In observational studies, 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.

**PP24 First Aid Kit for an Observational Study**

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.

---

**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.

---

**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`.

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.

---

**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!