Risk Based Monitoring for Investigator Initiated Trials

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BACKGROUND

Oncology clinical trials are becoming more complex, posing challenges for sponsors and investigators to design trials that ensure rapid enrollment, timely publication, and lay groundwork for subsequent trials.

The University of Florida Health Cancer Center (UFHCC) Compliance team utilizes 100% monitoring, but growth in study complexity has introduced a demand to adopt more adaptive monitoring focusing on the critical data points.

GOALS

The FDA requires studies to include monitoring plans for trial conduct and data quality. Sponsors are obligated to develop data management and monitoring plans at the outset of a trial. Integrating Risk-Based monitoring (RBM) approaches allows for efficient review of data, while maintaining vigilance in data integrity. Monitoring alone cannot guarantee quality data, but minimizing data collection to focus on trial endpoints or research question(s) can support data integrity and study success by:

1. Focusing on data needed to evaluate study endpoints in eCRFs, minimizing data irrelevant to study endpoints
2. Accelerating result dissemination by eliminating extraneous data points
3. Reducing staff effort for data entry; minimizing data errors

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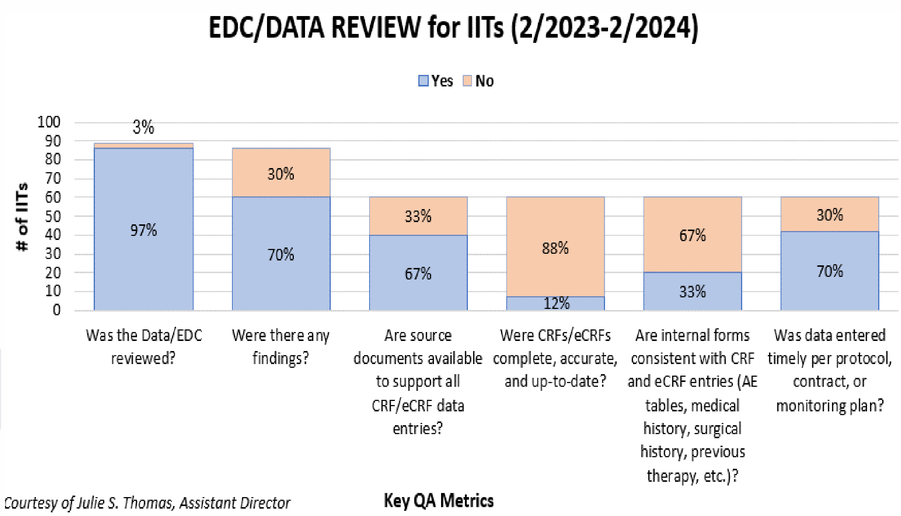
METHODS

- Project Management Office (PMO) supports conduct of UF IITs
- PMO and Compliance Office work closely to facilitate validation of study data
- The data management and monitoring plan is developed by PMO, with input from investigator and statistician.
- The Compliance Office recently delivered a RBM presentation to PMO, to encourage a risk-based mindset.
- The presentation will be included with UFHCC New Investigator training.
- Audit/monitoring data metrics, such as the baseline metrics illustrated in the table below, will be compared post- RBM implementation.



Courtesy of Julie S. Thomas, Assistant Director Talent Development

OUTCOMES

A review of 3 UFHCC IITs was conducted using a RBM mindset. It was discovered that only 13%-30% of data collected was actually associated with a protocol-specified endpoint (see Table below).

UFHCC IITs	# Data Points	# Data Points associated with an endpoint
Study A, multi-site	**232**	**42**
Study B, multi-site	**523**	**67**
Study C, single site	**497**	**149**

Courtesy of Alex Leggett, PMO Clinical Data Analyst

FUTURE DIRECTIONS

Many UFHCC IITs collect superfluous data points which are not useful in supporting study endpoints. At IIT development, we hope to engage in efforts to streamline data entry and validation using RBM, and evaluate impact based on measurable outcomes. We will evaluate query response turnaround, conciseness of source documents, and publication completion timelines (target 1 year).

We hope to alleviate data entry and validation burden through RBM, which we expect will also have the following benefits:

- Streamline eCRFs and source documents
- Show 30% decrease in data entry burden post-RBM implementation
- Decrease data errors found in validation by 30-40%