolds.

Exciting news comes from National Institute on Drug Abuse (NIDA) about the progress of its novel initiative to promote a product development partnership for new

drug treatment for smoking cessation (Medications Initiative for Tobacco Dependence). We have had the privilege of providing feedback and assistance in the development of this initiative—including review and ongoing scientific oversight—and see the terrific potential it has to allow the Federal Government to contribute to initiating the development of new therapeutics. There is also exciting news from the National Institute of Arthritis and Musculoskeletal and Skin Diseases about next steps in the NIH Osteoarthritis Initiative (NIHOAI) and how NIHOAI resources and the Foundation for the NIH's Biomarkers Consortium together can make progress in developing and qualifying biomarkers for the common and debilitating disease of osteoarthritis, thus providing important tools for drug development in this challenging disease.

The larger reach of the PPP Program and the NIH includes involvement in the National Academy of Sciences (NAS) Government-University-Industry Research Roundtable (GUIRR), which has spawned several groups that are particularly interested in PPPs. The University-Industry Demonstration Partnership (UIDP) is one such group, bringing universities and companies together to discuss issues related to sponsored research and technology transfer across a broad range of disciplines. The PPP Program serves as the NIH representative to the UIDP board of directors and participates actively in the UIDP's three annual meetings, which are spread geographically across the United States to engage the largest possible number of

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constituents. Another GUIRR activity focuses on international collaborative research agreements. The GUIRR's Working Group on International Research Collaborations (I-Group) held a workshop on this topic in October 2010 and published a meeting summary report that was released by the NAS in October 2011 (report available for free download at http://www.nap.edu/catalog.php?record_id=13192). The I-Group is planning a "Culture Matters" workshop for early 2013 that will focus on cultural determinants and culturally specific understandings of topics such as research ethics and practice; responsibilities toward the environment, the public, and the labor force; and how to manage the tensions between progress and respect for past and existing institutions and practices. This activity should prove to be interesting and worthwhile for PPP aficionados, since many PPPs involve international partners that represent the global nature of science.

As always, lots of buzz about PPPs comes from the NIH ICOs, with interest leading to PPP discussions at meetings focused on the National Plan to Address Alzheimer's Disease, glomerular disease, and many other topics. We are always ready to assist in the conceptualization, development, and implementation of PPPs, so we encourage you to call on us!

Best regards for a wonderful summer. �

We are taking the opportunity to mark, with this issue, the suspension of the PPP newsletter, *PPP Advisor*. After more than 4 years since its inception, we would appreciate your feedback regarding the value you have found in the *PPP Advisor*, and more generally in the NIH PPP Program. This information will help us understand how to proceed while we take the time to evaluate our functions. Please provide your feedback and comments by e-mail to pppartnerships@od.nih.gov or to mittlemb@od.nih.gov. Thank you for your reading attention, contributions, and input.

ALZHEIMER'S DISEASE RESEARCH SUMMIT 2012:

PATH TO TREATMENT AND PREVENTION

Suzana Petanceska, Ph.D., Laurie Ryan, Ph.D., and Lorenzo Refolo, Ph.D., Program Directors, Division of Neuroscience, National Institute on Aging, National Institutes of Health

Alzheimer's disease (AD) is an irreversible brain disease that affects as many as 5.1 million Americans. It slowly destroys brain function, leading to cognitive decline, behavioral and neuropsychiatric symptoms (depression, psychosis, and agitation), and decline in the ability to engage in activities of daily living and self-care. As the number of older adults continues to increase over the next decades, the annual incidence of AD and other dementias is predicted to nearly double. According to the Alzheimer's Association's 2012 Alzheimer's Disease Facts and Figures report, the socioeconomic burden associated with AD and other dementias is projected to be over \$200 billion per year in the United States alone. In response to this looming public health crisis in the United States and worldwide, a growing number of countries are increasing their investment in all aspects of AD research.

On January 4, 2011, President Obama signed into law the National Alzheimer's Project Act (NAPA), requiring the Secretary of the U.S. Department of Health and Human Services to establish the National Alzheimer's Project to:

- Create and maintain an integrated national plan to overcome AD
- Coordinate AD research and services across all Federal agencies
- Accelerate the development of treatments that would prevent, halt, or reverse the course of AD
- Improve early diagnosis and coordination of care and treatment of AD
- Improve outcomes for ethnic and racial minority populations that are at higher risk for AD
- Coordinate with international bodies to fight AD globally

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As part of the Strategic Planning Process for the implementation of NAPA (http://aspe.hhs.gov/daltcp/napa/), the National Institute on Aging (NIA), National Institutes of Health (NIH), with support from the Foundation for the NIH (FNIH), organized and hosted the Alzheimer's Disease Research Summit 2012: Path to Treatment and Prevention, on the NIH campus, May 14-15, 2012. NIH Director Dr. Francis Collins opened the Summit and emphasized its importance for charting the trajectory of AD research for successful therapy development. The overarching goal of the Summit was twofold: (1) to formulate a blueprint for a new integrated, multidisciplinary research agenda that will enable the development of effective therapies (disease-modifying and palliative) across the disease continuum for the cognitive as well as neuropsychiatric symptoms of AD and (2) to identify the resources/infrastructure and public-private partnerships (PPPs) necessary for the successful implementation of this translational agenda.

Over 50 national and international experts in AD research and leading researchers from other disease fields (for a complete list see http://www.nia.nih.gov/agenda-alzheimers-disease-research-summit-2012) took the stage in the course of a day and a half in front of an international audience of over 500 scientists, advocates, and members of the public. The Summit proceedings were webcast in real time, and the video of the entire Summit is available on the NIA's Web site (http://videocast.nih.gov/summary.asp?Live=11196).

