



## Center for Biomedical Innovation

### **MIT Center for Biomedical Innovation Agreement with FDA Seeks to Develop New Tools for Post-Marketing Drug Surveillance Under Critical Path**

(Cambridge, MA-August 17, 2006) The MIT Center for Biomedical Innovation today announced an agreement with the Food and Drug Administration where CBI will work to develop new tools to improve the detection of adverse drug events and reactions once new products are introduced into the market. The agreement to work on post marketing drug surveillance will respond to the FDA's Critical Path Opportunities List, and will seek to create a new model of real-time drug safety monitoring, building upon methods developed for identifying infectious outbreaks, detecting bioterrorism, and modeling the spread of pandemic influenza. The FDA will work with CBI in an advisory capacity.

Under this collaboration, CBI will work to identify alternative methods for monitoring the safety and efficacy of new and well-established pharmaceutical products and medical devices. In addition to voluntary reports the FDA receives from patients and the healthcare community, the CBI model uses large healthcare datasets to recognize patterns that indicate unexpected efficacy or problems with safety. Currently, techniques used to detect such adverse effects, because they are voluntary, result in underreporting of incidents.

"The goal of this Critical Path Initiative is to evaluate and take advantage of new scientific tools to overcome existing challenges in safety assessment," Dr. Janet Woodcock, the FDA's Deputy Commissioner for Operations. "With recent advances in bioinformation sciences, it is possible to mine and analyze large sets of data to make more rapid post-market identification of safety issues that could not be identified during clinical trials."

CBI's new approach to post marketing surveillance will be based on advanced computerized methods to automate the process of recognizing unusual patterns of infectious disease. Such systems, developed by the researchers who will take part in this project, are now key tools used by public health departments and the CDC in the fight against bioterrorism and pandemic influenza. The group plans to emulate biosurveillance methods developed over the past eight years to help detect outbreaks and track influenza and SARS and applying them to the problem of post-marketing surveillance.

"Over the past year FDA has introduced several new policy and regulatory initiatives to improve post-marketing surveillance and strengthen the agency's oversight and protection of patients, said Scott Gottlieb, MD, Deputy Commissioner for Medical and Scientific Affairs. "This new partnership seeks to greatly enhance the ability of the FDA and the pharmaceutical industry to quickly determine the safety, efficacy or optimal use of a product."

Another critical aspect to the project is the establishment of a Data Safety Monitoring Board (DSMB), which includes medical, scientific and government experts to provide independent oversight and ensure the validity of results. DSMB's are required during clinical trials of drugs before they are released on the market. The DSMB created for this

project will be designed to serve as a national model for post-marketing surveillance programs.

“Our goal through this collaborative effort is to rapidly respond to signals that we find, while balancing the need for scientifically rigorous analysis with sensitive and timely detection of issues that may impact the public,” said Frank L. Douglas, Ph.D., M.D., Executive Director of MIT Center for Biomedical Innovation. “We will have real, adjudicated data that provides the best guidance for decision-making, and create a model that will hold great promise for the future.”

### **About the Critical Path Initiative**

The Critical Path Initiative is the FDA's premier initiative to identify and prioritize the most pressing medical product development problems and the greatest opportunities for rapid improvement in public health benefits. Its primary purpose is to ensure that basic scientific discoveries translate more rapidly into new and better medical treatments by creating new tools to find answers about how the safety and effectiveness of new medical products can be demonstrated in faster timeframes with more certainty and at lower costs. For more information about the Critical Path Initiative and for status of projects on the Opportunities List go to <http://www.fda.gov/oc/initiatives/criticalpath/>

### **About The Center for Biomedical Innovation**

The MIT Center for Biomedical Innovation (CBI) was formed in 2005. CBI is a collaboration of the MIT Schools of Engineering, Management, and Science and the Harvard-MIT Division of Health Sciences & Technology (HST). CBI's goal is to create a "safe haven" in which thought leaders across the biomedical spectrum - from medical researchers to federal regulators and payers, to experts in finance and marketing - are able to conduct pre-competitive research and catalyze industry-wide adoption of the resulting solutions. For more information about CBI, please contact Cheryl Mottley at (617) 253-0257, or visit the CBI web site at <http://web.mit.edu>.