Public-Private Partnership Program

PPP Advisor

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Message From the Director

Dr. Barbara B. Mittleman

This issue of the *PPP Advisor* is chock-full of news and activities—the upcoming mHealth Summit, the 2010-2011 National Institutes of Health (NIH) Public-Private Partnership (PPP) Coordinating Committee series focusing on partnerships with not-for-profit entities, the National Academy of Sciences Government-University-Industry Research Roundtable (GUIRR) activities focusing on international agreements and ongoing research interactions across sectoral divides, and more. We also have word in this issue from the Foundation for the National Institutes of Health's (FNIH) incoming Executive Director and CEO Scott Campbell, Ph.D., who will share with us his thoughts on the next phase of activities at the FNIH.

Spotlight

The National Institutes of Health (NIH) Public-Private Partnership (PPP) Program is pleased to include in this issue a guest feature article by Scott Campbell, Ph.D., Executive Director and CEO, Foundation for the National Institutes of Health (FNIH). Dr. Campbell shares his vision and plans for the next phase of the Foundation's operations. Also featured is an article by Richard Scarfo, Director of Marketing, Communications, and Strategic Alliances, FNIH. Mr. Scarfo provides an update on the upcoming mHealth (Mobile Health) Summit.

Also in this issue are program updates from the PPP staff regarding The Biomarkers Consortium, the mHealth Summit and mHealth-related activities, and PPP Coordinating Committee meetings.

Audie Atienza describes elsewhere in the *Advisor* the plans for the 2010 mHealth Summit. This promises to be the premier event in this field—really! Around 3,000 representatives from all parts of the mHealth (mobile health) ecosystem—United States and international, technical and programmatic, research and policy, service and device—will join together to examine what data are being generated and what data are needed to make the very best uses of mobile technologies for health, health research, health care delivery, and health policymaking. The focus on research is unique among the plethora of meetings in this space, and the extent of the multisector international involvement is also unique. The meeting, sponsored by the FNIH and cosponsored by the NIH and a number of private organizations, is a partnership in and of itself. That said, meetings and conferences alone are not enough; therefore we expect a number of research partnerships to be developed, so look for upcoming announcements! Dr. Atienza will also report on the successes of the relatively new mHealth Inter-Institute Interest Group in sharing information across the many NIH Institutes and Centers (ICs) with mHealth activities in their portfolios and in providing a venue in which speakers on related topics can access interested NIH staff in an efficient manner.

"The PPP Program staff continues, in our ongoing activities, to support the NIH ICs in partnership development, memorialization, and implementation. Some new areas of development include exploring how PPPs for translational research might be effective in hastening the commercialization of NIH-supported scientific discovery and in bringing industry-developed information management and analysis tools to wide accessibility through the development of a broad-based PPP."

The Biomarkers Consortium (BC) continues apace, with ongoing projects generating data and insights into the utility and applications of biomarkers from research, clinical and regulatory uses,

(continued on page 2)

Inside This Issue

(CONTINUED FROM PAGE 1)

projects in development, and strategic decision-making about how to advance biomarker science. Shawnmarie Mayrand-Chung discusses the activities, progress, challenges, and operations of the BC in this issue's BC Update.

Finding the alignment among various organizations' goals, missions, and business practices is challenging when working inside a common legal framework, but is significantly more complicated when crossing national boundaries and legal systems. As science is increasingly global and as private companies in biomedical science are increasingly multinational in their structure and operations, international agreements are becoming commonplace. The National Academy of Sciences GUIRR International Agreements Group (I-Group) held a recent meeting in Washington, D.C., to examine cultural aspects, ethical principles, the responsible conduct of research, export controls, risk management, intellectual property, and legal considerations relevant to negotiating and executing international research agreements among diverse organizational entities and across national borders. Expected products from this conference include a published summary as well as the development of a primer for international agreements. A followup meeting to focus more specifically on several content areas may also be in the offing. Another GUIRR component, the University-Industry Demonstration Project (UIDP), is working to accomplish similar goals within the domestic United States setting, with a particular focus on funding, technology transfer, evaluation of early-stage technologies, and development of a researcher handbook and negotiation tools. UIDP membership includes universities, companies in a variety of business sectors, and NIH and the National Science Foundation (NSF). The fall 2010 UIDP meeting will be held in October in Charlotte, North Carolina, and will have a heavy informatics concentration. Among the topics of discussion will be drug repurposing and how the NIH Clinical and Translational Science Awards (CTSAs) can engage effectively with the UIDP. More information about the GUIRR, the I-Group, and the UIDP is available at www.nas.edu.

