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

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

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1. Background
The University of Michigan (UM) Rogel Cancer Center's Oncology Clinical Trials Support Unit (O-CTSU) primarily utilized UM's Institutional Review Board (IRBMED) for industry studies. In the second quarter of 2021, a project was instituted to increase utilization of Central Institutional Review Boards (cIRBs) to reduce approval and study activation timelines. While IRBMED does cede oversight to cIRBs, other required institutional ancillary committees do not cede oversight resulting in duplicative submissions. O-CTSU Regulatory shared a common opinion that, comparatively, there was increased effort and resources being spent on cIRB studies. This is an update to our initial data that was pulled in June of 2022.

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

3. Solutions and 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. We looked at total effort per working day reported by startup coordinators and maintenance coordinators.

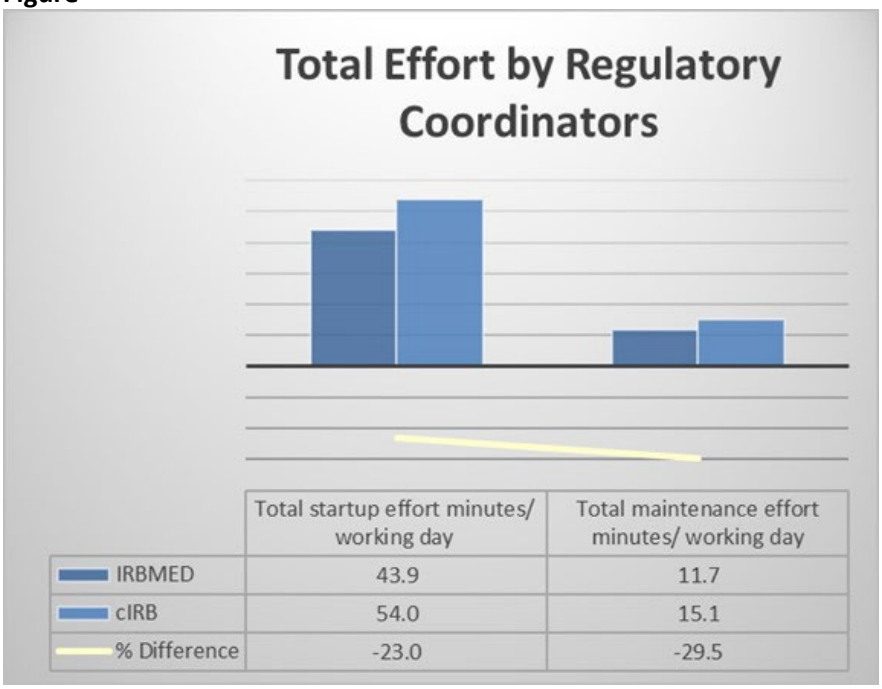
4. Outcomes
We identified 41 IRBMED and 41 cIRB studies. RETA data was analyzed again in May 2024. The data verified that cIRB studies spent less time in startup (79 working days) when compared to IRBMED studies (114 working days) resulting in a 31 percent decrease in initial IRB approval time. The biggest time savings were attributed to the effort spent on initial application and ICF development which decreased by 26 percent and 69 percent respectively for the cIRB studies. Our activation timelines improved by 32 percent when utilizing the cIRBs. The median activation time frame was 164 days for cIRB studies compared to 240 days with IRBMED.

However, total effort per working day reported on studies by the coordinators showed an increased effort spent when utilizing a cIRB rather than IRBMED. Our effort data showed an increase of 23 percent in total start-up effort spent (per working day) and an increase of 30 percent in total maintenance effort spent on a study utilizing cIRBs.

5. Lessons Learned and Future Directions
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.

Figure



	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