



## **TRIAL DESIGN EXAMPLES ON THE CDISC WEBSITE for MEMBERS ONLY**

The TDM (Trial Design Model) Team has published several examples on the CDISC website for “Members Only” – “Case Studies” – “Trial Design Examples” at <http://www.cdisc.org/content1038>

Currently, the Study Data Tabulation Model Implementation Guide (SDTMIG) explains the concepts used in the Trial Design datasets, and includes a number of examples. The additional examples posted on the CDISC website are being published separately from the SDTMIG for the following reasons:

1. These examples have not received the degree of consultation and review that the examples in the SDTMIG received.
2. Separate publication allows examples to be provided more quickly than if they were incorporated into the SDTMIG.
3. The examples include some “experimental” features, variables and datasets which are being considered and tested for incorporation into SDTM, but which are not currently part of the standard.
4. These examples are based on actual trials and are more complete than the examples in the SDTMIG. They contain all five Trial Design datasets, as well as a Trial Design Matrix, a summary of the protocol and a description of issues considered in the creation of the datasets.
5. The additional examples on the CDISC website provide a greater variety of study designs to aid users in preparing Trial Design datasets.

Members of the TDM team prepared the initial examples. The Trial Design Team now would like others to participate and provide additional examples. The process for submitting examples:

- 1) Obtain Trial Design Template from CDISC Website “Members Only” – “Case Studies” – “Trial Design Examples” at <http://www.cdisc.org/content1038>
- 2) Use the “Best Practices” and “Spreadsheet Hints and Tips” tabs for guidance. Other posted examples are helpful references.
- 3) Submit completed Trial Design Template to [membercomments@cdisc.org](mailto:membercomments@cdisc.org)
- 4) Trial Design Team will discuss example and provide feedback to submitter. Submitter may be invited to a Trial Design teleconference.
- 5) Submitter will make changes (if any) to example and re-submit to Trial Design team for final review.



- 6) Trial Design Team member will place completed example on "Members Only" section of the CDISC Website.
- 7) Trial Design team will notify the CDISC community when enough new examples are posted.

Questions or comments may be sent to [membercomments@cdisc.org](mailto:membercomments@cdisc.org). The Trial Design Team will update the examples to correct errors or provide clarification in response to feedback. The Trial Design Team will not answer questions unrelated to the examples.