PUBLIC-PRIVATE PARTNERSHIP PROGRAM

PPP ADVISOR

VOLUME 1 – ISSUE 8
SPRING 2010

MESSAGE FROM THE DIRECTOR

Dr. Barbara B. Mittleman

Welcome to the spring edition of the National Institutes of Health (NIH) Public-Private Partnership Program's (PPP) newsletter, *PPP Advisor*. The weather is improving, hibernating staff members are emerging, and programs are heating up. One such program is the mHealth (Mobile Health) Summit. See Dr. Audie Atienza's article to learn about the NIH planning committee, mHealth Inter-Institute Interest Group (mHealth IIIG), which was inaugurated in January 2010, as well as some preliminary information about the upcoming mHealth Summit, which will be held at the Washington Convention Center November 8-10, 2010. Dr. Atienza also mentions the many contacts he is developing with other Federal agencies, industry members, foundations, and trade organizations.

Dr. Shawnmarie Mayrand-Chung's article will catch you up on some of the exciting and press-worthy activities of The Biomarkers Consortium and also about her interactions with U.S. and European executives in pharmaceutical research and development at the annual Global Discovery and Development Innovation Forum meeting in Edinburgh, Scotland, United Kingdom. Our interactions and conversations with industry executives represent our ongoing efforts to understand industry's interests, priorities, and plans in order to serve as a bridge between the NIH Institutes, Centers, and Offices (ICOs) and industry contacts. We follow up on such contacts in several ways, including engaging in private conversations to enhance our understanding, extending invitations to speak to the PPP Coordinating Committee to share industry insight with a larger trans-NIH group, and facilitating specific partnership opportunities, which grow out of the initial meetings and conversations.

Also in this edition you'll find an article by Dr. Wendy Smith, who recently returned to the PPP Program from a detail in the NIH Clinical Center, discussing some of the ways in which landscape analysis of areas of scientific activity at the NIH can be captured and why they are of interest to potential partners—sometimes as a validation of their willingness to invest in partnerships with the NIH and to expand our research capacity. The article addresses some of the challenges of accomplishing such a landscape analysis. This issue of the *PPP Advisor* also includes information about the upcoming 2010 Biotechnology Industry Organization (BIO) International Convention to be held this year in Chicago, IL, May 2-6, 2010. Dr. Shawnmarie Mayrand-Chung will be moderating the cross-sector panel "Cost and Risk Sharing To Advance Drug Development: A Unique Opportunity" (BIO Session ID: 5314); Dr. Barbara Mittleman will be participating in the cross-sector panel "The Aftermath: The Future of the Life Sciences Industries Beyond the Global Recession" (BIO Session ID: 5085); and Dr. Lynn Hudson (Director, Office of Science Policy Analysis) will be speaking on a panel on Comparative Effectiveness Research, an area of active and broad interest to both the public and private sectors and one that features significantly in the recently passed health care reform bill. The PPP Program staff will also be participating in the

(continued on page 2)

SPOTLIGHT

The National Institutes of Health (NIH) Public-Private Partnership Program (PPP) is pleased to include in this issue a guest feature article authored by Mr. Ralph Marcello, Senior Manager, Deloitte Consulting. Mr. Marcello was a speaker at the PPP Coordinating Committee last year, to rave reviews, and has provided information about the benefits of industry partnerships for the ultimate goal of improving public health.

In a follow-up to the winter 2010 newsletter, a guest article is provided in this issue by the Office of Technology Transfer (OTT), Office of the Director. This article, the second in a three-part series, provides information about the Pipeline to Partnerships, a web-based database where NIH licensees and Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) grantees can publish information for potential partners about their technologies and product development.

