Implementation of a Dashboard to Improve Protocol Oversight and Data and Safety Monitoring Committee (DSMC) Reviews

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Background

- The Data and Safety Monitoring Committee (DSMC) requires the submission of a database report.
- Historically, the database report came from the study's primary database(s); however, there were no standards or requirements for how data was provided, and integration of multiple data sources was manual.
- Raw data was often submitted which made the evaluation of data challenging. With over 690 reviews conducted in 2022, improvements to the current process were necessary.

Goals

Create an electronic database report that:

- Provides visualization of real-time data from multiple sources
- Eliminates the submission of raw unorganized data
- Automates and streamlines the data reporting process

Methods

In collaboration with DSMC Leadership and Clinical Research Information Technology (CRIT), the Protocol Review Core (PRC) implemented the Protocol Overview Dashboard (POD) (Figures 1-3) using the data visualization software, Tableau.

Careful project management using the following steps was required to achieve our goals:

Confirmed goals with stakeholders and created working groups

- Stakeholders included: DSMC, investigators, study teams, regulatory groups, and institutional leadership

Finalized dataset needed to conduct monitoring oversight

- **Protocol Details:** high-level overview to provide a snapshot of the study (e.g., study type, phase, risk level, status, target accrual)
- **Participant Summary:** in-depth overview of participant data to monitor study progress (e.g., demographics, disease/survival details, enrollment/evaluability status, site accrual details)
- **Serious Adverse Event (SAE) / Adverse Event (AE) Summaries:** organized by organ system and grouped by cohort, grade, and intervention in order to monitor safety and identify trends

Identified data sources

- Clinical Trials Management System (CTMS)
- MSK's Protocol Information Management System (PIMS)
- Clinical Research Electronic Data Capture Systems (EDCs)

Chose functionality that supports use at DSMC

- Designed aesthetically appealing and user-friendly data visualization (Figure 2)
- Finalized data field terminology, filter settings, and custom views (Figure 3) requested by DSMC
- Customized access and security script to secure participant data
- Granted DSMC members access to view and filter data directly

Prepared the institution for use at DSMC

- Piloted a diverse set of departments/services for inclusive feedback
- Provided multiple training sessions for study teams and DSMC
- Publicized to investigators (e.g., institution-wide announcement, advertisements)
- Updated requirements and instructional resources

Figure 1: Dashboard Landing Page

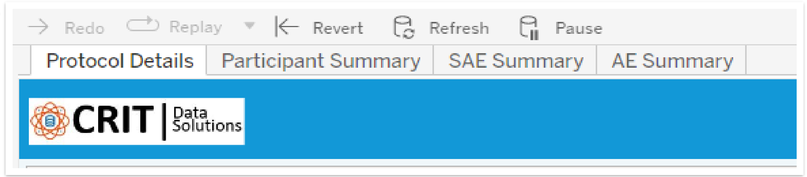
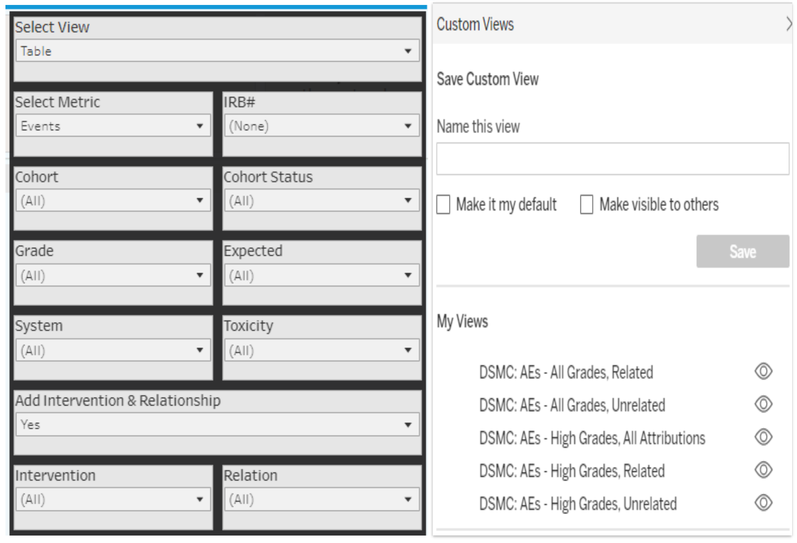


Figure 2: Adverse Event (AE) Example

System	Toxicity	Grade=1 CISPLATIN Possible	Probable	Unlikely	Unrelated
CONSTITUTIONAL SYMPTOMS	Weight loss	1 (3.03%)			
DERMATOLOGY/SKIN	Flushing			1 (3.03%)	
	Pruritus/itching			1 (3.03%)	
Ear and labyrinth disorders	Hearing impaired				
ENDOCRINE	Thyroid function, low (hypothyroidism)				
GASTROINTESTINAL	Anorexia	1 (3.03%)			
	Constipation	1 (3.03%)	1 (3.03%)		
	Dry mouth/salivary gland (xerostomia)			1 (3.03%)	
	Nausea		3 (9.09%)		

Figure 3: AE Filter Settings and Custom Views



Outcomes

- Following the pilot, use of the dashboard became a submission requirement for the majority of the DSMC portfolio (300+ studies).
  - Note the AE tab cannot be used for certain older studies and for external sites of multicenter studies.
- Implementation of the dashboard enhances the submission and monitoring of trial data:

Leverages data from multiple systems that updates daily and exports data into PDF format

Creates a standard way of viewing trial data across all study types

Replaces raw data with tabulated data tables and graphs

Ensures more accurate submissions and improves monitoring by the DSMC

Facilitates interpretation of data by Principal Investigators with potential to enhance patient safety with improved data integrity

Future Directions

- Incorporate additional data into the dashboard:
  - Laboratory toxicity
  - Toxicity heat map
  - External toxicity data from multicenter studies
- Better track outcomes to demonstrate the impact of the dashboard:
  - Collect committee review data in support of the hypothesis that fewer administrative comments and more substantive comments are a result of clear data being provided for review
- Extend use of the dashboard to other key committees (e.g., MSK's Pediatric-specific DSMC)
- Broaden use of dashboard by investigators to oversee their data:
  - Monitor trial data
  - QA data entry
- Use dashboard data to produce graphs and figures for presentations and publications