Category: Prioritization and Scientific Review – Completed Project

Revamping Clinical Trials Accrual Monitoring

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1. Background

As a National Cancer Institute (NCI)-designated comprehensive cancer center, Mayo Clinic Comprehensive Cancer Center (MCCCC) is required to conduct rigorous scientific oversight of cancer clinical trials through a formalized Protocol Review and Monitoring Committee (PRMC). This includes monitoring and closing underperforming trials. An internal analysis at MCCCC (2020- 2022) revealed that 60 percent of studies enrolled their first patient within three months of activation, with 73 percent accruing by six months. This indicated that accrual likelihood significantly declined after three to six months. Historically, MCCCC's Low Accrual Policy engaged investigators less frequently, typically at 12 months post-activation.

2. Goals

- Revise accrual monitoring criteria to include stricter accrual targets at more frequent timepoints to act on underperforming trials earlier.
- Initiate earlier engagement with investigators to support remediation or more timely closure of underperforming trials.

3. Solutions and Methods

A project team was established to assess the existing accrual monitoring criteria, benchmark against other designated cancer centers, and identify areas for revision. Based on this assessment, the institutional Cancer-Related Low Accrual Policy was revised in March 2023 to outline specific performance expectations at set timepoints based on trial phase and disease rarity (Table 1). Disease rarity is determined during Stage 1 scientific review by the Disease Group and defined as cancers with an incidence of <5 newly diagnosed cancers per 100,000 persons per year. PRMC monitors clinical trial actual accrual compared against target accrual across four categories: NonPhase I, Phase I, Rare, and Pediatric.

Trials with low accrual first receive an at-risk notification, and if accrual remains low, investigators must work with their Disease Group to submit a remediation plan or close the trial to accrual. Reviews occur at set time points (e.g., 6, 12, 18, or 24 months), with stricter criteria for Non-Phase I and Phase I trials. Trials with no accrual for 12–24 months risk closure unless justified. PRMC has sole authority over trial activation and closure. Applicable accrual monitoring criteria for each trial is communicated to investigators at the time of Stage 2 scientific review set clear performance expectations prior to activation.

4. Outcomes

The revised Low Accrual Policy enabled PRMS to take more deliberate, objective action on underperforming trials. When comparing 2023-2024 monitoring activities with the prior two-year period, 813 accrual notifications were sent (148% increase) and 68 studies were closed due to underperformance (656% increase). These activities improved MCCCC's overall portfolio performance. Of the 1056 total trials on the MCCCC's NCI Data Table 4 in 2024, 6 percent of open, nonrare trials had 0 accruals at 12+ months (target <10%).

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5. Learned and Future Directions

Lessons Learned:

- Consistent and timely communication is critical when monitoring and acting on
- underperforming trials.
- Engaging with investigators and their Disease Group early and often regarding trial performance
- supports accountability and open dialogue.
- Consistent criteria and timepoints for trial performance made implementing and enforcing
- stricter criteria much simpler across a large, multi-site organization.

Future Directions:

- Determine impact on accrual performance for trials that remain open following PRMC
- engagement.
- As the only three-site designated cancer center, further explore how to expand monitoring of
- underperforming trials by site

Figure

Table 1. PRMC Low Accrual Monitoring Criteria Tables

Time (months)	Accrual threshold	Action	Time (months)	Accrual threshold	Action
Non-Phase I Trials Categorized as Non-Rare			**Phase I Trials Categorized as Non-Rare**		
3	0	At-risk Notification	6	0	At-risk Notification
6	0	Justification or Closure	12	0	Justification or Closure
	<25%	At-risk Notification		<3	At-risk Notification
12	<25%	Justification or Closure	18	<3	Justification or Closure
	<50%	At-risk Notification		3–4	At-risk Notification
18 (then every 6 mo)	<25%	Justification or Closure	24 (then every 6 mo)	<25%	Justification or Closure
	<50%	At-risk Notification		<50%	At-risk Notification
	0 in 12 mo preceding	Justification or Closure			
All Trials Categorized as Rare			**Pediatric Trials**		
6	0	At-risk Notification	12	0	At-risk Notification
12	0	At-risk Notification	18	0	At-risk Notification
18	0	Justification or Closure	24	0	Justification or Closure
24 (then every 6 mo)	0 in preceding 12 mo	Justification or Closure	36 (then every 6 mo)	0 in preceding 24 mo	Justification or Closure