Commercial vs. Internal IRBs: Regulatory Burden of IRB Submissions, Three Years In

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Background

The University of Michigan Health Rogel Cancer Center's Oncology Clinical Trials Support Unit (O-CTSU) primarily has utilized UM's internal IRBMED as the Institutional Review Board (IRB) for industry studies. In second quarter of 2021, a pilot was instituted to increase the utilization of Central Institutional Review Boards (cIRB) such as Advarra and WCG to reduce approval and study activation timelines.

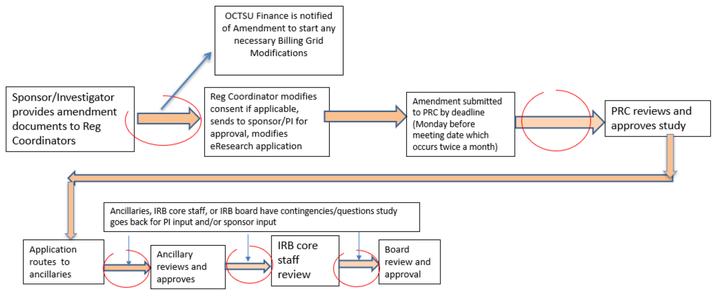
O-CTSU's Regulatory team is separated into two units:
- Start-Up- focus on coordination through initial IRB approval
- Maintenance - focus on coordination after initial approval through termination

The Regulatory team consists of 1 manager, 3 leads, 1 project coordinator/administrator, 5 start-up coordinators and 10 maintenance coordinators. The team supports over 400 projects at any given time.

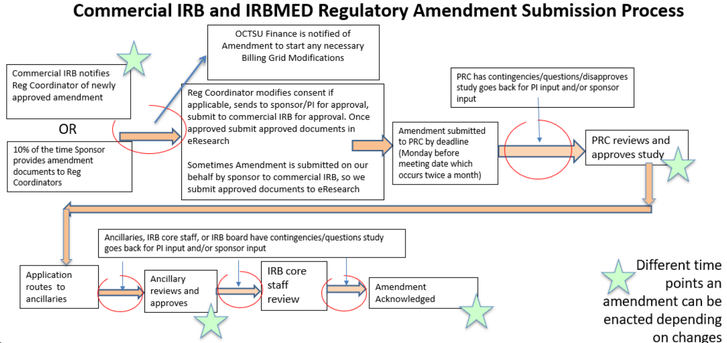
The Regulatory team standardized the utilization of IRBMED across the entire portfolio of studies with established guidelines and reporting requirements. In addition, O-CTSU and IRBMED have a collaborative feedback loop in place to address changes, issues, and questions that arise. In comparison, use of cIRBs for O-CTSU was minimal and without standardized processes. Furthermore, when using a cIRB, IRBMED does not cede oversight of all aspects of trials and institutional ancillary committees remain linked to the IRBMED application, thus resulting in duplicative submissions in IRBMED and cIRB systems.

While IRB approval and activation timelines showed an improvement, the O-CTSU Regulatory team expressed an increase in effort and resources being spent on managing cIRB studies.

IRBMED Regulatory Amendment Submission Process



Commercial IRB and IRBMED Regulatory Amendment Submission Process



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Goal

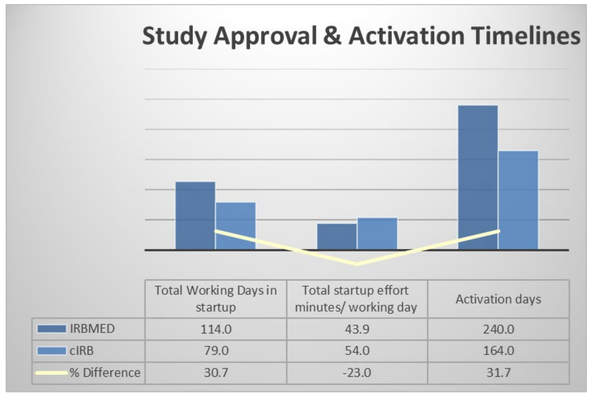
Evaluating activation timelines and effort of utilizing cIRBs compared to IRBMED to inform potential budgetary changes of regulatory costs.

