



# A Guide to SDTM Mapping - The Process, Typical Scenarios, & Best Practices.

## SDTM MAPPING - **WHAT YOU'RE UP AGAINST**

For clinical trial data to be accepted by regulatory reviewers, your submission must be in the correct format. If CDISC standards aren't adhered to, it could jeopardize your clinical trial. That could mean lots of time, money and hard work down the drain.

In order to be CDISC compliant, raw datasets must be mapped from the structure used in your clinical data management system (or another database) to the CDISC SDTM structure. This can be a long, complex and daunting process. Not least because there isn't always a perfect match.

This guide describes the steps to successful SDTM mapping, and the typical scenarios you're likely to face. Our best practice approach explains how the mapping process can be made quicker and easier, saving you time when it comes to submission.

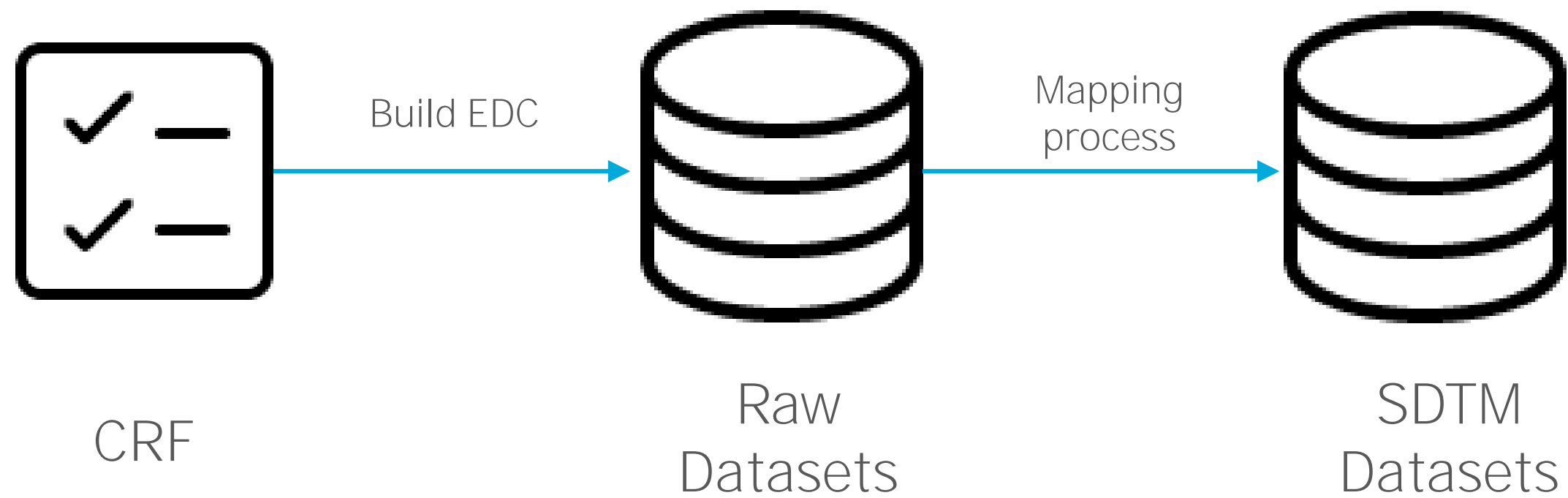
## THE SDTM IMPLEMENTATION GUIDE (SDTMIG)

It's really important to have a good understanding of SDTM domains and their structure. The SDTM Implementation Guide (SDTMIG) is there to help with this.

It gives a detailed overview of SDTM specifications and metadata for all SDTM domains. It includes guidance for producing SDTM datasets. If you make yourself familiar with the SDTMIG before you start SDTM mapping, it'll make the process much smoother.

# HIGH LEVEL MAPPING PROCESS

From CRF to SDTM



## KEY SDTM MAPPING STEPS

We've identified 6 key steps in a typical mapping scenario as follows:

1. Identify all the datasets you want to map.
2. Identify all the SDTM datasets that correlate with those datasets.
3. Get the dataset metadata.
4. Get the SDTM dataset metadata that corresponds to Step 3.
5. Map the variables in the datasets identified in Step 1 to the SDTM domain variables.
6. Create custom domains for any other datasets that don't have corresponding SDTM datasets.

# TYPICAL SDTM MAPPING SCENARIOS

There's 9 likely scenarios in a typical SDTM mapping process. Get to grips with these, and SDTM mapping becomes much more achievable:

1. The direct carry forward.
2. The variable rename.
3. The variable attribute change.
4. The reformat.
5. The combine.
6. The split.
7. The derivation.
8. The variable value map and new code list application.
9. The horizontal-to-vertical data structure transpose.

# TYPICAL SDTM MAPPING SCENARIOS - EXPLAINED

## The direct carry forward

Variables that are already SDTM compliant can be directly carried forward to the SDTM datasets. They don't need to be modified.

