

STATEMENT OF WORK

The purpose of the Protocol Information Office (PIO) support contract is to:

- Facilitate the development of quality clinical trials in the most efficient and expeditious manner possible.
- Minimize the administrative burden related to clinical trial development and management on Cancer Therapy Evaluation Program (CTEP) staff and the extramural community.
- Utilize various database and document tracking/reviewing applications to electronically track a protocol throughout its lifecycle.
- Abstract key information including data elements, milestones and treatment descriptors into the CTEP Enterprise System (CTEP-ESYS) to facilitate informed and timely Program decision-making.
- Promote, inform and educate all concerned parties regarding NCI programs, policies and objectives related to clinical trial development and management.
- Support CTEP staff and the external community with various reports (both scheduled and ad hoc) to assist in various activities including timeline analyses, resource allocation, goal-setting, etc.
- Assist CTEP with the implementation and tracking of Operational Efficiency Working Group (OEWG) timelines

Specific Tasks

- 1.1.** Government will provide a suite at CTEP (9609 Medical Center Dr, Rockville, MD) which is comprised of fourteen cubicles for all Contractor staff working on-site on this project. All on-site Contractor staff will have at their workstation a computer and phone as well as access to printers, copiers, fax machines and scanners in order to complete the tasks specified in this Statement of Work (SOW). In addition to the equipment listed above, the Government will provide the Contractor with the office supplies that are necessary to perform the tasks specified in this SOW. The Contractor shall monitor all equipment and office supplies, and shall request replenishment/replacement of equipment and supplies, as needed, from the Contract Office Representative (COR).
- 1.2.** The COR will provide guidance on the specific work being performed, when needed, requested or as required by the Statement of Work. The Contractor, however, shall be responsible for the management and supervision of all Contractor employees (including any subcontractor employees, if applicable) that are working under this contract.
- 1.3.** The Contractor shall staff the PIO each business day (Monday-Friday), except Federal holidays, during normal business hours (8:30 AM ET-5:00 PM ET).
- 1.4.** Contractor shall utilize the Government-provided computer hardware, software and other IT tools in order to conduct the tasks specified in this SOW.
- 1.5.** The Contractor shall review and be familiar with the information provided on the CTEP web site and in CTEP-ESYS user manuals, including but not limited to the Investigators Handbook, CTEP Amendment Request Submission Policy, Treatment Assignment Code and Descriptor Guidelines, etc. to understand CTEP policies. The Contractor shall reference this information when communicating with submitting sites as well as CTEP and other Government personnel regarding incomplete or incorrect submissions, responding to general queries, and to complete the tasks set forth in this SOW.
- 1.6.** The Contractor shall utilize the email address PIO@ctep.nci.nih.gov for the receipt of all emails and document submissions related to CTEP-sponsored trials. This email address may also be used for the

submission of inquiries. The Contractor shall triage such inquiries and respond to them in a timely fashion or forward the inquiry to the appropriate department or individual best able to respond. The Contractor shall use established CTEP business rules to help determine who to forward queries to if the Contractor is not the appropriate party to handle them. The Contractor shall query the COR if there is any question about the action to be taken with any inquiry made to the PIO. The Contractor shall acknowledge receipt of each email sent to the PIO email address within 1 business day.

