

5th Annual Celebration of Biotechnology in Kendall Square “Collaborative Innovation in Action” Forum

Personalized Medicine & CNS Disorders

On Thursday, August 17, 2006, the MIT Center for Biomedical Innovation (CBI) hosted a discussion on **Personalized Medicine & CNS Disorders: The Changing Landscape of Mental and Neurological Illness** as part of the 5th Annual Celebration of Biotechnology in Kendall Square. Dr. Frank Douglas, Executive Director of CBI, and Professor Ernie Berndt, Louis E Seley Professor of Applied Economics at the MIT Sloan School of Management, co-chaired the session. Dr Douglas and Dr. Gualberto Ruano, President of Genomas and co-founder of the Personalized Medicine Coalition (PMC) served as moderators for the panel discussions. The session featured presentations on the discovery, research and development of targeted therapies for Central Nervous System (CNS) disorders, and on the practice of personalized neurology and psychiatry from the perspective of researchers, practitioners and payers. The speakers discussed a range of challenges facing the application of personalized medicine to CNS disorders, and attempted to identify the particular areas where further work was needed. The panel of experts touched on two fundamental questions:

- Are we ready to do personalized CNS medicine?
- What are the priorities for making personalized CNS medicine a reality?

Priority Areas for CNS Personal Medicine

Need for Standardization

Standardization is fundamental to advancements in personalized medicine generally, and is particularly important to CNS medicine which presents a unique set of problems, including the difficulty of studying the human brain directly, and the lack of consensus about identifying and treating behavioral problems.

Dr. Scott Gottlieb from the Food and Drug Administration suggested that one necessary step was to use information technology to increase the amount of data openly available about new, post-market drugs among doctors and researchers to build a wider consensus about how to administer drugs. Dr. Evian Gordon’s Brain Resource Company seeks standardization of data so that researchers can begin to find meaningful trends among the many studies conducted within the field of neuroscience. Dr. David Whitehouse from United Behavioral Health described a problem of terminology that makes all discussion of CNS medicine difficult. Approaching the question of standardization he asked the question, “Value for Whom?” Psychiatric problems manifest behaviorally, and therefore even basic agreement about diagnosis is difficult. Once diagnosed, the ideal treatment can vary depending on who asks the question. He used the example of a depressed employee, who may work, but once diagnosed is less likely to work. It is not clear whether working or not will help or harm the diagnosed patient to recover.



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Creative Types of Analyses

Due to the unique constraints imposed on the study of CNS disorders, there is an urgent need for creative analyses that combine or reinvent established research methods. Dr. Stephen Furlong from AstaZeneca and Dr. Gualberto Ruano from Genomas discussed emerging technologies, including DNA typing to predict the best drug combinations for different individuals according to multiple variables. Dr. Gordon discussed novel types of research that become possible once information from a large number of neuroscience studies is standardized and centralized.

Use of Information Technology

New information technology tools are vital to the development of personalized medicine, because they allow the accumulation, dissemination and comparison of large bodies of data necessary to make informed decisions about treatment on the level of condition, population, individual and gene. Dr. Gottlieb discussed the use of post-market drug data at the FDA, emphasizing that openness about emerging information on new drugs can prove very important. He described the “Snowman” protocol, which requires drug companies to submit new drug labels electronically, making doctors aware of potential side-effects as soon as they are identified in the wider population. He also described a new regular FDA report that will provide health care professionals with information about adverse drug events while maintaining the anonymity of patients.

Tailoring

Most current therapies are empirically prescribed based on mean, population-derived information with little understanding of effects on specific individuals. Dr. Eiry Roberts from Eli Lilly outlined the idea of “tailoring scenarios,” as one way to improve upon this. Tailoring would involve adapting the drug, dose, timing of treatment and relevant informational tools to the individual patient. This would depart from the historical drug discovery and development process that emphasized a “one-size-fits-all” approach focused on a mean response across homogeneously selected patient groups.

Need to Understand Basal Incidence

The understanding of complex CNS disorders is very limited. This is in part due to the difficulty of studying the human brain, and partly due to a lack of agreement concerning the definitions of the disorders. Dr. Scott Rauch from Massachusetts General Hospital pointed out that in the area of psychiatric illnesses, there were no diseases (as they might be defined in other fields of medicine), but rather there were syndromes.

Need for Predictive Animal Models & Development of Human Models

There currently exist no widely accepted predictive animal models for psychiatric and neurological disorders. There is a great potential for the development of better predictive human models, and agreement about how to use animal models.

Participants

The MIT Center for Biomedical Innovation gratefully acknowledges the sponsorship of the Personalized Medicine Coalition and AstraZeneca.

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