The program was organized around six major themes of critical importance for identification of successful interventions for AD (see below). The Summit program began with a plenary lecture by Dr. Ken Langa from the University of Michigan; he highlighted the growing social and economic impact of AD in the United States and the dire consequences to public health and the health of the U.S. economy absent effective ways to treat and prevent this devastating disease. Following is a summary of the programmatic goals and proceedings for each session.

INTERDISCIPLINARY APPROACH TO DISCOVERING AND VALIDATING THE NEXT GENERATION OF THERAPEUTIC TARGETS FOR AD

The enormous complexity of the human brain and the disease process is recognized as a major obstacle for successful translation of basic discoveries to effective therapies for AD. One of the new concepts emerging in recent years is that AD is a network disorder affecting a large number of neuronal cell types, organized into functionally connected networks across many brain regions and not a disease of discrete lesions

limited to specialized brain regions associated with cognition and learning. Within this network concept, AD is believed to be a response to a shift from normal to pathological networks and not just a response to a pathogenic change in a single target. The lack of understanding of the molecular, cellular, and physiological underpinnings of the normal to pathological shift in networks poses a special challenge with regard to the selection of truly disease-relevant therapeutic targets. This session addressed the need to formulate a new, integrated, interdisciplinary, basic science research agenda that will lead to a more accurate depiction of the networks underlying the AD process at the cellular, tissue, and organ/organism levels and enable the identification and selection of disease-relevant therapeutic targets.

The speakers provided an overview of the current understanding of the multifactorial nature of AD and discussed how the use of systems biology and emerging networked approaches can provide a better understanding of the context in which existing therapeutic targets operate and inform the identification, selection, and validation of new therapeutic targets. Some of the key issues raised by the panelists included (1) leveraging existing knowledge and resources; (2) enabling cross-talk between epidemiology and basic and translational research to identify disease-relevant therapeutic targets; (3) providing open access to large data sets such as various "omics," imaging, and phenotyping data; (4) standardizing and validating translational tools for target validation; and (5) creating new multidisciplinary translational teams.

CHALLENGES IN PRECLINICAL THERAPY DEVELOPMENT

The goal of this session was to address the major causes of the failure of AD drug candidates in the clinic, due either to lack of efficacy or unforeseen toxicity. The speakers discussed the obstacles to successful AD drug discovery stemming from (1) the limitations of using a target-based reductionist approach, (2) the lack of sufficient biology and chemistry quality control in preclinical research, and (3) the challenges associated with the use of animal models in preclinical drug development. Possible solutions were also discussed, such as the use of the quantitative and systems pharmacology (QSP) approach.4 QSP (the merging of systems biology and pharmacology) draws on existing ideas and established concepts from traditional pharmacology, physiology, and targetbased drug discovery. As such, it breaks decisively with the "one-gene, one-receptor, one-mechanism" approach in favor of a network-centric view that relies on mathematical models to achieve the necessary integration of data and hypotheses.

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The session featured case studies of the use of QSP in other therapeutic areas and examples of ways by which it may tackle root causes of attrition in AD therapy development.

The panelists raised additional issues such as the importance of translatable biomarkers in preclinical drug development, the need for implementing best practices for use of animal models in preclinical therapy development, and the need for collaboration and the sharing of information between all sectors involved in preclinical therapy development.

WHO TO TREAT, WHEN TO TREAT, AND WHAT OUTCOMES TO MEASURE?

The AD field has made significant advances in characterizing the prodromal asymptomatic phase of the disease. These findings have opened new opportunities for early diagnostics and intervention. At the same time, the number of patients with clinically symptomatic disease is rapidly growing, demanding effective treatments for both the cognitive and neuropsychiatric sequelae of the disease. This session addressed the formidable challenges associated with clinical development for AD.

The speakers provided an overview of the reasons for the failure of AD therapeutics in clinical trials and highlighted the critical importance of testing the right target and the right drug at the right stage of the disease. They discussed how lessons learned from the failure of candidate therapeutics in the clinic can inform the clinical development of new drug candidates. Also addressed were regulatory issues related to trials in presymptomatic patients and the use of biomarkers for patient selection and as outcome measures.

The panelists addressed issues associated with intervening at different stages of the disease in a highly heterogeneous patient population, including (1) using pharmacogenetics and brain imaging for patient selection and stratification, (2) novel trial designs and the use of biomarkers in special populations, (3) the importance of biomarkers of target engagement and staging biomarkers for use in clinical development, and (4) challenges in patient selection and recruitment associated with ethnic and cultural diversity.

DRUG REPURPOSING AND COMBINATION THERAPY

Drug repurposing or repositioning typically refers to the pursuit of new uses/disease indications that are different from those initially studied. Repurposing has a number of advantages over the development of new drugs and has been done successfully for a number of disease conditions. Despite several failed attempts at drug repurposing for AD, this approach is considered as a promising therapeutic avenue and is being actively pursued. The session addressed the scientific

and economic rationales for drug repurposing and highlighted the recent launch of the NIH-Industry Drug Rescue and Repurposing Pilot Program: Discovering New Therapeutic Uses for Existing Molecules (http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/therapeutic-uses/therapeutic-uses.html).

Also addressed was the need for developing combination therapies for AD and the extraordinary challenges associated with this therapeutic approach. The session featured the usefulness of the network pharmacology approach for drug repurposing and for the development of combination therapy. Some of the key issues addressed by the panelists in this session were lessons learned from failed AD trials with repurposed drugs, the importance of repurposing and combination therapy for treating the neuropsychiatric symptoms of AD, and the value of mining electronic medical records and large registries along with biobanks for identifying promising drugs for repurposing.

