

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 in to the protocol



Selection Sheet for Study Grid: 1 ONC

Select Assessment Library: [Dropdown]

Create Study Grid #: [Input]

Protocol Number: [Input]

Back/Study Grid Parameters

of Visits: [Input]

of Days in Visit (1-100): [Input]

Hourly Assessment Time Interval: [Input]

Study Days/Week/Visit Period/Cycle: [Input]

Setup Worksheet

Table 1: Study Grid 1

eCRF

Opt SoA

Cycle	Form OID	Subject Level Forms	Screening	Visit 1					Day 5
Day	0-28 to 0-2			Day -1	Day 1	Day 2	Day 3	Day 4	Day 5
Visit Window			notime						
Assessments									
Enrollment	EN		X						
Visit Date	VISIT		X	X	X	X	X	X	X
Randomisation	RAND		X						
Demography	DM		X						
Eligibility	ELIG		X						
Medical History	MH		X						
Subject Charac									

Table: Schedule of Assessment 1

Day	Screening/ Baseline	Visit 1		Visit 2	
	-28 to -1	-1	1	-1	1
Informed Consent					
Physical Examination					
Randomisation	X				
Demography	X				
Eligibility	X				
Medical History	X				
Anthropometric Measurements					
Vital Signs			X	X	X
ECG - 12 Lead			X	X	
PK Blood Samples			X		
Adverse Event or Intercurrent Illness					
Previous and Concomitant Treatments					

- 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')
- 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**

eCRF Design

Select Variables



Create upload File for automatic eCRF build



Automatic eCRF build via file upload

Visit Date	FormOID	FieldOID	PreText	Add to Form (X)	Type	In Study Grid(s)	Recommended Parameters/Units	Comment - Unique Grid	Justification
Visit Date	VISIT	VISIT_DC	Date of Visit	X	REQUIRED	0	dd MMM yyyy		
Demography	DM	DSSTD_DC	Consent	X	REQUIRED	0	dd mon yyyy		Safety req
Demography	DM	AGE	Age		REQUIRED	0	years		Ethics

Integrate MLT

MDD	Library	Assess Name	FormOID	FieldOID
		Enrollment	EN	
		Enrollment	EN	SUBJNR

Upload Draft Spreadsheet

Select File: [Browse...]

Upload

☒ Save Upload History for Roll-Back (this may slow down the upload)

- 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 eform. '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**

→ **Deviations from standards highlighted to the study team**

→ **Direct upload of agreed standards into study eCRF**

Benefits on Downstream Processes



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 s 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

Conclusion

- 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 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