

## MESSAGE FROM THE DIRECTOR

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

2011 will be over by the time this issue is published, and 2012 is beginning. Much has happened in the past year, and the National Institutes of Health (NIH) Public-Private Partnership (PPP) Program activities have covered a wide range:

- The third annual mHealth (mobile health) Summit took place in December 2011 at the Gaylord Resort and Convention Center, with more attendees, more presenters, and more new technologies and even more projects to report. Conversations and contacts at the Summit identified lots of new and existing common interests and shared goals, providing both opportunities and pain points that can be addressed by research and data. The mHealth Winter Training Institute was sponsored by the NIH and the NIH Office of the Director's Office of Behavioral and Social Sciences Research (OBSSR) to provide an interdisciplinary perspective and training experience for junior faculty from all over the world and to ensure that there will be a trained and connected workforce to generate those needed data in a rigorous and well-conceived manner.
- We are pleased to announce a newly launched project, conceived jointly by folks at the NIH PPP Program and the National Heart, Lung, and Blood Institute (NHLBI), Indian Health Service, Northern Arizona Healthcare, and Qualcomm Incorporated, with help from Zephyr Technology and Verizon Wireless, which has enrolled the first patients in a study examining how mobile technologies can improve clinical outcomes, prevent hospital readmissions, increase satisfaction, and decrease costs for patients with congestive heart failure.
- Multiple stakeholders are discussing the shape and goals of a potential PPP in the realm of mHealth. This issue contains details about this and other mHealth-related activities by Dr. William Riley, NHLBI; Dr. Wendy J. Nilsen, OBSSR, Dr. Heather Patrick, National Cancer Institute, and Dr. Riley; Ms. Erica Whinston, Qualcomm Incorporated; and Mr. Richard Scarfo, Foundation for the National Institutes of Health.
- The NIH has worked with the National Health Council (NHC) to develop the concept for NHC's recently launched Web site HealthResearchFunding.org, which offers an opportunity for match making between applicants for NIH funding whose applications failed to gain funding and non-NIH organizations with funds to support research. Applicants enter demographic data and information about their applications, organizations can seek applications in areas of interest, and a match can be made. This accomplishes several important goals:

## SPOTLIGHT

In consideration of our environment, the National Institutes of Health (NIH) Public-Private Partnership (PPP) Program is pleased to announce that we will be transmitting the newsletter electronically, starting with this issue, instead of in hard-copy format. This first electronic, or "e Issue," is one of many ways in which we have made efforts to be "green."

Lots to peruse in this issue: research funding and how the foundation sector can fill gaps for unfunded applicants; mobile health activities with which the PPP Program has been involved such as the recent announcement of a mobile health (mHealth) partnership, mHealth training, news about the mHealth Summit, and research efforts to understand PPPs and stakeholder alignment. This New Year brings opportunities to share your partnerships and or partnership needs with the community. Please consider contributing to the newsletter to share yours. ❖

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(1) provides funding opportunities to scientists who may not otherwise be able to continue their work or support their labs through this difficult economic time, (2) allows organizations to foster the careers and scientific development of junior faculty applicants, and (3) may encourage more established scientists to apply their insights and experience to questions and disorders not previously part of their focus. Marc Boutin of the NHC describes this in greater detail in this issue.

- PPP Program members collaborated with Dr. Joel Cutcher-Gershenfeld, Dean of the School of Labor and Employee Relations at the University of Illinois at Urbana-Champaign, to examine The Biomarkers Consortium structure and functioning as one of three subject partnerships under a grant from the National Science Foundation. In this issue he summarizes some of the findings from that study and hints at coming next steps.

We wish you all a wonderful New Year and lots of fruitful collaborations and partnerships, and we are always here to help you accomplish that. ❖

## GIVING PATIENTS HOPE BY HELPING RESEARCHERS FIND FUNDING

Marc Boutin, J.D., Executive Vice President and Chief Operating Officer,  
National Health Council

In just one year, HealthResearchFunding.org has grown into a recognized depository of biomedical research proposals and funding sources—with proposals from more than 2,000 investigators and 75 different non-profit funding organizations. A “match-making” service conceived by patient advocacy organizations, this initiative has plans to expand its reach in the coming months.

This one-of-a-kind web database was developed by the National Health Council (NHC) with input from the National Institutes of Health (NIH). On this site, researchers who have worthwhile but unfunded proposals that have been peer reviewed by the NIH or by NHC member patient advocacy groups can post their abstracts for funding sources to see. There is no charge for use of the site by investigators or their institutions.