Nonpharmacological Interventions

Nonpharmacological interventions such as exercise and cognitive training are considered to be promising therapeutic avenues for AD prevention and treatment. This session focused on the unique challenges related to the selection, testing, and implementation of nonpharmacological interventions. The speakers discussed how studies of exercise, behavioral enrichment, and diet in animal models shed light on disease mechanisms and new targets and provide preclinical proof of concept and pointed to the gaps in our understanding of the effects of these interventions in humans. The discussion led by the panelists centered on the following issues: (1) methods for effectively integrating findings from epidemiology and basic and translational research in order to select the right nonpharmacological intervention(s), (2) challenges associated with the design of cognitive training and exercise trials at different stages of the disease, and (3) the importance of nonpharmacological interventions for improving the quality of life for patients and caregivers.

NEW MODELS OF PPPS

It is clear that the formidable challenge of identifying successful therapies for AD will require not only a high level of integration of scientific disciplines but also a real partnership between government agencies, academia, industry, and nonprofit organizations. This session highlighted the importance of partnerships to create synergies between stakeholders to overcome existing barriers in AD therapy development. The session featured examples of successful NIH-led PPPs such as the Alzheimer's Disease Neuroimaging

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Initiative (ADNI) and The Biomarkers Consortium and discussed new models of PPPs that may be applicable to the advancement of various stages of AD therapy development such as the Arch2POCM precompetitive partnership for target validation,⁶ product development PPPs at the NIH and at large, and the latest trends of partnering in industry. The panelists addressed existing barriers to the successful pursuit of these new enterprises such as intellectual property (IP)/patent issues and highlighted additional venues for partnering around open-access data sharing, standardization, and validation of translational research tools and patient engagement.

At the end of the general program, a writing committee composed of a subgroup of speakers and panelists was convened to synthesize the recommendations received from all Summit participants and attendees. Several overarching, transformative concepts were identified by the Summit participants as critical to achieving success in AD therapy development, and these emerged repeatedly throughout the Summit:

- Recognize the heterogeneity and multifactorial nature of the disease
- Employ new research paradigms such as systems biology and network pharmacology
- Enable rapid and extensive sharing of data, disease models, and biological specimens
- Build new multidisciplinary translational teams and create virtual and real spaces where these teams can operate
- Develop strategies to overcome IP barriers to AD drug development

- Develop new PPPs
- Establish a National Institutional Review Board for AD clinical research

The complete set of final recommendations can be found at http://www.nia.nih.gov/newsroom/alzheimers-disease-research-summit-2012-recommendations.

These recommendations will help guide both the public and private sectors toward meeting the research goals set forth in the National Plan to Address Alzheimer's Disease, a national strategy announced at the Summit by Health and Human Services Secretary Kathleen Sebelius. We hope that the Summit and the initiatives emerging from it will accelerate and transform AD therapy development. This will require engaging all stakeholders (government, academia, industry, private foundations, and citizens) in various partnerships centered around specific goals. ��

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EARTHCUBE

Clifford Jacobs, Ph.D., Senior Advisor, Geosciences Directorate, National Science Foundation

Almadena Y. Chtchelkanova, Ph.D., Program Director, Computing and Communication Foundations, National Science Foundation

INTRODUCTION

EarthCube, a transformative endeavor undertaken by the National Science Foundation (NSF), uses an innovative process to create an integrated data and knowledge management system extending across the geosciences. To do this, EarthCube engages geoscientists along with experts in cyberinfrastructure (CI), big data, and computer science to create and implement this new vision. For more information on EarthCube, please see http://earthcube.ning.com.

To understand and predict the Earth system from the center of the Sun to

the center of the Earth is a bold call to action by the Advisory Committee for Geosciences Directorate at the NSF. Similar calls can be found through a search of the global scientific literature (e.g., the National Academies Division on Earth & Life Studies). The dominant

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theme in these reports is how such understanding and ability to predict affect humanity, now and in the future. It is important to note that almost all of these reports recognize the importance of the use of CI to derive knowledge from a cornucopia of information and data about our planet, the Sun, and the near-space environment (the portion of space between the Sun and the Earth).

Propelled by an industry-driven technology revolution over the last decade, geoscientists working with informaticists have created an everincreasing array of CI solutions that serve research and educational needs. A number of communities within the geosciences have created, or are in the process of creating, highly functional and robust CI systems to increase the productivity and capability of research communities, for example, UNIDATA (meteorology), IRIS (seismology), and OOI (oceanography).

Although outputs from these systems are of great value to the communities they serve, the outcome with respect to understanding and predicting the Earth as a single complex system remains to be fully realized. Insufficient community dialog and sharing of ideas, practices, data, etc., across disciplines within the geosciences have led to redundancy and reduplication in cybertechnologyenabled solutions to solve similar problems.

Without an overall guiding framework to promote convergence, the diversity of approaches becomes a barrier to the holistic study of the Earth system. Although there is evidence of a community movement toward increased compatibility through the use of common standards and software, this process, if left unstimulated, would be too slow to allow the geosciences community to address the most pressing challenges outlined in various

reports (e.g., the crossroad challenges articulated in the GEO Vision report [download PDF report at http://www.nsf.gov/geo/acgeo/geovision/nsf_ac-geo_vision_10_2009.pdf]).

EARTHCUBE

The NSF is facilitating a community dialog in an effort to transform the conduct of research in the geosciences by supporting the development of a community-guided CI to integrate data and information across the geosciences.

The purpose of the project is to significantly increase the productivity and capability of researchers and educators by integrating all geosciences data, information, knowledge, and practices in an open, transparent, and inclusive manner. No integrated framework currently exists that is sufficiently functional and robust to allow a holistic view of the Earth system.

This is not for lack of investment in CI by the NSF, other agencies, or international partners. Rather, it is an outcome resulting from a long history of making needed tactical investments in subdisciplines of the geosciences. Most of these investments effectively serve the communities that have come to depend on them. Through these investments and concurrent investments in people, other tools, and ideas, the community helped establish a strong CI foundation and user-savvy CI culture. However, recent surveys and community dialog reveal a frustration with CI-created incompatibilities across the geosciences and a readiness to strategically address the incompatibilities.