2. Abstraction of Protocol Related Information

- 2.1.** The Contractor shall obtain the necessary email accounts, usernames and passwords needed to access all relevant IT systems, including but not limited to, NIH email (Outlook), network folders, SharePoint site and CTEP-ESYS applications.
- 2.2.** The Contractor shall abstract information from protocol-related documents (including but not limited to Project Team Member Applications (PTMAs), Letters of Intent (LOIs), Concepts, new protocols, protocol revisions or amendments) received for all CTEP-sponsored trials as well as a subset of trials sponsored by other Institutes, Divisions or Programs including, but not limited to the National Heart, Lung and Blood Institute, the Division of Cancer Prevention and the Cancer Imaging Program. The Contractor shall utilize established Standard Operating Procedures (SOPs), the Investigator Handbook and PATS User Guides as tools to determine what information needs to be abstracted depending on the type of document received. Types of information to be abstracted include, but are not limited to, title of protocol, name and contact information of the principal investigator, treatment information, trial phase, lead organization on the trial, and discussion date by CTEP. The Contractor may be tasked with additional data entry of other NCI sponsored grants.
- 2.3.** The Contractor shall review all submitted documents for completeness and accuracy, in accordance with established SOPs. The Contractor shall communicate electronically with the submitter to provide information on the submitted documents.
- 2.4.** The Contractor shall communicate electronically with the site regarding “incomplete submissions”, as defined by current CTEP business rules. For any submission deemed incomplete, the Contractor shall notify the submitter of the elements missing and ask for resubmission.
- 2.5.** The Contractor shall utilize a CTEP designed module, for the process described above, to abstract data elements.
- 2.6.** Unless otherwise directed by the COR, the Contractor shall abstract the relevant information for each complete and non-duplicative document submitted into CTEP-ESYS and other CTEP provided databases. This includes, but is not limited to, the original submission of the following documents as well as their various revisions and/or amendments: Project Team Member Applications, Letters of Intent, Concepts, Protocols, or other document types that are identified throughout the contract.
- 2.7.** The Contractor shall utilize a CTEP designed module to enter milestones on each protocol related record created when the milestone occurs. Milestones refer to pre-determined points in the trial development process which allow for the tracking and monitoring of activities related to the review and approval of a submission. The Contractor shall select the appropriate milestone from a list of values in the module.
- 2.8.** The Contractor shall create a process for performing quality control (QC) checks on abstracted information as well as the contents of the protocol folder. The Contractor shall perform all QC checks at

intervals prior to the distribution of submission information and documentation to either CTEP reviewers or the submitter. The Contractor shall create QC checklists which shall be used to conduct the QC process.

3. Distribution of Protocol-Related Material

- 3.1.** Following the abstraction of a completed submission into PATS, the Contractor shall prepare an electronic protocol file for storage within NCI's computer servers. The protocol file will be established following CTEP business rules. The Contractor shall also prepare an electronic review packet for each CTEP reviewer involved in the review of a particular submission. The Contractor shall use a list developed by CTEP from which to select the appropriate reviewers.
- 3.2.** The Contractor shall distribute the review packets via email or software such as Share Point.
- 3.3.** The Contractor shall expect to receive the reviews generated by CTEP reviewers electronically. If CTEP reviewers do not submit their reviews to the Contractor on time, the Contractor shall issue an electronic reminder to the CTEP reviewer(s).
- 3.4.** The Contractor shall review the submitted reviews for comments or information that is to be added to the submission record in PATS.
- 3.5.** The Contractor shall store the reviews electronically in NIH folders, on NIH servers, following established SOPs.
- 3.6.** The Contractor shall include additional reviewers, committees, or process steps at the request of the COR.
- 3.7.** The Contractor shall issue electronic acknowledgement letters, consensus review letters, follow-up review letters, decision letters, and coding letters to the submitter. The Contractor shall follow established SOPs, as well as the Treatment Assignment Guidelines and Amendment Submission Guidelines, to determine when each letter shall be distributed. Each letter may be system-generated by the module or provided by a CTEP reviewer. The Contractor shall review the letter for accuracy and completeness of administrative information regarding the submission. Prior to the distribution of each letter, the Contractor shall ask the CTEP reviewer approve the letter electronically. A digital signature may also be required on the letter.
- 3.8.** The Contractor shall comply with CTEP business rules that govern processes related to the regulatory requirements that CTEP is required to follow, in accordance with the Investigators Handbook and established SOPs.
- 3.9.** The Contractor shall, at the direction of the COR, issue special mailings and notices regarding various safety, regulatory or other related information to sites conducting CTEP-sponsored trials. Special mailings include Notice to Investigators about an adverse event suffered by a patient. The Contractor will receive the special mailing from the Government with instructions defining what will be included in the mailing and to whom the mailing will be sent. The Contractor shall issue all mailings electronically. The Government will provide the Contractor with a log that the Contractor will use to track the mailings issued. Submitters will respond to the mailings by a date specified in the mailing. For submitters that do not respond by the date specified, the Contractor shall issue an email reminding the submitter of the requirement to respond, which may include, at the direction of the COR, any actions the Government may take for failure to respond.