HealthResearchFunding.org was conceived several years ago by a group of chief medical officers and research directors from NHC member patient advocacy organizations. They recognized the need to make best use of the significant expertise and funds spent on the rigorous scoring of research proposals. With the help of the NIH, the NHC set out to develop an innovative solution to make the most out of the nation’s investment in biomedical research.

HealthResearchFunding.org enables investigators and their respective research institutions to spend less time and effort looking for funding and more time conducting research that will help improve the lives of patients living with chronic diseases and disabilities. The proposals posted on the site cover a broad range of topics, but three of the top conditions are: cancer, diabetes, and cardiovascular disease. More than

45 percent of the investigators posting proposals express an interest in translational research.

Researchers, whose proposals have been peer-reviewed, scored, and unfunded, are invited to register with HealthResearchFunding.org, add an abstract, and enter as much information as they choose. They also have the ability to search for funding sources and requests for proposals. However, researchers are not able to view proposals from other investigators, nor are they able to search researcher profiles. The website is designed to protect the individual researcher’s privacy.

Funding sources that utilize HealthResearchFunding.org range from large patient organizations, such as the American Cancer Society and the American Heart Association, to smaller groups, such as the National Alopecia Areata Foundation and the National Psoriasis Foundation. Last fall, the NHC member nonprofit organizations, such as HealthHIV and the National Venture Capital Association, were invited to participate as funding sources.

In 2012, HealthResearchFunding.org will expand its reach to include business and industry members of the NHC, followed by non-NHC member funding sources. By continually increasing the number of entities interested in funding research, this database can support investigators in their quest for funding and thereby advance the search for new treatments and cures for people with chronic conditions.

The success of the database depends on the research community for feedback and to help spread the word about

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this initiative. Once registered, investigators are encouraged to complete and submit surveys and suggest improvements needed to optimize this unique opportunity for collaboration. Surveys are presented to registered investigators at different intervals throughout the year, and past feedback has resulted in changes to the site.

With the help of the research community, this database can grow into an even richer source for funding worthy research proposals.

The NHC encourages investigators to register with [HealthResearchFunding.org](http://HealthResearchFunding.org). If you are already registered, tell us how the database can better meet your needs as a researcher by writing to [healthresearchfunding@nhcouncil.org](mailto:healthresearchfunding@nhcouncil.org). ❖

## MOBILE HEALTH PROJECT ENHANCES THE CARE OF PATIENTS WITH HEART FAILURE

Erica Whinston, Senior Manager, Qualcomm Government Affairs, Wireless Reach, Qualcomm Incorporated

**C**ongestive heart failure (CHF) is a complex disease that is tough to manage as it progresses. According to the 2010 statistics from the American Heart Association:

- Heart failure is one of the leading causes of hospitalization and death in the United States.<sup>1</sup>
- Nearly 1 million people are hospitalized with CHF in the U.S. annually, of which 30 to 60 percent have to be readmitted.<sup>2</sup>
- The estimated direct and indirect cost of heart failure in the U.S. for 2010 was \$39.2 billion.<sup>3</sup>

Some readmissions are avoidable and some are not. In a past Medicare Payment Advisory Commission (Medpac) report to Congress, Medicare spending on potentially preventable readmissions represented \$12 billion for cases readmitted within 30 days.<sup>4</sup> The report included a suggestion that improved communication with patients and better coordination of their care upon discharge could help reduce the number of readmissions.

Qualcomm, through its Wireless Reach™ initiative, is participating in a public-private mobile health (or “mHealth”) project that demonstrates how the always-on, always-connected capabilities of 3G-enabled smartphones and wireless medical devices can extend the reach of medical professionals beyond the walls of a hospital or physician’s office and enhance the care of patients with CHF.

Launched in December 2011 at Flagstaff Medical Center (FMC) in Flagstaff, Arizona, the Care Beyond Walls and Wires project provides mobile broadband tools to CHF patients with the goal of improving the coordination of their care following a discharge from FMC. This program aims to engage patients in

their own health care, decrease hospital readmission rates for CHF within 30 days and increase patient satisfaction.

The public-private alliance supporting this project includes diverse participants with complementary expertise from across the mobile health ecosystem; an approach that Qualcomm believes is effective for innovating solutions to complex issues. Facilitated by the National Institutes of Health (NIH) Public-Private Partnership Program, Qualcomm is lending technical expertise and donating wireless devices to FMC for the project. Zephyr Technology is providing advanced, in-home health-monitoring systems to patients. Verizon Wireless is providing 3G-enabled Motorola Droid X2 smartphones. The phones are pre-loaded with a mobile application that allows patients to rapidly record and send health data to FMC via the 3G network. NIH is also assisting FMC with project planning and evaluation.