The challenge faced by funding agencies lies in transforming substantial previous CI investments in collecting, curating, and disseminating geosciences data so that these investments can become more "interworkable" and be shared more uniformly with a myriad of end users. The good news is that

technologies emerging from industry will create an opportunity to greatly facilitate the convergence process within the geosciences, because all the technologies used today by the subdisciplines of geosciences will be completely refreshed over the next decade. The framework developed under the auspices of EarthCube will guide the refreshment choices toward establishing an interworkable structure to study the Earth system.

When created, EarthCube will be a (cyber)tool for anyone interested in environmental-data-enabled science, which will greatly facilitate the understanding of pertinent connections among the biological sciences and human health issues. Illuminating these connections will be useful to researchers and policymakers when merging health data with environmental data (e.g., soil, water, climate, and atmosphere).

CURRENT EFFORTS

The second EarthCube Charrette (active community meeting) was held June 12-14, 2012. The goal of the meeting was to create robust drafts of community-derived roadmaps for the funded community groups and to discuss and provide input into the roadmaps for the present concept award portfolio. After the meeting, all roadmap documents were posted for public comment to allow the broadest possible input from the community and all interested parties. The final versions of the community group roadmaps will be made public in mid to late summer in preparation for continued funding opportunities. Roadmaps, deemed by the NSF to be representative of community input and addressing the guidance provided, will form the basis of additional funding opportunities in late 2012 or early 2013. The meeting was open to all participants. Similar to the November 2011 Charrette, there

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were opportunities to participate either locally (at the Key Bridge Marriott in Arlington, VA) or virtually (via WebEx and other online technologies). The expected outcome goal of the EarthCube Charrette (through the face-to-face meeting and subsequent virtual dialog) was a collaboratively produced framework that provides a coherent structure of how currently funded activities can form an integrated and synergistic path forward with a clear sense of sequencing, interdependencies, and missing pieces that could define a set of activities over the next 3 to 5 years. Another goal was to produce a set of roadmaps/project plans with short-term priorities, which will guide the focus, timing, and resources required for amendments to the EarthCube solicitations.

EARLY EFFORTS

The NSF Geosciences Directorate and the Office of Cyberinfrastructure established a partnership to address the multifaceted challenges of modern, data-intensive science and education. The EarthCube program is one manifestation of the NSF-wide program "Cyberinfrastructure for the 21st Century." A "Dear Colleague Letter" initiated EarthCube in June 2011 and was followed by several WebEx-enabled dialogs with the community. These and other events set the stage for the Charrette held November 1-4, 2011. The Charrette provided the opportunity for the community to come together (face to face and virtually) to clarify the breadth and scope of EarthCube, identify potential new science that could be accomplished within a future

framework, and develop a rough order to the set of capabilities that would be needed to realize the EarthCube vision. Information on the Charrette and its outcomes is available at the EarthCube Web site (http://earthcube. ning.com/page/charrette). A second "Dear Colleague Letter" was released on December 16, 2011, and provided guidance for proposals to the NSF that would explore transformational ideas to enable EarthCube. As with these early efforts and the second Charrette, the NSF will continue to facilitate a broad-based community dialog through a variety of modern and traditional methods to further develop a strategic framework for EarthCube and encourage convergence of collaborations within the geosciences and beyond. �

OTT LAUNCHES ENTREPRENEUR-IN-RESIDENCE PROGRAM

Steven M. Ferguson, CLP, Deputy Director, Licensing and Entrepreneurship, Office of Technology Transfer, Office of the Director, National Institutes of Health

The industry expertise of entrepreneurs-in-residence was once the sole preserve of venture capital organizations, but today research organizations are tapping that expertise to help catalyze the development of important research discoveries they have made. Now, the further development of leading-edge discoveries in the biosciences increasingly takes place in new or recently started firms. The need to focus on startup firms to commercialize early-stage technologies from the National Institutes of Health (NIH) and U.S. Food and Drug Administration (FDA) intramural research programs has led the NIH Office of Technology Transfer (OTT) to partner with BioHealth Innovation, Inc. (BHI) to place an entrepreneur-in-residence (EIR) at the OTT. The new EIR will support the formation and development of new companies based on the most innovative discoveries in the areas of drugs, vaccines, therapeutics, diagnostics, and medical devices from the NIH and FDA intramural research programs.

Although the FDA has separately launched an EIR program focused on regulatory matters affecting new companies, the OTT EIR will focus on the development and commercialization of new health care technologies. Even though it is still early in the process, specific activities for the new program are expected to assist NIH technology transfer functions in five primary areas:

- Aid the launch of new entrepreneurial ventures based on NIH and FDA intramural technologies
- Assist in the evaluation of existing technologies in NIH and FDA intramural invention portfolios where the EIR has
 particular expertise
- Provide functional expertise to the OTT in evaluating new license proposals from startup companies

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 Mentor and coach intramural scientists to help them better understand when their research becomes truly commercially valuable

Advise those intramural scientists who leave the NIH with the intention of starting companies based on NIH and FDA intramural technologies

The NIH program is one of the initial efforts sponsored by BHI, a new regional public-private partnership focusing on commercializing market-relevant biohealth innovations and increasing access to early-stage funding in central Maryland. BHI describes itself as funded by businesses, universities, foundations, and nongovernmental organizations as well as by local, State, and Federal Governments. Businesses can make contributions to BHI either as a tax-deductible contribution to the 501(c)(3) organization or as an investment in new biohealth early-stage investment funds. The initial contributors to BHI include Montgomery County Maryland Government, MedImmune, LLC, Human Genome Sciences, Inc., Johns Hopkins University, and the University System of Maryland. Because of the size of the NIH and FDA intramural research programs, the OTT was selected as the site for the first of what is hoped to be many regional EIRs sponsored by BHI, each looking to help startups based on innovative discoveries from laboratories in the area.

