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DCTD CONCEPT REVIEW

Clinical Trials Monitoring Service (CTMS)

Contract Officer Representatives:

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Clinical Trials Monitoring Branch, CTEP, DCTD

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CTMS CONTRACT

- Competitive/Re-competition
- Level of Effort/Cost Plus Fixed Fee

Incumbent Contractor

Theradex® - HHSN261201700009C

- 10 year Contract (Base + 9 Option years) with a Start Date of 5/1/2022

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PURPOSE OF CTMS

- Provides infrastructure and core services for data management, quality assurance, and monitoring for the ETCTN and other early phase clinical trials, including limited support of the NCTN, and other projects
- Ensures protection of human subjects, collection of high quality clinical data, and compliance with HHS, NCI, FDA and Good Clinical Practice (GCP) requirements

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CTMS RESPONSIBILITIES

Task I

To provide a centralized patient registration system, protocol patient data capture resource using Medidata Rave, and a systematic process for data quality control reviews for ETCTN studies and other early phase clinical trials. Provides coordination of a Data Safety Monitoring Board for randomized ETCTN studies. Display of key data items in Web Reporting for IDB Medical Officer review and oversight for all ETCTN and NCTN studies conducted under CTEP held IND.

Task II

Provides on-site auditing to assure clinical investigations are conducted in compliance with federal regulations, NIH/NCI policies, guidelines, and procedures and process for verification of data via source data review

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CTMS RESPONSIBILITIES

Task III

Co-site visitation of NCTN Network Group audits primarily focusing on sites with past performance issues

Task IV

Conducts audits at Cancer Centers and other institutions (non-NCTN) participating in DCTD sponsored clinical trials to assure that trials are in compliance with protocol and regulatory requirements and NIH/NCI policies and procedures

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EXPERIMENTAL THERAPEUTICS CLINICAL TRIALS NETWORK (ETCTN)

Lead Academic Organizations (LAOs)
Affiliated Organizations (AOs)
Experimental Drug Development Opportunities Program (EDDOP)

March 2020

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ACCOMPLISHMENTS FOR RECENT CONTRACT YEAR

Task 1

30 new studies built in Medidata Rave
47 new eCRFs were implemented
359 protocol amendments were processed

1,148
Patients enrolled

Task 2

59 Annual Site Visits conducted
68 Data Audits conducted

1,070
Patient Cases reviewed

Add'l Audits

19 COG Phase 1 Consortium visits conducted
39 Cancer Center Site Visits conducted

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ETCTN STUDIES BY PHASE (5/1/2017 – 6/1/2020)

Phase	Number of Studies
Phase 1, Pilot, Other	40
Phase 1-2	8
Phase 2	24
Randomized Phase 2	8

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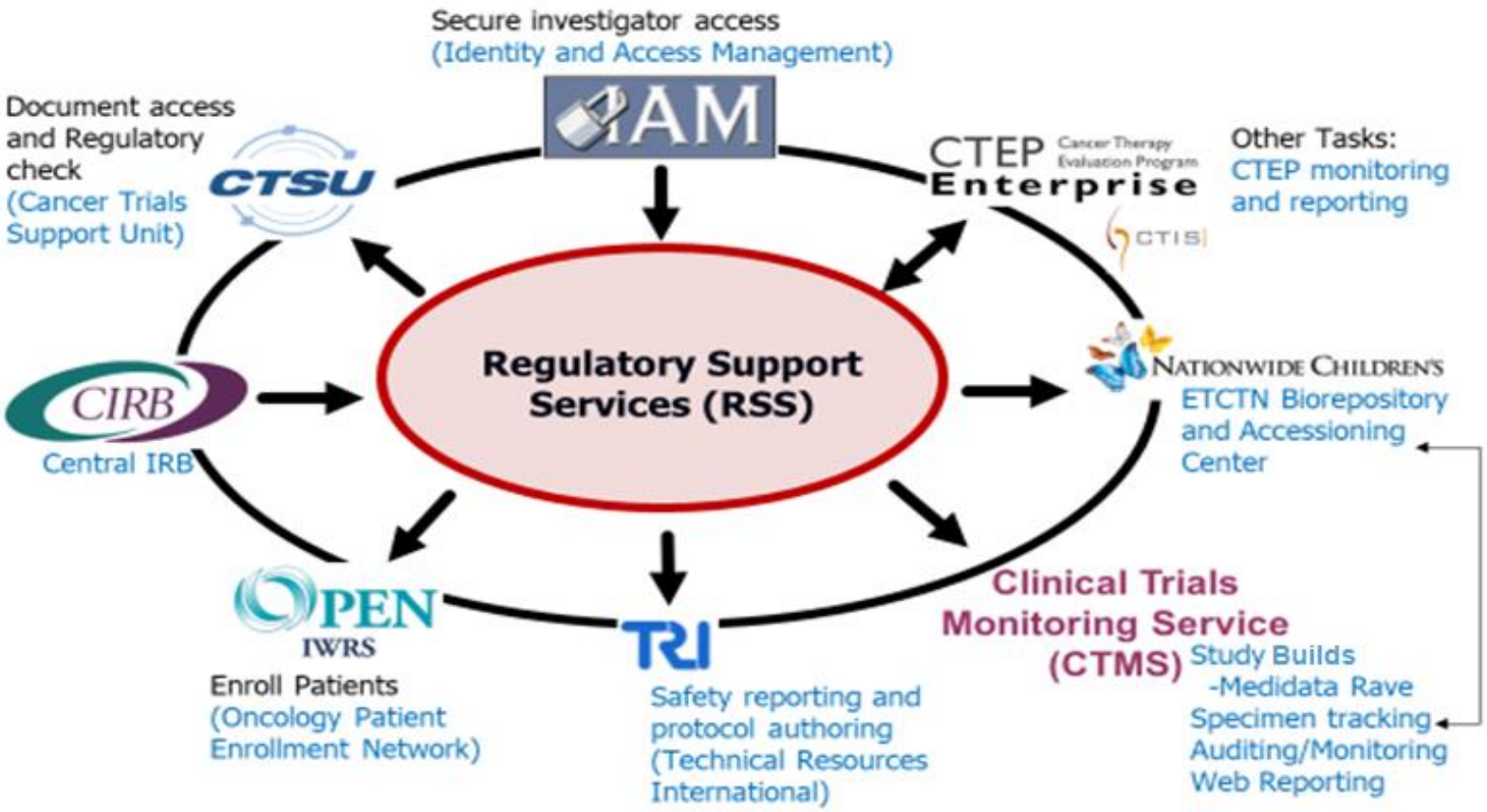
ETCTN CENTRAL INFRASTRUCTURE SUPPORT