### ENABLING EARLY INTERVENTION IN HEALTH DECLINES

As a world leader in developing next-generation mobile broadband technologies, Qualcomm believes that access to 3G and next-generation mobile technologies can improve people’s lives. Qualcomm’s Wireless Reach initiative is a strategic program that brings wireless technology to underserved communities globally. By working with partners, Wireless Reach invests in projects that foster entrepreneurship, aid in public safety, enhance the delivery of health care, enrich teaching and learning and improve environmental sustainability.

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In health care, Qualcomm believes that the mobility and access to information offered through 3G technologies can help lower costs, facilitate remote care, increase efficiencies and connect people to their health care providers. To that end, we support the development of the mobile health ecosystem, including software, systems, devices and work processes.

Through this project, smartphones, wireless medical devices and training will be provided to 50 patients who have been discharged from FMC following an admission for CHF or related cardiac condition and who are at high risk for readmission. Some patients will also receive home visits from outreach staff.

The mobile tools will collect and transfer critical patient data such as weight, blood pressure and heart rate to nurses at FMC. Information will be sent daily for three to six months after the patient's hospitalization. This daily exchange of information will enable health care professionals to detect a decline in a patient's health status early and intervene rapidly, helping to reduce unnecessary travel, physician office visits, costs and readmission to a hospital.

Although patient enrollment in this project has only recently begun, we anticipate that many participants will be

individuals living in underserved and rural communities or on nearby Native American reservations. The always-on, always-connected capabilities of the project will be important to people living in outlying areas where landline phones might not be available and finding transportation to visit physicians can be challenging.

Care Beyond Walls and Wires shows the important role that mobile technology can play in health care especially with regard to the constant management that heart failure and other chronic diseases require. Qualcomm is proud to participate in this innovative project, which brings patients closer to their health care providers while empowering them to have better control over their wellbeing. ❖

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## NATIONAL INSTITUTES OF HEALTH MHEALTH TRAINING INSTITUTES

Wendy J. Nilsen, Ph.D., Health Science Administrator, Office of Behavioral and Social Sciences Research, Office of the Director, National Institutes of Health

Heather Patrick, Ph.D., Program Director, Health Behaviors Research Branch, Division of Cancer Control and Population Sciences, National Cancer Institute

William T. Riley, Ph.D., Program Director, Clinical Applications and Prevention Branch, National Heart, Lung, and Blood Institute, and Chair, NIH mHealth Inter-Institute Interest Group

**M**obile and wireless health (mHealth) systems have the potential to revolutionize health care and health science by providing patients, health care providers, and medical researchers with the tools to observe and analyze—continuously and in real time—the health status of individuals as well as relevant environmental, lifestyle, and social factors. By enabling us to monitor and gather biological,

behavioral, and environmental data, mHealth will improve our understanding of the etiology of health and disease, especially when those data are integrated with data from genomics and electronic medical records. These data are also critical to our ability to answer difficult questions about the interplay of genes and the environment in health and disease, in therapeutic adherence, and in the developmental origins and

trajectory of chronic illnesses. Moreover, they are essential to the development of personalized and adaptive treatments and prevention programs.

Given the rapid advances in the development of wearable sensors, global positioning system technology, and mHealth applications, many anticipate an explosion in the number and variety

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of health conditions that may be addressed using mHealth. However, the hypothesis that better monitoring will lead to better management, better outcomes, and reduced disease burden has yet to be adequately tested. The need for rigorous research that examines the potential, as well as the challenges, of harnessing mobile technologies to improve health outcomes is critical, but progress in integrating and translating these cutting-edge technologies into rigorously evaluated health research and health care tools has been slow. As a result, it is likely that, although new applications will be developed, they will have little impact on improvements in public health—precisely because they were developed without an empirical and theoretical foundation and without input from the health research community.

These rapid technological advances in mHealth generate both opportunities and challenges. One challenge is to foster interdisciplinary collaboration in the development of mHealth. Currently, much of the work in the field is done within single disciplines, without the advantages of a more integrated approach that brings together expertise from the behavioral and social sciences, from the biomedical and clinical sciences, and from the fields of engineering and computer science. Another challenge is building on the findings from research in gaming and human-computer interaction, which have revealed new methods for engaging participants in ways that could improve the efficacy of existing interventions and treatments. By working together and capitalizing on their respective disciplinary strengths, experts from across the behavioral and social sciences, biomedical research, engineering, and computer science will be better able to optimize mHealth tools that can effectively measure and improve health. Working within the

confines of disciplinary silos is no longer a viable approach to the advancement of mHealth.