In April 2012 BHI and the OTT jointly selected the initial EIR for the NIH program by choosing Todd Chappell, a venture-capital-backed entrepreneurial leader and inventor with more than 10 years of experience in molecular biology research, drug development, and life sciences business strategy.

Before coming to BHI and the NIH, Mr. Chappell served for 3 years as Vice President of Operations at venture-capital-backed Shape Pharmaceuticals, Inc. In that role, he directly oversaw the advancement of a discovery-stage oncology program into a human clinical study. Previously, Mr. Chappell spent 9 years at CombinatoRx, Inc. (now Zalicus Inc.), where he served as Director of New Products. He received his Bachelor of Science in biology from the University of California, Los Angeles, and his Master of Business Administration from Boston University. •

2012 MHEALTH SUMMIT—CONNECTING THE MOBILE HEALTH ECOSYSTEM

Richard M. Scarfo, Vice President, Vendor Events, Healthcare Information and Management Systems Society

The 2012 mHealth (mobile health) Summit returns for its fourth year with a new partnership, increased attendance, a larger exhibit floor, themed pavilions, and a strong focus on research.

The Summit will be held December 3-5 at the Gaylord National Resort and Convention Center just outside of Washington, DC. The Healthcare Information and Management Systems Society (HIMSS), an organizing partner of the Summit in 2011, recently acquired the event from the Foundation for the National Institutes of Health (FNIH). The Summit will be presented by mHIMSS, the mobile initiative of HIMSS, in partnership with the National Institutes of Health (NIH), the mHealth Alliance, and the FNIH. The FNIH team that launched and has organized the Summit since 2009 also has joined HIMSS.

The event will continue its history of partnerships and inclusion and, through its strategic affiliate program, welcomes new industry organizations to the mix this year, including

the Consumer Electronics Association, CTIA-The Wireless Association, eyeforpharma, and GSMA. They join veteran groups that include Ashoka, The Anson Group, LLC, Amplify Public Affairs, LLC, CDC Foundation, Continua Health Alliance, GBCHealth, iMedicalApps, LLC, Rock Health, StartUp Health, WestHealth, Wireless-Life Sciences Alliance, and the United Nations Foundation.

The mHealth Summit is the only event focused on bringing together the most complete range of stakeholders in the mHealth value chain and on fostering new relationships and multisector partnerships and growth strategies that will advance the integration of mHealth into the greater health care ecosystem. Through the conference program, exhibit floor, and networking events, the Summit is the premiere global platform for transforming mobile and wireless innovation in health care.

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A broader diversity of sectors will be represented at this year's Summit, with attendance expected to surpass 5,000 people from over 50 countries—a 38-percent increase over last year's Summit. As the mHealth ecosystem expands and as mHealth technologies continue to permeate health care delivery and research, attendees from across the world and



across various sectors continue to see the mHealth Summit as the leading global convener of this space. In addition to researchers, clinicians, policymakers, foundations, and nongovernmental organizations (NGOs), attendees also will include payers, providers, patient groups, pharma, wireless access providers, system integrators, device makers, and others related to wireless health, connected health, and telehealth.

The exhibit floor will serve as a key indicator that the industry is growing and evolving. Exhibits will fill three contiguous halls with stands from industry heavyweights Verizon, Qualcomm, AT&T, and others that will showcase the latest applications and technologies. A series of pavilions will help define the event. In addition to the NIH, Rock Health, StartUp Health, and Qualcomm Life Wireless Health Pavilions, attendees will experience the Interoperability Showcase and the Better Health Through mHealth Pavilion.

"Better Health Through mHealth" represents the emergence of disease-specific focus areas and will be presented by iMedicalApps. The exhibit will highlight emerging mHealth systems that will transform the management of diabetes and chronic heart failure, two diseases that together affect over 30 million people in the United States. Increasingly, sophisticated data networks are enabling the real-time collection of patient data, and powerful analytic tools are providing remarkable clinical insights. This pavilion will guide the visitor through the data pathway ranging from sensors, wireless gateways, and electronic health records—to the physician and back to the patient. At scheduled intervals on a stage in the pavilion, mHealth researchers will discuss their research; these presentations will underscore evidence-based, mobile-enabled regimens of care, which are gaining significance as accountable care organizations and other outcome-centric payment decision models emerge.

This year's conference program will focus on global research and on business, policy, and technology issues around mHealth. The program will consist of a series of supersessions and tracks, including the new topic areas of "Health and Health Care Delivery" and "Global Health." The Global Health track will highlight mHealth efforts, progress, and challenges for improving health care outcomes in lowand middle-income countries. Additionally, pharma and life sciences will have an increased content presence, and disease management issues are front and center in this year's program. This will all be rounded out by sessions aimed at payers, providers, and military-related health care issues.

The NIH is once again taking the lead in setting the research agenda at the mHealth Summit. NIH Director Dr. Francis A. Collins will open the event with a keynote address and set the tone for the following 3 days of activities, which will include the NIH Pavilion, topical morning research roundtable discussions, and more than 20 sessions focused on disease management, preventive medicine, health promotion, and research and diagnostic tools. In addition, 2012 will mark the return of the NIH mHealth Winter Training Institute, which will be hosted and funded by mHIMSS and the mHealth Summit in an ongoing commitment to the importance of research and the unique intersections it offers at the event.

"In this quickly evolving mHealth ecosystem, the mHealth Summit has become the most impactful event for serious discussion, collaborations, and knowledge-sharing among the science and health care sectors, policymakers, foundations, NGOs, and the mobile/wireless industry. These cross-sectoral partnerships are central to harnessing the power of technology to create a healthier world by extending patient

access, enabling greater institutional efficiencies, reducing costs, and improving the quality of health outcomes and patient satisfaction," commented Richard Scarfo, Vice President of the mHealth Summit at HIMSS.