The PPP Program staff continues, in our ongoing activities, to support the NIH ICs in partnership development, memorialization, and implementation. Some new areas of development include exploring how PPPs for translational research might be effective in hastening the commercialization of NIH-supported scientific discovery and in bringing industry-developed information management and analysis tools to wide accessibility through the development of a broad-based PPP. More news of these efforts will be available as they gain structure. As always, please call early and often as you consider scientific and clinical partnerships between the NIH and outside entities. ❖

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

Perspectives from the New Executive Director of the Foundation for the National Institutes of Health

Dr. Scott Campbell, Executive Director and CEO, Foundation for the National Institutes of Health

The Foundation for the National Institutes of Health (FNIH) was established by Congress in 1990 as an independent nonprofit organization to raise private funds and create public-private partnerships in support of the mission of the NIH. The actual work of the FNIH began in 1996, and for the past 14 years the Foundation has been an active and dedicated partner with most, if not all, NIH Institutes and Centers (ICs), as well as with the NIH Office of the Director. As the New Executive Director and Chief Executive Officer (CEO) of the FNIH, I am committed not only to continuing our diligent efforts on behalf of the NIH, but also to utilizing more creative approaches to engage and commit new funding partners and to expand the engagement of our NIH colleagues. In the soon-to-be post-ARRA (American Recovery and Reinvestment Act) era and with the expected

(continued on page 3)

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budget challenges at the NIH in the foreseeable future, these partnerships will be needed now more than ever in order for the NIH to fulfill its mission. My intent is to diversify our corporate funding partners beyond the pharmaceutical and biotechnology sectors, which have been highly supportive of the FNIH and therefore the NIH mission and have historically been our largest partnership base. I am also putting in place the staff to reinvigorate our cultivation and stewardship of planned giving and individual giving donors. Finally, having spent the past 9 years in the voluntary health agency/patient advocacy sector, I would like to expand collaborative efforts with these potential partners as well.

By nature, the FNIH is a reactive organization. We take our cues from the NIH Office of the Director and are presented with potential partnership opportunities from NIH Institutes and Centers' Directors and their staffs. In an effort to be more proactive, I would like the FNIH to choose a few areas of concentration above and beyond the multitude of projects to which we are currently committed. Of particular interest to me are the areas of global health and translational medicine. We currently have a very active global health staff that is largely driven by funding from the Bill & Melinda Gates Foundation, but I would like to diversify and expand this effort with new funding partners/projects. The FNIH already has several ongoing efforts in translational medicine, but we are trying to better coordinate and expand these programs. Of course, we need to be flexible and nimble as topics such as comparative effectiveness research, systems biology, the microbiome, etc. come to the fore as potential research areas for which we may be asked to seek funding. I look forward to the challenges ahead and remain dedicated to the NIH and its mission. ❖

"As the New Executive Director and Chief Executive Officer (CEO) of the FNIH, I am committed not only to continuing our diligent efforts on behalf of the NIH, but also to utilizing more creative approaches to engage and commit new funding partners and to expand the engagement of our NIH colleagues."

The Biomarkers Consortium: *Becoming Involved as an NIH Representative*

Dr. Shawnmarie Mayrand-Chung

This installment of The Biomarkers Consortium (BC) activities presents a look at the ongoing BC operations and updates and explains the various levels of involvement that the National Institutes of Health (NIH) has in the selection, development, execution, and analysis of BC projects.

The BC is a precompetitive public-private partnership managed by the Foundation for the NIH (FNIH) and includes the NIH, the United States (U.S.) Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers of America (PhRMA) as founding partners. This multistakeholder collaboration was launched in October 2006 for the joint discovery, development, and qualification of biomarkers. The BC's products and outcomes include (1) identification and execution of cross-sectoral biomarker projects; (2) publications (Table 1), and (3) cross-sector familiarization, increased trust, new approaches to collaboration, and improved cultural competency among the more than 60 participating organizations, agencies, and companies (Table 2).

One hallmark of the BC is that there is an absolute requirement that the founding members participate in all activities and at every level (e.g., Executive and Steering Committees, Project Teams and Subteams, and Work Groups [Figure 1]) of the BC.

"The NIH has three representatives on the BC Executive Committee (EC), the overall governance body charged with the review and decision-making responsibility to uphold the mission, policies, and procedures of the BC."

Participation by the NIH means having one or more NIH representatives participating in the evaluations and discussions that take a BC project from the concept stage to a project plan

(continued on page 4)

