Category: Clinical Trial Operations – Work in Progress

Data Talks: Using Non-Compliance Tracking to Improve Patient Safety

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1. Background

Since 2012, the division of oncology has tracked reportable non-compliances (also known as major deviations), defined as changes in research made without prior institutional review board (IRB) approval that have the potential to negatively impact the rights, safety, or welfare of a participant. Non-compliance tracking was managed by various teams over the years and tracking terminology was not standardized, resulting in inconsistent categorization and unreliable non-compliance data.

While the reportable non-compliances were reviewed monthly by management, aggregate data was not analyzed for trends, leading to missed opportunities to prevent future non-compliances (i.e., by establishing re-education plans).

2. Goals

- Analyze current categorization to determine areas for improvement
- Update and standardize terminology to eliminate redundant and mislabeled non-compliances
- Re-categorize historical data to increase sample set for analysis
- Establish a method to improve consistent categorization moving forward
- Develop plan for continued aggregate data review
- Identify trends and present to stakeholders

3. Solutions and Methods

After reviewing available non-compliance data, the quality assurance (QA) team found that the current tracking system did not clearly define non-compliance types or include tracking guidelines. User interpretation of non-compliance categories varied, leading to similar non-compliances being tracked differently. Additionally, new categories were created for each unique non-compliance, resulting in 18 different “types” of non-compliances.

In response to these issues, we simplified the possible non-compliance types to seven categories: consent, IRB submissions/approvals, standard operating procedures, study procedures, treatment, and other (to capture one-off situations). We also clarified subtype terminology and created a reference key with examples to ensure all users categorize in a consistent manner.

Utilizing the updated terminology, we re-categorized and analyzed data from 2015-2021. We implemented quarterly management presentations on annual data and team-specific trends.

4. Outcomes

Upon full review of the system and tracking methods, we found areas to improve our tracker and developed strategies to maximize its impact. While we gained insight on historical non-compliances, the plan for how to utilize that knowledge moving forward is still in progress. We expect improved tracking will lead to improved data, which will better inform our priorities for re-education, staffing, standard operating procedures, and protocol development.

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5. Lessons Learned and Future Directions

We learned the importance of clear guidelines and consistent execution, especially when it comes to shared tools. We will continue to track non-compliances using the new category system. Quarterly presentation of aggregate data will serve to better inform our leaders and more quickly identify trends in non-compliances. We will partner with our division's education and training team to target areas needing re-education. By collecting clear and consistent data on errors made, we will use the knowledge gained to create tools and training aimed at improving patient safety and clinical trial data.