

# Stop copying CDISC standards

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## 1. What is an MDR?

A Metadata Repository (MDR) has many definitions, but the simplest definition is "A Metadata Repository is a database created to store metadata". But what is "Metadata"? By definition, "Metadata is information about the structures that contain the actual data". In other words, an MDR is a library of data about data.

## 2. When to use an MDR?

An MDR can be used throughout a study's life-cycle, for example an MDR could be used to produce the SDTM data set specifications or even the data sets themselves. An effective MDR can increase efficiencies in production.

## 3. How to create an MDR?

There are a plethora of successful and well established MDRs out there. They all come with pros and cons, however, anyone can create a simple MDR. The vast number of MDR tools available is not a negative for the industry, this competition promotes growth and innovation which is great for the industry. The simplest MDR can be created using Microsoft EXCEL.

## 4. Determining the source of your MDR?

An MDR can be built from pre-existing documentation, data sets, legacy studies or from scratch. Personally, why re-write something which already exists? Consider SDTM data sets, both CDISC and the National Cancer Institute (NCI) teams produce and update their documentation very frequently. The NCI team bring out new controlled terminology lists every three months for SDTM. All this documentation is freely available and comes in a variety of formats, ODM, XLS, XML, PDF, etc. With this in mind why not build a MDR from these?

### 6a. The Template Approach

Most companies will have an in-house template, based primarily on the SDTM Implementation Guide (IG) with maybe some additional "sponsor rules". The user will adapt the static template to fit their needs.

**Pros:** Promotes consistency amongst the company.

**Cons:** Static templates become outdated when a new version is released.

### 6b. The MDR Approach

Some companies will have an in-house or third party MDR. Again based on the SDTM Implementation Guide (IG) with maybe some additional "sponsor rules".

**Pros:** Speedy mapping process.

**Cons:** Typically reliant on the perfectly structure input data set, effectively making it as effective as the static template method above.

### 6c. SQN's Approach

At SQN we use a hybrid approach, it combines automation with expectation that the standards documentation will change one day. The process utilises the documentation freely available from CDISC and the NCI team to create a dynamic approach which can use any version of the SDTM IG, past, present and future.

**Pros:** Dynamic, i.e. requires little to no input when a new version of the IG is released. Utilises software most companies already have, Microsoft EXCEL.

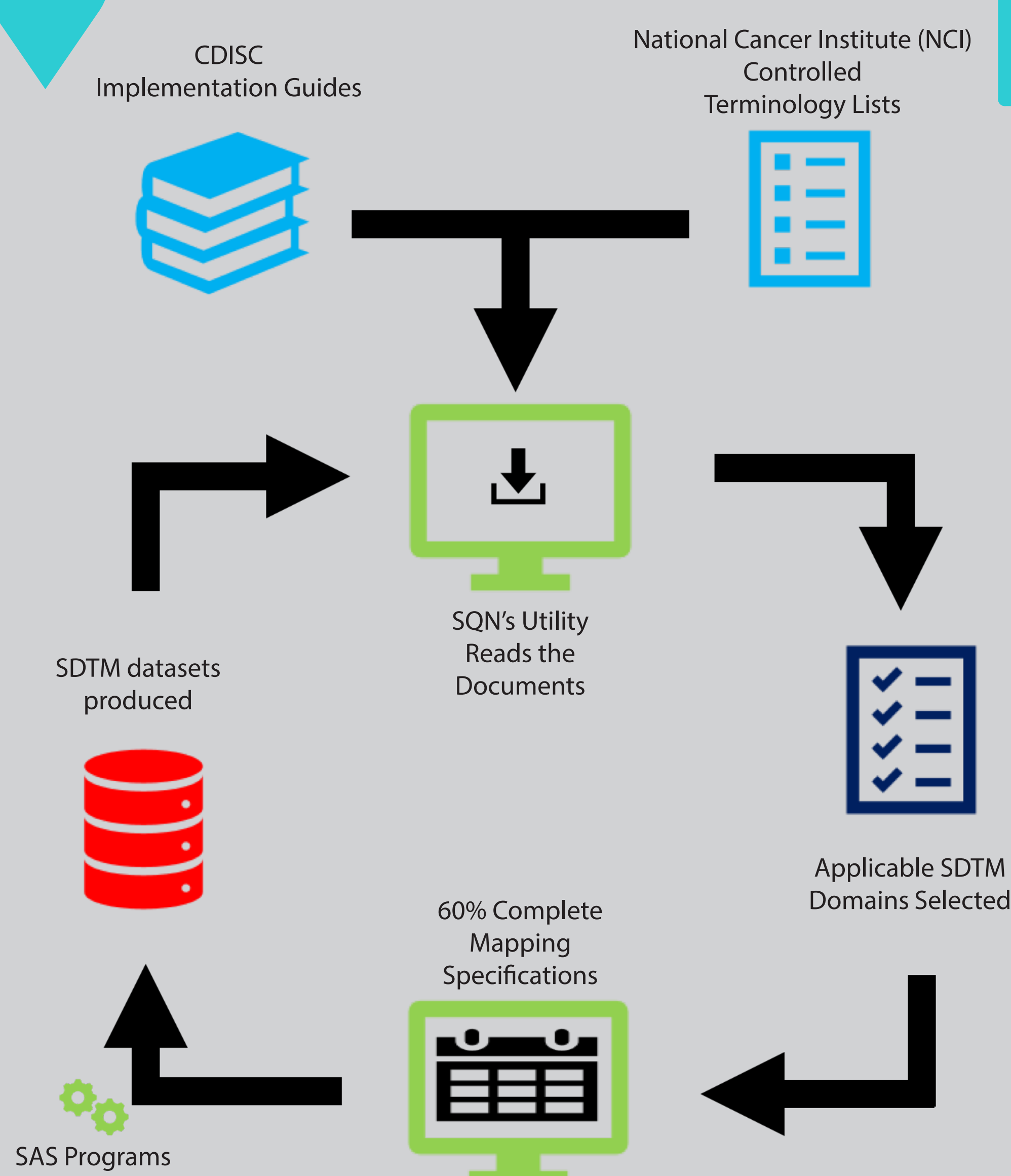
**Cons:** Reliant on CDISC and the National Cancer Institute (NCI) teams to produce EXCEL versions of their documentations.