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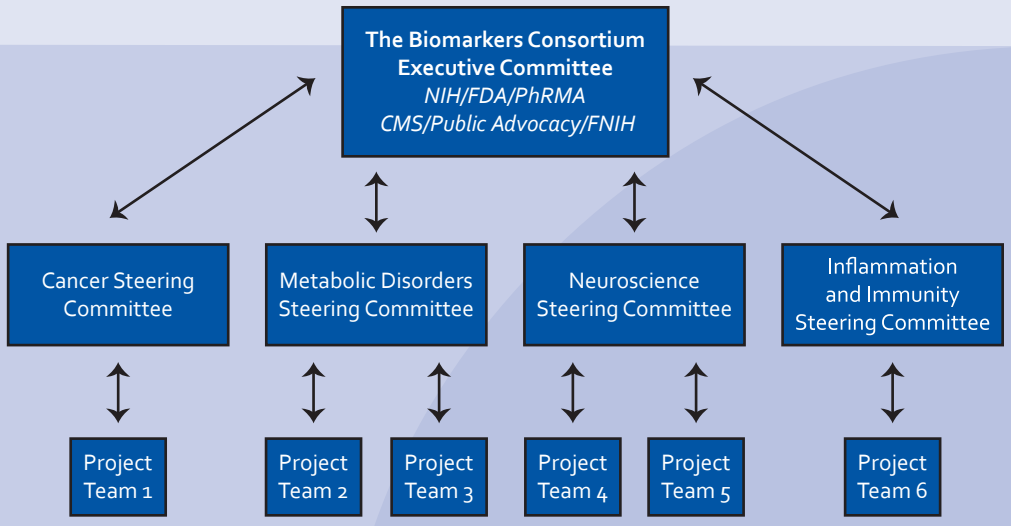
to implementation and analysis. It is often easy to identify the appropriate NIH representative to fill the needed role through a solicitation of the NIH's Institutes and Centers (ICs) to locate the necessary expertise and input. Some practical examples of the types of participation and how NIH representation is identified follow.

The NIH has three representatives on the BC Executive Committee (EC), the overall governance body charged with the review and decision-making responsibility to uphold the mission, policies, and procedures of the BC. Currently, three IC directors (selected by the NIH Director) represent the NIH on BC governance matters. With only three slots available to represent the interests of all 27 ICs, the NIH representatives keep an agency-wide perspective when deciding about the scope of projects and direction of growth that the BC should undertake. The Public-Private Partnership (PPP) Program can solicit input from other IC directors and staff to provide a broader perspective regarding the NIH position on BC matters when needed.

Figure 1



The process of project development and selection resides within the four therapeutic Steering Committees (SCs): Cancer SC, Neuroscience SC, Metabolic Disorders SC, and Inflammation and Immunity SC (Figure 1). Each SC has cross-sectoral representation, with the additional requirement that the NIH, FDA, and PhRMA have at least one active representative. Each SC is managed by two cochairs (each representing a different stakeholder group [e.g., government, industry, academia]) who serve a renewable 2-year term. SC cochair nominations come from both the BC's EC members and the BC's Contributing Members (see Table 1), and nominations are voted on by EC members only. NIH nominees come from either the EC representatives themselves and/or suggestions from fellow IC directors. During the solicitation process, the PPP Program solicits input from the IC directors and staff in naming candidates for NIH representation to the SC and shares this information with the NIH EC members.

Following a nomination period, an election by the EC members is held to determine which nominees will preside as the SC cochairs; currently, only three of the four SC cochair positions are

(continued on page 5)

Table 1. Biomarkers Consortium Publications

"Competitors Try Collaboration To Speed Drug Development" – *Journal of the National Cancer Institute*, 2010, Vol. 102 (12): 841-843.
"Biomarker-Led Adaptive Trial Blazes a Trail in Breast Cancer" – *Nature Biotechnology*, 2010, Vol. 28: 383-384.
"The Biomarkers Consortium: Practice and Pitfalls of Open-Source Precompetitive Collaboration" – *Clinical Pharmacology and Therapeutics*, 2010, Vol. 87 (5): 539-542.
"Biomarker Qualification via PPPs" – *Clinical Pharmacology and Therapeutics*, 2010, Vol. 87 (1): 21-23.
"The Road From Discovery to Clinic: Adiponectin as a Biomarker of Metabolic Status" – *Clinical Pharmacology and Therapeutics*, 2009, Vol. 86 (6): 592-595.
"Emerging Concepts in Biomarker Discovery: The US-Japan Workshop on Immunological Molecular Markers in Oncology" – *Journal of Translational Medicine*, Vol. 17 (7): 45.
"Utility of Adiponectin as a Biomarker Predictive of Glycemic Efficacy Is Demonstrated by Collaborative Pooling of Data From Clinical Trials Conducted by Multiple Sponsors" – *Clinical Pharmacology and Therapeutics*, 2009, 86 (6): 619-625.
"I-SPY2: An Adaptive Trial Design in the Setting of Neoadjuvant Chemotherapy" – *Clinical Pharmacology and Therapeutics*, 2009, Vol. 86 (1): 97-100.

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staffed by the NIH, but ideally there would be continuous NIH cochair representation on all four SCs. If you or someone you know would be interested in learning more about what it takes to hold this position, please contact me at mayrands@od.nih.gov.

Since a broad spectrum of expertise is required to cover all aspects of the four therapeutic SCs, membership on the SCs is driven largely by the knowledge and experience required to inform the project selection and decision-making process by the SC. Nomination to an SC can come from any BC founding or contributing member, and there is no need for EC approval of nominees. Rather, the decision to accept a nomination is made by the SC cochairs upon review of the nominee's credentials. Currently, each SC has several NIHers participating; however, the BC is always looking for enthusiastic participants to bring new and/or needed scientific expertise to the SCs.