To increase the cross-fertilization of mHealth disciplines, in 2011 the Office of Behavioral and Social Sciences Research began developing a training institute focusing specifically on wireless and mobile health technologies. The Office was joined in the planning process by members of several other National Institutes of Health (NIH) Institutes, Centers, and Offices, including the Fogarty International Center, National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute of Biomedical Imaging and Bioengineering, National Institute on Drug Abuse, National Institute of Diabetes and Digestive and Kidney Diseases, and National Institute of Mental Health. In addition, the group embraced a public-private partnership model because industry has a major role in developing the technology on which mHealth research is based. Thus, early in the planning process, Qualcomm Incorporated joined the group and became an integral member. This planning team represented a wide range of interests and stakeholders in the area of global mHealth.

The training was designed to maximize interdisciplinary learning by providing problem-based learning opportunities developed by faculty with diverse expertise. Faculty from engineering, behavioral and social sciences, medicine, and computer science worked together to provide a unique training and learning experience in which participants were grouped into teams and then asked to generate a solution to a pressing public health problem. The team projects were supplemented with didactic sessions with the faculty and guest lecturers.

Interest in the training was high, and in June 2011, the initial cohort of 28 participants joined faculty and NIH staff members in San Diego, California, for learning in a weeklong intensive series of workshops and group projects. The training institute brought together leaders in mobile technology, behavioral sciences, and clinical research to lead a transdisciplinary training event for early-career investigators with interests in mHealth. The training curriculum covered the current state of the science in mobile technology and engineering, behavior change theory, and medical applications and highlighted the intersection among these areas for health research. Daily didactic sessions targeted the major crosscutting research issues. Participants took part in lectures with established researchers and leaders in the mHealth industry. Afternoons were devoted to team projects, which were mentored by the faculty, NIH staff members, and engineers from Qualcomm. Evenings included additional keynotes and time for informal teamwork. The week culminated in each team's submission of a project, which was jointly reviewed by faculty and Qualcomm engineering experts. To complete the training institute, participants also submitted written proposals with their groups after the training was finished.

Demand for this initial training institute was very high, so a second institute was developed through a partnership with the Foundation for the NIH to coincide with the 2011 mHealth Summit. This winter training institute followed a format similar to that of the summer institute, with the added benefit of being held in conjunction with the mHealth Summit. Thus, participants had the opportunity to learn from top researchers, participate in teams, and explore a wide range of research,

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industry, and policy presentations during the 2011 mHealth Summit.

By design, participants represented the four disciplines that are central to mHealth: biomedicine, behavioral and social sciences, engineering, and computer science. The faculty grouped participants into teams by broad interest areas (e.g., infectious disease, chronic illness, prevention, etc.) to ensure that each team included members from the four primary disciplines. Teams were asked to develop a proposal for an mHealth tool that could address their team's health problem focus from any perspective they chose, including, but not limited to, assessment, diagnosis, treatment, epidemiology, and surveillance. Mentors guided the teams in the process of developing a shared understanding of the health problem and ways to approach an mHealth solution to the health problem. As teams evolve, they learn about the factors that make successful careers across the disciplines

and ways in which they can partner that will enhance each of the academic credentials.

In both venues, participants rated the value of the training institutes very highly, and many have gone on to submit grants together based on the projects developed at the training institute. As of December 2011, ten grants had been submitted by summer institute participants, suggesting that the collaborations that they developed with their teams in the training institute have continued long after the event concluded. One participant noted that the "mHealth Training Institute was a fantastic experience for me and my career... I developed collaborations with other participants and faculty at mHealth that have directly led to plans for two grant applications" (Eric Hekler, 2011). In addition to collaborations between and among participants, new scientific projects have been generated by faculty and participants and through

collaborations between and among training institute faculty. All of these continuing relationships highlight the need for forums in which individuals with diverse forms of expertise can come together to strengthen mHealth research. Without opportunities for exposure and cross-pollination, mHealth technology will likely develop into siloed areas without the benefits that each of the sciences brings to improving health research and the health of the population.

Additional mHealth training institutes are planned, including institutes that involve partnerships with other industry experts and that target scientists at different points in their career trajectories. These training institutes will facilitate the capacity for quality mHealth research in this country and around the world. ❖

## NIH MHEALTH IIIG 2011 UPDATE

William T. Riley, Ph.D., Program Director, Clinical Applications and Prevention Branch, National Heart, Lung, and Blood Institute, and Chair, NIH mHealth Inter-Institute Interest Group

To facilitate mobile health efforts at the National Institutes of Health (NIH), the NIH mHealth (mobile health) Inter-Institute Interest Group (IIIG) was formed approximately two years ago. The NIH mHealth IIIG is coordinated by the NIH Public-Private Partnership Program in the Office of Science Policy, Office of the Director, NIH, and consists of more than 100 members from the various NIH Institutes, Centers, and Offices (ICOs). In addition to sharing mHealth research support efforts across the NIH, the NIH mHealth IIIG also develops trans-NIH initiatives and coordinates workshops and training efforts.