INSIDE THIS ISSUE

(CONTINUED FROM PAGE 1)

one-on-one partnering sessions at BIO as a means to increase NIH visibility and the understanding of collaborative and partnership opportunities with the NIH on the part of BIO members. As we interact with industry more and more, we are always surprised at how little government and industry know about one another, in terms of our cultures, how we operate, and what each group can and cannot do. Such one-on-one conversations with parties that elect to seek us out are very effective in increasing that awareness. We hope that any NIH-ers who will be attending BIO will join us at these sessions and participate in the discussions. And, as always, we continue to engage with NIH ICOs to discuss partnership opportunities, review documents, and strategize about novel means to extend our ability to meet our public health mission. ❖

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

The Biomarkers Consortium: Springing Into 2010

Dr. Shawnmarie Mayrand-Chung

Newest Project Launch

On March 17, 2010, The Biomarkers Consortium (BC) launched the largest so far of BC projects: the I-SPY 2 (Investigation of Serial Studies To Predict Your Therapeutic Response With Imaging and Molecular Analysis 2) trial. This adaptive breast cancer trial is designed to help screen promising new drugs being developed for women with high-risk, fast-growing breast cancer—women for whom an improvement over standard treatment could dramatically change the odds of survival.

The I-SPY 2 trial will employ a groundbreaking clinical trial model that uses genetic biomarkers from individual patients' tumors to screen promising new treatments, identifying which treatments are most effective in specific groups of stratified patients. Additionally, the innovative adaptive Bayesian trial design will enable researchers to use early data from one set of patients to guide decisions about which treatments might be more useful for future patients having similar biomarker profiles. This adaptive strategy will increase the positive effects of the tested drugs, decrease nonresponders, and eliminate ineffective treatments more rapidly.

In addition to identifying new breast cancer drugs by using biomarkers to identify those agents that are effective in specific subpopulations of breast cancer patients, the unique design of this study will serve as a pilot study for advancing smaller and less expensive Phase III trials that test the right drugs in the right patients.

The I-SPY 2 trial will focus on breast cancer treatment in the neoadjuvant therapy setting, in which chemotherapy is given to patients to reduce tumor size before surgery. All patients will receive the current standard of care, and most participants will receive one investigational drug. A unique feature of the trial is that it will screen multiple drugs from multiple companies—with up to 12 candidate breast cancer drugs being tested over the course of the 5-year trial.

To execute this adaptive clinical trial model, the Foundation for the NIH (FNIH) sought and received a master Investigational New Drug (IND) approval from the U.S. Food and Drug Administration (FDA), which allows the I-SPY 2 trial team to "graduate" as successful, drop as unsuccessful, and add new drugs seamlessly throughout the course of the trial without having to stop and draft a new protocol for IND approval. This feature of I-SPY 2 will drastically reduce the time required to add and drop drugs from consideration.

Five investigational agents have already been selected for testing as part of the first phase of the trial, with each agent representing a different drug class or type of chemical mechanism for attacking cancer. The first agents selected for testing include:

- **ABT-888 (veliparib)**, a PARP inhibitor being developed by Abbott Laboratories, Abbott Park, IL
- **AMG 655 (conatumumab)**, an APO/TRAIL inhibitor, and **AMG 386**, an angiogenesis inhibitor, both under development at Amgen Inc., Thousand Oaks, CA

(continued on page 3)

(CONTINUED FROM PAGE 2)

- **CP-751871 (figitumumab)**, an IGFR inhibitor, and **HKI-272 (neratinib)**, a Pan ErbB inhibitor, both under development at Pfizer, Inc., New York, NY

Note: These agents will be donated by the respective developing companies.

I-SPY 2 will be coordinated by two principal investigators, Laura Esserman, M.D., M.B.A., Professor and Director, Carol Franc Buck Breast Care Center, University of California, San Francisco (UCSF), and Donald Berry, Ph.D., Professor and Chair, Department of Biostatistics, Division Head, Division of Quantitative Sciences, The University of Texas M.D. Anderson Cancer Center. Clinical operations of the trial will be managed by Angie DeMichele, M.D., M.S.C.E., Associate Professor of Medicine and Epidemiology, Abramson Cancer Center, University of Pennsylvania Medical Center. Nola Hylton, Ph.D., Professor of Radiology and Director, Breast MRI Research Program, UCSF, developed new tools to use MRI as a quantitative measure of response to therapy developed in a previous research study, I-SPY 1; these tools will be an integral part of the I-SPY 2 trial and will help validate whether MRI tumor volume change, rather than surgery, can be used as a way of determining patients' response to treatment.