The commitment to join an SC can be a very rewarding experience; however, there is an expectation that NIH representatives will be active participants to ensure that the NIH is effectively represented in the BC. SC members will be asked to participate in regular monthly teleconferences to discuss the selection and development of BC projects. The SCs also hold face-to-face meetings on an annual or biannual basis, to afford an opportunity to interact as a group and discuss the operations and direction of the SCs' efforts. There are also opportunities for NIH researchers to become further involved in the BC through (1) participating on SC subteams, which are responsible for vetting newly received Project Concepts and/or vetting emerging ideas for Project Concepts or (2) joining an SC work group, which explores the need for biomarker research in a particular disease area and then frames the question(s) that need to be addressed. The decision to participate on an SC subteam and/or work group is voluntary and usually is motivated by an SC member's personal research interests and/or expertise in the subject matter covered by the emerging biomarker Project Concept. To learn more about the benefits and/or responsibilities of joining one of the BC SCs, please e-mail me at mayrands@od.nih.gov.

Steering Committees have a broad perspective on a topic area, whereas the BC Project Teams are populated by a small group of scientists who are materially involved in the conduct of the project. This multisector group works to develop the approved Project Concept (3-4 pages) into a complete Project Plan (20-30+ pages). The requirements for qualification as a member of a Project Team are more involved than those for an SC member, but the benefits are great, including authorship on any resulting peer-reviewed publications. If you are interested in being apprised on a regular basis of the newly approved BC Project Concepts, please e-mail me at mayrands@od.nih.gov to be added to the distribution list.

Table 2. Contributing Members to the BC – August 2010

For-Profit Companies (28)	Nonprofit Organizations (34)
Abbott Laboratories	Academy of Molecular Imaging
Amgen	Advanced Medical Technology Association
Amylin Pharmaceuticals	Alliance for Aging Research
AstraZeneca	Alzheimer's Association
Banyan Biomarkers	American Association for Cancer Research
BG Medicine	American College of Neuropsychopharmacology
Boehringer-Ingelheim	American Diabetes Association
Bristol-Myers Squibb	American Health Assistance Foundation
Celgene Corporation	American Society of Clinical Oncology
Daiichi-Sankyo, Inc.	American Society for Clinical Pharmacology and Therapeutics
Eisai, Inc.	American Society for Therapeutic Radiology and Oncology
Eli Lilly and Company	Arthritis Foundation
F. Hoffmann-La Roche	Association of Clinical Research Organizations
Genstruct, Inc.	Autism Speaks
GlaxoSmithKline	Avon Foundation
InfraReDx, Inc.	Battelle Memorial Institute
Johnson & Johnson	Biotechnology Industry Organization
Merck and Co., Inc.	CHDI Foundation
Meso Scale Discovery	Cystic Fibrosis Foundation Therapeutics
Metabolon, Inc.	Federation of Clinical Immunology Societies
NextGen Sciences	The Hamner Institutes for Health Sciences
Orasi Medical, Inc.	The Immune Tolerance Institute, Inc.
Pfizer Inc.	International Society of Biological Therapy of Cancer
RareCyte, Inc.	Juvenile Diabetes Research Foundation
Scout Diagnostics	Kidney Cancer Association
Sepracor	The Leukemia & Lymphoma Society
Takeda Pharmaceuticals	Michael J. Fox Foundation for Parkinson's Research
XOMA, Ltd.	Ontario Cancer Biomarker Network
	Osteoarthritis Research Society International
	Pharmaceutical Research and Manufacturers of America
	PROOF Centre of Excellence
	Radiological Society of North America
	Society for Nuclear Medicine
	University of Illinois

(continued on page 6)

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When the BC Project Concepts are submitted from outside the NIH, there is a need to evaluate the scope of the proposed research to determine whether it is of interest to the NIH. In these instances, the PPP Program (via the NIH Program Director for the BC) solicits input from the appropriate IC. This request for evaluation and guidance ensures that the NIH is in support of the scientific question being proposed by the prospective BC Project Concept. From time to time, NIH staff members may be called on by the PPP Program to share their scientific expertise and opinion—so, thanks in advance!

"The BC is always looking for ways to help promote the discovery, development, and qualification of biomarkers as one means to accomplish the NIH's mission and to leverage the NIH's investment in research leading to and/or focused on biomarkers."

A final way for NIHers to become involved in the BC is by proposing a biomarker project. As the NIH Program Director for the BC, I am always available to explore the development of a Project Concept for a particular biomarker question and/or to help evaluate and submit a Project Concept. If you already know what you'd like to propose, the Project Concept submission form can be found on the BC Web site at http://www.biomarkerconsortium.org/index.php?option=com_content&task=section&id=7&Itemid=41. The BC is always looking for ways to help promote the discovery, development, and qualification of biomarkers as one means to accomplish the NIH's mission and to leverage the NIH's investment in research leading to and/or focused on biomarkers. Finally, attached here is a table of publications generated from BC projects as well as the current list of members of the BC, representing a wide range of organizations with interests in a similarly wide range of biomarker science. ❖

Progress in mHealth Research at NIH

Dr. Audie A. Atienza

Both the weather and mHealth (Mobile Health) were hot this summer! The 2010 mHealth Summit is developing into a major international event, with visionaries and luminaries confirmed as keynoters. In addition, the NIH mHealth Inter-Institute Interest Group (IIIG) continues to gain steam.

