Supporting End to End Standards in Study Set Up

It all starts with the protocol

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End to end standards

It is understood that data standards are essential in many aspects of clinical trials but compliance to standards is not always high. A common problem is the data collection standards are often not considered until the eCRF is being designed and approved by the study team. pRED Roche are looking at ways to improve standards compliance by starting the discussions earlier in the clinical trial set up process. The obvious place to start is with the protocol but with many different authors across different sites and countries and different type of studies and disease areas to cover it was apparent a tool to support this step was needed. In this poster, we will present how eCRF standardization can be considered earlier in the protocol writing stage.

The Schedule of Assessments Tool

Select Library

Select Assessments – eCRF Forms

Create SoA for inclusion into the protocol

cRF Design

Select Variables

Create upload File for automatic eCRF build

Automatic eCRF build via file upload

Benefits on Downstream Processes

Conclusion

 Sites:
- Reduction of optional variables reduces data collection burden on subject
- Standard SoA used on all studies, easier to understand with less footnotes
- Improved standards compliance increases consistency of eCRFs across studies.

 Data Cleaning, Review and Exploration:
- Higher standard compliance less study specific edit checks required
- Standards allow usage of standard templates for data review tools e.g. Spotfire in pRED

 Data Extraction for statistical programming:
- The standard data collected is compliant to SDTM which makes extraction and mapping more straightforward
- Fewer errors in datasets due to mapping issues

- By selecting ‘eCRF’ in the study grid worksheet it will create an eCRF worksheet with all the assessments selected in the SoA set up step. It will list all the associated standard variables available
- Each variable will have guidance on their use, whether they are ‘Required’, ‘Recommended’ or ‘Optional’ in line with CDIS terminology along with additional information when applicable
- Working with the study team the data manager can then select the standard variables needed for their study on each form. ‘Required’ and ‘Recommended’ variables will be pre selected
- Any changes to the standard will be highlighted by turning red. These will then be sent to the standards committee for approval.
- Justification is required for addition or any optional variables to ensure study teams really require the variable in the study
- Once the study team are happy with the selection a file can be created using the ‘Integrate MLT’ button to create a Master Library Template which contains all the standards selected in a format ready for direct upload into Rave

- Starting from the protocol: pRED Roche created a single protocol template suitable for all study phases and disease therapy areas
- The associated Schedule of Assessments (SoA) is prepared using the ‘SoA Tool’. Initially metadata of the protocol (e.g. therapy area and number of visits, cycles or study days) are provided
- Completing the ‘Selection sheet’ and selecting ‘Set up Worksheet’ results in a study grid containing all available standard assessments for safety and the selected therapy area
- The study grid assessment names are aligned with the pRED data collection standards. These are stored in the pRED Rave® Global Library which was built based on CDASH and SDTM standards
- Science can then select the standard assessments to be performed at each visit. For some assessments e.g. Vital signs/ECG also at what time points (‘Hourly study grid’) are selected
- Mandatory standard assessments are automatically selected e.g. Adverse Events, Concomitant Medication
- Assessments not selected for any visit are automatically removed by selecting ‘Opt SoA’
- The approved Optimised SoA can then be added to the final protocol

→ Standards embedded during protocol development

→ Deviations from standards highlighted to the study team

→ Direct upload of agreed standards into study eCRF

Both the SoA and eCRF design aspect of the tool will help promote standards at an early stage in study set up.
Data managers can encourage the use of standards during protocol and SoA development. Deviations will be highlighted immediately via the eCRF design step
Starting the discussions on standards use in study set up early on reduces the bottle neck at eCRF review meetings where deviations to standards are often requested at short notice
With more transparency around the standards used and implications of making changes study team members are more likely to refrain from requesting too many deviations
By being able to upload the agreed standards directly in to the study in Rave as part of study set up it should improve set up time
To realise the benefit of the tool is vital to get study teams on board with both the SoA and eCRF design tool. Ongoing collection of feedback is therefore essential.