One of the major efforts of the mHealth IIIG was to coordinate the research track for the 2011 mHealth Summit. The mHealth Summit, led by the Foundation for the NIH, with the NIH as an organizing partner, brings together individuals with expertise in health research, policy, business,

and technology. In its third year, the mHealth Summit, held December 5-7, 2011, at the Gaylord National Resort and Convention Center, had over 3,500 registered attendees. The program included keynote and panel plenary sessions as well as research, technology, policy, and business tracks.

Keynote addresses were made by Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services; Regina Benjamin, Surgeon General of the United States; Julius Genachowski, Chairman, Federal Communications Commission; and Hamadoun Touré, Secretary-General, International Telecommunications Union. Other keynotes were presented by such corporate leaders as Paul Jacobs, Chairman of the Board and Chief Executive Officer, Qualcomm Incorporated, and John Stratton, Executive Vice President and Chief Operating Officer, Verizon Wireless.

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The NIH mHealth IIIG coordinated the research track at the mHealth Summit. Members reviewed nearly 900 abstracts and accepted approximately 60 presentations and 100 posters. The research track included presentations on the evaluation of mobile and wireless applications in chronic disease management, preventive health, and research and diagnostic tools. Highlights from the research track included presentations on mobile phone applications for the management of hypertension, heart failure, and diabetes; mobile interventions for smoking cessation and weight management; and the use of mobile phones and wireless biosensors for remote research trials. The research track also included an invited session that provided an overview of the NIH mHealth Evidence Workshop held on August 16, 2011. This workshop, sponsored by the NIH, the Robert Wood Johnson Foundation, the National Science Foundation, and the McKeeson Foundation, brought together experts in mHealth research, research methodology, data analytics, biostatistics, and computer science to discuss and identify more effective methods of generating evidence of efficacy and effectiveness for the emerging science of mHealth.

The NIH Pavilion enjoyed a prominent place in the mHealth Exhibit Hall and gave attendees the opportunity to meet with representatives from the various NIH ICOs, learn about their research interests in mHealth, and obtain information on funding support for this research. In all, 13 NIH ICOs were represented at the NIH Pavilion: National Cancer Institute, National Eye Institute, National Heart, Lung, and Blood Institute, National Institute on Alcohol Abuse and Alcoholism, National Institute on Aging, National Institute of Biomedical Imaging and Bioengineering, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute on Drug Abuse, National Institute of Environmental Health Sciences, National Institute of Mental Health, National Library of Medicine, Office of Behavioral and Social Sciences Research, and Office of Dietary Supplements. The NIH Pavilion was coordinated by the NIH mHealth IIIG, and many of the members were available at various times in the Pavilion to meet with prospective grantees and others interested in the NIH's role in mHealth.

The NIH mHealth IIIG also coordinated and facilitated the Morning Networking Discussion Groups. These sessions were informal discussions organized around a particular mHealth topic or health problem to allow the diverse Summit attendees to network across disciplines. The discussion groups provided the opportunity for health researchers, health care providers, engineers, computer scientists, business people, policymakers, and attendees from other professions and

disciplines to meet, learn about their common interests in a particular area of mHealth, and pursue possible collaborations. These Morning Networking Discussion Groups were introduced this year and, based on the positive feedback from attendees, are likely to become a recurring part of future mHealth Summit programs.

The fourth annual mHealth Summit is planned for December 3-5, 2012, at the Gaylord National Resort and Convention Center. The NIH mHealth IIIG again anticipates being part of the planning and coordination of the 2012 Summit. The mHealth Summit is a unique experience for the NIH and its extramural research community. The corporate business and technology cultures strongly represented at the Summit are often inconsistent with the culture of science and research. This diversity of cultures is also a key strength of the mHealth Summit, exposing the business and technology communities to the importance of research and evaluation of these mobile and wireless applications and exposing the health research community to cutting-edge technology advances and to the business models necessary to disseminate and implement mobile and wireless health applications. The mHealth IIIG plans to continue to work toward improving the visibility and quality of research at the mHealth Summit.