2010 mHealth Summit

The 2010 mHealth Summit has established an all-star lineup of keynote speakers, including Dr. Francis Collins (National Institutes of Health [NIH] Director), Ted Turner (Founder, United Nations Foundation), Bill Gates (Founder, Bill & Melinda Gates Foundation), and Dr. Julio Frenk (Dean, Harvard School of Public Health). In addition, over 400 abstracts from 28 countries were submitted in response to the Call for Presentations/Technology Demonstrations. Many NIH mHealth IIIG members graciously participated in the abstract review process and are to be commended. The mHealth Summit Executive Working Group selected 30 abstracts to be presented as oral presentations during themed concurrent sessions, with a mix of United States (U.S.) and international research selected for each session. Furthermore, 150 abstracts were selected for poster presentations, and 40 were selected for the technology demonstration session. We anticipate 3,000 participants at the 2010 mHealth Summit from many different sectors of the mHealth ecosystem.

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NIH mHealth IIIG

The NIH mHealth IIIG continued its monthly meetings during the summer, highlighting both NIH activities and those outside NIH:

(continued on page 7)

(CONTINUED FROM PAGE 6)

- In June 2010 David Hale from the National Library of Medicine (NLM) gave a presentation on Pillbox, a partnership between the NLM and the U.S. Food and Drug Administration (FDA) to "enable rapid identification of unknown solid-dosage medication (tablets/capsules) based on physical characteristics and high-resolution images." (http://pillbox.nlm.nih.gov/). He discussed plans to develop mobile applications for Pillbox. Mr. Hale's presentation also highlighted other mobile applications developed by the NLM, including the Wireless Information System for Emergency Responders (WISER, http://wiser.nlm.nih.gov), Radiation Emergency Medical Management Tool (REMM, http://remm.nlm.gov), and Haiti Earthquake People Locator (HEPL, http://hepl.nlm.nih.gov/inw/).
- In July 2010 Dr. Erik Augustson from the National Cancer Institute (NCI) gave the presentation "Tools vs. Toys: Future mHealth Activities for NCI's Web-Assisted Tobacco Interventions." This presentation described the NCI SmokeFreeWomen Program (http://women.smokefree.gov/), and Dr. Augustson also discussed mobile applications being developed by the NCI for teen smokers to be launched in fall 2010.
- The August 2010 NIH mHealth III meeting featured Dr. Adam Slote from the U.S. Agency for International Development (USAID). Dr. Slote discussed international mHealth activities being conducted by the USAID and possible collaborative opportunities between the USAID and the NIH.

The NIH Public-Private Partnership (PPP) Program and the NIH Office of Behavioral and Social Science Research cosponsored the workshop "Reducing Barriers to Mobile Technology Usage in Behavioral and Social Science Research" in June 2010 on the NIH Campus. Mobile technology and health experts from academia (e.g., Massachusetts Institute of Technology, University of California, Los Angeles, University of Wisconsin at Madison), industry (e.g., Qualcomm, AT&T, Sprint, Google), and the Federal government (e.g., FDA, Federal Communications Commission [FCC], National Institute of Standards and Technology [NIST], Indian Health Service [IHS], U.S. Department of Health and Human Services [HHS] Office of Human Research Protections [ORHP], HHS Office of the National Coordinator for Health Information Technology [ONC], the White House Office of Science and Technology Policy [OSTP]) attended this workshop to discuss solutions to logistic, technologic, and policy barriers in mHealth. A white paper is being developed by NIH staff to summarize the ideas generated during the workshop. Immediately following the workshop, the NIH PPP Program hosted a postmeeting of Federal government organizations to share information about mHealth in the respective agencies, including NIH, FCC, FDA, NIST, ORHP, ONC, OSTP, IHS, Health Resources and Services Administration (HRSA), Agency for Healthcare Research and Quality (AHRQ), Center for Medicare & Medicaid Services (CMS), and Centers for Disease Control and Prevention (CDC). A followup meeting of Federal government organizations is planned for the 2010 mHealth Summit in November. Clearly, there is a great deal of interest in mHealth across the Federal government and beyond.

"With fall upon us and the 2010 mHealth Summit quickly approaching, mHealth will be front and center in the coming months at the NIH. This will provide opportunities not only to take stock of the state of the science but also to build partnerships and collaborations to move the field of mHealth research forward beyond the Summit."