4. Meeting Support

- 4.1.** The Contractor shall prepare the meeting packets for the Investigational Drug Branch (IDB), Concept Review Meeting (CRM), Biomarker Review Committee (BRC), Protocol Review Committee (PRC) meetings and other CTEP study related meetings.
- 4.2.** The Contractor shall prepare review packets electronically prior meeting as specified in the SOW. The packets shall be navigable electronically.
- 4.3.** The Contractor shall generate the preliminary and final meeting agendas. The Contractor shall distribute these agendas based on a CTEP designated schedule
- 4.4.** At the request of the COR, the Contractor shall include additional invitees on the agenda notifications.
- 4.5.** The Contractor shall send a representative to each meeting. The Contractor shall bring a laptop with connectivity to CTEP networks in order to answer any questions through access to CTEP applications and protocol-related documents, and to project the meeting packet. The Contractor shall record the decisions and comments made about each review and shall transfer the information to the module, the protocol file, or any other location or person required. The Contractor shall address or record PIO-related issues for resolution. The Contractor shall attend CRM, BRC, PRC and IDB meetings to address PIO-specific issues or record PIO-related issues for follow-up at future meetings. The Contractor shall circulate OEWG conference call attendance forms to the Lead Reviewer for approved LOIs, Protocols and Concepts.

5. OEWG Functions

- 5.1.** The Contractor shall schedule conference calls for approved or on hold LOIs, concepts and protocols between selected CTEP staff and study team members. The Contractor may also be asked to schedule ad hoc calls between CTEP staff and study team members.
- 5.2.** The Contractor shall attend the conference calls and prepare meeting minutes for the calls. The Contractor shall have the minutes available to the Lead Reviewer no later than 3 business days after the call. The Contractor shall have the CTEP approved meeting minutes distributed to call attendees no later than one week after the call, unless otherwise directed by the COR.
- 5.3.** The Contractor will track OEWG timelines for all approved LOIs, approved concepts and protocols in review and will contact the study team as needed to receive updated documents; interface with all trial development participants including NCI and extramural professional and support staff; NCI contractors; and FDA and pharmaceutical company personnel to shepherd a study through the protocol development process in the most efficient, effective and timely fashion possible.
- 5.4.** The Contractor shall prepare consensus reviews using the CTEP approved template for Protocols after PRC. The Contractor shall send them to the Lead Reviewer for approval within 3 business days after PRC. The Contractor shall distribute the approved consensus review to the study team no later than 2 business days prior to the scheduled OEWG conference call.
- 5.5.** The Contractor will be required to prepare follow up reviews for protocols in review or amendments. The Contractor may also be required to prepare other typing requests for CTEP staff for distribution to study teams.

