Category: Investigator Initiated Trials – Completed Project

Investigator Initiated Trials in the Wild Wild West: Implementation of the Oncology Clinical Research Support Team at the University of Colorado Cancer Center

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1. Background

Investigator Initiated trial accruals lagged below targets for the CU Cancer Center and were a critique from NCI during CCSG site visit. The clinical trial office(s) did not have expertise to assist PIs in developing protocols and supporting FDA submissions. In order to improve chances of success for IITs, a central support office (Oncology Clinical Research Support Team – OCRST) was established in 2015 to provide regulatory expertise, clinical project coordination, and data monitoring for interventional investigator-initiated trials.

2. Goals

Goals of the central office included:

- Increase IIT accruals for CCSG competitive renewal
- Reduce burden to clinical trials office in managing FDA submissions and project coordination
- Develop infrastructure necessary to conduct high quality investigations including provision of clinical data monitoring

3. Solutions and Methods

IIT Incubator meeting was established to foster peer feedback for trial design and provide preliminary feedback to guide development and recommend additional preclinical studies needed. Once a concept is developed further, projects were submitted to the IIT Review Committee for approval of staff and/or funding support. Projects approved by the IIT Review Committee were provided with an OCRST project team with expertise in protocol development, regulatory, clinical project management, and clinical data monitoring. OCRST developed protocol templates and instructions for interventional- drug, non-drug interventional and chart review projects. Multicenter research project support was developed including a process to assess site qualifications and provide multicenter coordination. The OCRST project team developed electronic case report forms using templates that can be customized for each study. Procedures were established to ensure study conduct and data quality by hiring clinical data monitors to validate data throughout the study. In addition, SOPs and guidance documents were been developed to support regulatory and operational management of all IITs.

4. Outcomes

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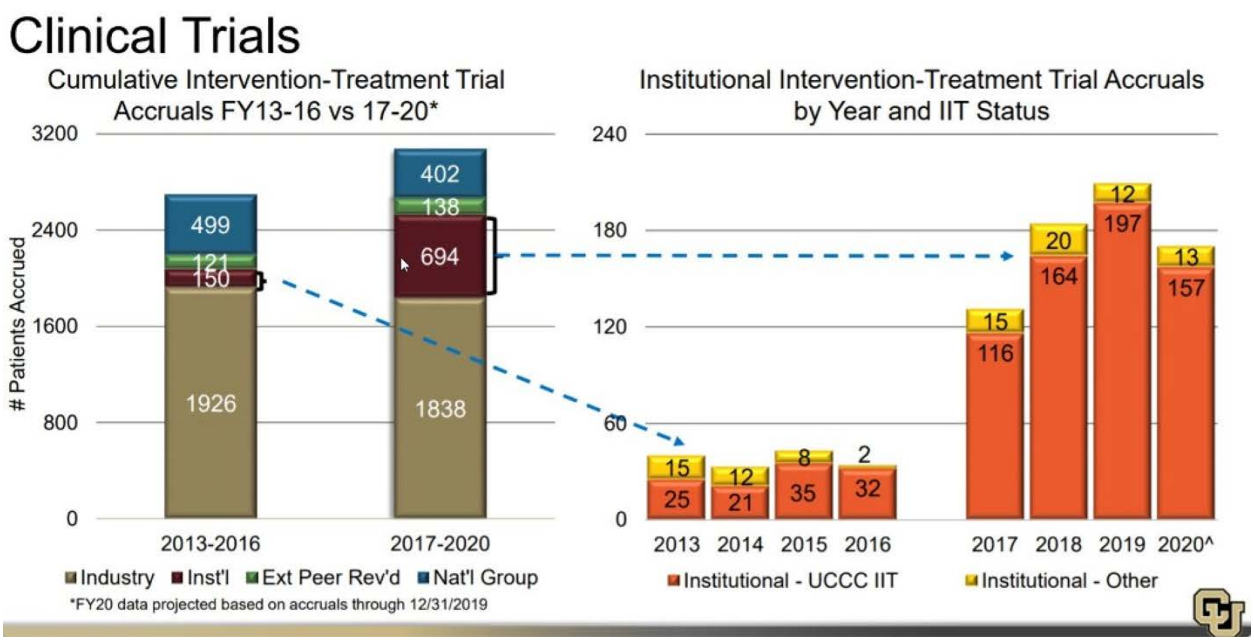

- IIT Interventional treatment trial accruals increased from 21 in FY2014 to 197 in FY2019.
- The number of IITs open to accrual has increased each year since OCRST was established. In 2016, 5 trials were opened to accrual, 10 in 2017, 14 in 2018 and 10 in 2019, with the OCRST currently managing over 30 active interventional IITs, 10 of which required INDs and 13 multisite trials
- SOP and guidance documents (n=13) for unique work of coordinating IITs, including multicenter IIT coordination and conduct. This is part of larger effort to establish SOPs governing all oncology research (N=34)
- Fee schedule for IITs that secure external funding support
- Current IIT staff include 14 FTEs (3 Managers, 2 Clinical Project Coordinators, 4 Regulatory Affairs Coordinators, 5 Clinical Research Monitors)

5. Lessons Learned

- Volume and complexity of projects much higher than was first envisioned
- IIT prioritization scoring being implemented to align approval with CC strategic plan
- Monitoring is largest resource requested/needed to ensure quality study conduct and data entry; work underway to implement risk based/targeted monitoring approach
- Protocols undergo a high number of amendments; in response, OCRST is developing a protocol review checklist to include items that may get missed in initial review processes to minimize future amendments
- Implement ForteEDC and electronic regulatory binder solution to improve efficiency and provide tools to streamline tasks