HAVE QUESTIONS? CONTACT A MEMBER OF THE MHEALTH SUMMIT PLANNING COMMITTEE:

William Riley, Research Tracks wiriley@mail.nih.gov

Wendy Nilsen, Training Institute nilsenwj@od.nih.gov

Peggy Diab, Call for Presentations pdiab@himss.org

Richard Scarfo, General Inquiries rscarfo@himss.org

For more information on the mHealth Summit or to register at the special Federal Government rate, please go to www.mhealthsummit.org. Additional information regarding mHIMSS can be found at www.mhimss.org. ��

OSTEOARTHRITIS BIOMARKERS PROJECT MAY IMPROVE QUALITY OF LIFE FOR THOSE WITH KNEE OSTEOARTHRITIS

Jonelle K. Drugan, Ph.D., M.P.H., Office of Science Policy and Planning, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health

The National Institutes of Health (NIH) Osteoarthritis Initiative (OAI), an ongoing public-private partnership (PPP) to facilitate development of treatments for people who have knee OA, is the basis for a new Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium project.

The new biomarkers study will be conducted over the next 2 1/2 years by an international team of OA scientists and clinicians with funding from Abbott; Amgen Inc.; Arthritis Foundation; Bioiberica S.A.; DePuyMitek, Inc.; Flexion Therapeutics, Inc.; GlaxoSmithKline; Merck Serono; Rottapharm|Madaus; Sanofi; and Stryker. In-kind donations to support biochemical tests will be provided by Alere Inc.; ARTIALIS S.A.; BioVendor Laboratorni Medicina; IBEX Pharmaceuticals Inc.; Immunodiagnostic Systems Inc.; and Quidel Corporation.

Two world-renowned scientists from the Osteoarthritis Research Society International (OARSI), Dr. David Hunter at the University of Sydney (Australia) and Dr. Virginia Byers Kraus at Duke University, will head the effort. OARSI, the leading professional society in this field, has been involved in this project from its inception. The researchers will analyze biomarkers that were selected after a series of OARSI-sponsored meetings, which were convened in response to a request from the U.S. Food and Drug Administration to examine the existing evidence for imaging and biochemical markers of OA onset and progression.

OA, the most common form of arthritis, involves cartilage loss and bone restructuring resulting in abnormally shaped joint bones, loss of function, and pain. Knee OA is a leading cause of disability in older adults and is expected to become more prevalent, given trends such as increased participation in sports, improved longevity, and the worldwide upsurge in obesity. Early medical intervention for those with OA is currently hampered by a lack of welldefined, clinically relevant physical or biological measures (or "biomarkers") that can be used to determine its onset and to assess progression. The FNIH study seeks to evaluate multiple biochemical and imaging biomarkers with the aim of finding more precise ways to measure both the progression of the disease and, potentially, the effectiveness of new treatments.

"This project has incredible potential to improve our ability to accurately monitor the progression of OA, could lead to early intervention, and decrease the debilitating, life-altering effects of this disease," say Drs. Hunter and Kraus. "Early therapeutic intervention can lead to a better quality of life."

An advantage of this project is that it will make use of the OAI, a public-domain repository of medical images, patient data, and biospecimens that is funded by a PPP of seven NIH Institutes, Centers, and Offices and four pharmaceutical companies and that is jointly led by the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute

on Aging. Since the NIH launched the OAI in 2002, over a 3-year period the initiative has collected, deidentified, and archived biological specimens, images, and clinical data from almost 5,000 men and women age 45 years and older who are either at high risk for developing knee OA or in an early stage of the disease. The breadth of information that the OAI contains allows researchers to develop hypotheses about possible OA biomarkers of disease risk factors, onset, and progression; test their theories; describe the natural history of OA; and investigate factors that influence disease severity and progression.

"The Osteoarthritis Initiative was developed to enable the discovery of biomarkers and new treatment targets for knee osteoarthritis," says Dr. Gayle Lester, the NIAMS Program Director who oversees the OAI. "NIH is pleased to see the use of this research resource in a biomarker project funded by the FNIH Biomarkers Consortium and led by a team of international experts. Results from these investigations hold promise for the development of new therapies for this debilitating disease." *

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IN REVIEW: NIH PUBLIC-PRIVATE PARTNERSHIP COORDINATING COMMITTEE MEETINGS

Marjorie A. Bonorden, Office of Science Policy, Office of the Director, National Institutes of Health

The National Institutes of Health (NIH) Public-Private Partnership Coordinating Committee (PPPCC) is a trans-NIH committee with representation from all 27 Institutes and Centers (ICs) and from the Office of the Director (OD). The goals of the PPPCC are several: to serve as a bidirectional communication venue between the Office of Science Policy/OD and the ICs, to gather and disseminate new and relevant information and models for PPPs, and to provide focused guidance for the NIH staff regarding the development and implementation of PPPs. The monthly PPPCC meeting, first convened in June 2006, has grown in attendance from committee members only to include any NIH employees who are interested in attending. The meetings are held on the third Thursday of each month from 2:30 - 4:30 pm at the NIH, and speakers from within and outside the NIH provide informative presentations at the meetings. Each year we try to connect PPPCC meeting speakers and presentations to a particular theme or subject matter and have included speakers from industry, Federal agencies, foundations, academia, etc.

The following are highlights from some of the PPPCC meetings over the past 18 months:

2010 - 2011 MEETING TOPICS/SPEAKERS: PPPS: WORKING WITH NOT-FOR-PROFIT ENTITIES

September 2010, *Vardit Ravitsky*, Ph.D., Assistant Professor, Bioethics Programs, Faculty of Medicine, University of Montreal. Dr. Ravitsky, a Canadian bioethicist trained in the United States and a former NIH bioethics fellow, discussed the ethics of PPPs from an international perspective.