- 5.6.** The Contractor shall establish a project timeline for each protocol and identify/track key and appropriate sub-task milestones and responsible study development participants and their contact information (i.e. telephone, e-mail).
- 5.7.** The Contractor shall utilize existing NCI and site databases to capture and or track relevant milestones, key-words and study development participants (i.e. CTEP-ESYS, CTSU RSS, CIRB IRB Manager, Group databases).
- 5.8.** The Contractor shall as necessary capture pertinent information in the database module.
- 5.9.** The Contractor shall Collaborate with other NCI staff and contractors involved in the protocol development process (i.e. CTSU, CIRB, CTMS) to minimize redundancy and gaps in supporting the protocol development process. It must be emphasized that the contractors are not intended to replace or duplicate activities currently being performed by other CTEP contractors or government staff, but rather it is intended to provide proactive coordination to assure that protocol development and implementation timelines are met.
- 5.10.** The Contractor shall communicate with study development participants (i.e. scientific reviewers, support staff, study coordinators) via email, telephone, or other suitable mechanisms.
- 5.11.** The Contractor shall prompt and/or remind study development participants to address issues in a timely fashion.
- 5.12.** The Contractor shall develop prompts or triggers to alert appropriate personnel (i.e. study participants, NCI/extramural site leadership) regarding any potential or actual delays.
- 5.13.** As needed, The Contractor shall escalate awareness of any issues that might delay trial development to the appropriate NCI and extramural site leadership.
- 5.14.** When approved by NCI leadership, The Contractor shall adjust/modify protocol development timelines to accommodate unforeseen delays.
- 5.15.** The Contractor shall recommend policies to further streamline the protocol development and amendment process. All policies must be approved by the NCI.
- 5.16.** By collecting information regularly, The Contractor shall maintain up to date electronic reports documenting current status of each protocol, which shall be a working/living document that gets updated in real-time and can be accessed via IPAD. The reports shall be user friendly and highlight and prioritize any potential or actual delays in protocol development or accrual. The reports shall be able to be sorted by trial type (i.e. phase, lead site participant, disease, CTEP coordinator). Reports shall reflect actual versus expected timelines. Contractor will review these reports regularly with CTEP lead investigator/reviewers and with members of CTEP's OEWG at regular meetings.
- 5.17.** The Contractor shall develop metrics to assess overall performance of protocol development timelines based on trial type to identify trends, bottle-necks and successes.
- 5.18.** The Contractor shall identify potential roadblocks or impediments to the clinical trial development process, including the protocol amendment process and recommend solutions.

- 5.19.** The Contractor shall identify and implement any other tasks and or processes that will facilitate and improve the protocol development process and the protocol amendment process in collaboration with NCI staff and contractors.
- 5.20.** The Contractor shall coordinate regular OEWG meetings, solicit agenda items from OEWG, provide updates on action items, accomplish action items and resolve issues after meeting and collaborate with members of the OEWG when needed to address issues, prepare minutes of OEWG meetings that focus on action items needed and action items completed.
- 6. Storage of Protocol Related Material**
- 6.1.** The Contractor shall utilize the main PIO email address for all PIO-related correspondence. The Contractor shall use the established NCI network drives to store all protocol-related documents, as directed by the COR.
- 6.2.** Electronic file - The Contractor shall prepare and maintain an electronic protocol file that will contain all protocol-related documents for each CTEP-sponsored study.
- 6.3.** All CTEP documents are considered confidential. The Contractor shall ensure the physical security of all files and materials. This includes but is not limited to, prevention of unauthorized entry, theft, misuse, or damage to files and Government materials.
- 7. Documentation**
- 7.1.** The Contractor shall have in place a set of Standard Operating Procedures (SOPs) to describe the process for completing the tasks required by the SOW. The COR will be provided the opportunity to review and comment on the SOPs before the procedures are implemented. The SOPs shall be developed within 90 calendar days after the effective date of the contract. The Contractor shall update the SOPs whenever business processes are modified or as directed by the COR. The development of the SOPs shall be based, in part, upon current, existing CTEP business rules.
- 7.2.** The Contractor shall provide any scheduled reports and conduct special queries of CTEP-ESYS, as directed by the COR. To protect patient confidentiality and proprietary data, all requests from non-CTEP sources shall first be reviewed and approved by the COR. Scheduled reports will include reports required for the evaluation of the QASP. Regular scheduled reports are reports that can be generated by the Contractor through the CTEP-ESYS. The Contractor shall work with the COR to determine the need for any additional scheduled reports to be generated, based upon CTEP business needs.
- 7.3.** The Contractor shall provide presentations that communicate processes or results on activities to CTEP leadership. The Contractor shall first give the presentation to the COR for review. The Contractor shall then deliver the presentations, as directed by the COR.
- 8. Quality Assurance Surveillance Plan**
- 8.1.** The Contractor shall develop a Quality Assurance (QA) plan that addresses all of the items that performance will be measured on in the Quality Assurance Surveillance Plan (QASP). The QASP measures performance in areas of timeliness and quality and is conducted on a semiannual basis. The Contractor shall produce reports, at the request of the COR, to assist in the evaluation of performance against the QASP. The QA plan may address other business processes or areas that fall outside the scope of the QASP. The QA plan will provide a process to address and resolve any area of performance that

