

Cancer Trials Support Unit (CTSU) Contract Renewal Proposal

*Board of Scientific Advisors
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Cancer Trials Support Unit (CTSU)

The CTSU is a service of the National Cancer Institute (NCI) that supports clinical trial management and conduct. The CTSU provides services to NCI-sponsored programs such as the National Clinical Trials Network (NCTN), the Experimental Therapeutics Clinical Trials Network (ETCTN), and the NCI Community Oncology Research Program (NCORP), and other Multi-Center Organizations.

- CTSU use across clinical trials steadily increased since the start of the program
- ~87% of actively enrolling treatment trials utilize CTSU services
- Greater than 95% of newly activated (2017, 2018) treatment trials utilize CTSU services

CTSU Objectives

- Provide centralized operational support activities for NCI Clinical Trials conducted by the NCTN, ETCTN, NCORP, and other Multi-Center Organizations
- Facilitate investigator/research staff participation in NCI multi-center programs/clinical trials
- Increase investigator and patient awareness and enrollment
- Provide standardized, integrated, and comprehensive support services
- Identify best practices and streamline or eliminate redundant processes
- Improve operational efficiency, enhance productivity and deliver products offering measurable business value

CTSU Background

- Established in 1999 to streamline and harmonize support services for Phase III Cooperative Group cancer clinical trials funded by the NCI
- Scope has expanded to include support of multiple NCI-funded networks and clinical trials of all phases and types:
 - cancer treatment
 - prevention and control
 - advanced imaging
 - correlative science studies
- IOM report and follow-up workshops cited CTSU as a mechanism to reduce duplication and assure consistency in Group (NCTN) processes

CTSU Scope

- 24/7 Operational support for the entire lifecycle of a clinical trial
- Supports an NCI Grant portfolio with a combined FY 2019 funding level of ~\$343M/Year
 - CTSU ~\$23M/year budget represents 5-6% of the Grant portfolio budget

Recent analysis of average cost of PHARMA-led oncology clinical trials:

Phase	Cost per Study	# of CTSU supported trials
Phase 1	\$4.5M per study	74 (Phase 0, 1, 1/2)
Phase 2	\$11.2M per study	200 (Phase 2)
Phase 3	\$22.1M per study	298 (Phase 2/3, 3)

Reference: Sertkaya, A., Wong, H.-H., Jessup, A., & Beleche, T. (2016). Key cost drivers of pharmaceutical clinical trials in the United States. *Clinical Trials*, 13(2), 117–126. <https://doi.org/10.1177/1740774515625964>

CTSU's Integral Role in Support for NCI's Clinical Trials Network Programs

Pre-enrollment/Local Site Study Set-up

IRB Approval/Site activation

CTSU Regulatory Support System:

- Integration with NCI Central IRB

Access to protocol/study documents

CTSU Website

- Uniform document posting (single document used by Groups, Sites, NCI, Central IRB)

Electronic Medical Record (EMR) Build

CTSU Website

- EMR "Cheat Sheet" prepared by CTSU

Billable Procedures Determination

CTSU Website:

- National Coverage Analysis documents prepared by CTSU

Site staff ready to initiate the study.



Protocol Activated by Lead organization.

Ready for enrollment

Subject Enrollment

Streamlined process with multiple checks to ensure GCP compliance



Oncology Patient Enrollment Network (OPEN)

Subject ready to enroll.



Study Eligibility Confirmed

Treatment Assignment/ Randomization

IRB Approval Confirmed

Protocol Specific Requirements met

Investigator Registration (1572) Confirmed

Subject Enrolled

Study Conduct/Monitoring



Clinical Data



Targeted
Source Data
Verification

Data Quality
Portal

Central
Monitoring

Source
Document
Portal

Performance
Assessment
Score for Sites

Multi-faceted Data Quality Support

Standardization:

- Clinical Data Management System (Rave)
- Core Rave configuration
- Selected Case Report Forms
- Reporting time frames

Access/Training:

- Investigator credentialing
- Site staff access roles
- Site staff training
- Auditor training

Science/Safety support:

