

## **An Introduction to SDTM - 298 pages (plus a 9 page how to use guide)....in another 20 minutes?!**

My 2012 paper and presentation provided an introduction to the SDTM framework, some basic SDTM implementation examples and tips, and also talked a little about how to check if your SDTMs are compliant. The objective of this paper is to build on that the introduction, so let us consider this paper as Part II! This paper will discuss other SDTM concepts such as

- SUBJID, USUBJID, SEQ, STDY
- Controlled Terminology
- Date Formats (ISO8601)
- Primary Keys - Natural keys
- Splitting Domains
- Custom Domains and Variables
- Reserved Domain Codes
- Grouping Variables
- Relative Timing & Timepoint Variables
- Linking Related Obs (CO, FA , RELREC)
- Casing, Missing Values, Multiple Values, CRF Free Text, 200 char limit