falls beneath stated acceptable levels. The Contractor shall have the opportunity to research and prepare a response for the reconsideration of the assessment of a QASP measure.

9. Miscellaneous

- 9.1.** The Contractor shall conduct two (2) satisfaction surveys annually. One survey will measure the satisfaction of CTEP personnel (including CTEP contractors) with PIO services. The other survey will measure the satisfaction of the customers that the PIO serves, outside of CTEP personnel. The COR shall have the opportunity to review the survey tool(s) prior to distribution. The Contractor shall collect, analyze and report the findings of the survey to the COR within one month following the completion of the survey.
- 9.2.** The Contractor shall conduct a minimum of four (4) training programs annually. The programs are developed by CTEP and will be at least one (1) hour in length and can occur in person, be web-based or conducted via a video conference. The programs shall be delivered to CTEP personnel, CTEP contractors or submitters and submitter personnel who interact with CTEP, as directed by the COR. The training programs shall serve as orientation of new personnel (i.e., CTEP personnel, CTEP contractors or submitters, and submitter personnel who interact with CTEP), training of new processes, or updates on existing processes. The Contractor shall measure the effectiveness of the programs (see the QASP for additional information on this aspect).
- 9.3.** The Contractor shall participate in the development or enhancement of IT tools affecting CTEP processes, as directed by the COR, and including, but not limited to, the review of IT project plans and the testing of the IT tools.
- 9.4.** The Contractor shall work with Government personnel outside of CTEP on matters that involve or affect CTEP protocol development processes and activities, as directed by the COR.
- 9.5.** The Contractor may be required to assist other NCI programs in the development of their SharePoint site so that it can collaborate and interact with the PIO SharePoint site.
- 9.6.** In addition to the deliverables specified in other sections of the Statement of Work, the contract shall provide the following technical reports to the COR: a monthly progress report, annual progress report, and final progress report.

10. Transition Activities

10.1. Phase-In Transition

The Contractor shall develop and submit a draft Phase-In Transition Plan at the time of proposal, which will describe the Contractor's strategy for taking over work from the incumbent Contractor, if required to ensure continuity of PIO services. The plan must include plans for provision of key personnel; transfer of relevant files, records, materials and data; transition of all activities from the incumbent Contractor. Within 5 business days of award, the draft phase-in transition plan will be revised, if necessary, and the draft Phase-in Transition Plan will become the Final Phase-in Transition Plan upon approval of the COR. The Final Phase-in Transition Plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities. Concerns anticipated or encountered shall be immediately communicated to the COR and an approved resolution pursued.

