Center for Biomedical Innovation

The Center for Biomedical Innovation (CBI) was formed in 2005 as a collaboration among the School of Engineering, the MIT Sloan School of Management, the School of Science, and the Harvard-MIT Division of Health Sciences and Technology (HST) to address the challenges within the pharmaceutical, biotechnology, diagnostics, and medical devices industries involving innovation, productivity, costs, and predicting and managing risks. The burden of these challenges is greater than industry, government or academia can support or overcome alone, and must therefore best be addressed collaboratively.

CBI is led by interim executive director Dr. Gigi Hirsch and by faculty codirectors Professor Ernst Berndt, Professor Anthony Sinskey, and Professor Steven Tannenbaum.

CBI's mission is to transform discovery, development, manufacture and distribution of cost-effective therapeutics and devices. To achieve this, it has created a safe haven in which academic, government, and industry experts communicate and collaborate to generate and disseminate high-impact systemic solutions that enhance efficacy, safety, and quality of patient care worldwide.

Through its research and educational programs, CBI focuses on four key areas:

- R&D redesign to improve productivity through new collaboration and research models
- Safety assessment breakthroughs driven by new biomarker technologies that are validated in human clinical trials, and postlaunch surveillance of electronic claims and medical records
- Manufacturing supply chain rationalization and new "Quality by Design" implementation
- Economic and regulatory risk management through systematic, holistic approaches that anticipate stratified medicine, regulatory change, and reimbursement evolution

CBI has focused on a three-pronged program to catalyze action in these four critical areas:

1. Create new solutions through collaborative research efforts with broad participation from scientists working in industry and in government agencies. Through our research programs, we seek to generate new methods, insights, and tools that are demonstrably effective in applied biomedical settings.
2. Educate the broader stakeholder community about new tools created by the focused collaborations. Building broad consensus for comprehensive implementation requires that the success of new solutions be disseminated to all relevant stakeholders, including those who did not participate in their development.

3. Transform biomedical innovation through broad adoption of the new methods. Achieving substantial change in the biomedical industry will require the concerted efforts of all stakeholders to implement the new solutions. CBI will help provide transparent mechanisms for change through its implementation consortia, safe haven approach, and generation of new concepts.

Accomplishments

FY2007 was an exciting and productive year for CBI. Key accomplishments include:

- In August 2006, CBI cohosted the 5th Annual Celebration of Biotechnology in Kendall Square, and sponsored the associated day-long educational forum which was attended by nearly 300 people. The forum's focus was twofold: (1) examining opportunities for innovative vaccine development by reviewing the case study ROTARIX®; and (2) discussing the application of stratified medicine to central nervous system disorders.
- At that forum, Scott Gottlieb, MD, associate commissioner of the Food and Drug Administration (FDA), announced a collaboration between the FDA and CBI on the development of an active postlaunch surveillance system.
- In September 2006, CBI held the second Stakeholders' Summit, an annual gathering of experts in industry, academia, government and the not-for-profit sectors. The theme for the summit was "Optimizing Productivity in Industry/ Academic Collaborations." There were more than 140 attendees with Janet Woodcock of the FDA and Steven Paul of Lilly Research Laboratories serving as keynote speakers. Working group sessions included R&D productivity, vaccines, postlaunch surveillance of marketed therapeutics, stratified medicine and its implications for clinical trials, and follow-on biologics.
- Following a successful initial membership drive in 2006, several new organizations were added to the CBI Consortium as founding members in 2007. They include Novartis AG, Amgen Inc., Vertex Pharmaceuticals Inc., Baxter Healthcare, Boehringer Ingelheim, and Brain Resource Company.
- Dr. Mark McClellan, former commissioner of the FDA and administrator, Centers for Medicare & Medicaid Services, Dr. Julie Gerberding, director of the Centers for Disease Control and Prevention, and Dr. Victor Dzau, chancellor for health affairs and president and CEO of the Duke University Health System, joined the CBI Strategy and Policy Council.
- In spring 2007, CBI completed the second year of its graduate course, Case Studies in Drug Discovery. Students produced five case studies based on the interactions they had with participating pharmaceutical and biotechnology industry experts. These experts brought real-life challenges to the classroom and discussed how they face emergent issues in the development of new drugs. The five participating companies and their studied therapeutics were NitroMed's BiDil®, Novartis' Gleevec®, Bayer's Rivaroxaban®, Biogen Idec's Tysabri®, and Merck's Gardasil®. The case studies are being written up and archived for use in future MIT and executive education courses.

Organizational Changes

Dr. Frank Douglas, the founding executive director of CBI, resigned from MIT on June 30, 2007. Dr. Gigi Hirsch has been appointed interim executive director to lead CBI through the leadership transition.

Finances and Funding

CBI received MIT internal start-up support from the School of Science, the School of Engineering, the MIT Sloan School of Management, the Office of the Provost, and the Office of the Vice President for Research and Associate Provost. We were successful in obtaining a grant from the Ewing Marion Kauffman Foundation and a gift from Bayer HealthCare to support our research and educational activities. The Merck Company Foundation also continued to support research efforts in clinical trials and stratified medicine. In addition, we attracted six additional members to the CBI Consortium. Membership fees support the research, educational, and administrative activities of CBI.

Future Plans

Following the departure of the founding director, CBI reached out to relevant stakeholders, members of the Strategy and Policy Council, and others to solicit guidance during the leadership transition. Based on those conversations, members of CBI have requested more transparency and frequent communications regarding research programs and other internal organizational structures. At their behest, CBI initiated a rigorous portfolio review, resulting in a clearly defined and more narrowly focused set of research programs and a new operating model that optimizes CBI's resource management while also providing the delivery of value that consortium members are seeking. Four research areas emerged as Transformational Research Programs on which to focus CBI's energies. They are postlaunch surveillance, R&D productivity, biomanufacturing, and stratified medicine.

CBI is dedicated to continuing its efforts to grow its membership and to search for new funding mechanisms for center operations and specific research programs.

CBI is also continuing its efforts to develop an executive education course targeted at research professionals that are transitioning into management in the healthcare industries. The focus of the course will be to examine research and development models and innovation from a comparative perspective. In particular, this course will seek to elucidate connections, or lessons learned, from other heavily regulated industries such as aeronautics and public utilities.

Gigi Hirsch, MD
Interim Executive Director

More information about the Center for Biomedical Innovation can be found at http://web.mit.edu/cbi/.