For details on the 2011 mHealth Summit, go to <http://www.mhealthsummit.org/>. ❖

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## 2011 MHEALTH SUMMIT

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

The 2011 mHealth (mobile health) Summit concluded its yearly event with a record attendance of 3,621 attendees representing 50 countries. The 2011 program agenda featured several extraordinary research sessions, organized by the National Institutes of Health (NIH) and made possible because of the strong partnership among the conference organizers: the Foundation for the National Institutes of NIH, the mHealth Alliance, and the Healthcare Information and Management Systems Society. The NIH played a prominent and critical role in the program agenda through its 15 research-based sessions across three tracks in the areas of Chronic Disease Management Research, Preventive Health Research, and Research and Diagnostic Tools.

The NIH also played a key role in developing and presenting 18 morning discussion groups at the event, each focusing on a specific topic of mHealth that allowed conference attendees to network across disciplines. Topics that were discussed included Diabetes Management; Tobacco, Alcohol, and Other Substance Abuse; HIV and Sexual Health; Prenatal Health; Mental Health; and Diet and Physical Activity, among others.

On the packed exhibit floor, the NIH Pavilion was one of several popular destinations. Thirteen NIH Institutes, Centers, and Offices that have mHealth research and outreach efforts were highlighted in the Pavilion.



2011 mHealth Summit exhibit hall. (Source: Foundation for the National Institutes of Health)

“We had wonderful research presentations this year and saw good traffic on the exhibit floor throughout the event. The NIH Pavilion was a place where we could answer questions and spark discussions with people interested in grant funding. We also had nearly 100 poster presentations at the event, all of which were highly attended,” said Dr. William Riley, Program Director at the National Heart, Lung, and Blood Institute.

Highlights from the 15 research-based sessions included a session on the Genes, Environment and Health Initiative. Panelists reported on results from the initiative, including new mobile and wireless applications they have developed to better evaluate environmental exposures, stress, physical activity, diet, etc., as well as assess the validity of some of those measures. Also discussed was a new generation of prototypical research tools.

The mHealth Evidence Workshop was based on a workshop held by the NIH during summer 2011 in collaboration with the Robert Wood Johnson Foundation, the McKesson Foundation, and the National Science Foundation. In this workshop, panelists discussed ways to speed the evaluation process in the mobile technology space.

A few research-based sessions on research and diagnostic tools looked at remote studies. One such study was the focus of a presentation from Pfizer Inc. on a project involving overactive bladder patients; the project is the first remote clinical trial



Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services, delivering the opening keynote address at the 2011 mHealth Summit. (Source: Foundation for the National Institutes of Health)

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NIH Pavilion at the 2011 mHealth Summit. (Source: Foundation for the National Institutes of Health)

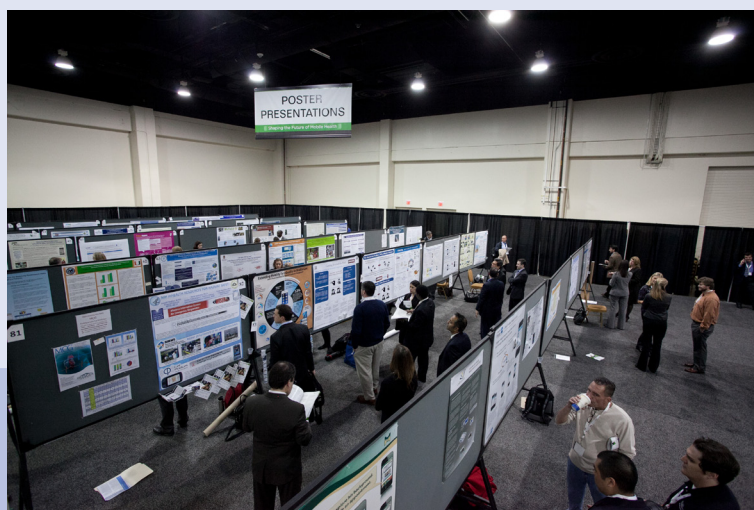
Officer, Qualcomm Incorporated; Dr. Hamadoun Touré, Secretary-General, International Telecommunication Union; and Ms. Sangita Reddy, Executive Director, Operations, Apollo Hospitals Group.

The three-day event was an unprecedented gathering of leaders from the mHealth ecosystem, including researchers, government, nonprofits, policymakers, providers, industry, nongovernmental organizations, entrepreneurs, technology innovators, and venture capitalists—all of whom took part in the many sessions, roundtable discussions, and networking events that spoke to the transformative role that mHealth may play in the lives of individuals and the successes and challenges of integrating mHealth as a tool for improving health care delivery around the world for the 21<sup>st</sup> century.

