Revamping Clinical Trials Accrual Monitoring

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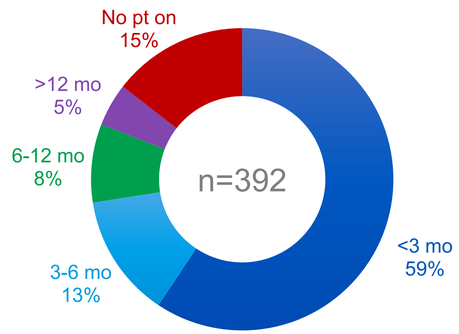
BACKGROUND

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 with PRMC holding the **sole authority** for trial activation and closure.

An internal analysis at MCCCC (2020-2022) revealed that 60% of studies enrolled their first patient within 3 months of activation, with 73% accruing by 6 months indicating that **accrual likelihood significantly declined after 3-6 months.**



Historically, MCCCC's Low Accrual Policy engaged investigators less frequently, typically at 12 months post-activation.

GOALS

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

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 for all study types (i.e., Interventional, Observational, Ancillary and Correlative).

ACCRUAL MONITORING CRITERIA

Time (months)	Accrual threshold	Action
Non-Phase I Trials Categorized as Non-Rare		
3	0	at-risk notification
6	0	justification or closure
	<25%	at-risk notification
12	<25%	justification or closure
	<50%	at-risk notification
18 (+every 6 mo)	<25%	justification or closure
	<50%	at-risk notification
	0 in 12 mo preceding	justification or closure
All Trials Categorized as Rare		
6	0	at-risk notification
12	0	at-risk notification
18	0	justification or closure
24 (+every 6 mo)	0 in 12 mo preceding	justification or closure

Time (months)	Accrual threshold	Action
Phase I Trials Categorized as Non-Rare		
6	0	at-risk notification
12	0	justification or closure
	<3	at-risk notification
18	<3	justification or closure
	3–4	at-risk notification
24 (+every 6 mo)	<25%	justification or closure
	<50%	at-risk notification
	0 in 12 mo preceding	justification or closure
Pediatric Trials		
12	0	at-risk notification
18	0	at-risk notification
24	0	justification or closure
36 (+every 6 mo)	0 in 24 mo preceding	justification or closure

APPROVAL TO ACTIVATE
Applicable accrual monitoring criteria communicated at the time of PRMC Stage 2 approval to activate

AT-RISK NOTIFICATION
Memo prompts PI to work with Disease Group to review and address barriers to accrual

JUSTIFICATION OR CLOSURE
Memo instructs PI to work with Disease Group to submit justification and remediation plan or voluntarily close to accrual

PRMC DECISION
Review justification/remediation plan and vote to keep open until next review timepoint or close to accrual with no appeal

How is MCCCC defining Rare?

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.**

OUTCOMES

- Revised Low Accrual Policy enabled PRMS to take more deliberate, objective action on underperforming trials.
- Relationships between PIs, Disease Groups, and PRMC were noticeably strengthened.
- Comparing 2023-2024 monitoring activities with prior two years:
  - ➢ **813 accrual notifications** were sent (148% increase)
  - ➢ **68 studies were closed** due to underperformance (656% increase)
- Improved overall portfolio performance with YE 2024 showing **only 6%** of open, non-rare trials had 0 accruals at 12+ months (target <10%).

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.