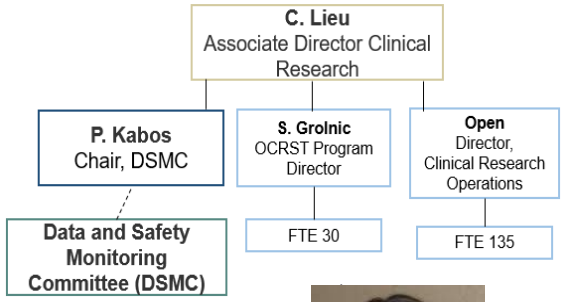
Automating Data Safety Monitoring Committee Progress Reports

OVERVIEW

The Oncology Clinical Research Support Team (OCRST) serves as central resource for Investigator Initiated Trial (IIT) support for CU Cancer Center members. Services provided include regulatory support, project management, data monitoring, and financial management.

The Data Safety and Monitoring Committee (DSMC) provides oversight for the data and safety monitoring for all CU Cancer Center clinical trials. Oversight includes risk assessment of all IITs, auditing, real time review of fatal events, ongoing review of Serious Adverse Events, quarterly DSMC meetings to review progress reports.

OVERSIGHT



KEY STAFF

S. Grolnic: OCRST Program Director

T. McSpadden: OCRST Clinical Project Manager, IIT Program

BACKGROUND

- DSMC requires Principal Investigators to submit regular progress reports on IITs; typically, every 6 months
- Progress Reports include summary of trial design, current status, enrollments to date (inclusive of all participating sites), adverse events (AE), protocol deviation listing, monitoring reports, meeting minutes, FDA reports, and any publications
- Previous DSM progress report template required data to be compiled manually resulting in time consuming process

GOALS

- Decrease time needed to complete DSM Progress Reports
- Standardize AE listing to improve DSMC safety review

METHODS

- Comprehensive review of data elements required for DSM Progress Reports; identified which elements existed in Clinical Trial Management System (CTMS) or available from another source
- Reviewed examples of previously submitted AE listings, gathered feedback from DSMC Director, Chair, and reviewers on key elements needed to facilitate safety review
- Custom report created to pull data from CTMS to populate the DSM Progress Reports; retained original report format that reviewers were accustomed to
- Created standard AE listing export report from EDC (REDCap or other) and Excel template with standard pivot tables and 'slicers'
- Developed instructions for use of new report and AE listing Excel template

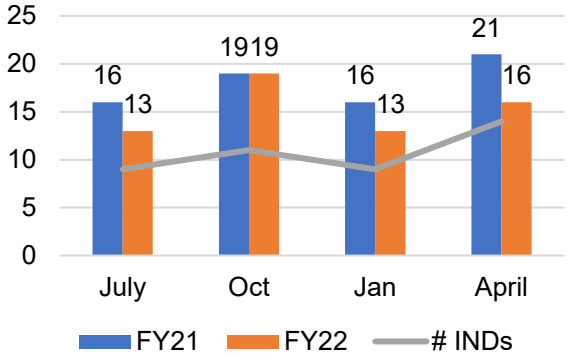
RESULTS

- Custom report pulls 63% of data elements from the CTMS into DSM Progress Report
- Reduced time needed to compile DSM Progress Reports by 75% from approximately 8 hours to 2 hours
- Positive feedback from DSMC reviewers on ease of AE review using the Excel template
- After successful pilot using the custom report and AE listing Excel template by OCRST, implemented across CU Cancer Center teams that compile data and submit DSM Progress Reports

FUTURE DIRECTIONS/LESSONS LEARNED

- Data definitions for consistent entry of information in the CTMS is critical to use of the DSM custom report
- Plans to develop guidelines for improved and standardized entry of deviations in CTMS in order to include in DSM Report are in process
- Report doubles as QA tool for data entry in CTMS (screen failures, withdrawals)

DSMC PROGRESS REPORT VOLUMES FY21-22



Improved AE review and safety oversight

Over 400 hours saved in compiling reports