DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE
Food and Drug Administration
Office of Translational Sciences
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Memorandum

Date: April 28, 2016

Subject: Critical Path Innovation Meeting: Regulatory Pathways for Biomarkers in Traumatic Brain Injury

Date of meeting: March 22, 2016

Requestor: Dr. Geoffrey T. Manley on behalf of the Traumatic Brain Injury (TBI) Endpoints Development (TED) Initiative Investigators

Note: Discussions at Critical Path Innovation Meetings are informal. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants.

ATTENDEES

FDA
Office of the Commissioner

Office of the Chief Scientist, Office of Scientific Professional Development
Lakshmi Kannan, Commissioner Fellow

Center for Drug Evaluation and Research

Office of Translational Sciences (OTS) Immediate Office
Shashi Amur, Ph.D., Biomarker Qualification Program Scientific Coordinator
Kylie Haskins, Ph.D., Biologist
Suzie McCune, M.D., Deputy Director
Marianne Noone, R.N., Senior Regulatory Project Manager
Ameeta Parekh, Ph.D., Senior Advisor for Scientific Collaborations
Sarmistha Sanyal, Ph.D., Staff Fellow
Alicia Stuart, Project Manager

OTS Office of Clinical Pharmacology
Hobart Rogers, Pharm.D., Ph.D., Reviewer, Genomics and Targeted Therapy Group, Biomarker Qualification Liaison to OTS
Xiaofeng Wang, Ph.D., Visiting Associate, Division of Pharmacometrics

OTS Office of Biostatistics
Sue-Jane Wang, Ph.D., Associate Director for Pharmacogenomics and Adaptive Design, Biomarker Qualification Liaison to OTS

Office of New Drugs (OND) Office of Drug Evaluation I
Billy Dunn, M.D., Director, Division of Neurology Products
Heather Fitter, M.D., Medical Officer, Division of Neurology Products

Nicholas Kozauer, M.D., Medical Officer, Division of Neurology Products
John Marler, M.D., Medical Officer, Division of Neurology Products

OND Office of Drug Evaluation IV
Brenda Ye, M.D., Medical Officer

Center for Devices and Radiological Health

Office of the Center Director
Peter Como, Ph.D., Division of Neurological and Physical Medicine Devices, Neurostimulation Devices Branch
Allison Kumar, Senior Project Manager

REQUESTER
The Traumatic Brain Injury Endpoints Development (TED) Team
General Peter Chiarelli - U.S. Army General (Retired), CEO, One Mind
Sureyya Dikmen, PhD - University of Washington
Joe Giacino, PhD - Spaulding Rehabilitation Hospital
Ramon Diaz-Arrastia, MD PhD - Uniformed Services University
Harvey Levin, PhD - Baylor College of Medicine
Christine Mac Donald, PhD - University of Washington
Geoff Manley, MD PhD - University of California, San Francisco (Contact PI)
Amy Markowitz, JD - University of California, San Francisco
Mike McCrea, PhD - Medical College of Wisconsin
Pratik Mukherjee, MD PhD - University of California, San Francisco
Ann Robbins, PhD - Critical Path Institute
Diane Stephenson, PhD - Critical Path Institute
Nancy Temkin, PhD – University of Washington
Kevin Wang, PhD - University of Florida
Steve Wisniewski, PhD - University of Pittsburgh

1. BACKGROUND

The Traumatic Brain Injury Endpoints Development (TED) team requested a CPIM to discuss their work to advance therapies for traumatic brain injury (TBI).

2. DISCUSSION

The TED team presented information that reviewed the status of neuroimaging and biofluid biomarkers for use in TBI clinical trials. There was discussion about potential regulatory pathways for biomarkers in TBI. MRI was discussed within the context of differing approaches from CDRH and CDER. TED will follow up with CDRH to discuss the approach to clearing diagnostics in this space. The Division of Neurology Products (DNP) in CDER discussed the use of biomarkers (imaging and biofluid) in drug development. There was discussion of how to provide opportunities for communication related to TBI biomarkers including a potential Letter of Support, public workshops with discussion summarized through white papers, and peer-reviewed journal articles. The importance of the meeting was eloquently summarized by General Chiarelli with an example of how a biomarker in this space could be used to prioritize triage for patients with TBI to prevent morbidity and mortality.

3. NEXT STEPS

- TED will follow up with CDRH to discuss plans for clearing diagnostics for TBI.
- FDA will provide information about the Letter of Support (LOS) program.
    - LOS information can be found at: http://www.fda.gov/drugs/developmentapprovalprocess/ucm434382.htm
- FDA will provide information on the Biomarker Qualification Program (BQP). It would be important to identify specific biomarkers for a well-defined context of use for discussion with the BQP.
    - BQP information can be found at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm284076.htm
- FDA encouraged TED to consider writing a peer reviewed article to help disseminate and promote the advancement of therapies for TBI.
- FDA encouraged TED to consider having another workshop to engage others in the standardization of therapies for TBI. A white paper could be published as an outcome of the workshop.
- FDA encouraged TED to continue engaging with the Division of Neurology Products with questions about biomarkers in the context of individual drug development programs.