

BSA CONCEPT REVIEW

Drug Development Support for the Cancer Therapy Evaluation Program

Contract Officer Representative

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BSA CONCEPT REVIEW

Contract Type

Competitive/Re-competition
Level of Effort/Cost Plus Fixed Fee
Research and Development Support

Incumbent Contractor

Technical Resources Intl, Inc. -
HHSN261201500006C

10 year Contract (Base + 9 Option years)

Start Date: 7/01/2022

Purpose of Drug Development Support Contract

- 1. Support CTEP in fulfilling FDA Regulations for Investigational New Drug (IND) Applications and CDRH submissions**
- 2. Triage Expedited Safety Reports and Draft FDA Safety Submissions, Maintain an Adverse Event Help Desk for Clinical Sites and Collaborators**
- 3. Support for the Investigational Drug Branch with the Study Solicitation/LOI review process, Draft Protocol Templates and Biomarker Review Committee**
- 4. Support of Collaborator Interactions including Protocol Review Requests, Publication Routing and forwarding IND documentation**

Drug Development Support Contract

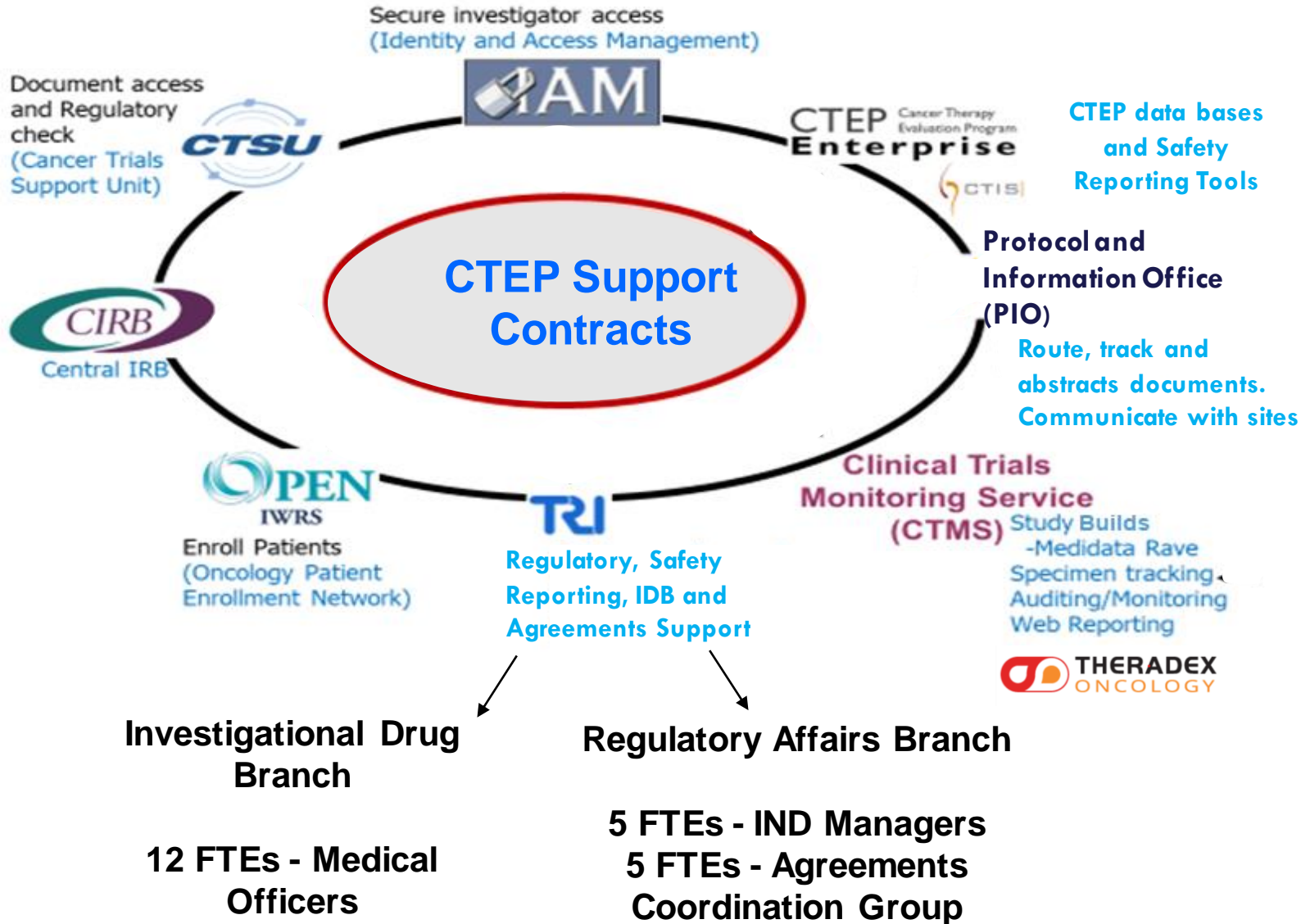
Select FY 2020 Funding Accomplishments

- **Support 190+ INDs, 391 protocols, file 27 new INDs and prepare and submit over 1700 electronic IND submissions**
 - **Precision Medicine Master Protocols: Adult MATCH (35+ sub-protocols) and Pediatric MATCH (13 sub-protocols)**
 - **SPRINT Trial Support**
 - **FDA Inspection and EMA Review**
 - **Approval of selumetinib**