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ETCTN CENTRAL INFRASTRUCTURE SUPPORT (CONT.)

- Most of the infrastructure is provided by and/or shared with ETCTN and other NCI consortia
- IT infrastructure specifically provided through the CTMS contract

Customization of Commercial Off-The-Shelf (COTS) products:

Data Management

- Rave
- Standardized Rave custom case report forms and functions have been developed

Trial monitoring and oversight

- Izenda a business intelligence tool
- Web Reporting – Clinical data dashboard provided via custom reports and graphics

- Custom functions, sample CRFs, reports and graphics will be shared with potential offerors to promote competition and ease contract transition

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WEB REPORTING OVERVIEW

Enables efficient and compliant Data Review by Medical Monitors and Primary Site Investigators by providing:

- Interactive, Graphical Data Visualizations with Drill-Down to more details
- Cross-study Safety Signal Reports
- Reminders of review due dates
- Online Safety Review Forms where user provides findings and recommendations
- Secure Audit Trail of Review History

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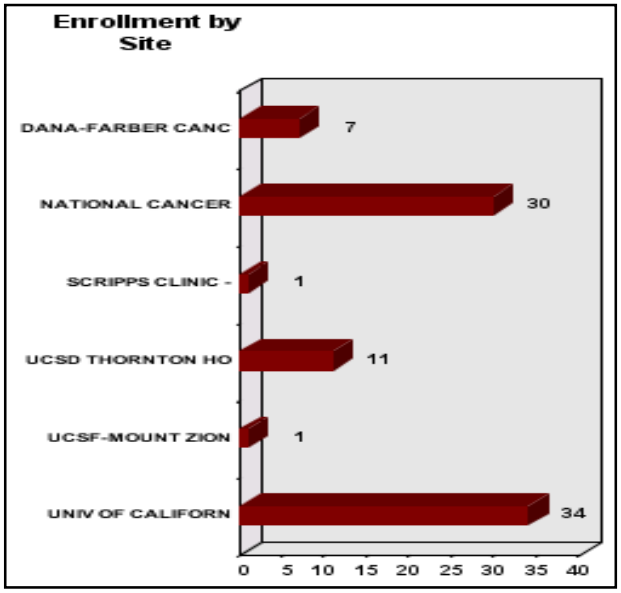
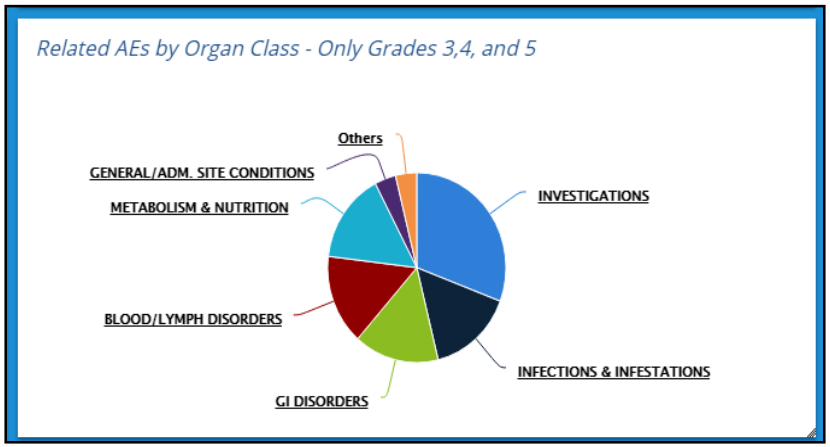
WEB REPORTING IMPLEMENTED

