TBI Endpoints Development (TED)

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Consensus Conference 1

Agenda | February 2-3, 2015

Natcher Conference Center | NIH Campus

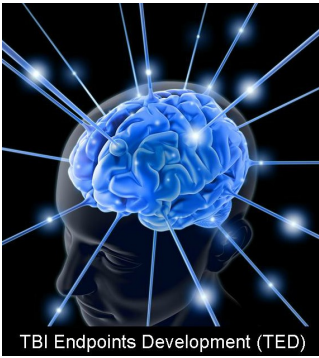| **DAY 1 | February 2, 2015** | |
| --- | --- |
| I. Breakfast, Introductions & Overview 7:45-9:15am | **Continental Breakfast at NIH Natcher Center (7:45 - 8:30am)**
Geoff Manley, MD PhD | Introductions and Overview of the TED Technical Objectives and Aims **(8:30am)**
Col. Dallas Hack | "The TED Initiative's Mission and Vision"
Q&A |
| II. Moderated Tri-Part Panel Sessions 9:15am-12:15pm | **Segment I Panel** | **FDA Regulatory Pathways**

Co-Moderators | **Diane Stephenson, PhD** C-Path and **Nicholas Kozauer, MD** Quintiles
Rapporteurs | Raquel Gardner, MD and Brian Fabian, MPA

Lead Speaker | **Douglas Throckmorton, MD** (Center for Drug Evaluation & Research [CDER] Deputy Center Director for Regulatory Programs) "Overview of FDA Innovation"

Panelists | "FDA Divisions' Roles in the Regulatory Readiness and DDT/MDDT Qualification Processes"
Billy Dunn, MD (Director, Division of Neurology Products, [CEDR])
Peter Como, PhD (Lead Reviewer and Neuropsychologist: Division of Neurological and Physical Medicine Devices, Neurodiagnostic and Neurosurgical Devices Branch)
Allison Kumar (Sr. Project Manager: Office of the Center Director - Center for Devices and Radiological Health [CDRH])
Yasmin Choudhry, MD (Medical Officer and Reviewer: Study Endpoints and Labeling Development [SEALD] Office of New Drugs (OND) [CDER])
Christopher Leptak, MD (OND Biomarker Diagnostic Lead and Scientific Lead: Letter of Support) [CDER])
James Kaiser, MD (Medical Officer and Scientific Lead: CDER Critical Path Innovation Meeting [CPIM])

Q&A | BREAK – 15 minutes

Segment II Panel | **Industry Perspectives on Regulatory Processes**

Moderator | **Jam Ghajar, MD PhD** Director, Stanford Concussion and Brain Performance Center

Panelists
Jonathan Murray and team (Victor Miranda, Pam Schaub, Glen Sabin) | GE
Beth McQuiston, MD RD | Abbott Diagnostics
Donna Edmonds | ImmunArray
Dick Moberg | Moberg Research
Mark Lovell, PhD | ImPACT

Q&A | BREAK – 10 minutes

Segment III Panel | **Regulatory Readiness Case Studies**
Moderator | **Ramona Hicks, PhD** One Mind
Panelists | **Diane Stephenson, PhD** C-Path; **Michael Ropacki, PhD** Janssen; **Michael Singer, PhD** BrainScope

Q&A |
| III. Lunch 12:15-1pm | Box lunches | Self-selected seating in the Atrium and breakout rooms |

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IV. Full Conference, followed by EWG Breakouts 1pm-4:30pm	**Geoff Manley, MD, PhD |** Introduction and charge to Expert Working Groups, Data Aggregation and Integration, and Landscape Analyses **Expert Working Group (EWG) Breakouts** 1) Landscape Analyses; Identify existing COAs and biomarkers to be analyzed 2) Define roles of EWGs' membership 3) Create workstreams to achieve TED Stage I Aims **OUTCOMES EWG** **Lead**	Michael McCrea, PhD **Co-Leads**	Murray Stein, MD; Harvey Levin, PhD; Joseph Giacino, PhD; John Whyte, MD PhD **Rapporteurs**	Yelena Guller Bodien, PhD and Sabrina Rose Taylor, PhD **BLOOD-BASED BIOMARKER EWG** **Lead**	Ramon Diaz-Arrastia, MD PhD **Co-Lead**	Kevin Wang, PhD **Rapporteur**	John Yue, BS **NEUROIMAGING BIOMARKER EWG** **Lead**	Pratik Mukherjee, MD PhD **Co-Lead**	Arthur Toga, PhD **Rapporteur**	Christine Mac Donald, PhD **EMERGING TECHNOLOGIES EWG** **Lead**	Jam Ghajar, MD PhD **Co-Lead**	Mona Hicks, PhD **Rapporteur**	Ethan Winkler, MD PhD
V. Day 1 Close 4:45-5:00pm	**Geoff Manley**	Preparation for Day 2

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DAY 2	February 3, 2015	
VI. Breakfast and Welcome 7:45-8:45am	**Continental Breakfast at NIH Natcher Center (**7:45am-8:30am**)** **Geoff Manley**	Welcome 8:30am
VII. EWG Reports 8:45-11:00am	**EWG Leads**	Report-back from EWG breakout sessions BREAK 15 mins
VIII. Forward Planning/Adjourn 11:15am-1:00pm	**Geoff Manley and EWG Leads**	Forward plan Execution of remaining Stage I Technical Objectives and Aims Q&A Wrap-up and Forward Plan