

Introduction

PP24 First Aid Kit for an Observational Study

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Observational studies are not the kind of studies most of us come across every day and in many aspects, they are similar to the formal clinical trials however have their own specifics. Of course, each observational study is different and has its own challenges but some of them are more likely to occur. The purpose of this poster is to highlight the most common challenges programmers experience while working on the observational studies and to suggest the means to deal with these challenges from the programming point as well as from the point of standards.

WHY REINVENT THE WHEEL WHEN YOU DON'T HAVE TO?



In an observational study investigator observes subjects or measures certain outcomes without manipulation or intervention in contrast to randomized controlled trials where investigators do intervene and are interested in the effects of the intervention on an outcome.

Worst case scenario keeps you on the safe side.
Imputation to the last day of month:
`date1=intnx('month', input(date, anydte7.), 0, 'END');`

Incomplete or Missing Dates

As the data is often collected retrospectively missing or incomplete dates are very likely to occur

ADaM has a set of variables that are used in such cases. ***DTF** variables represent the level of imputation of the ***DT** variable based on the source variable. ***DTF** = Y if the entire date is imputed. ***DTF** = M if month and day are imputed. ***DTF** = D if only day is imputed. ***DTF** = null if ***DT** equals the respective variable date part equivalent. If a date was imputed, ***DTF** must be populated and is required. Both ***DTF** and ***TMF** may be needed to describe the level of imputation in ***DTM** if imputation was done.

From our experience worst case scenario is the best one when it comes to date imputation.

For example, if we have an adverse event that could have started before or after initialization of study drug¹ it is considered as the event that started on or after the treatment start date and therefore treatment-emergent.

1. In case there is a study drug. Depending on study specifics it could be another date defined in the protocol.

Interim/Sensitivity Analyses

For observational studies, it's often required to perform interim analysis/analyses. For example, it may be envisaged by SAP to do such analyses each year using cutoff dates. Cutoff of findings data shouldn't be a problem however it may be challenging for events and subject status at the cutoff date. For example, if event stop date is after the cutoff date, the event should be considered ongoing. The cutoff date may be saved in ADSL in **EOSDT** and the subject status at the cutoff date - in **EOSSTT**. Similarly, the treatment status information may be placed into **EOTSTT**.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms
EOSSTT	End of Study Status	Char	(SBJTSTAT)
EOSDT	End of Study Date	Num	



Be efficient! If the analysis is likely to be repeated with some modifications, create macros where possible. Regular expressions, COUNTW function can save you lots of time when performing interim/sensitivity analyses. Another helpful hint is to store values, specific for certain analysis (such as cutoff date), in a global macro variable.

No visit collected

After the dates have been imputed where it was required it is possible to derive study day² (**ADY** in ADaM terminology)

2. The number of days from a reference date (not necessarily DM.RFSTDTC) to ADT.

For each visit assign analysis window target (**AWTARGET**), analysis window diff from target (**AWDIFF**), and other AW variables if needed.

Derivations/missing data imputation -

Based on ADY/AWTARTGET/AWDIFF and the rule in the SAP map values to the visit

For closest/first/last/worst/best value set ANL01FL to "Y" on the respective value	For imputation specified in the SAP set DTYPE to the respective values for the imputed records (LOCF = last observation carried forward. WOCF = worst observation carried forward etc.)	For average add a new record and set DTYPE to "AVERAGE" and ANL01FL ='Y'. Similar approach is applicable in case of any other derivation rule
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What's More out There?



Interested in the observational studies?
Want to share your knowledge with the others?
Join the PhUSE project 'Data Standards for Non-Interventional Studies' and contribute!

