Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Managing Study Amendments – Piloting a Centralized Approach

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1. Background
Increasing volumes of amendments & staffing constraints highlighted the opportunity to pilot a centralized approach at the Fred Hutch/University of Washington/Seattle Children's Cancer Consortium

2. Goals
Establish a Centralized Amendments Team to facilitate amendment triage, implementation, billing grid review, budget & contract negotiations on behalf of a pilot of four research groups within the Cancer Consortium. The team closely partners with regulatory, nurses, operations specialists, and post-award staff to ensure timely and accurate amendment implementation both at the institution and institutional review boards (IRBs) of record.

3. Solutions and Methods
The team established workflows rapidly in response to growing volumes.

- The workflow includes a Triage process which assesses the changes and determines the appropriate processing pathway including 1) Full Submission 2) Orders Only 3) Regulatory Only 4) CTMS Correction 5) Budget/Contract Only. Identifying a specific pathway allows for targeted workflow management tailored to each pathway.
- Smart Sheet (a leading project management platform) is being actively leveraged to establish a formal project management framework for trial tracking.
- Dashboard views accessible to research group managers and post-award financial personnel enabled real-time progress tracking and an overview of overall portfolio statuses.
- Integration between regulatory and budget team views, permitting visibility and cohesion of timelines running in parallel
- Twice weekly internal team meetings to ensure timely progression of amendment and discuss any identified issues.
- Weekly meetings with central regulatory partners for cohesiveness, project clarity, and discussion of time-sensitive IRB submission requirements
- Weekly meetings with site study teams to enhance transparency and continuity of portfolio statuses.

4. Outcomes

- Transitioning to a centralized team dedicated to amendment processing enabled high-volume, timely processing, close collaboration with clinical trial offices, clinic personnel, regulatory and contracting entities
- Smartsheet trial tracking tremendously enhanced early visibility and handoff of amendment packages to the Central Amendments team from Regulatory partners. Live dashboard view for site disease group managers greatly improved transparency of status.
- Help inform Institutional optimization of the 2-step budget & calendar release process for billing compliance.
- Billing compliance improvements as protocols were brought up to centralized team standards and workflows.

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5. Lessons Learned and Future Directions

Lessons Learned:

- Essential to build a budget team with cross functional skills and ability to interpret complex protocols while ensuring open & clear communication with clinic, regulatory, and contracting entity partners.
- Development of relationships with institutional partners as a new centralized team requires openness to collaboration as well as clear communication of expectations
- Improvement of processing speed of amendments requires detailed workflow and process delineation.
- Challenging to balance depth of review for aging trials compared to volume bottleneck with limited staff. Opportunities present to further develop scope and partnering expectations for team with non-central post-award staff as workload and bandwidth increases.

Future directions:

- Expansion to support additional study teams
- Integration with new financials working group to improve workflows upstream in pre-award and with post award.