Up to 20 of the Nation's leading cancer centers, including many of the National Cancer Institute's (NCI) Comprehensive Cancer Centers, will recruit and treat patients as part of the trial. Currently selected centers include:

- UCSF Helen Diller Family Comprehensive Cancer Center, UCSF, San Francisco, CA
- Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA
- University of Minnesota Medical Center, Minneapolis, MN
- Rebecca and John Moores University of California, San Diego (UCSD) Cancer Center, UCSD, La Jolla, CA
- The University of Texas M.D. Anderson Cancer Center, Houston, TX
- University of Colorado Cancer Center, Aurora, CO
- Mayo Clinic, Scottsdale, AZ
- Mayo Clinic, Rochester, MN
- Knight Cancer Institute, Oregon Health & Science University, Portland, OR
- Inova Health System, Falls Church, VA
- The University of Chicago Comprehensive Cancer Center, Chicago, IL
- Harold C. Simmons Comprehensive Cancer Center, University of Texas Southwestern Medical Center, Dallas, TX
- University of Southern California (USC) Norris Comprehensive Cancer Center, USC, Los Angeles, CA
- Winship Cancer Institute of Emory University, Atlanta, GA
- The University of Kansas Cancer Center, Kansas City, KS
- Cardinal Bernardin Cancer Center, Loyola University Chicago Health System, Maywood, IL

The I-SPY 2 trial is expected to cost approximately $26 million over 5 years, and the FNIH will head up the funding efforts in addition to overall management of the project. To maximize public health benefit, the nonprofit FNIH will serve as a trusted third party to manage data and intellectual property arising from the trial.

All results from the trial will be published by the investigators via articles in peer-reviewed scientific journals. The large amount of valuable data expected to be generated by the project will be stored in a database at UCSF and M.D. Anderson using tools developed as part of the NCI's Cancer Biomedical Informatics Grid initiative.

In closing, the I-SPY 2 trial will provide a path to personalized medicine as well as test a new model for conducting clinical trials, while proving the power of collaboration.

For more information

1. www.ispy2.org

2. AD Barker, CC Sigman, GJ Kelloff, NM Hylton, DA Berry, LJ Esserman. I-SPY 2: An Adaptive Breast Cancer Trial Design in the Setting of Neoadjuvant Chemotherapy. *Clinical Pharmacology & Therapeutics* 86:97-100 (1 July 2009) http://www.nature.com/clpt/journal/v86/n1/full/clpt200968a.html

Project Pipeline

At the May 10, 2010, BC Executive Committee face-to-face meeting, the newest project plan will be presented to the committee for a vote. This project, Clinical Evaluation and Qualification of Kidney Safety Biomarkers, is designed to

(continued on page 4)

(CONTINUED FROM PAGE 3)

identify which new biomarkers can outperform BUN (blood urea nitrogen) and serum creatinine for monitoring treatment with nephrotoxic agents, provide meaningful thresholds of change for each biomarker, and provide insight into their relative performance. The deliverables of this project will be (1) a joint submission between the Critical Path Predictive Safety Testing Consortium (PSTC) and The BC Project Team of all data and conclusions and a resulting published decision from the FDA, the European Medicines Agency (Europe), and the Pharmaceuticals and Medical Devices Agency (Japan) regarding the qualification claims for these biomarkers and (2) peer-reviewed publications of the findings from each clinical study. Additionally, the samples collected, as well as the final deidentified dataset from the clinical trials, will be available for access by the general public through submissions of applications to an Advisory Committee comprising 10 representatives from all sectors (industry, government, and academia) who will be appointed by the PSTC and the BC. ❖

Accelerating Mobile Health (mHealth) at the National Institutes of Health

Dr. Audie Atienza

Mobile health (mHealth) is quickly emerging in industry and government as a key example of how wireless and portal technologies can enable and accelerate improvements in health and health care. The topic of mHealth is increasingly being discussed at various health information technology conferences, wireless industry meetings, and government/regulatory forums. However, the scientific evidence base has not kept pace with the proliferation of mobile devices in the population and the burgeoning attention given to mHealth. Several activities at the National Institutes of Health (NIH) focus on exchanging knowledge and the state of the science on mHealth within the NIH, providing a venue for NIHers to access outside speakers and information, and coordinating a cross-sector dialogue on mHealth. The NIH Public-Private Partnership (PPP) Program, Office of Science Policy Analysis (OSPA), Office of the Director (OD), is coordinating aspects of the NIH mHealth effort as a natural outgrowth of the 2009 first mHealth Summit, for which we coordinated NIH participation, and because the remit of mHealth touches the missions of so many diverse NIH Institutes, Centers, and Offices (ICOs).