October 2010, *Scott Campbell*, Ph.D., then Executive Director and Chief Executive Officer, Foundation for the NIH (FNIH). Dr. Campbell discussed his vision and plans for the next phase of the Foundation's operations as he began his tenure at the FNIH.

November 2010. Two speakers discussed programs and prospects for PPPs for rare and neglected diseases:

- Christopher P. Austin, M.D., then Director, NIH Chemical Genomics Center, Senior Advisor to the Director for
 Translational Research, Office of the Director, National Human Genome Research Institute (NHGRI); Associate
 Investigator, Genome Technology Branch, NHGRI; and current Director, Division of Pre-Clinical Innovation, National
 Center for Advancing Translational Sciences. Dr. Austin's presentation "The Critical Role of Partnerships and TRNDs
 and the NCGC" focused on trans-NIH translational programs and on the NIH Chemical Genomics Center (NCGC) and
 provided an overview of therapeutics for rare and neglected diseases (TRNDs).
- *James O'Leary*, Chief Information Officer, Genetic Alliance, discussed reducing barriers to drug development through patient partnerships. Mr. O'Leary also discussed the Genetic Alliance's views and activities related to PPPs.

December 2010. Several speakers addressed the topic of "Novel Strategies for Problem Solving," with particular emphasis on open innovation to solve challenging needs within the life sciences: *Jeffrey R. Davis*, M.D., Director, Space Life Sciences (SLS), National Aeronautics and Space Administration (NASA); *Elizabeth Richard*, Senior Strategist and Manager, Strategic Planning and Execution, Wyle Integrated Science and Engineering Group; *Jason Crusan*, Chief Technologist for Space Operations, NASA; *Jennifer Fogarty*, Ph.D., Innovation and Development Lead, Directorate, Strategic Execution and Innovation Office, SLS, NASA; and *Robynn Sturm*, M.A., J.D., Advisor for Open Innovation, Office of the Deputy Director, Office of Science and Technology Policy, The White House.

March 2011, Garry Neil, M.D., Corporate Vice President, Corporate Office of Science and Technology, Johnson & Johnson. Dr. Neil discussed "Private Public Partnerships (P3)" from Johnson & Johnson's viewpoint and focused on challenges and opportunities in translational research, as well as on models and approaches to address these, and suggested some ways in which the private and public/government sectors can interact.

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May 2011, Karim R. Lakhani, Ph.D., M.S., Assistant Professor, Harvard Business School, and Faculty Associate, Berkman Center for Internet and Society, Harvard University, and Eva C. Guinan, M.D., Associate Director, Center for Clinical and Translational Research, Dana-Farber Cancer Institute; Medical Director, Harvard Catalyst Laboratory for Innovative Translational Technologies; Director, Harvard Catalyst Linkages Program; and Associate Professor of Pediatrics, Harvard Medical School. Drs. Lakhani and Guinan presented a challenge to develop new models of diabetes mellitus and discussed how that challenge played out, their research in the prizes and challenges arena, and how prizes and challenges can advance biomedical science. An important aspect of their presentation was the focus not only on the outcomes of the challenge but also on developing a robust research program to assess and improve the application of these open innovation methods to topics and fields consistent with, for example, the NIH's mission.

2011 - 2012 MEETING TOPICS/SPEAKERS: PPPS: INTELLECTUAL PROPERTY: PRECOMPETITIVE TOOLS, PLATFORMS, AND APPROACHES

October 2011, *Gretchen H. Weaver*, J.D., Senior NIH Ethics Counsel, Ethics Division, Office of the General Counsel, U.S. Department of Health and Human Services. Ms. Weaver led a discussion regarding the ethics and practices surrounding PPPs. *Elena Koustova*, Ph.D., M.B.A., Health Science Administrator, National Institute on Drug Abuse (NIDA), discussed NIDA's efforts to promote the development of smoking cessation therapeutics through a product development partnership.

November 2011, *Kenneth A. Savin*, Advisor for Special Projects, Global External Research and Development/Due Diligence, Eli Lilly and Company. Dr. Savin's presentation "Finding the Needles in the Haystacks . . . Building Partnerships for the Future" provided background about Eli Lilly and efforts at Lilly to assist in moving discovery to development and commercialization; what Eli Lilly considers when deciding to do a partnership; intellectual property (IP) considerations; and his views on the precompetitive landscape.

January 2012, *Barbara Mittleman*, M.D., Director, NIH PPP Program. Dr. Mittleman provided PPPCC meeting attendees with an overview of PPPs and a review of the PPP topics and projects that the PPP Program either has led or has been involved in over the past year, including The Biomarkers Consortium, mobile health (mHealth) partnerships and other related activities, research projects such as the Stakeholder Alignment in The Biomarkers Consortium, product development partnerships, and others. She also provided a slide set that IC staff members can share and use in their own PPP discussions and presentations.

February 2012, *Stephen H. Friend*, M.D., Ph.D., President, Co-Founder, and Director, Sage Bionetworks. Dr. Friend's presentation "If the Physicists Can Do It and the Software Engineers Can Do It, Why Can't We Do It?: Networked Team Approaches Among PPPs" provided background about Sage Bionetworks. He also discussed his views and experience about data sharing and collaboration across sectors, both from his vantage point of many years in industry as well as from the Sage/nonprofit point of view.

March 2012, Christopher D. Earl, Ph.D., President, Innotrove LLC. Dr. Earl's presentation "Everything You Always Wanted To Know About Venture Capital and Venture Philanthropy" offered his views on how to move technologies, novel insights, and inventions forward to market. He emphasized the extent to which scientific training and expertise, coupled with an understanding of the marketplace and both opportunities for and barriers to development, shape the investment environment.

