FDA Letter of Support

What is an FDA Letter of Support?

This is a letter issued to a requester that briefly describes Center for Drug Evaluation and Research's (CDER) thoughts on the potential value of a biomarker and encourages further evaluation. This letter does not connote qualification of a biomarker and does not endorse a specific biomarker test or device. It is meant to enhance the visibility of the biomarker, encourage data sharing, and stimulate additional studies. A complete list of Letters of Support issued by CDER can be found here [1].

TED Receives First Ever Letter of Support for TBI Biomarkers

The TED Initiative has reached an important milestone in securing an FDA Letter of Support to further explore neuroimaging prognostic biomarkers that may be used to enrich TBI clinical trials with patients who display particular pathoanatomic features that have been associated with poor short to medium-term outcome following mild TBI. This letter, signed by Dr. Janet Woodcock, Director, FDA Center for Drug Evaluation and Research, represents a significant step forward for the field and an important accomplishment for the TED Initiative. The FDA Letter of Support page can be found here [1] with a direct link to the signed letter [2].

TED Initiative Receives Recognition Letter of Research Importance from FDA?s CDRH

The TED Initiative is pleased to announce receipt of the first FDA Center for Devices and Radiologic Health (CDRH) Recognition of Research Importance Letter regarding TBI. This letter, under the signature of Jeffrey Shuren, MD, JD, Director of CDRH, demonstrates FDA?s acknowledgment and commitment to our field. It is signal recognition of the importance and value FDA specifically places on TED?s collaborative work with the NINDS-funded TRACK-TBI investigators and our public and private partners, to advance validation of clinical outcome assessments, neuroimaging biomarkers, and blood-based biomarker endpoints for TBI.

To view the letter, click here [3].

TED Initiative Receives Second FDA CDER Letter of Support

The TED Initiative has reached another important regulatory milestone with the issuance of an FDA Letter of Support to explore prognostic enrichment biomarkers to identify patients who are likely to develop persistent disability during the course of mild traumatic brain injury (TBI) clinical trials. This letter encourages the further study of blood levels of GFAP and UCH-L1 as a possible biomarker of neuronal injury.

To view the full letter, click here [4].

Contact Us
UCSF Main Site

Links
[1] https://www.fda.gov/drugs/developmentapprovalprocess/ucm434382.htm
[2] https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM550255.pdf
[3] https://www.dropbox.com/s/zq9nwrynxww0mgt/TED_CDRH%20Support%20Letter.pdf?dl=0
[4] https://www.fda.gov/media/112687/download