

## **Seven Challenges for Nanomedicine**

### **Supplementary Information**

#### **THE ALLIANCE FOR NANOHEALTH**

The Alliance for NanoHealth (ANH: <http://www.nanohealthalliance.org/>) is a multi-disciplinary, multi-institutional collaboration with a mission of facilitating the development and clinical translation of nanotechnology-based innovations that offer new clinical approaches to saving lives through improved diagnosis, treatment, and prevention. The ANH comprises eight institutions that reside in the Texas Medical Center and Greater Houston, Texas Region. Member institutions are: the Baylor College of Medicine, The University of Texas M.D. Anderson Cancer Center, Rice University, the University of Houston, The University of Texas Health Science Center at Houston, Texas A&M University, University of Texas Medical Branch and The Methodist Hospital Research Institute.

The barriers between medical research and nanotechnology can only be overcome through the establishment of an interdisciplinary organization such as the Alliance. The Alliance supports innovative multi-institutional collaborative research through internal seed grant programs, provides infrastructure development for shared core facilities, offers educational scholarships for graduate students and post-docs to attend conferences and seminars, hosts multi-institutional events to enhance investigator interactions and research exposure (i.e. lunch seminars, poster sessions, workshops, conferences), and advances the field of nanomedicine through strategic partnerships with industry, state, federal agencies, and international institutions.

#### **FDA-ANH SCIENTIFIC WORKSHOP**

The Food & Drug Administration (FDA) and the Alliance for NanoHealth (ANH) jointly sponsored a scientific workshop on March 10-12, 2008 at The University of Texas M.D. Anderson Cancer Center located in Houston, Texas. The workshop focused on identifying the top scientific hurdles and translational gaps in moving nanoengineered medical products to the clinic, with emphasis on the preclinical, clinical and manufacturing stages of development. These activities are in concert with FDA's Critical Path Initiative (<http://www.fda.gov/oc/initiatives/criticalpath/>) which seeks to modernize medical product development by developing predictive and evaluative tools that will reduce the uncertainties in bringing products to patients and consumers.

The workshop assembled over 70 key stakeholders from industry, government, academia, and non-profit organizations. The complete list of participants can be found on the ANH's website: (<http://www.nanohealthalliance.org/images/fda-anh-agenda-images/Confirmed-Workshop-Participants-Alliance-for-NanoHealth.pdf>). Over the course of 3 days, workshop participants discussed, analyzed, and prioritized in open forum and in focused breakout sessions, the scientific and translational gaps existing in nanoengineered medical product development and that are common to many stakeholders. A copy of this intensive workshop agenda can be seen at the ANH website: <http://www.nanohealthalliance.org/images/fda-anh-agenda-images/fda-anh-workshop-agenda.pdf>

## **MODELS OF PUBLIC-PRIVATE-PARTNERSHIPS**

The Biomarker Consortium (<http://www.biomarkersconsortium.org/>) is a public-private collaborative effort with partners from government (including FDA, the National Institute of Health, and the Center for Medicare and Medicaid Services), industry, academia, nonprofit organizations, and other stakeholders that focuses on common goals, in this case biomarker development and qualification. The overarching goal is to discover, develop, and qualify biomarkers—molecular, biological, or physical characteristics that indicate a specific, underlying physiologic state to identify risk for disease—to diagnose, guide treatment, and support development of new drugs.

The Critical Path Institute (C-Path: <http://www.c-path.org>) is an independent nonprofit institute working with scientists from the FDA, academia, and industry for public health. C-Path's overriding mission is to help inform a more predictable and efficient critical path for developing safe and effective medical products. C-Path is unaffiliated with any single entity and serves as a *neutral* third party to develop and fund programs that are aligned with the priorities under FDA's Critical Path Initiative.

To advance scientific knowledge on cardiac safety issues for new and existing medical products, FDA partnered with Duke University and others to form the Cardiac Safety Research Consortium (CSRC: <http://www.cardiac-safety.org>). Like other collaborations under the Critical Path Initiative, multiple stakeholders share existing knowledge and data to enhance, refine, and ultimately improve the processes used to evaluate and develop new medical products. Emphasis is being placed on the evaluative science of the approval process, including both efficacy and safety measures, in the context of cardiac safety.

A model for collaboration is SEMATECH (<http://www.sematech.org/corporate/index.htm>) a consortium of semiconductor manufacturing industries that began about two decades ago in an emerging field of technology plagued by both high costs and high risks. Its membership now represents about half of the world's semiconductor producers and includes a global network of alliances with equipment and materials suppliers, universities, research institutes, consortia, start-up companies, and government partners. In the semiconductor industry, it is clear that the SEMATECH model worked well in leveraging resources to keep that industry vital and growing, by focusing on solving pre-competitive manufacturing problems and providing their solutions openly to all members of the consortium. This yielded extraordinary savings for the member industries, allowing them to focus their resources on the development of their competitive products, and de-facto salvaged and re-established the leadership of the US semiconductor industry. We strongly believe that a similar model would be of great benefit for nanomedicine, since many of the scientific hurdles in the field (biodistribution, novel toxicity models, metrology assays) are really common to many different nanoparticle types – that is, they are indeed pre-competitive.