11. Options

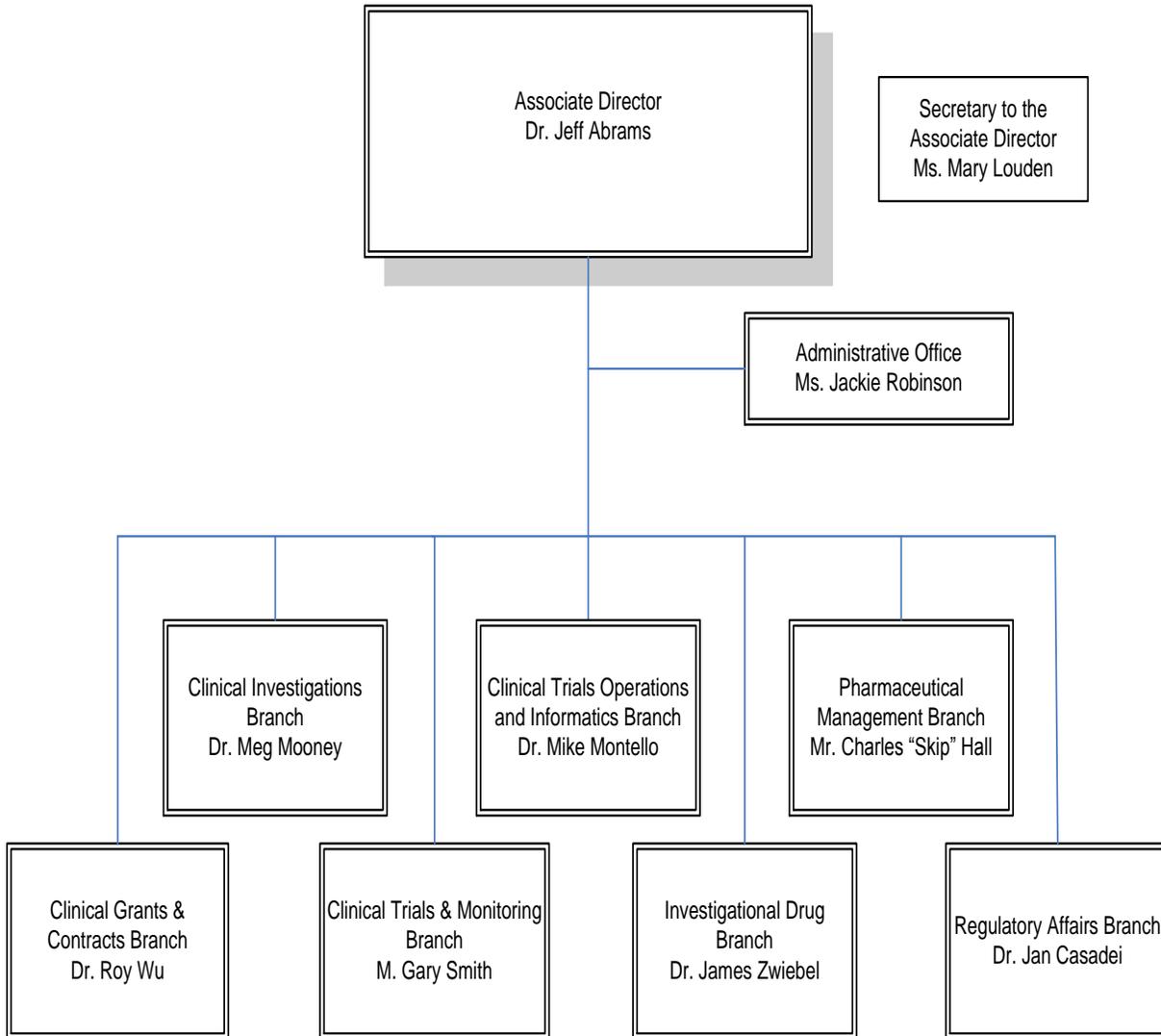
- 11.1. Increased Capacity Options** – NCI includes increased capacity options to supplement the base contract to

allow for additional support to cover an expansion of work in the major task areas mentioned at the beginning of the SOW that include: Abstraction, Distribution, and Storage of protocol related information as well as Meeting Support, OEWG Functions, Documentation and other tasks listed under Miscellaneous Activities.

