

# Consensus Development for Functional Endpoints in Schizophrenia Research

Marriott Bethesda North Hotel and Conference Center  
Bethesda, Maryland

August 21–22, 2007



Department of Health and Human Services  
National Institutes of Health  
National Institute of Mental Health

## AGENDA

### Day 1: Tuesday, August 21, 2007

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| 8:00 – 9:00 a.m.   | <b>Registration and Refreshments</b>  |
| 9:00 – 9:10 a.m.   | <b>Welcome</b><br>Ellen Stover, Ph.D., Director<br>Division of AIDS and Health and Behavior Research<br>National Institute of Mental Health<br><br>Thomas Insel, M.D., Director<br>National Institute of Mental Health  |
| 9:10 – 9:30 a.m.   | <b>Consortium Objectives, Process, and RAND Panel Methodology</b><br>Brendon Binneman, M.B.Ch.B., M.R.C.Psych., Pfizer Inc.<br>Stephen Marder, M.D., University of California, Los Angeles  |
| 9:30 – 10:00 a.m.  | <b>Measuring Functional Outcome – Opening Comments: FDA/EU and Industry Perspectives</b><br>Thomas Laughren, M.D., U.S. Food and Drug Administration<br>Karl Broich, M.D., Federal Institute for Drugs and Medical Devices, GERMANY<br>Richard Mohs, Ph.D., Eli Lilly |
| 10:00 – 10:30 a.m. | <b>Measuring Functional Outcome – Challenges in Measuring Real-World Functional Outcome</b><br>Philip Harvey, Ph.D., Emory University School of Medicine  |
| 10:30 – 11:00 am.  | <b>BREAK</b>  |
| 11:00 – 11:30 a.m. | <b>Summary of Selection Criteria Work Group (SCWG) Proposals</b><br>Keith Nuechterlein, Ph.D., University of California, Los Angeles  |
| 11:30 – 12:00 p.m. | <b>Open Discussion</b>  |
| 12:00 – 1:00 p.m.  | <b>LUNCH</b>  |
| 1:00 – 1:30 p.m.   | <b>Core Constructs Measured By the Array of Functionality Instruments</b><br>John Brekke, Ph.D., University of Southern California  |

1:30 – 2:00 p.m.	<b>Results from MATRICS PASS</b> Michael Green, Ph.D., University of California, Los Angeles
2:00 – 2:30 p.m.	<b>Real-World Validity of Simulated Functioning in Schizophrenia</b> Walter Heinrichs, Ph.D., York University, CANADA
2:30 – 3:00 p.m.	<b>Optimizing Data Sources (Patient, Caregiver, Performance-Based)</b> Dawn Velligan, Ph.D., University of Texas–Southwestern
<b>3:00 – 3:15 p.m.</b>	<b>BREAK</b>
3:15 – 3:45 p.m.	<b>Issues in Cross-Cultural Adaptability</b> Rangaswamy Thara, M.D., Ph.D. Schizophrenia Research Foundation, INDIA 1. Case Example: The Use of Western Methods for Functionality Assessment in a South Asian Population  Assen Jablensky, M.D., D.Med.Sci. University of Western Australia, AUSTRALIA 2. From Cultural Differences to Biological Universality
3:45 – 4:30 p.m.	<b>Expert Panel Commentary</b> Judith Jaeger, Ph.D. (Chair), Astra Zeneca Michael Davidson, M.D., Tel Aviv University, ISRAEL Til Wykes, M.Phil., Ph.D., Institute of Psychiatry, Kings College London Alan Bellack, Ph.D., University of Maryland George Awad, M.D., Ph.D., Humber River Regional Hospital, CANADA Thomas Patterson, Ph.D., University of California, San Diego
4:30 – 5:00 p.m.	<b>Open Discussion</b>

## Day 2: Wednesday, August 22, 2007

8:30 – 9:00 a.m.	<b>Refreshments</b>
9:00 – 9:15 a.m.	<b>Update on Translation</b> Keith Nuechterlein, Ph.D., University of California, Los Angeles
9:15 – 9:30 a.m.	<b>Discussion on Translation</b>
9:30 – 10:00 a.m.	<b>Issues in Developing a Validation Study</b> Michael Green, Ph.D., University of California, Los Angeles Nina Schooler, Ph.D., Veterans Affairs Medical Center, WASHINGTON, DC
10:00 – 10:45 a.m.	<b>Discussion of Validation Study</b>
<b>10:45 – 11:00 a.m.</b>	<b>BREAK</b>
11:00 – 11:45 a.m.	<b>Closing Comments: FDA/EU/Academic and Industry Representatives</b> Philip Harvey, Ph.D., Emory University School of Medicine Richard Mohs, Ph.D., Eli Lilly Robert Levin, M.D., U.S. Food and Drug Administration Karl Broich, M.D., Federal Institute for Drugs and Medical Devices, GERMANY
11:45 – 12:00 p.m.	<b>Summary of Meeting and Future Directions</b> Stephen Marder, M.D., University of California, Los Angeles Brendon Binneman, M.B.Ch.B., M.R.C.Psych., Pfizer Inc.