Select FY 2020 Funding Accomplishments

- **Address 14,204 Adverse Event Help Desk queries, process 5791 Adverse Event reports and over 300 Initial Written Reports (Expedited Safety Reports)**
- **Route review requests for 753 Publications to Industry Collaborators and forward all IND submissions**
- **Maintain 80+ Agent Comprehensive Adverse Events and Potential Risks (CAEPR) Lists**
- **Coordinate the review of protocol biomarkers via the Biomarker Review Committee**
- **Abstract and track responses for 184 Pre-solicitation LOIs/Project Team Applications**

CTEP Support Contracts



Funding

- **Fiscal Year 2020**
 - \$7.4 M
 - 190 INDs, 27 new INDs filed
- **Projected Fiscal Year 2022**
 - Projected Base of new contract \$8.68 M
 - Estimated 230 active INDs, 30 new INDs filed
 - 4+ Precision Medicine Master Protocols
 - Support for potential registration studies
 - Addressing evolving FDA guidance, regulations and data submission standards
 - Pharmaceutical Collaborator data requests

Precision Medicine Trial Support

- **AML/Myelodysplastic Syndromes (MDS) Basket Trial**
- **ComboMATCH**
- **ImmunoMATCH**

Each agent distributed by CTEP requires a Developmental Safety Update Report (DSUR) and CAEPR/Risk List

CDRH, FDA Risk Determination submissions for Integral Biomarkers

Abbreviated IDE laboratory monitoring visits

Contract Budget - IGCE

(1 Year Base + 9 Option Years)

	Phase-In	Base Work	Phase-Out	Contract TOTAL
Contract Year 1 (Base) (2022)	\$1,840,620	\$8,687,889	\$0	\$10,528,509
Contract Year 2 (Option Year 1)	\$0	\$8,948,526	\$0	\$8,948,526
Contract Year 3 (Option Year 2)	\$0	\$9,216,982	\$0	\$9,216,982
Contract Year 4 (Option Year 3)	\$0	\$9,493,492	\$0	\$9,493,492
Contract Year 5 (Option Year 4)	\$0	\$9,778,297	\$0	\$9,778,297
Contract Year 6 (Option Year 5)	\$0	\$10,071,646	\$0	\$10,071,646
Contract Year 7 (Option Year 6)	\$0	\$10,373,796	\$0	\$10,373,796
Contract Year 8 (Option Year 7)	\$0	\$10,685,010	\$0	\$10,685,010
Contract Year 9 (Option Year 8)	\$0	\$11,005,561	\$0	\$11,005,561
Contract Year 10 (Option Year 9)	\$0	\$11,335,728	\$0	\$11,335,728
Phase-Out	\$0	\$0	\$2,478,683	\$2,478,683
Total	\$1,840,620	\$99,596,927	\$2,478,683	\$103,916,230

INDUSTRY IND PREPARATION COSTS

Study of Non-Clinical Development Costs (2013 Tufts Center for the Study of Drug Development)

Activity	Average Cost (CoV, N of Projects)	Median (Min, Max)
CMC**	\$3.1M (1.0, 6)	\$2.7M (\$400K, \$8.9M)
Pharmacology	\$600K (1.0, 7)	\$400K (\$100K, \$2M)
Metabolism	\$500K (1.0, 5)	\$350K (\$10K, \$1.2M)
Pharmacokinetics	\$300K (1.0, 17)	\$200K (\$40K, \$1M)
Toxicology**	\$1.5M (0.9, 19)	\$1M (\$100K, \$6.5M)
IND Preparations	\$150K (0.9, 2)	\$150K (\$50K, \$250K)
Total Estimated Costs	\$6.2M	\$4.9M (\$700K, \$19.9M)

Note: Data gathered includes both rough estimates and actual data collected by original working group.

** Perceived to be the most expensive by respondents. CMC is most expensive followed by toxicology.

IND Preparations
\$196 K
(\$65 K, \$296 K)
Projected for 2022

Reference: https://www.contractpharma.com/issues/2013-06/view_features/characterizing-the-cost-of-non-clinical-development-activity/

COST COMPARISON TO INDUSTRY SPONSORED ONCOLOGY TRIALS

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

Phase	Cost Per Study
Phase 1	\$4.5 M
Phase 2	\$11.2 M
Phase 3	>\$22 M

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>