NIH mHealth Inter-Institute Interest Group (mHealth IIIG) Launched

In January 2010 the NIH mHealth Research Inter-Institute Interest Group (mHealth IIIG) held its first monthly meeting to share and coordinate mHealth activities across the NIH and invited speakers to give presentations on topics pertinent to mHealth research for the NIH community. This inaugural meeting was attended by representatives from ICOs across the NIH, including the Center for Scientific Review, Fogarty International Center, National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Biomedical Imaging and Bioengineering (NIBIB), Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institute on Drug Abuse (NIDA), National Institute of Environmental Health Sciences (NIEHS), National Institute of Mental Health (NIMH), National Library of Medicine (NLM), NIH Office of Dietary Supplements (ODS)/OD, NIH Office of Behavioral and Social Sciences Research (OBSSR)/OD, and PPP/OSPA/OD). Moreover, other NIH ICOs (e.g., National Center on Minority Health and Health Disparities [NCMHD], National Center for Research Resources [NCRR], and others) had indicated interest in attending the first mHealth IIIG but were unable to attend. This first meeting focused on discussing the overall structure and purpose of the interest group and setting initial goals. Based on recommendations from this initial meeting, an NIH listserv has been established so that mHealth IIIG members may share information.

The second mHealth IIIG meeting in February 2010 focused on discussing selected activities at various NIH ICOs. Dr. Wendy Nilsen (OBSSR) described the proposed workshop "Reducing Barriers to Mobile Technology Usage in Behavioral and Social Science Research," which is being cosponsored by the OBSSR and the NHLBI. Dr. Shoshana Kahana (NIDA) discussed the NIDA meeting "Intersection of Technology: HAART (Highly Active Antiretroviral Therapy) Adherence and Drug Abuse Treatment." Dr. Michael Sayre (NCRR) described the "Internet2 Health Sciences Initiative and 2010 Internet2 Member Meeting." In addition, I provided updates on the 2010 mHealth Summit planning (see below). Representatives from NCI, NCRR, National Institute on Aging (NIA), National

(continued on page 5)

(CONTINUED FROM PAGE 4)

Institute on Alcohol Abuse and Alcoholism (NIAAA), NIAID, NIBIB, NICHD, NIDA, NIEHS, NIMH, NLM, NIH ODS/OD, NIH OBSSR/OD, and NIH PPP/OSPA/OD were in attendance.

Clearly, there is a strong interest in mHealth research at the NIH! The NIH mHealth IIIG is open to all NIH staff members, and broad participation is welcomed. Future NIH mHealth IIIG meetings will feature presentations from industry (e.g., Qualcomm), Federal partners (e.g., Federal Communications Commission [FCC], U.S. Food and Drug Administration [FDA], the White House Office of Science and Technology Policy [OSTP]), and other partners in mHealth (e.g., Foundation for the NIH [FNIH]).

2010 mHealth Summit Planning Is in Full Swing

The 2010 mHealth Summit, sponsored by the FNIH in partnership with the NIH and a follow-on from last year's first mHealth Summit, is planned for November 8-10, 2010, at the Washington Convention Center (Washington, DC). The 2010 mHealth Summit will examine the intersection of mobile health research, technology, and policy in both developed and developing worlds, with ample opportunity for cross-sector dialogue throughout the meeting. An NIH mHealth Summit planning committee has been established to assist with the planning of the Summit, with representatives from NCI, NCMHD, NCRR, NHLBI, NIA, NIAAA, NIAID, NIBIB, NICHD, NIDA, NIEHS, National Institute of Nursing Research (NINR), NLM, NIH Office of Disease Prevention/OD, NIH ODS/OD, and NIH Division of Nutrition Research Coordination (DNRC)/OD. In addition to providing feedback to the Summit's overall description, the planning committee is assisting with crafting the call for abstracts and providing recommendations for session speakers. Additional partners to the 2010 mHealth Summit include the mHealth Alliance (whose members are the United Nations Foundation, The Rockefeller Foundation, and Vodafone Foundation), Microsoft Research, Qualcomm, and Global System for Mobile Communications Association. Stay tuned for further details! This will be a "not-to-be-missed" event! An important outcome expected from the Summit is the development of PPPs around mHealth to increase the NIH's capacity to support research in the development, use, and application of mobile technologies to improve public health.

