CDISC Technical News

CDISC is continuously progressing its standards and innovations. Regular updates on CDISC standards developments are available on the CDISC website. This month we would like to draw your attention to the following published standards that are now available on the CDISC website:

Standards and Technical Announcements Posted for Public Comment: (please click on the links below)

- CDISC Parkinson’s Disease Therapeutic Area User Guide Available for Public Comment – Comments due by 9 September 2012
- CDISC SHARE RFI Now Available – Comments due by 20 September 2012
- CDISC Terminology Package 12 Available for Public Review - Comments due by 28 September 2012
- Define-XML v2.0 Now Available for Comment - Comments due by 1 October 2012
- Virology Draft Standards for Public Review and Comment - Comments due by 5 October 2012

Standards and Technical Information Available for use: (please click on the links below)

- Updated CDISC Technical Plan
- ADAM V1.2 Validation Checks Now Available
- CDISC Pain Therapeutic Area Standards Now Available
- Updated SDTM and Questionnaire Controlled Terminology Files
- CDISC Study Data Tabulation Model (SDTM) v1.3 and Study Data Tabulation Model Implementation Guide (SDTMIG) v3.1.3 final documents released
- CDISC Tuberculosis Therapeutic Area User Guide Provisional Release
- Final Versions of ADaM Time-to-Event and Adverse Event Analysis Data Models Now Available
- The CDISC Protocol Representation Model Toolset Available for use on the Member’s Only area
- BRIDG Release 3.2 Now Available

In addition to these new standards and project documents mentioned above, several others are nearing completion and expected to be posted very soon:

- SDTM IG v3.1.4 Package 2 Draft for Review
- Polycystic Kidney Disease Therapeutic Area User Guide Draft for Review
- Virology Therapeutic Area Supplement to the SDTM for Review

Join us for the CDISC Standards Webinar - Latest Updates and Additions on Tuesday 18 September 2012 at 11:00 AM U.S.A Eastern Time.

The webinar topics will cover:

- 2012 International Interchange Preview
- Overview of the Final SDTM Device Standard
- Brief review of SDTM 3.1.4 Batch 2 posting
Please follow the link to register and attend

Please check back to the CDISC website for more updates.

Follow the monthly column of our new CDISC CTO, Wayne Kubick, published in Applied Clinical Trials. Please see the latest on “Transformation and Translation”.

![Wayne Kubick](image)