With fall upon us and the 2010 mHealth Summit quickly approaching, mHealth will be front and center in the coming months at the NIH. This will provide opportunities not only to take stock of the state of the science but also to build partnerships and collaborations to move the field of mHealth research forward beyond the Summit. ❖

NIH Public-Private Partnership Coordinating Committee: *Thank You and Update!*

Ms. Marjorie A. Bonorden

The National Institutes of Health (NIH) Public-Private Partnership (PPP) Program would like to take this opportunity to thank all of the speakers who presented at the 2009-2010 PPP Coordinating Committee (PPPCC) meetings for the speaker series *Industry Relations and Partnerships*. The speakers provided an array of viewpoints relevant to NIH-industry partnerships.

The series began with the perspectives of the NIH. The role of the Federal government in the development and implementation of PPPs from the Office of the General Counsel: **Annette Levey**, Senior Attorney, and innovative partnerships and the NIH: Office of Technology Transfer: **Mark Rohrbaugh**, Ph.D., Director, Office of Intramural Research, Office of Technology Transfer, and **Mark David Lim**, Ph.D., Innovative Molecular Analysis Technologies Program, Office of Biorepositories and Biospecimen Research, National Cancer Institute.

Providing information regarding the challenges and approaches to developing partnerships surrounding NIH partnerships: **Bonny Harbinger**, Ph.D., J.D., Deputy Director, Office of Intramural Research, Office of Technology Transfer, Office of the Director, and **Carl Roth**, Ph.D., LL.M., Acting Deputy Director and Associate Director for Scientific Program Operation, National Heart, Lung, and Blood Institute, and **Susan Streufert**, Ph.D., Special Assistant to the Director and Deputy Director, Office of the Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development.

Another Federal agency representative, **Vicki Seyfert-Margolis**, Ph.D., Senior Advisor for Science Innovation and Policy, Office of the Commissioner, United States (U.S.) Food and Drug Administration, discussed PPPs from the FDA's standpoint.

Speakers from outside the Federal government included the Foundation for the NIH (FNIH), **Amy Porter**, Executive Director, FNIH, who discussed the role of the Foundation and how the FNIH supports NIH partnerships. **Richard Scarfo**, Director of Marketing, Communications and Strategic Alliances, FNIH, discussed the practicalities and complexities of developing partnerships.

Industry representatives provided diverse views from within industry and included the pharmaceutical industry's trade organization, Pharmaceutical Research and Manufacturers of America (PhRMA), **Alan Goldhammer**, Vice President, Scientific and Regulatory Affairs, PhRMA, as well as pharmaceutical company representatives: **Christine Brennan**, Director of Strategic Alliances, Novartis Institutes of BioMedical Research, Incorporated (Inc.); **Karen Brown**, Ph.D., Senior Intellectual Property Counsel, Ironwood Pharmaceuticals, Inc.; and **Wendy Petka**, Ph.D., J.D., Senior Associate Director and Senior Counsel-intellectual property (IP), Boehringer Ingelheim Pharmaceuticals, Inc., who all provided partnership strategy from the pharmaceutical industry standpoint in relatively general terms, as well as IP concerns and solutions related to PPPs.

O. Prem Das, Ph.D., Principal, Das Advisors, provided his perspective on the business aspects of partnering from the viewpoint of a small business, in particular a startup company, plus how industry and the NIH can forge unique approaches to medical research and drug discovery. Representing the biotechnology trade organization, Biotechnology Industry Organization (BIO), **Lila Feisee**, Managing Director, IP, provided views about what goes into developing PPPs from the biotechnology industry's perspective and how/why the NIH can develop partnerships with the biotechnology industry; **Dr. Norman Garceau**, Ph.D., President and Chief Scientific Officer, Blue Sky Biotech, provided insights into partnerships from a startup biotechnology company's standpoint, including what goes into selecting partners and go/no-go decisions.

> *"The National Institutes of Health (NIH) Public-Private Partnership (PPP) Program would like to take this opportunity to thank all of the speakers who presented at the 2009-2010 PPP Coordinating Committee (PPPCC) meetings for the speaker series* Industry Relations and Partnerships.*"*

We also heard from academia, addressing how partnerships can be conceptualized and studied: **Joel Cutcher-Gershenfeld**, Dean and Professor, School of Labor and Employment Relations, University of Illinois, as well as from a wireless telecommunications research and development company, Qualcomm, Inc., **Mr. Robert Jarrin**, Director,

(continued on page 9)

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Government Affairs, who discussed Qualcomm's perspective on potential mHealth partnerships and Federal policies that may influence them.

