Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Cancer-Related Clinical Trials Reporting Compliance in a Matrixed Cancer Center

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1. Background

As a National Cancer Institute (NCI)-designated comprehensive cancer center, Mayo Clinic is obligated to report all cancer-related clinical trials as stated in PAR-21-321. This includes reporting to the NCI Clinical Trials Reporting Program (CTRP) in Data Table 4, and use of the Mayo Clinic Comprehensive Cancer Center's (MCCCC) Clinical Trial Management System (CTMS) and Patient Tracking System (PTrax). Based on external benchmarking, consulting, and internal stakeholder sessions, Mayo Clinic's institutional cancer-related clinical trial definition was expanded to include all prospective, hypothesis-driven trials that meet one or both of the following:

1. The objectives of the study involve the diagnosis, prevention, screening, evaluation, treatment, or support of cancer patients.
2. At least 25 percent of the patients involved in the study are likely to have an active cancer diagnosis.

Mayo Clinic is a matrixed organization consisting of both cancer and non-cancer specialties, therefor many new trials were brought under MCCCC's purview requiring compliance with NCI's reporting requirements.

2. Goals

- Identify reporting requirements for cancer-related trials in compliance with NCI requirements.
- Implement an institutional policy and procedure to support reporting compliance.
- Identify and reconcile existing trials in the institutional portfolio that require MCCCC oversight based on the revised definition.

3. Solutions and Methods

A multidisciplinary team was established that met with subject matter experts from across the institution to outline reporting requirements. Due to identified reporting differences depending upon trial type, and Food and Drug Administration (FDA) 21 CFR Part 11 compliance considerations, requirements were organized under four categories (Table 1): 1) Non-Interventional; 2) Interventional Treatment and Interventional Non-Treatment with an Investigational New Drug (IND)/Investigational Device Exemption (IDE) under FDA purview; 3) Interventional Treatment with no IND/IDE; 4) Interventional Non-Treatment with no IND/IDE. Requirements including Electronic Data Capture (EDC), Data and Safety Monitoring (DSM), PTrax tracking, training, and template requirements outlined were written into an institutional policy and corresponding procedure. The policy and procedure were socialized with stakeholders and approved by Leadership. Exemption rules were established to be used sparingly at the direction of Leadership.

To support compliance, the team developed an internal webpage providing further guidance, including a decision map, and opportunity for consultation to assist investigators and staff in navigating requirements. Systematic compliance checks were also implemented during study development and scientific review to ensure protocols were being set up in a compliant manner (e.g., planned EDC). The

team systematically identified trials within the institutional portfolio that met the revised definition, assigned the appropriate category (1-4), identified discrepancies in clinical trial management system (CTMS) data capture, and reconciled the studies, bringing them into compliance with the new policy.

4. Outcomes

The institutional Cancer-Related Clinical Trials Reporting Policy and Procedure were successfully implemented and communicated across the institution. More than 42,000 CTMS data variables were updated, and 1,171 trials were reconciled to bring them into compliance with the new policy.

5. Lessons Learned and Future Directions

- This change was not popular with some investigators and staff not previously subject to or familiar with MCCCC oversight and reporting.
- Deep stakeholder engagement, relationship building, and frequent communications were critical to socializing the change and improving compliance.
- The team will explore opportunities for automation to support compliance.

Table 1. Cancer-Related Clinical Trial Reporting Requirements

	CATEGORY 1 Non-Interventional	**CATEGORY 2** Interventional Treatment and Interventional Non-Treatment with an IND/IDE under FDA purview	**CATEGORY 3** Interventional Treatment w/No IND/IDE[1]	**CATEGORY 4** Interventional Non-Treatment w/ No IND/IDE[1]
DSM Oversight	No	Yes	Yes	No[1]
EDC	Medidata Rave or REDCap unless exemption	Medidata Rave	Medidata Rave	Medidata Rave or REDCap unless exemption
PTrax Tracking Required	Yes	Yes	Yes	Yes
CTRP Registration	Yes	Yes	Yes	Yes
MCCCC Training Required	No	Yes	Yes	No
MCCCC Protocol Templates Required	No	Yes	Yes[2]	Yes[2]