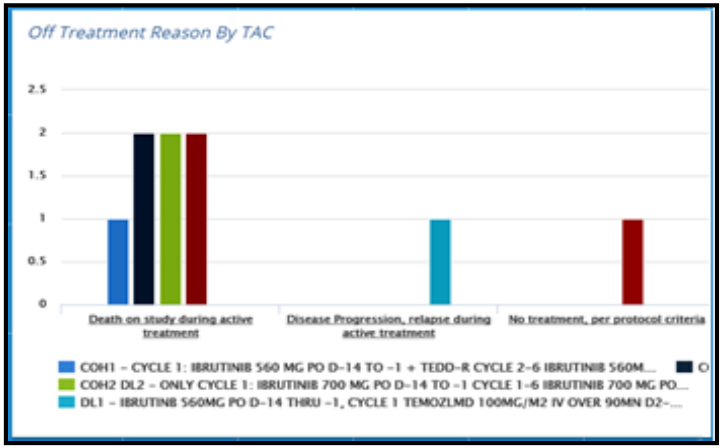
Examples of Summary Data:



Compliance Overall for a Protocol
Protocol: 5582

	Value	Percent
Number of Patients	51	
Number of Courses	101	
Investigator Eligible Patients	50	98.0%
Investigator Ineligible Patients	1	2.0%
Monitor Eligible Patients	49	96.1%
Monitor Ineligible Patients	2	3.9%
Monitor Missing Info	0	0.0%
Courses Evaluable	96	95.0%
Courses Complete	85	84.2%
Courses with Dose Modifications	47	46.5%
Courses with Significant Toxicities	70	69.3%
Average Lab Delay (Days)	69	
Labs Completed per Protocol	9644	81.3%





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OTHER SIGNIFICANT ACCOMPLISHMENTS

January 2020

- Data Mapping Utility launched – NCTN studies under CTEP IND adverse event data to be displayed in Web Reporting system

March 2020

- Rollout of eCRFs deployed to be compliant with CDASH (Clinical Data acquisition Standards Harmonization)

Currently On-going

- Modernizing tool for replacing current Annual Report to FDA with Data Safety Update Report
- Implementation of the DSMB for ETCTN studies
- Implementation of the Moonshot Biobank project
- COVID-19 Studies (NCCAPS, TRC-10446)

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CONTRACT OPTIONS

To be exercised as needed:

- Option C: Funding to conduct up to 3 Good Manufacturing Practice audits per year
- Option D: Funding to conduct up to 5 Good Laboratory Practice audits per year
- Option E: Funding for Major IT to support any immediate needs related to specific regulatory, legislative or IT system change
- Option F: Implementation of an electronic informed consent

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CONTRACT BUDGET
(1 Year Base + 9 Option Years)

	Phase-in	Base Work	Phase-Out	Contract TOTAL
Contract Year 1 Base	$524,087	$7,584,956	$0	$8,109,043
Contract Year 2 Option Year 1	$0	$7,812,505	$0	$7,812,505
Contract Year 3 Option Year 2	$0	$8,046,881	$0	$8,046,881
Contract Year 4 Option Year 3	$0	$8,288,288	$0	$8,288,288
Contract Year 5 Option Year 4	$0	$8,536,937	$0	$8,536,937
Contract Year 6 Option Year 5	$0	$8,793,046	$0	$8,793,046
Contract Year 7 Option Year 6	$0	$9,056,838	$0	$9,056,838
Contract Year 8 Option Year 7	$0	$9,328,544	$0	$9,328,544
Contract Year 9 Option Year 8	$0	$9,608,401	$0	$9,608,401
Contract Year 10 Option Year 9	$0	$9,896,654	$0	$9,896,654
Phase-Out	$0	$0	$1,365,460	$1,365,460
Total	**$524,087**	**$86,953,050**	**$1,365,460**	**$88,842,598**

Note: Phase-In only applicable if not incumbent

Note: Phase-Out only applicable if new awardee

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COST COMPARISON TO INDUSTRY SPONSORED ONCOLOGY TRIALS

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

Phase	Cost Per Study
Phase 1	$4.5M
Phase 2	$11.2M

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