

Clinical Trials Information Management & Support (CTIMS) Contract Proposal

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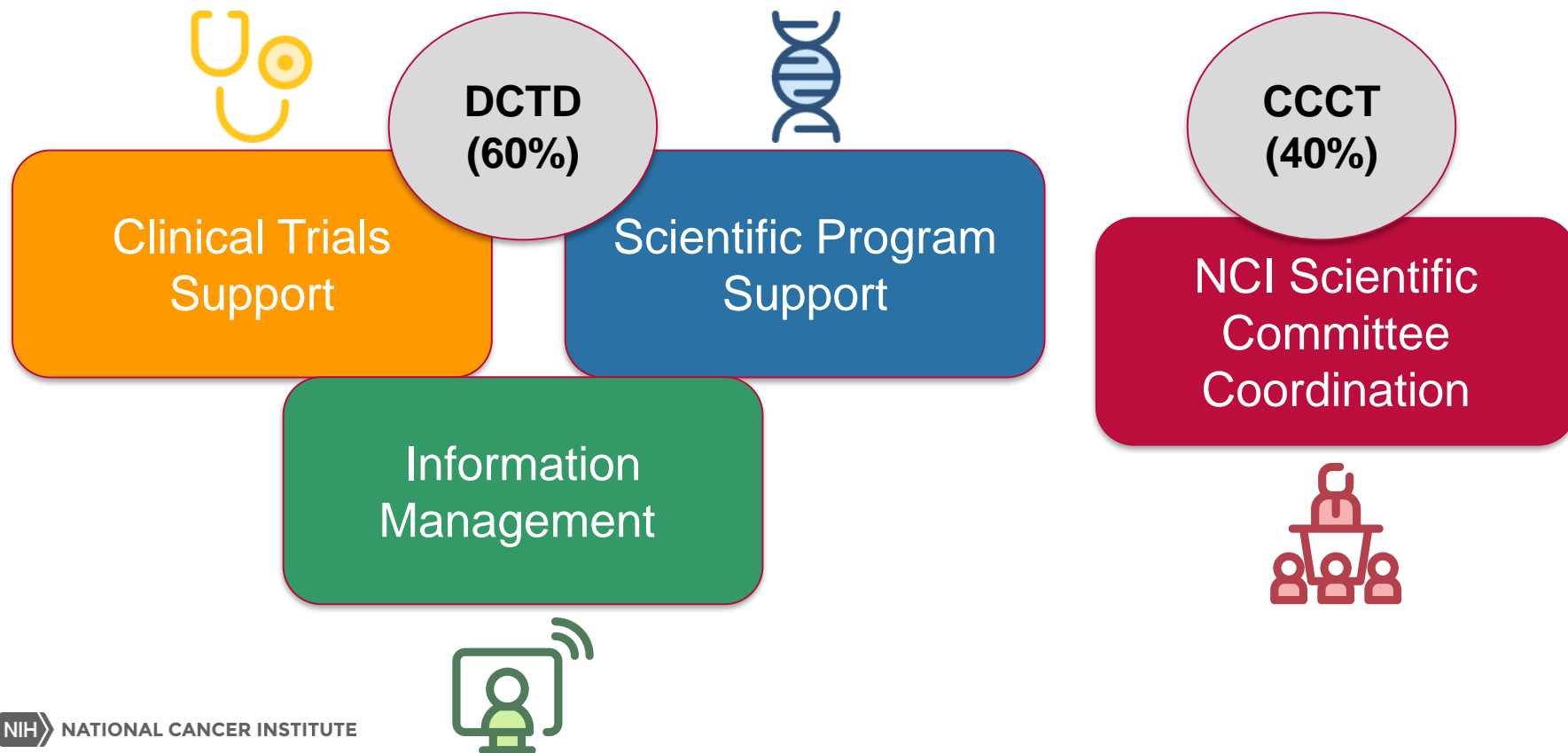
Contract Officer Representative (COR)
Clinical Investigations Branch (CIB)
Cancer Therapy Evaluation Program
(CTEP) Division of Cancer Treatment &
Diagnosis (DCTD)

Joint Meeting of the Board of Scientific Advisors &
National Cancer Advisory Board
June 10, 2019

CTIMS Contract: Scope and Objectives

- The scope of the CTIMS contract is to support:
 - Division of Cancer Treatment and Diagnosis (DCTD)
 - Coordinating Center for Clinical Trials (CCCT)
- The major objectives of this contract are to:
 - Provide project management (PM), organizational and information management support to NCI-sponsored clinical trials, related scientific programs, and their scientific evaluation process
- The intended outcomes of this contract are to facilitate efficient and effective development, review and completion of NCI-supported clinical trials, and related scientific projects