## 5. Problems with an MDR

Depending on how the MDR was setup there may be long term problems with using an MDR. Take a SDTM based MDR as an example, when the MDR was created it would have been based on a version of the SDTM Implementation Guide (IG) available at the time of its creation. Making it almost obsolete when a new version is released, unless updated. Another potential issue is the initial creation of the MDR, this may take a sole individual many sleepless nights copying, tweaking and maintaining the tool. This initial creation may repeat itself when a new version is released.

## 7. SQN's Approach Explain

At SQN we take a dynamic approach to creating mapping specifications.

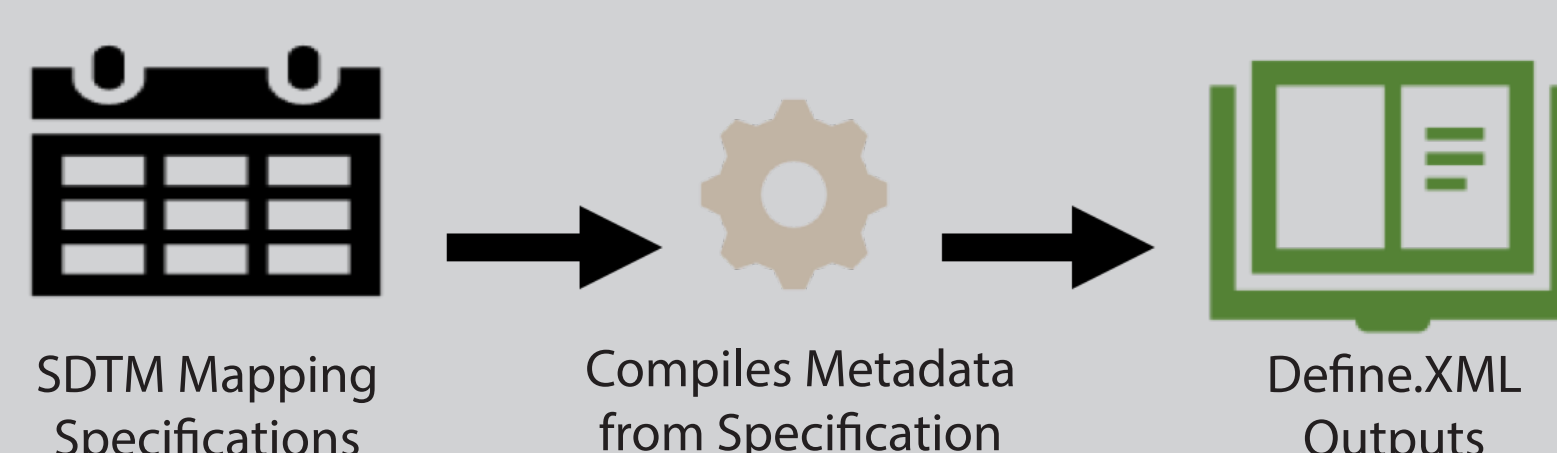


## 8. SQN & Our Utility

Our utility can not only create partially complete mapping specification, but the utility can also be used to create annotations for any Case Report Forms (CRFs) and Define.XML (v2.0) outputs without the need to have source data sets available. This means we can create Define.XML outputs before programming has even begun.

