



# TBI Endpoints Development Initiative

*A collaborative for advancing diagnosis and treatment of TBI*

## Consensus Conference 2 NIH Campus | Natcher Conference Center Agenda

April 4 | Day 1 | Ruth L. Kirschstein Auditorium

7:45 AM - 8:30 AM **Registration & Continental Breakfast**

8:30 AM - 9:00 AM **Welcome Remarks** | Geoff Manley, MD PhD

**Colonel Todd E. Rasmussen, MD USAF MC** | Director, U.S. Army Medical Research and Materiel Command's Combat Casualty Care Research Program

**Janet Woodcock, MD** | Director, Drug Evaluation and Research, Food and Drug Administration

**Walter J. Koroshetz, MD** | Director, National Institute of Neurological Disorders and Stroke

**In Memoriam | Peter Como, MD**

9:00 AM - 9:20 AM **Introduction and Objectives of Conference** | Geoff Manley, MD PhD

9:20 AM - 10:00 AM **TED FDA Deliverables**

◇ Neuroimaging Biomarkers | Pratik Mukherjee, MD PhD

◇ Biofluid Biomarkers | Kevin Wang, PhD

◇ Clinical Outcome Assessments (COAs) | Joseph T. Giacino, PhD

10:00 AM - 10:15 AM Coffee Break

10:15 AM - 10:45 AM **Overview of COAs | 'Where we stand with current measures'**

◇ Joseph T. Giacino, PhD | Nancy R. Temkin, PhD | Mike McCrea, PhD

10:45 AM - 11:00 AM **TED Metadataset Update** | Stephen Wisniewski, PhD

11:00 AM - 12:15 PM **TED Seed Project Progress Updates**

◇ Joseph T. Giacino, PhD | *An Evidence-Based Clinical Outcome Assessment Platform for Validation of TBI Assessment Measures (EB-COP)*

◇ Grant Iverson, PhD | *Development and Validation of a Cognition Endpoint for TBI Clinical Trials*

◇ Esther Yuh, MD PhD | *CT and MRI Prognostic Biomarkers for Mild to Moderate TBI*

◇ Kevin Wang, PhD | *Enhancing the Regulatory Readiness of 5 TBI Blood-based Biomarkers Toward FDA Validation*

12:15 PM - 1:15 PM Boxed lunches served

1:15 PM - 1:45 PM **About the precisionFDA Initiative | A Place for TBI**

◇ Elaine Johanson | Program Manager, precisionFDA Initiative

◇ Katherine Donigan, PhD | Personalized Medicine | FDA, Center for Devices and Radiological Health

2:00 PM - 5:00 PM **Concurrent Expert Working Group Breakouts**

COAs - Room E2 | Imaging Biomarkers - Room E1 | Biofluid Biomarkers - Room F1/F2

5:00 PM - 5:15 PM **Discussion | Key Takeaways from Breakout Sessions**

Moderators: Billy Dunn, MD - Director, FDA Division of Neurology Products & Geoff Manley, MD PhD



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## Consensus Conference 2 NIH Campus | Natcher Conference Center Agenda

April 5 | Day 2 | Ruth L. Kirschstein Auditorium

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|---------------------|--|
| 8:00 AM - 8:30 AM   | <b>Continental Breakfast</b>   |
| 8:30 AM – 8:45 AM   | <b>Opening Charge &amp; TED Next Steps</b>   Geoff Manley, MD PhD      |
| 8:45 AM – 9:45 AM   | <b>Takeaway Presentation from Day 1</b>   Clinical Outcome Assessments |
| 9:45 AM - 10:00 AM  | Break  |
| 10:00 AM - 10:30 AM | <b>Takeaway Presentation from Day 1</b>   Imaging Biomarkers           |
| 10:30 AM - 11:00 AM | <b>Takeaway Presentation from Day 1</b>   Biofluid Biomarkers          |
| 11:00 AM – 12:00 PM | <b>TED Future Planning</b>   |
| 12:15 PM & 12:30 PM | Shuttle back to Bethesda Marriott                                      |