We look forward to the 2010-2011 PPPCC meeting speaker series Public-Private Partnerships: *Working With Not-for-Profit Entities*, which will include a range of views and insights, all relevant to partnerships with nonprofit entities. Scheduled speakers are:

- September 16: **Vardit Ravitsky**, Ph.D., Professor, Bioethics Program, Faculty of Medicine, University of Montreal. Dr. Ravitsky will discuss the ethics of PPPs from an international perspective. **Gretchen Weaver**, J.D., Senior NIH Ethics Counsel, Office of General Counsel, Office of the Director, NIH, will discuss the ethics of PPPs from a U.S. Government perspective.
- October 21: **Scott Campbell**, Ph.D., Executive Director and CEO, Foundation for the NIH. Dr. Campbell has recently taken the helm at the FNIH and will discuss his vision and plans for the next phase of the Foundation's operations. An **FNIH board member** (speaker to be announced) will discuss the future plans and vision of the FNIH from an FNIH board member's view.
- November 18: **Christopher Austin**, M.D., Senior Advisor to the Director, NIH Translational Research, National Human Genome Research Institute. Dr. Austin will discuss partnerships, such as the Therapeutics for Rare and Neglected Diseases (TRND) Program, with not-for-profit entities. **James O'Leary**, Chief Innovation Officer, Genetic Alliance, Inc., will discuss Genetic Alliance's views and activities related to PPPs.
- December 16: **Garry Neil**, M.D., Corporate Vice President, Science and Technology (COSAT), Johnson & Johnson. Dr. Neil will provide a new view of translational research. **Lili Portilla**, M.P.A., Senior Advisor for Technology Transfer, National Center for Research Resources, NIH, will provide a new view of translational research from an NIH perspective.

". . .the 2010-2011 PPPCC meeting speaker series Public-Private Partnerships: Working With Not-for-Profit Entities, which will include a range of views and insights, all relevant to partnerships with nonprofit entities."

Please distribute news of this opportunity within your IC and invite all interested NIHers to join us. ❖

Momentum Builds for the 2010 mHealth Summit: *Dr. Francis Collins, Aneesh Chopra, and Bill Gates Among Notable Keynote Speakers*

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

After its highly successful debut last year, the 2010 mHealth Summit is quickly becoming the most important event in the field of mobile health, focusing world-class research, technology, and policy experts around a common agenda. This year's conference, scheduled for November 8-10 at the Walter E. Washington Convention Center in Washington, D.C., will bring together upwards of 2,000 international leaders and visionaries, representing all stakeholders from across the mHealth spectrum.

The Summit, organized by the Foundation for the National Institutes of Health (FNIH) in partnership with NIH and the mHealth Alliance, will feature more than 30 sessions of various sizes, over 150 exhibiting companies, 180 select abstracts, 40 technology demos, and 2 networking receptions, as well as a slate of world-renowned keynote speakers. Reflecting the multidisciplinary approach that is the

(continued on page 10)

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Summit's hallmark, speakers include our very own Dr. Francis A. Collins; Bill Gates, Co-Chair of the Bill & Melinda Gates Foundation; Aneesh Chopra, U.S. Chief Technology Officer, Office of Science and Technology Policy; Dr. Julio Frenk, Dean of Faculty at the Harvard School of Public Health; and Ted Turner, Chairman of the United Nations Foundation.

The goal of the Summit is to facilitate the use of mobile and wireless technologies to advance biomedical research and deliver health care in new and innovative ways. Its unique broad-spectrum format makes it a can't-be-missed opportunity for experts from government, private sector/industry, academia, and the not-for-profit sector to collaborate around that purpose.

"Reflecting the multidisciplinary approach that is the summit's hallmark, speakers include our very own Dr. Francis A. Collins; Bill Gates, Co-Chair of the Bill & Melinda Gates Foundation; Aneesh Chopra, U.S. Chief Technology Officer, Office of Science and Technology Policy; Dr. Julio Frenk, Dean of Faculty at the Harvard School of Public Health; and Ted Turner, Chairman of the United Nations Foundation."

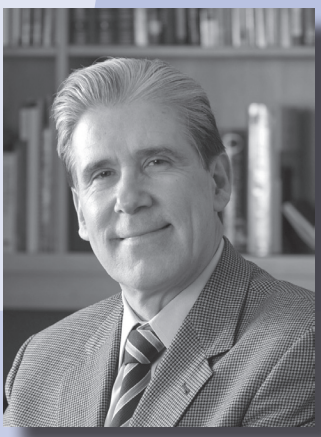
Ten Keynote Addresses, seven super sessions, and twenty-one concurrent sessions will identify, examine, and debate topics such as squeezing greater efficiencies from the health care system, delivering health services to underserved communities in the United States and abroad, and facilitating the growing trend toward aging in place. Among the sessions and technology exhibits are networking opportunities designed to pave the way for new public-private partnerships and funding opportunities to drive the field forward.

With its emphasis on finding high-impact, sustainable solutions that can reach millions of people, the Summit is attracting stakeholder buy-in from a wide range of sectors, countries, backgrounds, and philosophies. This cross-disciplinary interface promises to energize the Summit's comprehensive program agenda.

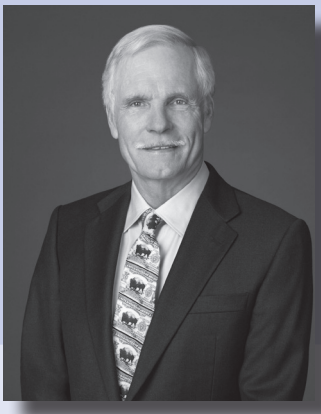
The FNIH is making available complimentary booth space to any NIH Institute or Center that wishes to exhibit. Please contact me at rscarfo@fnih.org for additional information.

