

Quarterly Safety Reporting:

Timely Analysis of Clinical Safety Data Using Qlik Sense Software

Yvonne Denkins, PhD – Assoc. Clinical Science Director

Agenda

- Quarterly Safety Reporting (QSR) Defined
- QSR Content
- QSR Functional Groups and Responsibilities
- QSR Process
- QSR Timeline
- QSR Charter
- Data Visualization

Quarterly Safety Reports

- Allows for a routine and structured review of safety data (AEs, Labs, Vitals) from the clinical data base every 3 months
- Includes subject demography, disposition, AEs/SAEs, dosing changes, labs and vitals
- Activities include working with:
 - Biostatistics to produce table specifications based on Sponsor input
 - Programmers to create the validated tables
 - A Data Visualization platform created in Qlik Sense for review of data and for graphics used in the QSR
 - QSR team to create, review, and QC report



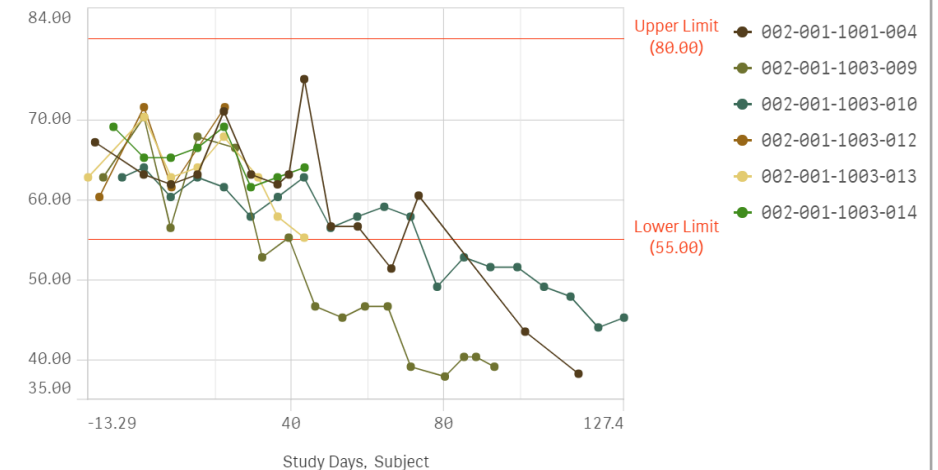
Table 3 - AE Summary by Dose - Data Cut DD-MMM-YYYY

Category	X.X mg/kg (N=5) (Count)	X.X mg/kg (N=2) (Count)	X.X mg/kg (N=2) (Count)
Number of subjects with one or more AE	XX	XX	XX
Total AEs (Serious and Nonserious)	XX	XX	XX
Total Nonserious AEs	XX	XX	XX
Nonserious AEs related to study drug	XX	XX	XX
Total Nonserious Grade 3, 4 AEs	XX	XX	XX
Nonserious Grade 3, 4 AEs related to study drug	XX	XX	XX
Total SAEs*	XX	XX	XX
SAEs related to study drug*	XX	XX	XX
AE uncategorized to AE/SAE	XX	XX	XX

* Numbers are based on the Clinical Data Base AE data listing unique subject highest grade

Total Protein - Normalized Values over time - 0.3 mg/kg

Normalized Values Over Time - Total Protein (g/L) - 0.3 mg/kg - 3 week cycle



Quarterly Safety Reports

- Table of Content includes:
 - Summary for the Quarter
 - Demographics
 - Disposition
 - Adverse Events
 - Adverse Events of Special Interest
 - Labs of Special Interest Summary
- Appendix Includes:
 - Figures Graphics, Additional Associations Requested by Sponsor



SCRX006 Table Shells



QSR Shells
ric Template with



QSR Template
Example



QSR Benign Info
Report

QSR Responsibilities

Clinical Scientist

- Provides study specific specifications to IT for DV platform and reviews completed platform
- Provides number and type of tables needed for report to Biostatistics (BIOS) with Sponsor agreement
- Writes a draft summary of the report's data for the quarter and oversees report finalization

QSR Coordinator

- Creates, reviews, and revises report
- Executes timeline
- Provides report graphics

Project Management

- POC for Mersana and develops timeline
- Distributes final report to sponsor and study team
- Schedules meetings to discuss the report as appropriate

IT

- Programs QS Platform dashboard for QSR
- Uploads data into the dashboard per Mersana and IT agreed timelines

Clinical Reporting

- BIOS
- SAS DATA Programming
- SAS STAT Programming

Data Management

- Clinical Coder completes Medical Coding according to the Data Management Plan
- Assure consistency and submits the forms to Sponsor for review and approval
- Codes terms per agreed timelines

Quality Control (QC)

- Performs a QC review of the QSR completed report per SOP

Medical Monitor

- Reviews draft report summary and provides a short medical interpretation of findings
- Alerts Safety Management and study team if potential safety signal is found
- Meets with Sponsor and safety to discuss potential safety signals

Safety Management

- If a potential safety signal is reported by MM, reviews report and meets w/ MM and Mersana to discuss
- If a safety signal has been confirmed by Sponsor, begins process for reporting as per either IQVIA Biotech SOP and WP or Mersana SOP/WP

Charter

- Meetings and Processes Cont'd
 - Process Flow chart
 - QSR Report
 - QSR Timeline
- References
- Appendix1:
 - TLF Shells for QSR
 - AESI and LSI

- Introduction
- The Quarterly Safety Report
 - QSR Charter Defined
 - Member Roles
 - Member Responsibilities
- Meetings
 - Organizational Meeting
 - QSR Standard Expectations