Landscape/Portfolio Analysis

During the planning and discussions at the 2009 mHealth Summit, it became clear that many NIH ICOs were funding research grants that incorporated mobile devices. The full extent of the NIH's investment in mHealth research, however, has not been formally examined. As such, the NIH PPP/OSPA/OD is conducting a landscape/portfolio analysis of NIH-funded grants. Preliminary analyses using the keywords "mobile phone" or "cellular phone" for active grants found approximately 60 grants currently being funded by the NIH. We know that this preliminary analysis underestimates the number of mHealth grants currently being funded by the NIH given that mHealth research includes other portable or wireless technologies beyond mobile phones, such as global positioning systems, short message service devices, accelerometers, portable heart rate monitors, physiological sensors, etc. The insight provided by this overview of NIH mHealth activities will facilitate the coordination and integration within the NIH to develop future programs and initiatives in mHealth. Furthermore, since prospective partners often use the NIH's investment in specific research areas as an indicator of scientific opportunity and priority, this analysis will help in the development of potential partnerships with non-NIH partners that leverage the investment and unique resources of the NIH to ultimately extend our ability to meet our public health mission.

Conversations With Other Federal Agencies

Although the development of the scientific evidence base for mHealth research corresponds well to the NIH mission, several other Federal agencies also have keen interests in mHealth. Conversations about mHealth with several of these Federal agencies have rapidly progressed during the first quarter of 2010. Notably, the FCC released the National Broadband Plan in March 2010 (http://www.broadband.gov/), with a chapter dedicated to implications for health care. In addition, the FDA's Center for Devices and Radiological Health is responsible for ensuring the safety and effectiveness of medical devices, such as the portable sensors used in medical settings. Furthermore, the OSTP is collaborating with industry and the health community to provide pregnant women with important health information in the Text4Baby program. The NIH PPP staff remains in discussions with FCC, FDA, and OSTP about coordinating mHealth activities across the agencies. There are also plans for dialogue with the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology, Health Resources and Services Administration, Substance Abuse and Mental Health Services Administration, Centers for Medicare & Medicaid Services, U.S. Department of State, and other Federal agencies with interests in mHealth. Coordination across Federal partners will be essential for the development

(continued on page 6)

(CONTINUED FROM PAGE 5)

and sustainability of mHealth programs, and the NIH plays a vital role in establishing the scientific evidence base that evaluates the efficacy, effectiveness, usability, and feasibility of using mobile devices to assess and improve health. Given the critical role that industry plays in developing mobile technology, there exist unique opportunities to establish public-private partnerships to accelerate progress in mHealth. In the year to come, mHealth will figure prominently—not only at the NIH but also broadly across the Federal Government, nonprofit organizations, and industry. ❖

Landscape Analysis as a Tool for Public-Private Partnership Development

Dr. Wendy B. Smith

Now that I am back from my recent detail to the National Institutes of Health (NIH) Clinical Center, I have been working on the Mobile Health (mHealth) initiative, starting a landscape analysis of current NIH activities in this topic. Landscape analysis is not just an issue for mHealth activities but also, in a more general sense, for understanding that the current landscape in a scientific field is often a critical step in the development of any public-private partnership. A first step in this process is to look at the current Federal investment in an area of interest. Although there are challenges in trying to map this information, the potential benefits make this process well worth the effort.

