Critical Path Innovation Meeting

Critical Path Innovation Meetings

The Critical Path Innovation Meeting (CPIM) was developed by Center for Drug Evaluation and Research (CDER) to address issues in drug development. The CPIM is a means by which CDER and investigators from industry, academia, patient advocacy groups, and government can communicate to improve efficiency and success in drug development. The goals of the CPIM are to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how this methodology or technology might enhance drug development.

FDA Response to TED CPIM Meeting

We are pleased to share the Official FDA summary of the 3/22/16 Critical Path Innovation Meeting between FDA and the TRACK-TBI/TED Initiative Investigators on Regulatory Pathways for Biomarkers in Traumatic Brain Injury.

In the Summary, FDA outlines the various regulatory pathways that were discussed at the meeting regarding our proposed MRI imaging biomarker, T2* gradient echo (T2*GRE) and proposed biofluid biomarker, using GFAP as a paradigm, along with some recommendations for further work.

In an extraordinary and meaningful addition to the scientific and regulatory content, FDA specifically called out the closing remarks made by General Pete Chiarelli, CEO of One Mind, regarding the absolutely critical need for validation of TBI biomarkers, and included the following statement in the summary:

?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.?

We invite you to read through the Summary, and will soon be sharing progress on activities, already underway, to operationalize FDA?s recommendations, including:

1. Seeking a Letter of Support regarding both the Neuroimaging and Biofluid Biomarkers

2. Collaborating directly with FDA?s Center for Devices and Radiological Health regarding the Medical Device Developmental Tool Pathway to Qualification

3. Collaborating directly with FDA?s Center for Drug Evaluation and Research Biomarker Qualification Program (BQP).

4. FDA encouraged TED to continue engaging with the Division of Neurology Products with

questions about biomarkers in the context of individual drug development programs.

5. 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.

The complete letter can be downloaded here:

FDA Summary of CPIM with TBI_TED 032216.pdf [1]

Contact Us
UCSF Main Site

Links
[1] https://tbiendpoints.ucsf.edu/sites/tbiendpoints.ucsf.edu/files/FDA%20Summary%20of%20CPIM%20with%20TBI_TE