## The variable rename

You need to rename some variables to be able to map to the corresponding SDTM variable. For example, if the original variable is GENDER, it should be renamed SEX to comply with SDTM standards.

## The variable attribute change

Variable attributes must be mapped as well as variable names. Attributes like label, type, length and format must comply with the SDTM attributes.

# TYPICAL SDTM MAPPING SCENARIOS - EXPLAINED

## The reformat

The format that a value is stored in is changed. However the value itself does not change. For example, converting a SAS date to an ISO 8601 format character string.

## The combine

Sometimes multiple variables must be combined to form a single SDTM variable.

## The split

A non-SDTM variable might need to be split into 2 or more SDTM variables to comply with SDTM standards.



# TYPICAL SDTM MAPPING SCENARIOS - EXPLAINED

## The derivation

Some SDTM variables are obtained by deriving a result from data in the non-SDTM dataset. For example, instead of manually entering a patient's age, using the date of birth and study start date to derive it instead.

## The variable value map and new code list application

Some variable values need to be recoded or mapped to match with the values of a corresponding SDTM variable. This mapping is recommended for variables with a code list attached that has **controlled terminology that can't be extended**. You should map all values in the controlled terminology, and not just the values present in the dataset. This would cover values that are not in the dataset currently, but may come in during future dataset updates.

# TYPICAL SDTM MAPPING SCENARIOS - EXPLAINED

## The horizontal-to-vertical data structure transpose

There are situations where the structure of the non-CDISC dataset is completely different to its corresponding SDTM dataset. In such cases you need to transform its structure to one that is SDTM-compliant.

For example, the Vital Signs dataset. When data is collected in wide form, every test and recorded value is stored in separate variables. SDTM requires data to be stored in lean form. Therefore, the dataset must be transposed to have the tests, values and unit under 3 variables. If there are variables that **can't** be mapped to an SDTM variable, they would go into supplemental qualifiers.

## HOW BEST PRACTICE MAKES MAPPINGS EASIER

There's things you can do to make SDTM mapping easier.

Part of the trouble is that SDTM mapping is typically done at *the end* of the clinical trial process - once patient data has been collected. Retrospectively trying to make your results data fit the SDTM structure takes a lot of time and effort.

For this reason, it's best practice to align raw datasets with CDISC standards *before* collecting any patient data.

That means implementing SDTM right from the start - when designing your CRFs. Doing it this way means it's much easier to convert your datasets. And it saves time later on in the process when you're pulling your submission deliverables together. You can submit your study much quicker!

# HOW BEST PRACTICE MAKES MAPPINGS EASIER

The process of mapping your CRFs to SDTM in Formedix

1. For each CRF, decide what SDTM domain it should map to.
2. For each question on the CRF, decide on a corresponding variable in the related SDTM domain. If there's any that don't correspond to SDTM, then add custom domains.
3. Create raw datasets based on your CRFs.
4. Add your mappings to map the raw datasets to SDTM variables.
5. Add your CRF page links to variables in your SDTM datasets.
6. Automatically create your SDTM datasets.

## HOW WE CAN HELP

A platform that helps with SDTM mappings, and does conversions for you!

Formedix follows best practice. Our SDTM mapping tools make creating and describing your SDTM mappings much easier. They let you make and validate simple variable to variable mappings, as well as more complex mappings with many steps.

Map your data upfront

Formedix shows you what your EDC datasets will look like - *before you get them*. That means you can do your mappings early on. This helps to ensure that all the relevant data is collected.

## HOW WE CAN HELP

### Human-readable mappings

You can make human-readable mappings that clearly describe how datasets and variables in your original (source) datasets map to their equivalents in SDTM. From there you can create a metadata specification for programmers.

### Machine-readable mappings

You can create machine-readable mappings. No programming knowledge is needed. Once your mappings are done and approved, use our templates to turn your source datasets into SDTM datasets.

## HOW WE CAN HELP

SDTM conversion is quick and easy in Formedix. Once mappings are done, they automatically convert datasets to CDISC SDTM.

**And there's more benefits with Formedix:**

- You don't need to be an expert in SAS, or do any programming!
- You can even convert your legacy datasets.
- If you standardize your mappings, you can reuse them over and over again. That means faster study designs, and better quality data.
- You can get reports that give you full traceability of all mappings to ensure data is accurately mapped.
- Once you're set up, it's only 1 click to get your SDTM datasets and define.xml.

## START THE BALL ROLLING...

If this sounds good, you've got nothing to lose by talking to us.

We can discuss what's going on in your company. Specific hurdles you're up against. And where you'd like to get to. We'll see if our automation platform could help.

Click to arrange a call here - <https://www.formedix.com/call-me/>

Or request a customized SDTM mapping and conversion demo here - <https://www.formedix.com/book-a-demo/>

We've been helping Pharmas and CROs with study automation for the past two decades. Learn more about how we could help you here:

<https://www.formedix.com/>