

A non-interventional study is defined by the **methodological approach used and not by its scientific objectives.**

Example of non-interventional studies:

- Intensive monitoring schemes
- Patient registries
- Prescription event monitoring
- Case-control studies
- Cross-sectional studies
- Case-only designs
- Safety review of class medicines
- Drug utilisation studies
- Administrative claims data



We asked the community to share the **challenges** they faced while working on the **Non-interventional studies**

Industry feedback to the quiz organized by the project

Challenge	% responses
Impossible to create certain SDTM domains or required variables	58.3
Incomplete, inconsistent data	25
Other	16.7

There is a solution provided by **CDISC**. It is possible to have two sets of person-data: one for patient and one for the **associated person** (observer, investigator, donor, etc.).

AP-domains specific variables	
Outcome	Definition
APID	Associated Persons Identifier
RSUBJID	Related Subject
RDEVID	Related Device
SREL	Subject, Device, or Study Relationship

For example, in situations where both **observer** and **patient** are of interest, it may be difficult to establish which of them should be considered the **subject**.



If it is still desired to have the **treatment** variables

No study **drug**

ARM and TRT01P can be filled with **cohort** information

ARM and TRT01P = "No treatment" or "No Drug"

ARM and TRT01P are required as per the **ADAM IG**

Data are not submitted to the **FDA**

Having the **treatment** variables is not crucial

ADY is the number of days from an **anchor date** (not necessarily TRTSDT)

Data transparency is one of the key aspects of every mapping process.
To support this, the following may be considered:

- keeping original records and variables
- making use of ADaM variables such as DTYPE and ANLXXFL as much as possible.
- creating additional variables with the imputed values and information about the imputation.
- while applying visit windowing, keep all the records in the data with either missing AVISIT or AVISIT assigned to 'Unscheduled'
- additional variables can be added to the datasets in order to improve transparency and facilitate assessment of validity