From Fragmentation to Flow: Utilizing Smartsheet® for Effective Investigator-Initiated Trial Management

Anschutz | Cancer Center

OVERVIEW

The Oncology Clinical Research Support Team (OCRST) serves as central resource for Investigator Initiated Trial (IIT) support for CU Cancer Center members. Services provided include regulatory support, project management, data monitoring, and financial management.

BACKGROUND

Centralized tracking needed in a remote environment

GOALS

- Reduce emails and meetings, and existing fragmentation in documentation
- Enable real-time portfolio visibility

SOLUTIONS

- Intake/master Smartsheet for all IITs with lifecycle task and timeline tracking
- Dashboards for team and leadership
- Automated data pulls from Clinical Trial Management System

OUTCOMES

- Extraneous weekly IIT meetings eliminated
- Improved Principal Investigator activation timelines
- Real-time operational and financial insight
- Streamlined quality assurance and workload planning

LESSONS & NEXT STEPS

- Expanded sponsor and finance tracking
- IIT incubator for emerging concepts
- Metadata initiative to reduce manual entry

KEY STAFF

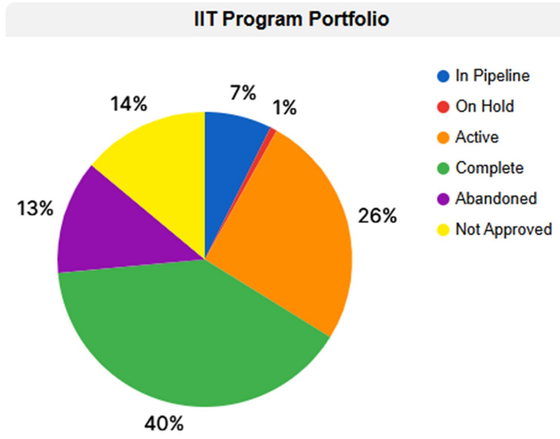

Tiffany Cull, Regulatory Affairs Manager

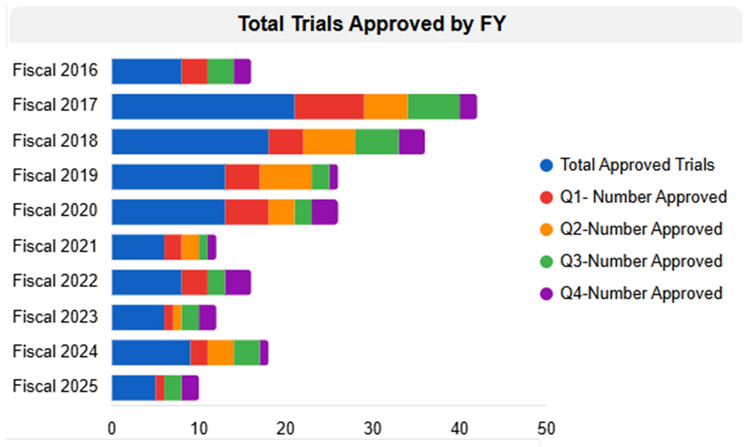

Tessa Drumm, IIT Program Director


Jessica Figura, Business Services Principal Professional


Stephanie Hill, Clinical Research Monitoring Manager

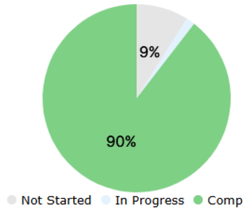

Anne Martin, Clinical Research Project Manager





Study Summary	
Title	
COMIRB	

Key Contacts
Regulatory
Monitor
Project Coordinator
Finance



Accrual Timeline	
03/06/25	OTA
09/26/25	LPLV Date
Projected Accrual	
Total Accrual	
IND/IDE?	

Milestone Dates	
Protocol Planning Mtg	02/01/24
Protocol Finalized	08/26/24
OTA Email Sent	03/06/25
Final Budget Approved	11/14/24
Contract with Sponsor fully executed	02/18/25
OnCore Build Complete	03/06/25
Database moved to Production	02/05/25
SIV Date	02/07/25
Database lock complete	
LPLV Expected Date	09/26/25

Duration of Task (Days)	
Protocol received from PI to Protocol finalized	178
PRMS Submission to Approval	17
COMIRB Submission to Approval	8
Open to accrual	316
Contract execution	81
Database development	57
Protocol Finalized to First FDA Submission	30
Protocol Finalized to PRMS Submission	47
Protocol finalized to COMIRB Approval	83

Individual Study Sheet	Amendment Sheet	All Study Sheet List	Clinical Trial Tracker	Clinical Trials Portfolio Dashboard

Average Trial Timelines (50 of 124 Trials)

Sheet Name	Protocol received from PI to Protocol finalized	Protocol Finalized to PRMS Submission	Contract w/ funding sponsor	Protocol Finalized to OTA Email Sent	OTA to LPLV	Close-out (LPLV to IRB Closure)
Total (Days)	Avg 93.57778	Avg 23.37778	Avg 99.41667	Avg 195.0625	Avg 1065.22222	Avg 681.81818

KEY TAKEAWAY: A unified Smartsheet® framework transformed IIT oversight into a transparent, scalable, and data-driven operation.