To guarantee your place at this must-attend event, please register at www.mhealthsummit.org and take advantage of the special government rates. ❖

Dr. Francis A. Collins



Dr. Julio Frenk



Mr. Ted Turner

Mr. Aneesh Chopra

Mr. Bill Gates

Calendar

Date	Meeting	Location & Time	Speaker
9.16.10	PPP Coordinating Committee Meeting***	NIH Campus Building 1, Wilson Hall 2:30 - 4:30 pm	*Public-Private Partnerships: Working With Not-for-Profit Entities:* **Vardit Ravitsky,** Ph.D., Professor, Bioethics Program, Faculty of Medicine, University of Montreal - Ethics of public-private partnerships from an international perspective **Gretchen Weaver,** J.D., Senior NIH Ethics Counsel, Office of General Counsel, Office of the Director, NIH - Ethics of public-private partnerships from the U.S. Government perspective
9.28.10	mHealth IIIG Meeting*	NIH Campus Building 1, Wilson Hall 3 - 4:30 pm	*Monthly trans-NIH committee meeting*
10.21.10	PPP Coordinating Committee Meeting***	NIH Campus Building 31, Room 6C10 2:30 - 4:30 pm	*Public-Private Partnerships: Working With Not-for-Profit Entities:* **Scott Campbell,** Ph.D., Executive Director and CEO, Foundation for the NIH (FNIH) - His vision and plans for the next phase of the Foundation's operations **FNIH Board Member** (speaker to be announced) - FNIH: Future Plans and Vision—An FNIH Board Member's View
10.26.10	mHealth IIIG Meeting*	NIH Campus Building 1, Room 151 3:00 - 4:30 pm	*Monthly trans-NIH committee meeting*
11.8.10	mHealth Summit**	Washington Convention Center, Washington, DC	For details and agenda: www.mhealthsummit.org
11.18.10	PPP Coordinating Committee Meeting***	NIH Campus Building 31, Room 6C10 2:30 - 4:30 pm	*Public-Private Partnerships: Working With Not-for-Profit Entities:* **Christopher Austin,** M.D., Senior Advisor to the Director, NIH Translational Research, National Human Genome Research Institute - partnerships, such as the NIH Therapeutics for Rare and Neglected Diseases (TRND) Program, with not-for-profit entities **James O'Leary,** Chief Innovation Officer, Genetic Alliance - Genetic Alliance's views and activities related to public-private partnerships
11.23.10	mHealth IIIG Meeting*	NIH Campus Building 1, Wilson Hall 3 - 4:30 pm	*Monthly trans-NIH committee meeting*
12.16.10	PPP Coordinating Committee Meeting***	NIH Campus Building 31, Room 6C10 2:30 - 4:30 pm	*Public-Private Partnerships: Working With Not-for-Profit Entities:* **Garry Neil,** M.D., Corporate Vice President, Science and Technology (COSAT), Johnson & Johnson - new view of translational research from an industry perspective **Lili Portilla,** M.P.A., Senior Advisor for Technology Transfer, NIH National Center for Research Resources - new view of translational research from an NIH perspective
12.28.10	mHealth IIIG Meeting*	NIH Campus Building 1, Wilson Hall 3 - 4:30 pm	*Monthly trans-NIH committee meeting*

*mHealth IIIG Committee meets the fourth Tuesday of each month. For additional information, please contact Dr. Audie Atienza at atienzaa@mail.nih.gov.

**For more information on the 2010 mHealth Summit, visit www.fnih.org or www.mhealthsummit.org.

***The PPP Coordinating Committee (PPPCC) meets the third Thursday of each month. For additional information, please contact Ms. Marjorie Bonorden at bonordenm@od.nih.gov.

All meeting locations are subject to change.

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

LOOKING FOR PPP INFORMATION?

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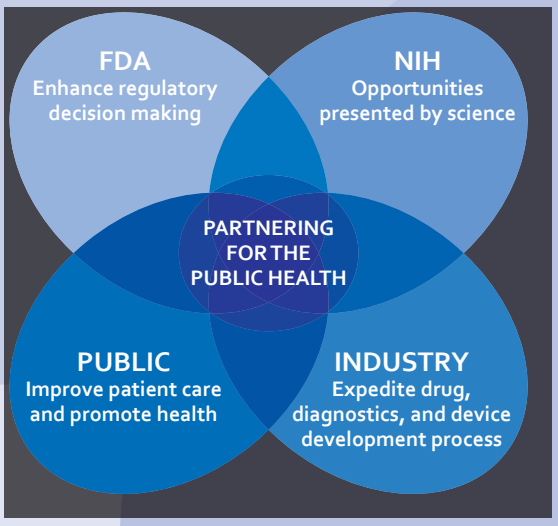
PPPs for Synergy and the Public Health



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