- **April 2012**, *Jack J. Young*, Lead Investment Manager, Qualcomm Life Fund, Qualcomm Ventures. Mr. Young's presentation "Wireless Health, a Life Story" provided background about mHealth, an overview of the Qualcomm Life Fund, how Qualcomm seeks and assesses investment opportunities, how Qualcomm sees its role in the ecosystem, and how Qualcomm believes it can or should interact with other players such as researchers, academics, government agencies, etc.
- **May 2012**, *Robert DeBerardine*, Vice President and Head, Global Patent Department, Sanofi US. Mr. DeBerardine provided a broad and deep dive into the IP landscape and focused on controversies and challenges related to IP, collaboration and open innovation, and redefining the extent of the precompetitive space.
- **June 2012**, *Carolyn Compton*, M.D., Ph.D., President and CEO, Critical Path Institute (C-Path). Dr. Compton's presentation "Rules, Tools and Data Pools: Drug Development Solutions and How To Get Them" was a special presentation to

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the 2011-2012 PPPCC discussion series. She discussed C-Path, its mission, how it works and its business model, its areas of interest, its partners, and how C-Path and the NIH can fruitfully interact.

In preparation for the meetings that will resume in fall 2012, we are inviting guest speakers for PPPCC discussions that will focus on "Patient and Public Engagement: Partnerships To Improve Public Health." As always, these presentations include an opportunity for questions/answers and open discussion. All meetings are regularly scheduled on the third Thursday of each month, from 2:30 - 4:30 pm. We encourage in-person attendance whenever possible to facilitate high-quality discussion and to get acquainted with potential partners through this series. The PPPCC meeting in June 2012 was the last meeting before breaking for summer, so there will be no meetings in July and August 2012. We hope you will be able to join us, and please feel free to distribute this opportunity within your IC and invite all interested NIHers to join us! See you in September! •

We are taking the opportunity to mark, with this issue, the suspension of the PPP newsletter, *PPP Advisor*. After more than 4 years since its inception, we would appreciate your feedback regarding the value you have found in the *PPP Advisor*, and more generally in the NIH PPP Program. This information will help us understand how to proceed while we take the time to evaluate our functions. Please provide your feedback and comments by e-mail to pppartnerships@od.nih.gov or to mittlemb@od.nih.gov. Thank you for your reading attention, contributions, and input.

CALENDAR

DATE	MEETING	LOCATION & TIME	SPEAKER
9.20.12	PPP Coordinating Committee (PPPCC) Meeting*	NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm	Erik Kuja, J.D., Associate Director, Worldwide Business Development and Innovation, Pfizer Inc. Public-Private Partnerships: Intellectual Property—Precompetitive Tools, Platforms, and Approaches
TBA	mHealth Inter-Institute Interest Group (mHealth IIIG) Meeting**	ТВА	Monthly trans-NIH committee meeting to discuss NIH mobile health and wireless activities and partnerships within NIH and with outside partners
10.18.12	PPPCC Meeting*	NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm	Patient and Public Engagement: Partnerships To Improve Public Health (speaker TBA)
ТВА	mHealth IIIG Meeting**	ТВА	Monthly trans-NIH committee meeting to discuss NIH mobile health and wireless activities and partnerships within NIH and with outside partners
11.15.12	PPPCC Meeting*	NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm	Patient and Public Engagement: Partnerships To Improve Public Health (speaker TBA)
ТВА	mHealth IIIG Meeting**	ТВА	Monthly trans-NIH committee meeting to discuss NIH mobile health and wireless activities and partnerships within NIH and with outside partners
12.20.12	PPPCC Meeting*	NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm	Patient and Public Engagement: Partnerships To Improve Public Health (speaker TBA)
ТВА	mHealth IIIG Meeting**	ТВА	Monthly trans-NIH committee meeting to discuss NIH mobile health and wireless activities and partnerships within NIH and with outside partners

^{*}The PPP Coordinating Committee Meeting is for the NIH staff and invited guests only and meets on the third Thursday of each month. For additional information, please contact Ms. Marjorie Bonorden at bonordenm@od.nih.gov.

All meeting dates, locations, and times are subject to change.

^{**}The mHealth Inter-Institute Interest Group meets on the fourth Tuesday of each month. For additional information about the group or the meetings, please contact Dr. Bill Riley at wiriley@mail.nih.gov.

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

SPECIAL EVENTS/NEWS

The following information was provided in an e-mail notice sent from the National Aeronautics and Space Administration's Human Health and Performance Center.

In February 2012, the United States Patent and Trademark Office (USPTO), along with The White House, launched Patents for Humanity, a pilot program that creates business incentives for patent holders to engage in public health and humanitarian issues. Through this competition, the USPTO will recognize those who effectively apply their technologies to global challenges and encourage additional innovation in this area.

From now through August 31, 2012, participants can send in applications describing how they have used their patented technology or products to address humanitarian challenges. Judges will select winners in four categories: medical technology, food and nutrition, clean technology, and information technology. The focus is on actions that achieve tangible results improving the lives of the poor. Because some of the most innovative models for humanitarian endeavors come from small businesses, the Patents for Humanity program seeks applications from small and medium-sized businesses as well as large firms.

In addition to a public awards ceremony hosted by the USPTO, winners will receive a certificate that can be redeemed to accelerate a patent application, an appeal, or an ex parte reexamination proceeding before the USPTO. The certificate can be used on any technology in a recipient's portfolio, not just the humanitarian technology that qualified for the award. This ability to more quickly obtain or resolve uncertainty about a patent provides businesses with a valuable return on their humanitarian investments.

For more information on the program, visit the Patents for Humanity Web page (http://www.uspto.gov/patents/init_events/patents_for_humanity.jsp).

To apply, visit http://www.nasa.gov/pdf/666312main_PatentsforHumanityAll-PFlyer.pdf.

The submission period closes August 31, 2012. Any questions may be directed to patentsforhumanity@uspto.gov.

LOOKING FOR PPP INFORMATION?

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) 301.480.1147 fax pppartnerships@od.nih.gov

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