Managing Study Amendments – Piloting a Centralized Approach

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Background

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

Goals

Our primary goal was to 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 IRBs of record.

Solutions & Methods

The initial scope for the team was limited to post-activation clinical trials—both industry-sponsored and non-industry, with limited exceptions. Dedicated Centralized Startup resources continue to support protocol amendments received during study startup. In response to increasing trial volumes, the team quickly established and adapted workflows to meet operational demands efficiently.

Smart Sheet was leveraged to establish a formal project management framework for trial tracking

- Live dashboard views accessible to research group managers and post-award financial personnel enabled real-time progress tracking.
- Integration between regulatory and budget team views, permitting visibility and cohesion of timelines running in parallel
- The central team meets weekly/bi-weekly with the participating research managers to review the dashboards

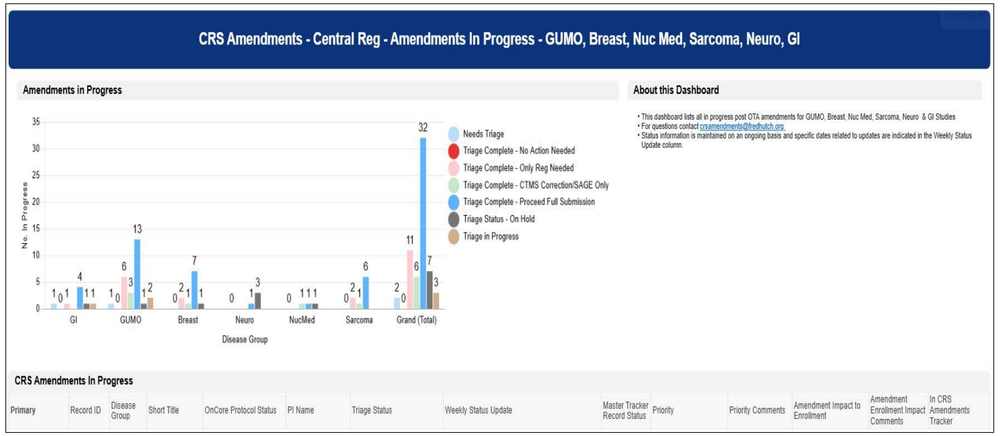

Figure 1. Smartsheet Dashboard

Intake & Triage

Central Regulatory Teams receive document package and prepare to submit for triage.

Documents are uploaded using SmartSheet and assigned a unique amendment identifier.

Regulatory routes to Central Amendments Team for triage & initial impact assessment. Triage helps determine timing of IRB submission.

Team aims to triage within three days of receipt. Partnering study teams & Regulatory staff are sent final triage outcomes and plan for next steps.

Study Team Partnerships

Research managers, Investigators, and Post-award staff provide collaborative approval & insight at the following steps:

- Coverage Analysis
- Draft Budget/CTA preparation
- Final Budget/CTA following negotiations facilitated by central team
- Orders review and validation following IRB approval

Processing

- The Amendments Team utilizes REDCap surveys to communicate amendment impacts to Clinical Trial Offices and Clinical Teams, with submissions targeted within three days of triage pathway determination.
- Impacts on vendor services (e.g., specimen processing labs) are communicated to study teams to coordinate necessary revisions .
- Each amendment then progresses through a dedicated OnCore task list, ensuring integration and collaboration with Clinical Trial Offices, study teams, and Clinical Teams for billing grid and order review.
- Following MCA finalization, team circles back to regulatory partners to ensure ICF language harmonization and pertinent regulatory requirements are accounted for.
- Budget & Contract revisions facilitated by central budget operations specialists through execution.

Status Meetings

- Twice weekly internal team meetings to ensure timely progression of amendment and discuss any identified issues.
- Weekly meetings with central regulatory partners for coherence, project clarity, and discussion of time-sensitive IRB submission requirements.

Outcomes

- The transition to a centralized team enabled high-volume, timely processing and fostered close collaboration with clinical trial offices, clinic personnel, regulatory partners, and contracting entities.
- Smartsheet trial tracking 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 statuses.
- Billing compliance improvements as protocols were brought up to centralized team standards and workflows.
- Help inform Institutional optimization of a 2-step budget & calendar release process for billing compliance.
- Expanded program to service two additional disease teams in early 2025.

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 teams with non-central post-award staff as workload and bandwidth continues to scale.