CTIMS Contract Major Areas of Focus



DCTD CTIMS Focus Area: Clinical Trials Support

Clinical Trials Support & PM

ETCTN

- Project Teams for Drug Development Plans arising from NExT
- Accrual Monitoring & Support



NCTN

- Precision Medicine Trials
- Adult & Pediatric MATCH
- Myeloid Neoplasms Effort
- Accrual Monitoring
- *ComboMATCH**
- *iMATCH**

PM: Project Management

ETCTN: Experimental Therapeutics Clinical Trials Network

NExT: NCI's Experimental Therapeutics Program

NCTN: National Clinical Trials Network

** Upcoming projects needing support*

How PMs Support New Clinical Trials Initiatives

- **Initiative to use project teams to involve extramural investigators in CTEP drug development planning:** PMs for 19 early-phase project teams lead to 78 Letters of Intent (LOIs)
- **Initiatives to increase ETCTN accrual in disease-specific clinics:**
 - Created & analyzed over 30 surveys to ETCTN investigators to assess accrual feasibility
 - Develop and maintain web-based tools for physicians to identify appropriate disease-specific trials
 - These initiatives contributed to a **100% increase in ETCTN trial accrual** over 2 years
- **Active management of clinical trial accrual:**
 - Managed and monitored over 50 early-phase Corrective Action Plans (CAPs) for slow accruing trials & monitored accrual goals for more than 200 ETCTN and NCTN trials
- **Project management support new NCI precision medicine initiatives:**
 - Coordinated working groups and committees for NCI-MATCH and Pediatric MATCH
 - Assisted with onboarding over 25 labs into the NCI-MATCH laboratory network, including SOP development, coordination of lab application review, and orientation of labs
 - Organizational support for the new Pediatric Early Phase Clinical Trials Network (PEP-CTN)

DCTD CTIMS Focus Area: Scientific Program Support

Scientific Program Support

Cancer Moonshot

- Drug Resistance Network
- CIMAC-CIDC Network
- NCORP Biospecimen Procurement Protocol



- NCTN Core Correlative Science Committees
- DTC Data Safety & Monitoring Committee
- Correlative Science Studies Reviews

CIMAC-CIDC: Cancer Immune Monitoring and Analysis Centers & Cancer Immunologic Data Commons

NCORP: NCI Community Oncology Research Program

DTC: Developmental Therapeutics Clinic

Scientific Program Support Accomplishments

- New NCI Cancer Moonshot initiatives required additional PM support
 - **Cancer Immunotherapy Monitoring and Analysis Centers (CIMACs) and Cancer Immunotherapy Data Commons (CIDC):** A new network of laboratories specialized in immunotherapy related assays required extensive PM support to build collaborative network and integrate network into CTEP clinical trials networks
 - **Drug Resistance and Sensitivity Network:** A new network of laboratories devoted to the study of cancer drug resistance required PM support to organize meetings, establish network structure, and develop working groups
 - **NCORP Biospecimen Procurement Protocol:** An NCI Cancer Moonshot Study to obtain paired biopsy specimens for research studies that required PM support to set up a national biospecimen acquisition network and protocol .
- Established a second NCTN Core Correlative Sciences Committee (NCTN-CCSC) due to increased workload & supported 57 proposals reviewed by the NCTN-CCSC as of February 2019