Plans are under way for the 2012 mHealth Summit, to be held December 3-5 at the Gaylord National Resort and Convention Center near the Washington, D.C., National Harbor.

approved by the U.S. Food and Drug Administration. Patients in the trial were completely remote, and data were collected via the World Wide Web and mobile sources, whereas laboratory results and drugs were mailed to patients. Other technologies presented in research sessions included a tool to measure blood pressure continuously without a cuff and a tool to measure cataracts using a clip-on device for a mobile phone that collects data.

The 2011 mHealth Summit also served as the platform for key announcements from government and industry leaders, such as keynote presenters Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services; Mr. Julius Genachowski, Chairman, Federal Communications Commission; Dr. Regina Benjamin, Surgeon General of the United States; Dr. Eric Topol, Vice Chairman, West Wireless Health Institute; Mr. John Stratton, Executive Vice President and Chief Operating Officer, Verizon Wireless; Mr. Paul Jacobs, Chairman of the Board and Chief Executive



2011 mHealth Summit poster session. (Source: Foundation for the National Institutes of Health)

### FOR MORE INFORMATION:

- YouTube: <http://www.youtube.com/user/mhealthsummitevent1>  
Session videos are available on our YouTube channel.
- Flickr: <http://www.flickr.com/photos/43520317@N05/>
- Livestream channel: <http://www.livestream.com/mhealthsummit>
- Twitter #mHS11: <https://twitter.com/#!/mHealthSummit>
- Program information: [www.mhealthsummit.org](http://www.mhealthsummit.org). ❖

# STAKEHOLDER ALIGNMENT IN THE BIOMARKERS CONSORTIUM

Joel Cutcher-Gershenfeld, Ph.D., Dean and Professor, School of Labor and Employment Relations, University of Illinois at Urbana-Champaign

The Biomarkers Consortium (BC) is one of three multi-stakeholder initiatives being studied as part of the National Science Foundation (NSF) project, “Stakeholder Alignment in Socio-Technical Systems” (NSF-Virtual Organizations as Socio Technical Systems 0956472). The research is designed to better understand new institutional forms associated with many areas of science, technology, and society. The project includes a study of a regional green energy initiative and a study of the U.S. network of “Fab Labs” (small-scale workshops offering personal, digital fabrication) that serve to build community literacy in design and fabrication. The broad aim of the research is to enable faster and more effective results across different types of multi-stakeholder initiatives.

The study of the BC has involved interviews with 24 stakeholders to date (more are planned) utilizing a set of tools and methods designed to provide feedback on points of alignment (and misalignment) among stakeholders. Key stakeholders considered in this case include the National Institutes of Health (NIH), the Foundation for the NIH, the U.S. Food and Drug Administration (FDA), pharmaceutical companies, biotechnology companies, academia, and patient advocacy groups and other organizations.

The stakeholder alignment framework centers on two core functions of any institutional arrangement: (1) “create value” and (2) “mitigate harm.” More specifically, stakeholder alignment is defined as “the extent to which interdependent stakeholders orient and connect with one another to advance their separate and shared interests.” This formulation draws attention to the orientation and engagement of stakeholders with one another, as well as what can be thought of as a double bottom line: serving separate interests and the interests of the whole.

In the case of the BC, stakeholders identified key elements of success as including identification, launch, and completion of projects; advancing the public-private consortium model; and, ultimately, having positive impacts on public health. There was broad stakeholder support for the structure of the BC, which includes the Executive Committee, the four Steering Committees (Cancer, Metabolic Diseases, Neuroscience, and Inflammation & Immunity), and the various projects. Key enablers of the BC include the evolution of (and improvements in) the ways in which projects are identified, as well as protocols and standards for matters such

as anti-trust, intellectual property, confidentiality, and conflict of interest.

Even though there is broad alignment on the elements of success, the structure of the BC, and key aspects of its operations, other areas pose challenges for the BC. These include the contrast between large pharmaceutical companies, for which biomarker diagnostics are typically pre-competitive, and smaller biotechnology companies, for which biomarker diagnostics are central to their businesses. Similarly, there is a contrast in the preferred focus of many at the NSF and in academia on discovery and the focus by industry and patient advocacy groups on biomarker development and qualification. And, of course, there are differences in mission and focus among the relevant government agencies. Moreover, many of the representatives serving on the Steering Committees and the Executive Committee are volunteers who also have “day” jobs.

At a deeper level, both the public and private organizations associated with the BC all have internal alignment challenges that need to be resolved to support the lateral alignment of the BC. Indeed, one industry member reported that his company had to form an internal committee for all the people serving on different consortia to ensure that they were approaching these various consortia in a coordinated way. Key skills are needed for success in a consortium such as the BC, particularly knowing how to lead based on influence rather than on authority.