- Harmonized Safety Reporting
- Link to bio-images
- Link to bio-specimens

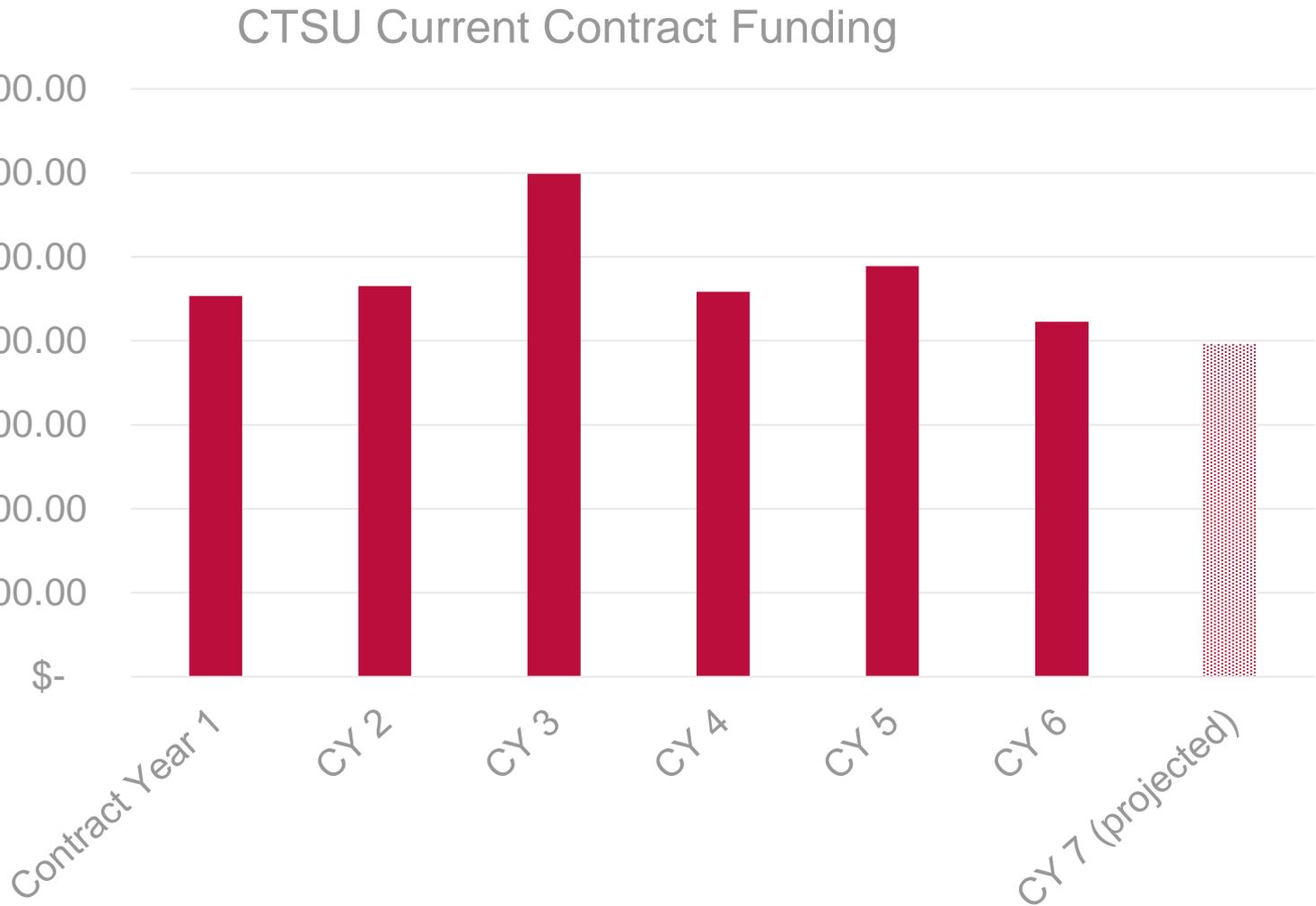
CTSU By the Numbers

Accruals via CTSU	40,451 Subjects (CY5) 180,565 Subjects (CY1-5)
Active, Unique Individuals Supported	21,348 Site Staff (Currently) 17,688 Investigators (Currently)
Average CTSU Website Logins/Month	85,548 (CY5)
Protocols Posted to the CTSU Website	587 (Currently)
Average IRB Approvals Processed/Month	21,391 (CY5)
Data Quality Portal (DQP) Data Warehouse	+150 million records (Currently)
Average Help Desk Inquiries Per Month	1,893 (CY5)
Studies using Targeted Source Data Verification (TSDV)	317 (Currently)
National Coverage Analysis	157 (Completed to Date)
NCI CIRB document postings	All studies

Accomplishments

- Supported transition to NCTN/NCORP/ETCTN
- CDMS (Rave) Integration across Networks
- Supported Precision Medicine trials
 - e.g., MATCH, Exceptional Responders, LUNG-MAP
- Implemented Biospecimen Navigator
- Safety Database Integration
- Implemented data standardization across Networks
- Supported increased regulatory compliance
 - Registration and Credential Repository (RCR)
 - Delegation of Tasks Log (DTL)
 - CDISC compliance
- Site support for Electronic Medical Record (EMR)/National Coverage Analysis (NCA)
 - ETCTN: 11 EMR builds/7 NCAs (project began in early 2018)
 - NCTN: 2 EMR builds/146 NCAs (EMR work deprioritized d/t budget constraints/competing priorities)

CTSU Current Contract Funding – decreasing over final years of contract



Moving Forward: Optimize Current Services and Integrations to Further Increase Efficiency

- Maintain and enhance/optimize operational, administrative, regulatory support of current Grant portfolios and new Grantees as identified
- Maintain and enhance/optimize integration activities/standardization
 - EMR/NCA
 - CDISC
 - Data Standards across Networks
- Leverage multiple contractors (vs. a single contractor/ “Jack of all trades”)
 - Divide contract service areas into smaller units
 - Flexibility to address new needs/regulations/requirements, emerging technologies, etc.
 - Increase Contract awardee pool
 - Current contract: 2 awardees, Future contract: 4-8 awardees
 - Benefits:
 - Increased competition
 - Utilization of experts without subcontracting costs
 - Ex. EMR builds

Budget for Contract Reissue

- Budget request for a 10 year Contract period
- Requested budget of \$23 million per year represents a small decrease over the average expenditure of current contract
 - Includes an allowance for COLA

Thank you.

Questions/Discussion



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