DCTD CTIMS Focus Area: Information Management

Information Management

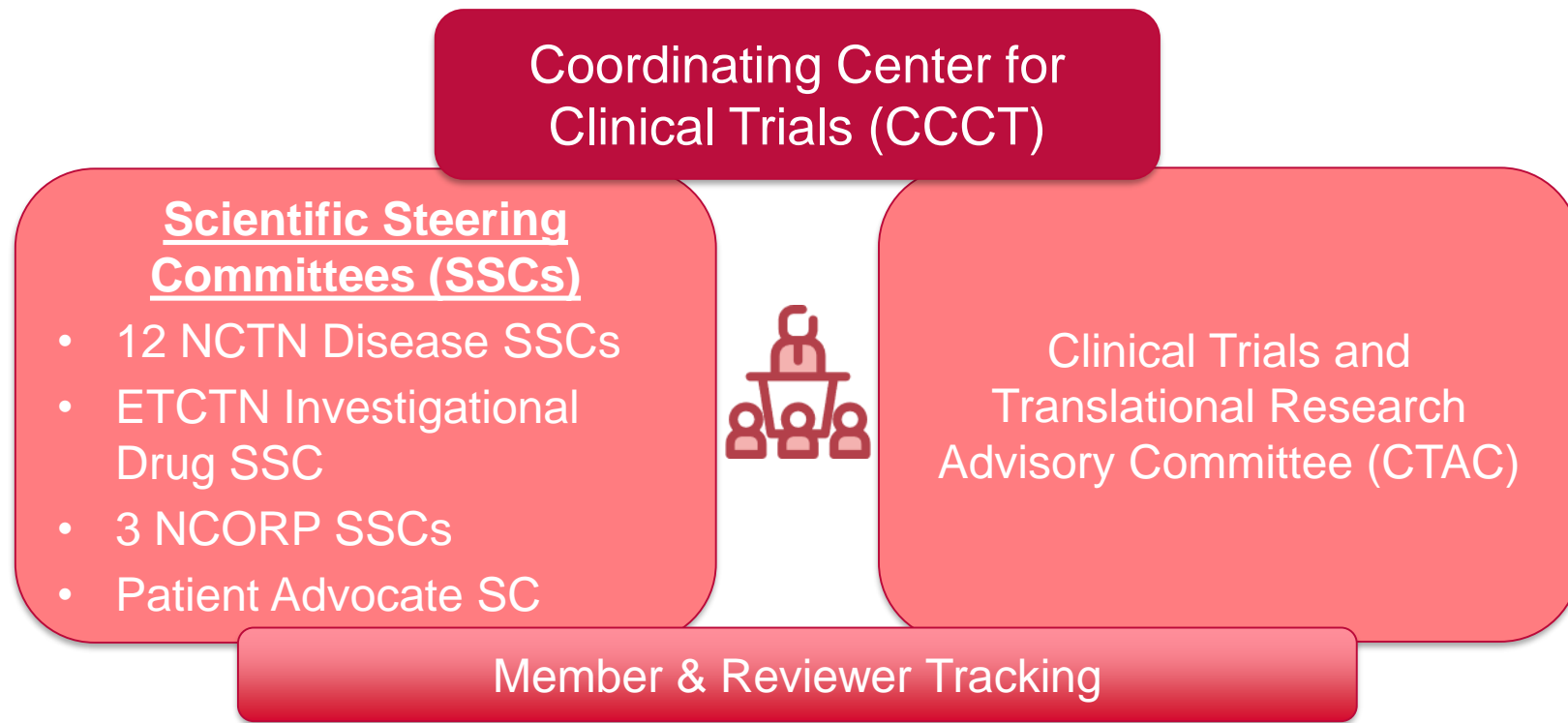


- NCTN/NCORP Data Archive
- Data Abstraction and Reporting
- Scientific Writing and Editing, e.g. DCTD meeting summaries and workshop publications
- NCI Clinical Trial Stewardship Content and Processes

Information Management Accomplishments

- NCTN/NCORP Data Archive: supported the publication of datasets for 35 completed trials (32,725 patients included) in this repository of patient-level data, begun Feb. 2017
- Clinical Trials Stewardship Committee: developed and coordinated review of Standard Operating Procedures (SOPs) to facilitate NCI's compliance with new NIH requirements for the monitoring and oversight of clinical trials
- Provided support to over 10 publications, including:
 - “The Current Understanding of the Endocrine Effects from Immune Checkpoint Inhibitors and Recommendations for Management” in JNCI-CS (July 2018)
 - “Seamless Designs: Current Practice and Considerations for Early-Phase Drug Development in Oncology” manuscript published in JNCI (December 2018)
 - “FACTS: Factors Affecting Combination Trial Success” (ASCO abstract 2544 2018; publication submitted to Frontiers in Medicine, January 2019)

CCCT CTIMS Focus Area: NCI Scientific Committee Coordination



NCI Scientific Committee (SC) Coordination Accomplishments

- Supported review by these SCs of 290 new/revised trial concepts and 69 new/revised Biomarker, Imaging and Quality of Life Studies Funding Program (BIQSFP) proposals
- Coordinated 17 SC Task Forces (TF), including the newly formed Breast Cancer SC Immuno-Oncology TF
- Supported over 40 working groups and subgroups
- Coordinated 9 Clinical Trials Planning Meetings (CTPMs)
- Coordinated over 70 face-to-face SC/TF meetings
- In 2018, begun support for CTAC and associated working groups

Moving Forward: Enhance PM to Support New and Ongoing Trials and Projects

- Provide and enhance PM support to current clinical trials networks and new precision medicine trials as identified
- Provide flexible, high-quality PM support to ongoing and evolving scientific programs
- Maintain and optimize information management support to facilitate data sharing and harmonization
- Maintain and enhance PM support and coordination of NCI scientific steering committees

Budget for Contract Reissue

- Budget request for a 7-year contract period
- Requested budget of \$6.5 for initial year with total contract costs over 7 years to be \$49 million
 - This represents an 18% increase over the current contract year related to increased project management needs of new scientific projects and growth of complex precision medicine trials. Industry funding through DCTD's Cooperative Research and Development Agreements (CRADAs) is anticipated to cover the increase.
 - This includes an allowance for COLA

Discussion & Questions