Several databases are available for the NIH staff to assess NIH investment in a topic area and include such information as titles and abstracts of applications for NIH funding, along with details useful for grants management (career information regarding the investigators, budget information, other support, and more). Much of this information is confidential in nature and thus is available only to qualified Federal employees. Research Portfolio Online Reporting Tools (RePORT), however, is a database of funded projects available to the public. Focusing only on the relevant information available in any of these databases can be a challenge. The first step is to identify appropriate search terms. This sounds straightforward but in practice can yield unexpected results. Many search terms overlap with one another, yielding the same information multiple times, whereas other terms, which may have several meanings or connotations, may identify irrelevant activities. For example, our first search for NIH-funded activities in mobile health resulted in over 47,000 projects; clearly, the search terms were not specific enough to capture only the relevant projects. Weeding through the results to identify relevant activities can be a time-consuming process. However, reworking the search terms yields a more focused and specific set of "hits." This information permits both mapping out current activities funded by the NIH as well as helping identify potential gaps in the science. Examining the particulars of the portfolio can also help identify organizations, individuals, and NIH groups with which to explore partnering possibilities as well as allow potential partners to leverage the NIH's investment and assessment of scientific priorities and opportunities.

The RePORT research portfolio website developed and maintained by the Office of Extramural Research at the NIH provides access to basic information on NIH programs and includes several tools and filters for searching this information. By using RePORT (accessible to anyone at http://report.nih.gov/index.aspx), users can access funding, abstract, publication, and patent information from several additional databases, including the NIH electronic research administration (eRA) databases. Through RePORT, NIH grant information, as well as patent and invention records for 25 different Federal agencies, can be accessed, along with Medline, the Medical Literature Analysis and Retrieval System Online, and its free digital archive, PubMed Central, the National Library of Medicine's searchable bibliographic database, which contains over 16 million references with a concentration on biomedicine. IMPACII (Information for Management, Planning, Analysis, and Coordination) is another tool, although it is available only to authorized users at the NIH and other select Federal grantor agencies. This system includes data on both proposed and funded grant applications and is used for grants management. It is one more interface that can aid the NIH staff in assessing current or past relevant scientific activities in a specific topic.

We in the PPP Program office work closely with the NIH ICOs and potential outside partners to use all available tools to focus and refine our partnerships in the context of NIH priorities. The ability to do landscape analysis is an excellent tool for the PPP Program. In the context of the mHealth Initiative, it allows us to discuss within the NIH what synergies exist across NIH programs as well as to converse with other Federal agencies and outside partners as we prepare for the mHealth Summit and the PPPs we expect to develop from it. ❖

Benefits of Public-Private Partnerships in the Life Sciences Industry

Ralph Marcello, Senior Manager, Deloitte Consulting

Over the past few years, a paradigm shift occurred in the marketplace as to how companies in the pharmaceutical, biotechnology, and medical device sectors work together to discover and develop novel drug compounds. A large number of companies are shifting away from traditional, short-term transactional relationships and collaborations based on the lowest cost solution to establishing longer term, outcomes-based, risk-sharing partnerships. Initially, this shift in behavior occurred within and among the private sector, but more recently, there has been a renewed interest in capitalizing on the benefits of partnerships with public, academic, and nonprofit research institutions. Although there is a long history of these organizations working together to discover and develop new compounds for patients, this history is also littered with challenges in overcoming intellectual property rights, technology licensing and transfer agreements, public policy issues, and basic working agreements.

Industry executives believe the research and development (R&D) operating model of the future must enable high-quality scientists and clinicians to focus on innovation, have flexible resourcing, and adapt to scientific breakthroughs and roadblocks with fluid decision-making. Companies that effectively partner—not only with each other, but also with public, academic, and nonprofit institutions—can benefit from their partners' abilities to:

- Provide operating agility and flexible capacity to support unexpected changes in demand due to scientific, regulatory, or market shifts (private, public)
- Enable a more flexible cost structure and the sharing of risk that would otherwise be too concentrated in a "go-it-alone" strategy (private, public, academic)
- Provide access to high-talent pools, diverse knowledge bases, emerging technologies, and innovative treatment solutions (private, public, academic, nonprofit)
- Accelerate the discovery and development of compounds for underserved populations that may not be profitable (public, academic, nonprofit)
- Pool scientific expertise to create better methods and tools that streamline R&D (public, academic, nonprofit)
- Resolve incentive and financial barriers that are specific to increased industry involvement in the development of safe and effective pharmaceutical products (nonprofit)