11.2. Phase-Out Transition

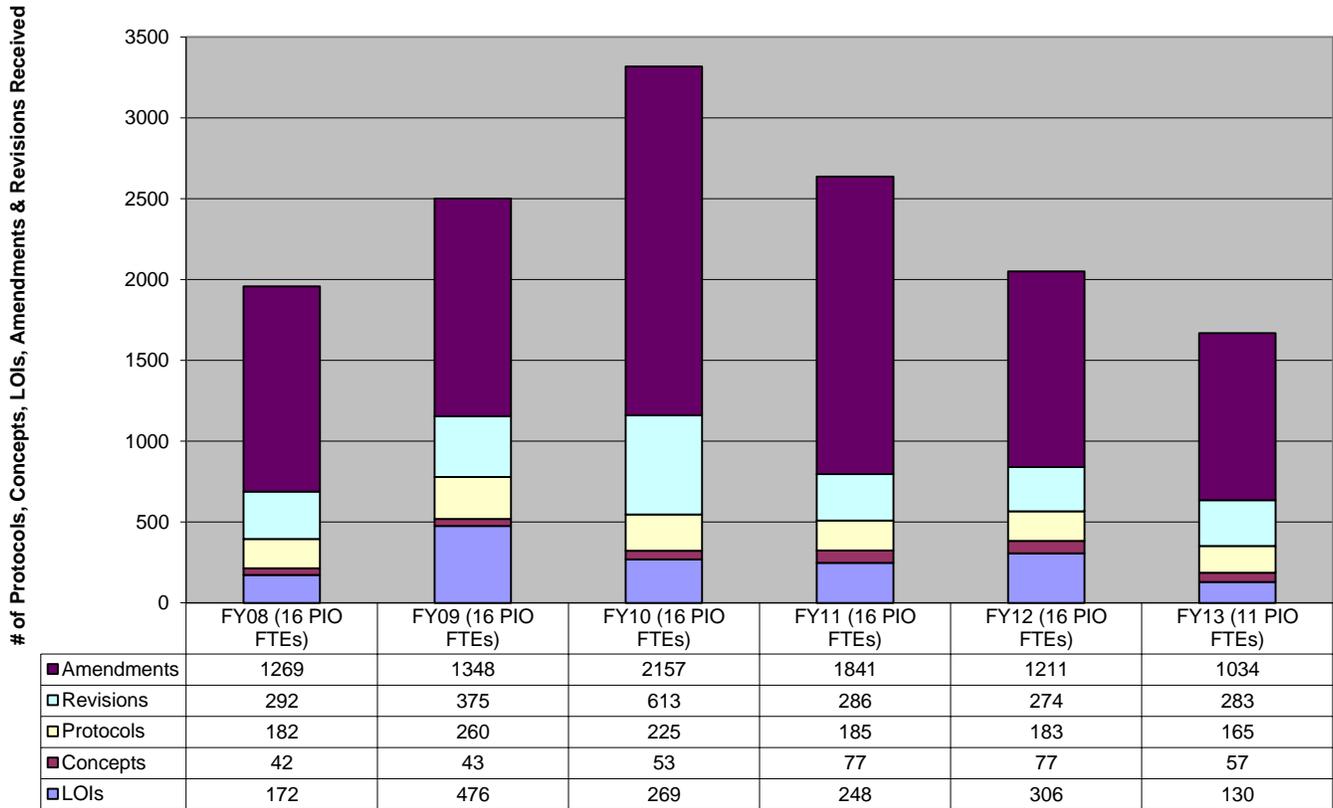
- 11.2.1. The Contractor shall, within 90 days before the completion of the contract, submit a plan for the transfer of all materials stored by the Contractor to the successor Contractor. This plan shall include a quality assurance element that provides for determination that all files and data have been completely and accurately transferred to the successor Contractor. This plan shall be reviewed and approved by the COR.
- 11.2.2. In the event that The Contractor is not awarded the successor award, the Contractor shall assist in the transition of this contract to a successor Contractor. The transition period shall consist of 90 calendar days. The following shall apply only to a transition wherein the Contractor is not the recipient of the successor award.
- 11.2.3. Contractor shall provide the successor Contractor with detailed briefings regarding the policies and procedures for managing all aspects of the project. As part of these detailed briefings, the Contractor shall provide the successor Contractor with all documentation of PIO processes and products, which shall include, but not be limited to, SOPs, orientation materials, training materials, presentations on PIO activities and samples of PIO-generated reports.
- 11.2.4. The Contractor shall provide instruction to the successor Contractor on the policies and procedures utilized in the performance of the contract. This instruction shall be accomplished by permitting personnel of the successor Contractor to work with current contract personnel in an apprentice capacity.

