Capturing Metrics for the First Stage of Protocol Review at a Consortium Cancer Center

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Background

The Case Comprehensive Cancer Center (Case CCC) is a consortium of Case Western Reserve University, The Cleveland Clinic, and University Hospitals of Cleveland. Though there is a collaborative relationship among all the consortium partners, each system has their own departmental structure, IRB, and Clinical Trial Units. The entire cancer center utilizes the same OnCore™ clinical trials database, a single PRMC, and a single Data Safety & Toxicity Committee. When the new FOA requirements were announced in November of 2019, we developed a way to capture our phase 1 review processes as it already existed in order to fulfill the new grant requirements.

In November of 2019 new CCSG P30 guidelines were published. These guidelines changed the reporting requirements for the PRMS for the first time in over 10 years. The FOA delineated two phases of protocol review, the first phase is at the disease team/hospital level and the second stage is at the PRMC level. Though the first stage of review was happening before the most recent FOA, the formal documentation of this process is novel.

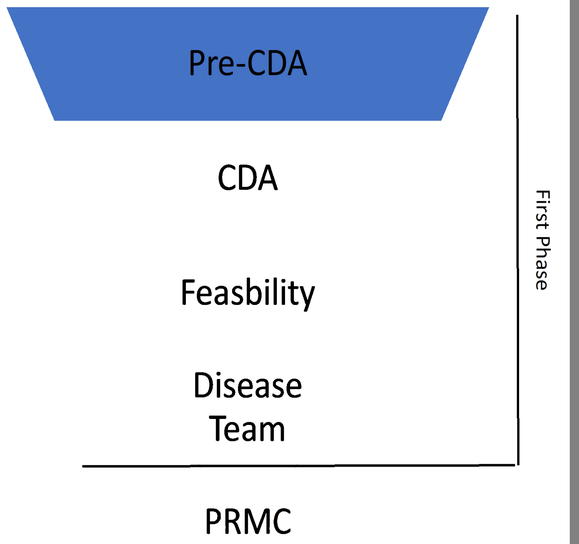
Cleveland Clinic implemented formal, first stage, disease-focused scientific review through a feasibility process with an approved Standard Operating Procedure (SOP) on October 15, 2009. University Hospitals implemented formal, first stage disease-focused scientific review through a feasibility process with an approved Standard Operating Procedure (SOP) on January 8, 2018.

Feasibility

The lead, non-clinical research coordinator (RC) distributes the protocol and associated documents to the entire research team, inclusive of research nurses (RN) and non-licensed clinical coordinators (CRCs and CRAs), pharmacy personnel, additional non-clinical research coordinators (RC), all disease team physicians, and financial analysts, at least 2 weeks prior to the regular Disease Oriented Group (DOG) meeting in which first review will occur. At the DOG meeting the PI presents the trial and physicians each have time to comment on the scientific merit and viability of the trial. In addition, all team members have time and are expected to discuss any issues discovered. The Program Leader then has authority to approve or deny opening the clinical trial. Implemented in 2019, team members are expected to have identified the issues, reported them to the lead RCs and developed solutions as appropriate before the meeting. The meeting then consists of discussion about both issues and solutions and decisions on whether it is feasible or not to open the study. Many of the teams have implemented PowerPoint presentations of the potential trials to support the discussion of feasibility.

Phase 1 Review

Figure 1. This depicts a graphical representation of the phase 1 review process. This shows how the largest number of studies are rejected prior to PRMC review.



Pre-CDA and CDA Process

During regular disease team research meetings, all MDs present are asked to recount how many trials they personally rejected sine the last meeting (meetings are typically every 2 weeks). These are trials that based on the title or concept alone, the MDs have no interest in learning more about. Results are tallied and recorded in meeting minutes.
Brief email surveys are also periodically asked of the program leaders to confirm the % of trials rejected pre-CDA across their disease team.

If an MD is interested in pursuing a CDA and receiving a protocol, they will ask the research contract analyst to process the CDA. The contract analyst meticulously tracks these details for every disease team. Information such as PI, sponsor and dates of processing are entered onto a spreadsheet and are tracked at the research disease team level and at a macro level.

Data for 2020

Table 1. 2020 up-to-date rejection rates for each disease team at one of our consortium partners. The highest rejection rate is at the disease team

DOG	MD rejection pre-CDA	Rejection at Disease Team	Rejection at Feasibility
Brain	0%	36%	0%
Breast	0%	0%	0%
GI	11%	0%	0%
GU	17%	0%	0%
GYN	0%	20%	10%
H&N	0%	25%	0%
Heme	4%	20%	0%
Melanoma	0%	25%	0%
Peds	0%	0%	0%
Sarcoma	0%	0%	0%
Phase 1	0%	13%	0%
Thoracic	4%	18%	0%
Average	3%	13%	>1%

Table 2. 2020 up-to-date rejection rates for each disease team at one of our consortium partners. The highest rejection rate is at the CDA review by the investigating physicians.

DOG	MD rejection pre-CDA	MD rejection at CDA	Rejection at Feasibility
Phase 1	7%	10%	0%
GI	20%	13%	33%
Lung	33%	20%	0%
Breast	10%	17%	0%
RadOnc	10%	0%	0%
Melanoma	10%	0%	0%
GU	45%	60%	0%
H&N	55%	100%	0%
Phase 1	7%	10%	0%
GI	20%	13%	33%
Lung	33%	20%	0%
Breast	10%	17%	0%
BMT	45%	0%	0%
Lymphoma	62%	50%	0%
Leukemia	40%	11%	21%
MM	50%	25%	0%
Benign Heme	30%	0%	0%
BTI	10%	28%	0%
Average	31%	24%	4%

Disease Team Sign Off

In order to promote collaboration within the consortium, communication between each hospitals' disease team is required prior to PRMC study submission. Lead hospital disease team sends protocols to the non-lead hospital to see if they have interest in participating in the study. For sponsored studies, the study team explains our consortium to the sponsor and ask if both hospitals can participate on the study. For IIT studies, opportunity for both hospitals to participate is discussed between the disease team and Cancer Center leadership.
For National Group studies each hospital communicates to the other side that they are participating in the study and the study can be found on the CTSU.org website.

Conclusions

- **Capturing phase 1 reviews of protocols can be completed using existing hospital SOPS.**
- **Best practices are shared amongst consortium partners even though the structures and reviews are not identical.**
- **Documenting all levels of review, Pre-CDA, CDA, Disease Team, and Feasibility allows for specific data points to fulfill reporting requirements.**