A Successful Formula

Regardless of the type of partnership (e.g., private-private or public-private), successful partnerships depend most on leadership commitment and ongoing, proactive management. Key principles for building partnerships include:

- **Commitment at the top levels of the organization:** Engage senior leadership to avoid the pursuit of tactical objectives at the expense of the broader portfolio. Articulate a clear vision that links to broader business goals and is promoted throughout the organization.
- **Know your core needs and objectives:** Establish explicit objectives, requirements, and incentives and build arrangements that reward targeted outcomes and minimize transactional incentives. Consider how a partnership may enable, or potentially hinder, long-term objectives.
- **Identify the right partners:** Take a holistic approach to partner selection, looking beyond price as the single criterion. Partnerships evolve; some partners may not be ready to deliver on "day one."
- **Build a mutually beneficial relationship:** Invest time and resources upfront to jointly build the capabilities that will be the foundation of a long-term partnership. Foster a culture of continuous improvement and focus on measuring performance and sharing leading practices throughout both organizations.
- **Manage partnerships to achieve outcomes:** Make alliance management an operational line unit, outside of procurement, with full management support and governance structures. Create a dedicated and centralized team of resources initially to build the competency, with the goal of diffusing responsibility over time.

Strategic partnerships will continue to play a key role in providing access to scientific and clinical expertise, innovative technologies, process efficiencies, and risk-sharing. A continued focus on efforts that encourage the exchange of innovative ideas, expertise, and tools between public and private institutions not only will increase access to innovative treatments but also will improve overall public health. ❖

Visit us at **http://ppp.od.nih.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)
301.402.0280 fax
pppartnerships@od.nih.gov

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

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

Pipeline to Partnerships: *A Virtual Marketplace (2 of 3)*

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

The National Institutes of Health (NIH) is continually exploring ways to facilitate the development of biomedical discoveries and technologies into products that can enter the marketplace. Pipeline to Partnerships (P2P), a Web-based resource, was launched jointly by the NIH Office of Technology Transfer (OTT) and the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Office to advance development of the NIH's intramural licensed technologies and those for which it has provided SBIR/STTR funding.

P2P is a virtual space where NIH licensees and SBIR/STTR grantees can publish their technologies and product development for an audience of potential strategic partners, licensees, and investors that can partner with them in the product development pathway to share costs, infrastructure, and expertise as the research and development progresses to later stage clinical trials.

Currently, 153 companies have showcased more than 150 technologies that are available for partnering. These can be accessed on the OTT Web site as a searchable index by category of technology and stage of development. Once a company looking for later stage opportunities identifies a technology of interest, the awardee's website can be accessed directly to start the process of reviewing the awardee's technology and contacting the awardee. All submissions to the site by licensees and grantees are voluntary at the P2P site. Although the NIH screens all postings for valid licensing activity or SBIR funding, the NIH is not involved directly in the partnering activities. Companies can access the P2P site directly at http://www.ott.nih.gov/p2p. Please send questions, concerns, or feedback to p2p@mail.nih.gov. ❖

Calendar

Date	Meeting	Location & Time	Speaker
4.15.10	PPP Coordinating Committee Presentation: Innovation	NIH Campus 1 - 3 pm	Mark Rohrbaugh, OTT, OD, NIH Mark Lim, IMAT Program, NCI, NIH
5.2.10-5.6.10	BIO Conference	McCormick Place, Chicago, IL	http://convention.bio.org/default.aspx
5.20.10	PPP Coordinating Committee Presentation: Partnerships—A Small Company's Perspective	NIH Campus 1 - 3 pm	Norman Garceau, Blue Sky Biotech Robert Jarrin, Director, Government Affairs, Qualcomm Susan Berson, Member, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
6.17.10	PPP Coordinating Committee Presentation: Panel Discussion	NIH Campus 1 - 3 pm	TBA
11.8.10-11.10.10	mHealth Summit	Washington Convention Center, Washington, DC	

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

NIH Publications No. 08-6531
Printed April 2010