Category: Regulatory - Completed Project

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

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1. Background

The Data and Safety Monitoring Committee (DSMC) requires submission of a database report for review. 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. Additionally, raw data was typically submitted, which made the review of data challenging. With over 690 reviews conducted in 2022, the current process was not efficient for staff or DSMC reviewers. Thus, a report to automatically summarize large amounts of complex data in a consistent and tabulated way was needed.

2. Goals

Create an electronic database report that:

- Eliminates the submission of raw unorganized data
- Provides real-time data visualization from multiple sources
- Tabulates data to enhance review and monitoring
- Streamlines the data reporting process

3. Solutions and Methods

In collaboration with DSMC Leadership and Clinical Research Information Technology (CRIT), the Protocol Review Core (PRC) implemented the Protocol Overview Dashboard (POD) using the data visualization software Tableau. Careful project management using the following steps was required to achieve our goals:

1. Confirmed goals with stakeholders (e.g., DSMC, investigators, study teams, regulatory groups, institutional leadership) and created working groups
2. Finalized dataset needed to conduct monitoring oversight
    a. Protocol details: high-level overview of trial characteristics to provide a snapshot of protocol for users (e.g., PI, accrual target(s), protocol phase/type/risk)
    b. Participant summary: detailed overview of participant status for users to monitor study conduct and progress (e.g., enrollment by cohort/arm, demographics, disease/survival details, evaluability, and participating site accruals)
    c. S/AE details: list of S/AEs organized by organ system and grouped by cohort, grade, and intervention for users to monitor safety and identify trends
3. Identified data sources needed to provide consistent summary data in one location
    a. Clinical Trial Management System (CTMS)
    b. Protocol Information Management System (PIMS)
    c. Clinical research databases
4. Chose functionality that supports use at DSMC
    a. Designed visualization and report requirements to be visually pleasing and user-friendly (e.g., tables/graphs, data export, and download)
    b. Finalized data field terminology and settings to provide data requested by DSMC (e.g., information overlays, default filters, and custom views)

    c. Customized access to secure participant data (e.g., investigator, study team, DSMC)
5. Prepared the institution for use at DSMC
    a. Piloted across a diverse set of departments/services for inclusive feedback
    b. Provided multi-session trainings for study teams and DSMC
    c. Publicized use to investigators (e.g., institution-wide announcement, advertisements)
    d. Updated requirements and resources (e.g., How To, decision tree)

4. Outcomes

Following the pilot, use of the dashboard became a submission requirement for the majority of the DSMC portfolio (300+ studies). Implementation of the dashboard leverages data from multiple systems, creates a standard way of viewing trial data, and ensures more accurate submissions and better monitoring by the DSMC.

5. Lessons Learned and Future Directions

Use of the dashboard cannot be a mandatory requirement for all studies based on data requirement changes (e.g., older studies) and complexities with multicenter protocols. Future directions will include further refinement of data (e.g., laboratory toxicity, toxicity heat map) and use beyond the DSMC.

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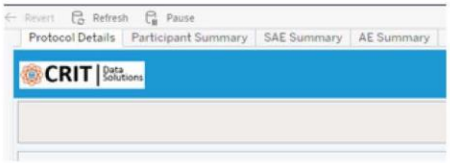
Protocol Overview Dashboard

Interactive data visualization starts here!

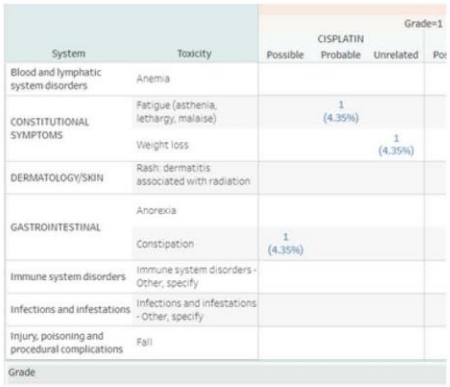
Links

- Protocol Overview Dashboard
- Instructions to Download Data
- DSMC SharePoint

Dashboard Landing Page



Adverse Events Example



System	Toxicity	Grade=1 CISPLATIN Possible	Probable	Unrelated	Po
Blood and lymphatic system disorders	Anemia				
CONSTITUTIONAL SYMPTOMS	Fatigue (asthenia, lethargy, malaise)		1 (4.35%)		
	Weight loss			1 (4.35%)	
DERMATOLOGY/SKIN	Rash: dermatitis associated with radiation				
GASTROINTESTINAL	Anorexia				
	Constipation	1 (4.35%)			
Immune system disorders	Immune system disorders - Other, specify				
Infections and infestations	Infections and infestations - Other, specify				
Injury, poisoning and procedural complications	Fall				

Grade

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For questions related to DSMC submissions, email **DSMC@mskcc.org**

For access or data issues in tableau, submit a CRIT ticket or send general inquiries to **zzPDL_RTM_CRITDataSolutions@mskcc.org**

OVERVIEW

The Protocol Overview Dashboard is an easy way to see clinical trial data from multiple sources (e.g., CRDB, CTMS, PIMS, CIS) in one place.

PURPOSE

The dashboard can be used for study oversight, monitoring, data visualization, and review committee (e.g., DSMC) submissions. Filters are available to narrow down and more easily visualize large quantities of data.

DATA IS DISPLAYED ACROSS FOUR TABS

1

Protocol Details

High level overview of the trial characteristics

2

Participant Summary

Detailed overview of enrollment by study cohort and/or arm, including demographics, disease and survival data, treatment and analysis details, and site accruals

3

Serious Adverse Events

Tabulated serious adverse event data by event or participants (available in table or graph visuals) and grouped by cohort, grade, relationship, and intervention

4

Adverse Events

Tabulated adverse event data by event or participants (available in table or graph visuals) and grouped by cohort, grade, relationship, and intervention