Methods

O-CTSU's Regulatory team has two units: Start-Up (focus on coordination through initial IRB approval) and Maintenance (focus on coordination after initial approval). Due to staff recording effort in a web-based research effort tracking application (RETA), we determined the effort spent over a standard time frame for 41 IRBMED studies and 41 cIRB ceded studies. These trials were first identified in 2022 and were re-analyzed in May 2024. We looked at the total effort per working day reported by the startup and maintenance coordinators.

Outcomes

The data verified that cIRB studies spent less time in startup (79 working days) when compared to IRBMED studies (114 working days), resulting in a 31% decrease in initial IRB approval time. Our activation timelines improved by 32% when utilizing the cIRBs. The median activation time frame was 164 days for cIRB studies compared to 240 days with IRBMED.



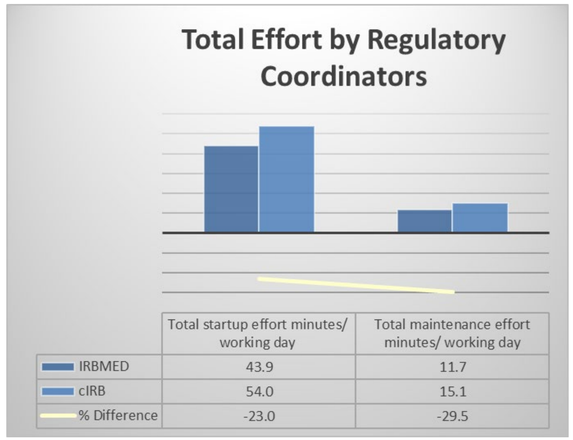
	Total Working Days in startup	Total startup effort minutes/ working day	Activation days
IRBMED	114.0	43.9	240.0
cIRB	79.0	54.0	164.0
% Difference	30.7	-23.0	31.7

The biggest time savings were attributed to the effort spent on initial application and ICF development, which decreased by 26% and 69%, respectively, for the cIRB studies.

	IRB/PRC Application effort in minutes, Initial	ICF Deveop effort in minutes
IRBMED	1068.0	1008.0
cIRB	792.0	318.0
% Difference	25.8	68.5

Outcomes Cont.

However, total effort per working day reported on studies by the coordinators showed an increased effort spent when utilizing a cIRB rather than IRBMED.



	Total startup effort minutes/ working day	Total maintenance effort minutes/ working day
IRBMED	43.9	11.7
cIRB	54.0	15.1
% Difference	-23.0	-29.5

Our effort data showed an increase of 23% in total start-up effort spent (per working day) and an increase of 30% in total maintenance effort spent on a study utilizing cIRBs.

Discussion

The OCTSU Regulatory team has standardized the utilization of IRBMED across the entire portfolio of studies with established guidelines and reporting requirements; there is a collaborative feedback loop in place to address changes, issues, and questions that arise. In comparison, the utilization of cIRBs is without standardized processes; cIRB support and collaboration are not as easily accessible as IRBMED.

When this project was initially conceived, there was a feeling that cIRB studies caused more effort and 3 years in our data does support this feeling. While utilizing cIRBs have decreased start-up timeline, our effort data shows that for every 60 minutes start-up and maintenance coordinator spends working on IRBMED studies, the same work will take 74 and 77 minutes, respectively, on cIRB studies.

Overall, this increase in effort on cIRB studies needs to be considered to ensure effort is appropriately allotted and budgeted.

Future Directions

We want to evaluate this same group of studies during their lifetime at our institution and compare the time saved at start up to the effort increase in maintenance to help inform our finance team to adjust budgets more appropriately.

We want to break the studies down further to see if the phase and complexity of the cohorts under the protocol affects the time requirements.

Acknowledgments

Michigan Medicine Oncology Clinical Trials Support Unit SC-Reg for all of their tireless efforts and contributions to Oncology Clinical research studies.