



# INVESTIGATOR INITIATED TRIALS IN THE WILD, WILD WEST:

## Implementation of the Oncology Clinical Research Support Team at the University of Colorado Cancer Center

### ONCOLOGY CLINICAL RESEARCH SUPPORT TEAM (OCRST)

The Oncology Clinical Research Support Team (OCRST) serves as a central resource for CU Cancer Center Consortium members.

The resources and services provided are aimed at supporting clinical research across the CU Cancer Center research enterprise.

Areas of expertise include: Investigator Initiated Trial (IIT) development and support, data quality and reporting, education and training, NCTN/LAPS trial support and Oncology Research Information Exchange Network (ORIEN).

### FUNDING: LEVERAGING UCCC INVESTMENT

\$17.5M Total

\$0.9M Cancer League

\$5.7M Investigator-Controlled Funds

\$10.9M Industry Funding

\$4.6M UCCC Investment

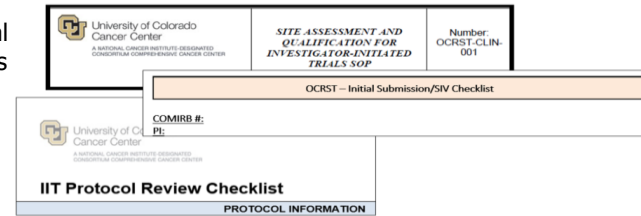
**BACKGROUND:** Investigator Initiated Trial (IIT) accruals lagged below targets for the CU Cancer Center and were a critique from NCI during CCSG site visit. In order to improve chances of success for IITs, a central support office (Oncology Clinical Research Support Team – OCRST) was established in 2015 to provide regulatory expertise, clinical project coordination, and data monitoring for interventional IITs.

**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

**METHODS:**

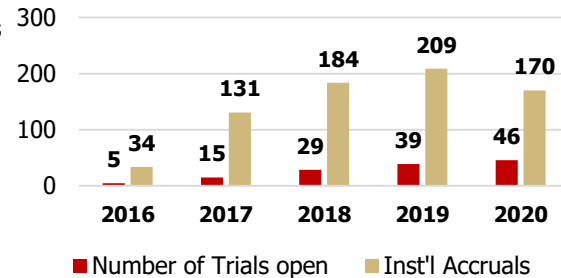
- Establish IIT Incubator and IIT Feasibility Review/Approval
- OCRST team of regulatory, clinical and monitoring experts
- IIT specific protocol templates
- Multicenter project assessment
- Case Report Form development
- Clinical monitoring
- SOP and Guidance document development



**RESULTS/CONCLUSIONS:**

- Accruals to IITs increased by 6x since 2016
- Increase number of active trials from 5 in 2016 to 46 in 2020
- >30 active interventional IITs; 10 with INDs; 13 multisite trials
- Implemented IIT specific SOPs and Guidance documents
- Increased OCRST dedicated resources from 6 FTEs in 2016 to 14 FTEs in 2020
- Implemented fee schedule to secure revenue on externally funded projects for OCRST services
- Leveraged UCCC funding support paired with industry and philanthropy to support IITs
- Conducted 161 monitoring visits in CY2019

### IIT Trials Open and Accruals FY16-20 (projected)



**FUTURE DIRECTIONS/LESSONS LEARNED**

- Volume and complexity of projects much higher than was first envisioned, multiple amendments
- IIT scoring being implemented to align approval with CC strategic plan
- Monitoring team underway to implement risk based/targeted monitoring approach for most requested resources
- OCRST developed tools and processes to minimize amendments, enhance protocol review, interim/safety analysis, and study closeout
- Implement electronic solutions to improve efficiency (ECRF, e-regulatory platform)

### Investigator-Initiated Trials Review Process

