

Weekly Tip for Oct. 13, 2020

The FDA issued an update to the Technical Conformance Guide (TCG) at the end of July, with two fairly major changes requested to the SDTM SV domain:

1. SV should now contain records for all visits for a subject, both planned and unplanned, instead of only those visits which actually occurred.
2. Three Non-Standard Variables (NSVs) should be added to SV in order to identify visits that were missed or affected by the pandemic: SVREASOC (Reason for Occur Value), SVEPCHGI (Epi/Pandemic Related Change Indicator) and SVCNTMOD (Contact Mode). In addition, SVPRESP should be added to differentiate scheduled and unscheduled visits, and SVOCCUR to distinguish between visits which did and did not occur.

It is acknowledged that the addition of these visits and NSVs will generate P21 error or warning messages, and that is acceptable- just document them in the cSDRG. According to the TCG, "Submitting subject visits information in one single structured dataset allows both the human and technology consumer of this information to operate efficiently and with confidence that all visit data are considered during regulatory review.", so the benefits are worth the deviation from the current standard.

For more information, please see Appendix D of the July 2020 version of the TCG.

This week's tip was contributed by Nancy Brucken. Nancy is a Standards Engineer at Clinical Solutions Group, Inc., and has been a member of the ADaM team since 2011, co-leading the ADQRS sub-team, and currently working with the COVID-19 sub-team.