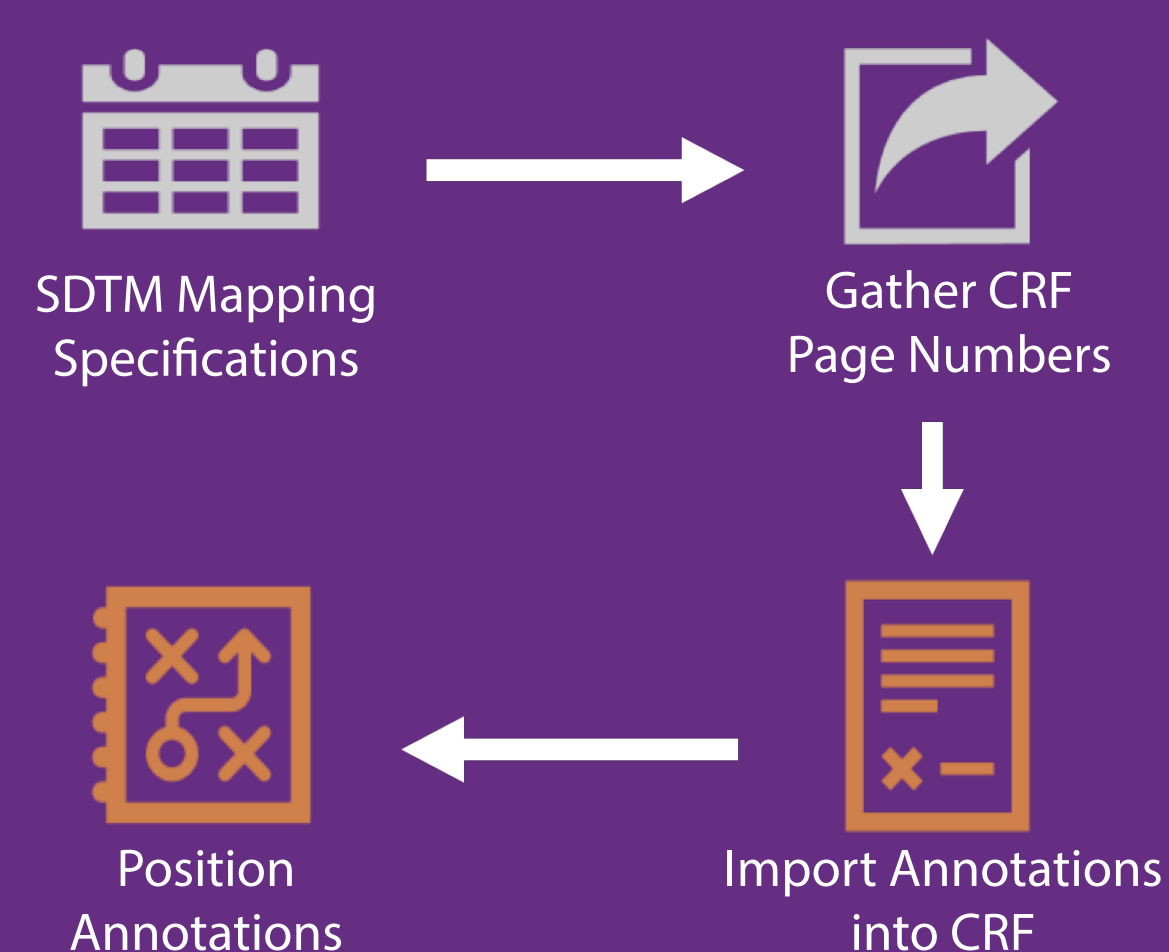
## 11. Creating a Define.XML

Our utility can also produce CDISC compliant Define.XML outputs by picking up the metadata directly from the mapping specifications in a matter of seconds.



## 9. Annotating a CRF

Once the programmer has created the mapping specifications (not the data set program) for at least one domain they can use the utility to create the annotations for said domain.



## 10. Annotations Explained

Consider the following mapping specification and blank CRF. First the utility gathers the CRF page numbers directly from the mapping specification, then the utility outputs an annotation file. This annotation file is imported into the CRF and the annotations will appear on the applicable pages. The user simply positions them correctly.

