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 with respect to 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 was formally launched on August 18, 2005 at the 4th Annual Celebration of Biotechnology in Kendall Square. This launch was preceded by a two-day Stakeholders' Summit in June 2005, at which more than 125 prominent stakeholders from industry, government, and academia, including key experts from the Food and Drug Admnistration (FDA) and the National Institutes of Health (NIH), outlined a bold biomedical research agenda targeting areas where breakthroughs would have formidable and immediate impacts on healthcare innovation, productivity, regulation, and practice. This first summit confirmed CBI's four initial priority research areas: safety; redesigning research and development (R&D); manufacturing and distribution systems; and economics, finance, and risk. Summit participants also encouraged the development of educational programs, both for postgraduate students and for stakeholders.

CBI is led by executive director Frank L. Douglas PhD, MD and by codirectors Professor Ernst Berndt, Professor Anthony Sinskey, and Professor Steven Tannenbaum.

CBI's mission is to transform the 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.

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

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

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

1. Create new solutions through collaborative research efforts called Transformational Research Programs (TRPs). CBI expects the TRPs 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. CBI addresses this dissemination need through its comprehensive Transformational Education Programs (TEPs). CBI will also design and conduct specific programs for graduate and medical students at MIT and Harvard to prepare new leaders for the biomedical industry.
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

FY2006 was an exciting and productive year for CBI. Key accomplishments include:

- The public launch of CBI on August 18, 2005 with a day-long symposium on the convergence of innovation and safety in the drug development process. This forum was attended by more than 200 people, including MIT president Susan Hockfield and provost Robert Brown.
- A successful initial membership drive, bringing ALTANA Pharma AG, AstraZeneca International, Bayer AG, Eli Lilly & Company, Gene Logic, Inc., and Merck & Co., Inc. into the CBI Consortium as founding members.
- Receipt of $150,000 in start-up funding from the Massachusetts Technology Collaborative under the John Adams Innovation Institute (MTC/JAII) program and $600,000 over three years from the Merck Company Foundation to fund initial research efforts in clinical trials and stratified medicine.
- Formation of CBI's Strategy and Policy Council, which advises on CBI's research and education agendas as well as its overall vision. The council is chaired by the vice president for research and associate provost and consists of the deans of the School of Science, the School of Engineering, and the MIT Sloan School of Management, as well as senior executives in the biomedical fields and from the FDA.
- The development and launch of CBI's first graduate course, Case Studies in Drug Discovery, which brought pharmaceutical and biotechnology industry experts into the classroom to share the real-life challenges they face in developing new drugs, and to engage with students on ways in which recent technological advances might have been applied to reduce cycle time and improve efficacy and safety.

- The launch of our first research program in collaboration with the FDA, in which Professors Ernst Berndt and Frank Douglas supervised five MIT and Harvard students in investigating the reasons for the increasing complexity of clinical trials.
- Significant strengthening of CBI's administrative infrastructure, including our move into new offices at 3 Cambridge Center; the design and launch of our website at http://web.mit.edu/cbi; and the hiring of three staff members, Sherene Aram, assistant director for finance and administration, Dr. Gigi Hirsch, research staff, and Cheryl Mottley, administrative assistant.

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 additional grants from MTC/JAII and the Merck Company Foundation to support the development of CBI's business plan and other launch activities and to support research efforts in clinical trials and stratified medicine. In addition, we attracted six founding members to the CBI consortium, and membership fees support the research, educational, and administrative activities of CBI.

Future Plans

Building on the successful launch of our first graduate course, and modeled after the successful BP Projects Academy program, CBI will design and launch our first executive education program, the BioPharm Academy. Our objective is to provide mid-career industry associates with the tools and knowledge to improve technical leadership of product pipeline and overall cost-effectiveness of healthcare innovation and delivery. The course will be cotaught by faculty from academia, industry, and government who will present tools, frameworks, and systems as foundations for transforming biomedicine.

In addition, we will continue to expand our research efforts, seeking to launch a second major collaboration with the FDA in the area of postapproval drug safety, as well as research programs focusing on biomarkers, R&D productivity metrics, follow-on biologics, vaccines, and applications of stratified medicine. We will continue our membership and funding drive, with the intention of growing CBI significantly over the next few years.

Frank L. Douglas
Executive Director
Professor of the Practice

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