Importantly, the research has involved developing new tools and methods for displaying the interests of stakeholders in a complex system. Presenting these are beyond the scope of this article, but they allow a more nuanced consideration of the views of different stakeholders. It is hypothesized that improved visualization of interests (while preserving confidentiality) will enable more robust forms of alignment and faster, more effective decisions and actions.

Early in the research, in December 2009, the NIH Public-Private Partnership (PPP) Coordinating Committee was briefed on the principles of stakeholder alignment in complex systems. In May 2010, the research was featured as part of a panel on “Cost and Risk Sharing to Advance Drug Development” at the Biotechnology Industry Organization conference, and in June 2010 the research was featured at the

*(continued on page 11)*

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Industry Studies Association. Most recently, in January 2012, an update on major findings was provided to The Biomarkers Consortium Executive Committee. Joining Dean Cutcher-Gershenfeld on the research team are Dr. Barbara Mittleman,

NIH PPP Program, Dr. Anthony Dickherber, National Cancer Institute (NCI), Dr. Shawnmarie Mayrand-Chung, FDA, and Ms. April Franks, NCI. For more information, contact Dr. Cutcher-Gershenfeld at [joeleg@illinois.edu](mailto:joeleg@illinois.edu). ❖

**CALENDAR**

| DATE    | MEETING                                 | LOCATION & TIME  | SPEAKER  |
|---------|---|--|--|
| 2.16.12 | PPP Coordinating Committee Meeting*     | NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm                            | <b>Stephen H. Friend, M.D., Ph.D., President, Co-Founder, and Director of Sage Bionetworks</b><br>Dr. Friend's presentation "If the Physicists Can Do It, the Software Engineers Can Do It, Why Can't We Do It: Networked Team Approaches among PPPs, will provide background about Sage Bionetworks and discuss 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. |
| 2.28.12 | mHealth IIIG Interest Group Meeting**   | Teleconference, 12:00 - 1:00 pm  | Monthly trans-NIH meeting to discuss NIH mobile health and wireless activities   |
| 3.15.12 | PPP Coordinating Committee Meeting*     | NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm                            | <b>Christopher D. Earl, Ph.D., President, Innotrove LLC</b><br>Dr. Earl will discuss partnerships and opportunities from his current vantage point as a venture capitalist as well as from his experience as the first CEO of Bio Ventures for Global Health, a PDP (product development partnership) for global health.   |
| 3.27.12 | mHealth IIIG Interest Group Meeting**   | Teleconference, 3:00 - 4:00 pm   | Monthly trans-NIH meeting to discuss NIH mobile health and wireless activities   |
| 4.19.12 | PPP Coordinating Committee Meeting*     | NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm                            | <b>Jack J. Young, Qualcomm Life Fund, Qualcomm Ventures</b><br>Mr. Young will provide insight into the thinking and activities of the Qualcomm Ventures fund focused on opportunities in mobile health and investment and development opportunities.   |
| 4.24.12 | mHealth IIIG M Interest Group Meeting** | Teleconference, 3:00 - 4:00 pm   | Monthly trans-NIH meeting to discuss NIH mobile health and wireless activities   |
| 5.17.12 | PPP Coordinating Committee Meeting*     | NIH Campus, Building 1, Wilson Hall, 2:30 - 4:30 pm                            | <b>Robert DeBerardine, J.D., Vice President and Head of Global Patent Department, Sanofi</b><br>Mr. DeBerardine will provide insight and perspective in deciding what can or should be pre-competitive, what constitutes a competitive advantage (and how that may be changing), and how Sanofi considers partnerships and consortia among the tools available in seeking new knowledge and technologies.  |
| 5.22.12 | mHealth IIIG Interest Group Meeting**   | Teleconference, 3:00 - 4:00 pm   | Monthly trans-NIH meeting to discuss NIH mobile health and wireless activities   |
| 6.14.12 | PPP Coordinating Committee Meeting*     | NIH Campus, Building 31, C Wing, 6th Floor, Conference Room 10, 2:30 - 4:30 pm | <b>Carolyn Compton, M.D., Ph.D., President and CEO, Critical Path Institute</b><br>Dr. Compton, former head of NCI's OBBR and now heading up the Critical Path Institute, will discuss the Critical Path Institute's process and thinking regarding partnerships and consortia, IP considerations, and the precompetitive landscape.   |

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

\*\* The mHealth IIIG Interest Group meets on the fourth Tuesday of each month via teleconference. For additional information about the committee or the meetings, please contact Dr. Bill Riley at [william.riley@nih.gov](mailto:william.riley@nih.gov).

All meeting locations are subject to change.



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