CDISC Technical News

CDISC is continuously working to release new standards and innovations to support our mission. Visit our website for frequent updates on the CDISC standards open for public review and comment. This month we would like to draw your attention to the following postings that will soon be available on the CDISC website:

- SDTM Implementation Guide for Medical Devices (Provisional)
- CDISC Parkinson’s Disease Therapeutic Area Standards (Provisional)
- SDTMIG 3.1.4 Batch 2 for Comment
- Polycystic Kidney Disease Therapeutic Area Standards for Comment

Follow the link to view Standards open for review and comment as well as new standards available for use.

Please Support CDISC at the 5 November FDA Public Meeting on Study Exchange Standards

FDA has scheduled a public meeting on November 5 to discuss Solutions for Study Exchange Standards. CDISC is requesting our members and volunteers to support of the use of CDISC ODM for study data exchange with FDA. If you are willing to sign our letter of support, or would like a copy, please click here.

CDISC will also be submitting a direct response to the questions posed by FDA in the Federal Register notice regarding these exchange standards. Responses to the docket are due on Friday, 5 October. If you would like to request a copy of the CDISC response to the Docket to help you prepare your own response, please click here.

CDISC encourages you to respond to the FDA Docket and hopes to see many of our members and volunteers at the public meeting.

Join us for the CDISC Standards Webinar - Latest Updates and Additions on Thursday 29 November 2012 at 11:30 AM U.S.A Eastern Time.

A meeting, entitled “Sharing Clinical Research Data” has been organized by the Institute of Medicine (IOM), National Academy of Sciences; this meeting will take place 4-5 October in Washington, DC. There will be a webcast available for those who wish to listen.

Strength Through Collaboration