SCRX006 Table
Shells



QSR Template
Example

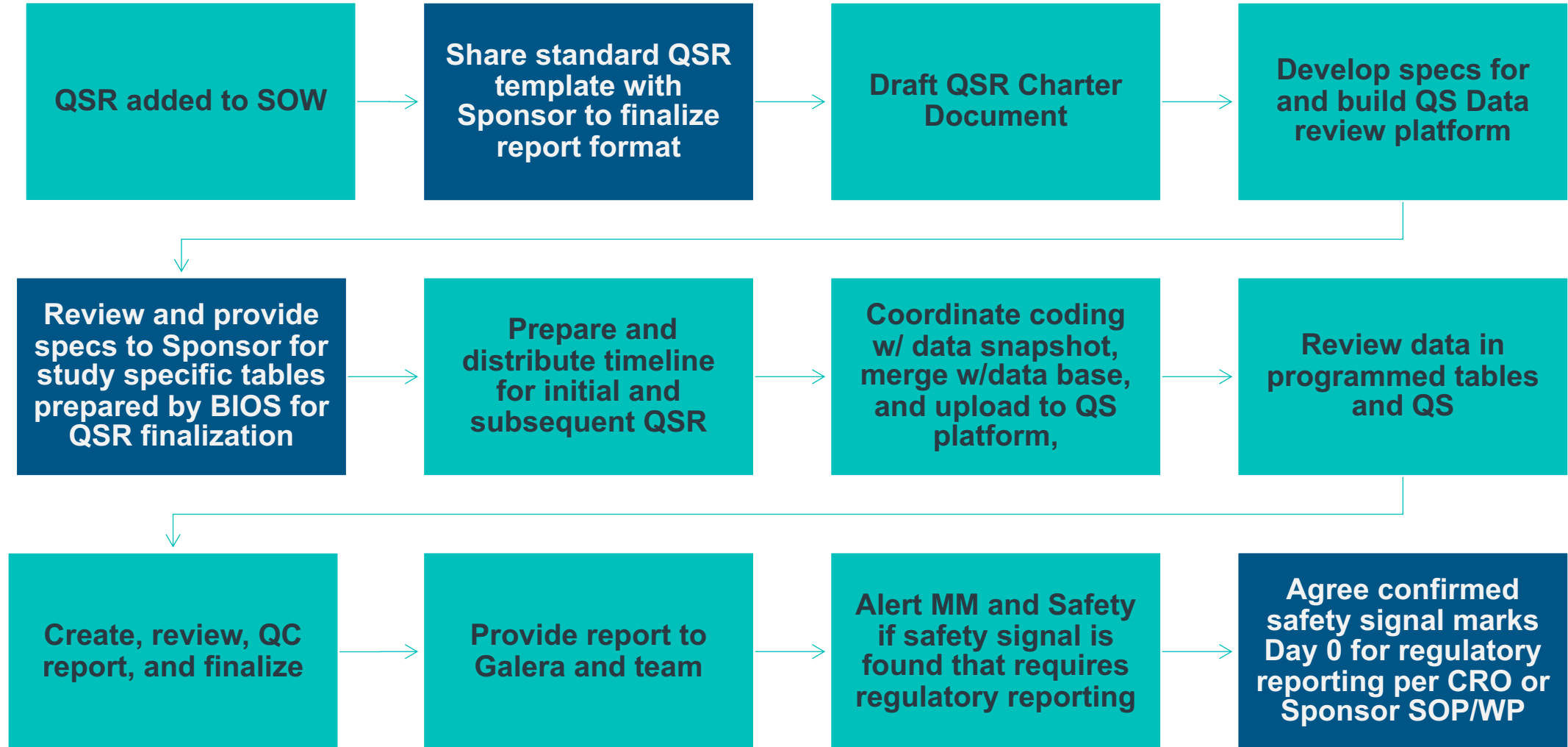


QSR Benign Info
Report



QSR Shells
ric Template with

Process Flow Chart



QSR Activities Timeline

Project No. Safety Review	Projected Timespan
Validated Table Preparation - CS prepares shells of initial tables and discusses with BIOS. - BIOS prepares sponsor-ready table shell document. - SAS STAT Programmers program initial tables. Tables reviewed by BIOS and CS – Corrections made	5 Months (initial QSR) – Subsequent occurs 4 weeks prior to report due date
Programming QS - CS maps data set variables to QS - IT programs QS Clinical Data Review Tool - CS QCs tool and releases to customer (if in scope)	5 Weeks
Extract data for Data Snapshot	4 weeks prior to report due date
SAS STAT Programmers Produce Tables	4 days (all other QSRs) – occurs 4 weeks prior to report due date
Quarterly Snapshot Review - Review Data in conjunction with the table output to ensure accuracy and capture new information/trends from the last quarter. - Review data in QS to further identify trends and define graphics to be included in the report.	3.5 weeks (prior to report due date)
Create, review and revise report	2 weeks (prior to report due date)
Post report to secure site for Sponsor	Report due date

Data Visualization Platform

Provides Ability to Review Data

- Presented in multiple formats (diagrams, tables, & charts)
- Drill-down capability to the individual patient level
- Easy access for data analysis by multiple team members
- Updated daily and available on demand

Basic Platform Includes

- Demographics, patient disposition, adverse events, labs (including DILI analysis), vitals
- Individual patient profile data

Customization

- Additional tabs can be added to include specialized data

Qlik Sense Clinical Data Review **Demonstration**

Questions?