

# CDISC Standards End-to-End: Transitional Hurdles



## Aversion to Supplemental Qualifiers (SUPP)

Common changes to standard:

- Eliminating SUPPs – forcing values into non-ideal field or domains
- Adding non-standard variables - adding variables to parent domain to hold values that should have been included in a SUPP

## Expansion of SDTM Structure

Common changes to standard:

- Expanding variables kept in SDTM parent domain to eliminate SUPPs
- Adding analysis variables to SDTM
- Keeping system variables which do not apply to SDTM
- Keeping values which are needed in define.xml and not SDTM

## Controlled Terminology (CT) Struggles

Common changes to standard:

- Creating company specific terminology which does not comply with CDISC CT
- Issues with “mapping to standard value” concept when CRFs are not CDASH compliant
- Abusing extensible terminology by not mapping values that could be mapped

## Attachment to non-ADaM Analysis

Common changes to standard:

- Changing purpose of standard ADaM variables
- Changing vertical vs horizontal structure
- Eliminating required and/or expected variables in ADaM structure

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## Pre-Race Jitters Holding us Back from CDISC:

Like a first time racer, you may be more than a little apprehensive about showing up to your first meet with CDISC. Those model documents and implementation guides are quite long and packed with all sorts of nuggets of information. Aside from intimidation, you may have something you like to use and might be resistant to changing what works currently. You may:

- Think it is more convenient to store supplemental data in the same datasets as the related values
- Have existing utilities which do not use the standards
- Not believe current ADaM standards are sufficient for the study needs
- Prefer horizontal datasets for ease of analysis rather than vertical datasets
- Not understand purpose of standard structure

For all of these reasons and more, we find those CDISC-ish flavors. SDTM-plus. ADaM-like. The intent to use CDISC is there, just not yet the ability or maybe knowledge to commit to 100% compliance. A bit of training and, at times, more than a little bit of creativity can result in successful implementation of CDISC. Step one on the path is deciding to run the race and embrace CDISC. But why should you do this, how will you be rewarded and how do you put together a training regimen that works for you and your organization?



## Training Regimen Includes:

Wonderful, you have decided it is time to transition to compliant CDISC! Now how do you get yourself and your organization up to par? There are numerous options out there for training. Depending on budget, staff skillsets, location and other factors, not one training regimen will work for everyone. Some of those options include:

- CDISC training courses
- Online standards specific webinars
- CDISC applicable conferences
- Live group trainings
- Small group trainings
- Mentorship within or between companies
- Client specific CDISC introduction guides
- Self-study of the vast resources available to public at [www.CDISC.org](http://www.CDISC.org)

Like a marathon runner, you would not expect to train for a few hours and then successfully complete a marathon. Regardless of training method(s) selected repetition and usage are key. Practice, practice, practice! What a rare individual would know every word and spirit of usage of a standard with one training session of a few hours. Learning, reinforcement, putting that standard to use in a real world environment, and keeping current with updates are steps that will make the goal of CDISC compliance achievable.



## Importance of Running the CDISC Race:

Great move, you shook off the pre-race jitters and decided to run. You will soon be on your way to embracing CDISC open data standards. The rewards of the CDISC race are extensive thanks to the important collaborative efforts made by industry leaders to improve the quality, efficiency and cost effectiveness of clinical research process from protocol through analysis and reporting. The race course you are on will provide important advantages, like:

- Having parent SDTM domains maintain the core data for a particular topic
- Providing the FDA expected/requested specific reserved variables defined by CDISC standards
- Embracing a structure that allows all data points collected during the study can be maintained
- Promoting high quality work by leveraging an industry accepted standard
- Allowing for a more collaborative presence within clinical trials community

You are almost on your way, lace up your shoes and start stretching, the vast rewards of running an efficient race with CDISC are on the horizon.



## Rewards for an Efficient Race!

Implementing standards correctly has many incentives for you, your employees, and your company. The first among these are that in terms of structure for mapping, SDTM is the only aspect which will have a varied input structure of raw data, and even that is expedited if CRFs follow CDASH standards! With SDTM as it's base, ADaM specifications can be started earlier in the process since the location of data in SDTM is known. CT is a helpful addition to this process since even the many specific variable values are known before SDTM datasets exist. Integrations without using CDISC can be lengthy, expensive, and quite a headache depending on the state of the data. However, when all involved studies are already CDISC compliant, you only need to update for consistent versions of SDTM, ADaM, CT, and dictionary versions. Many tools already exist, or can be easily created, to check the compliance and to ensure a high quality data standard when data is formatted consistently to CDISC standards. In this way, industry level experts in standards exist which eliminates the need to teach new employees a company-specific standard. In addition to datasets, TFL programming is also much more efficient with a standardized structure. In fact, often the TFL programming process can even be automated for basic study TFLs. Finally, after everything is submitted, the FDA reviewers are very familiar with SDTM and ADaM datasets. When standardized data is submitted, this accelerates the review process because the reviewer knows exactly where to go to find the information they need, getting your drug to the market faster!

The Goals:

- First prize for **EFFICIENCY!**
- Blue ribbon for **CONSISTENCY!**
- Gold medal for **HIGH QUALITY!**