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

B. Bachman, L. Winkowski, A. J. Youssef, J. Zbacnik, R. Hardtke, G. Nowakowski, M.D., K. Van Abel, M.D., A. Mansfield, M.D., A. Fritsche

Mayo Clinic Comprehensive Cancer Center

BACKGROUND

- National Cancer Institute (NCI)-designated cancer centers are obligated to report all cancer-related clinical trials.
- Reporting to NCI **Clinical Trials Reporting Program (CTRP)** for Data Table 4.
- Based on benchmarking, consulting, and internal stakeholder sessions, MCCCC's cancer-related clinical trial definition was expanded.
- The expanded definition brought many new trials under MCCCC's purview.

GOALS

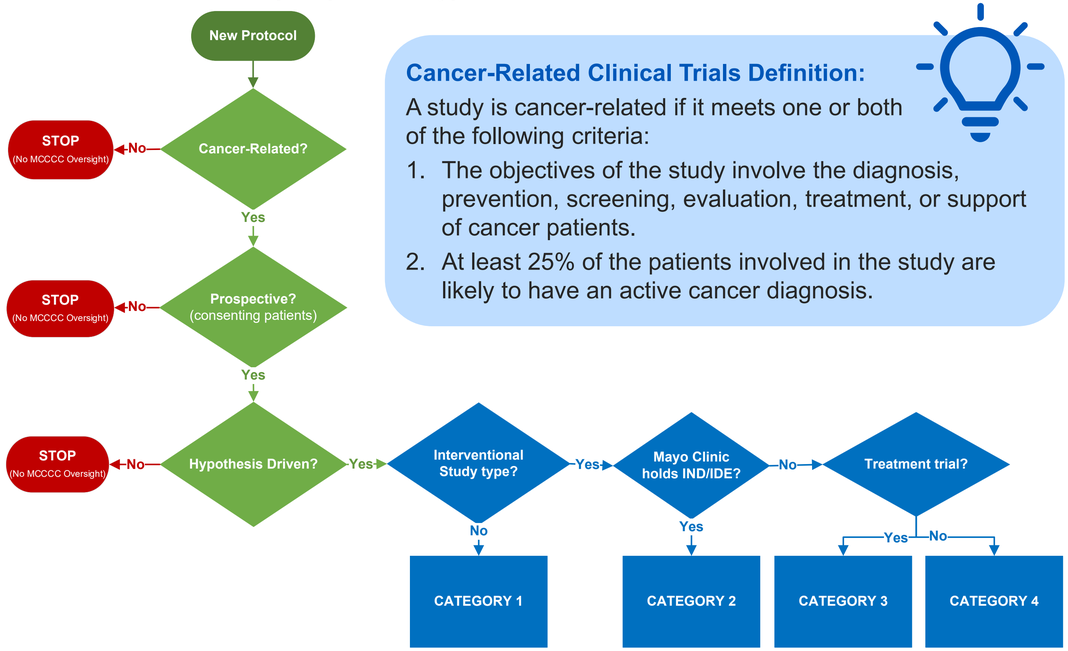
1. Identify reporting requirements for cancer-related trials in compliance with NCI requirements.
2. Implement an institutional policy and procedure to support reporting compliance.
3. Reconcile existing trials in Mayo Clinic's portfolio that require MCCCC oversight based on the revised definition.

METHODS

- A multidisciplinary team was established from across Mayo Clinic to outline reporting requirements.
- Requirements were organized under four categories based on FDA 21 CFR Part 11 compliance and whether an IND/IDE was present.
- Requirements including **Electronic Data Capture (EDC), Data and Safety Monitoring (DSM),** participant tracking, training, and template usage were written into an institutional policy and corresponding procedure.

CANCER-RELATED CLINICAL TRIAL REPORTING REQUIREMENTS

Includes all cancer-related, prospective, hypothesis-driven cancer-related clinical trials.



Cancer-Related Clinical Trials Definition:

A study is cancer-related if it meets one or both of the following criteria:

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

	CATEGORY 1 Non-Interventional	**CATEGORY 2** Interventional Treatment and Interventional Non-Treatment with an IND/IDE under FDA purview	**CATEGORY 3** Interventional Treatment with no IND/IDE [1]	**CATEGORY 4** Interventional Non-Treatment with no IND/IDE [1]
DSM Oversight	No	Yes	Yes	No [1]
EDC Usage	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]

[1] May required additional oversight at the direction of DSM (e.g., if serious adverse events are a concern).
[2] Minor adjustments to the protocol templates may be allowed at the discretion of DSM.

IMPLEMENTATION

- The policy and procedure were socialized with stakeholders and approved by Leadership.
- Exemption rules were established to be used sparingly and at the direction of Leadership.
- To support compliance, an internal **webpage** was developed to provide guidance and includes the **decision map** and offers **consultation** opportunities to help navigate the requirements.
- Systematic compliance checks during study development and scientific review assures compliance
- Identified trials which met the revised definition were assigned a category (1-4), discrepancies in CTMS data capture were identified and reconciled, bringing them into compliance with the new policy.

OUTCOMES

MCCCC's Cancer-Related Clinical Trials Reporting Policy and Procedure were successfully implemented and communicated across the institution.

42,000+ CTMS data variables updated

1,171 studies reconciled under new policy

LESSONS LEARNED & NEXT STEPS

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