Appendix 1 – CTEP Organizational Chart



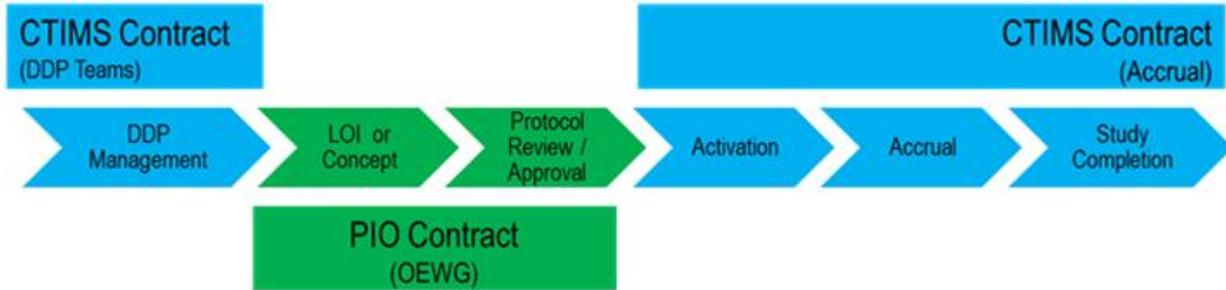
Appendix 2 – PIO Document Counts

**Detailed Protocol Workload - Protocols, Concepts, LOIs, Amendments & Revisions
(FY08-13)**



Appendix 3- Process Flow Diagram of CTEP Study Development as it Relates to CTEP Contractors

Major Steps in the Clinical Trials Development and Completion Process and Relevant Oversight from CTIMS Clinical Trials Project Managers (blue) and CTEP PIO Protocol Specialists (green).



Appendix 4 – Definitions and References

Definitions

AE – Adverse Event – An unexpected medical problem that happens during treatment. Adverse events do not have to be caused by the drug or therapy being studied, and they may be mild, moderate, or severe.

AQL – Acceptable Quality Level

BRB – Biometrics Research Branch, DCTD, NCI – Statistical Branch who reviews CTEP protocols

BRC- Biomarker Review Committee- The committee within NCI that meets weekly to review all new biomarkers proposed in potential studies.

CDE – Common Data Elements – Standardized language for case report forms used in reporting data collected during clinical trials

CDP – Cancer Diagnosis Program, DCTD, NCI – Laboratory study experts

CDUS – Clinical Data Update System – a CTEP trial monitoring system. Part of the CTEP-ESYS.

CGCB – Clinical Grants and Contracts Branch, CTEP, DCTD, NCI

CIB – Clinical Investigations Branch, CTEP, DCTD, NCI

CIBISCIT – Clinical Investigations Branch Information System and Clinical IT. Part of the CTEP-ESYS.

CIRB – Central Institutional Review Board

CBIIT – Center for Biomedical Informatics and Information Technology, NIH IT contractor

COR- Contracting Officer’s Representative

COTS – Commercial off-the-shelf product. A product which can be purchased commercially without being specifically developed for a client. The contractor installs and maintains the product for the client.

CRADA – Clinical Research and Development Agreement

CRF – Case Report Form

CTA – Clinical Trials Agreement

CTCAE – Common Terminology Criteria for Adverse Events – CTEP’s adverse event language used to standardize data reporting and to allow for easier analysis across trials

CTEP – Cancer Therapy Evaluation Program, DCTD, NCI

CTEP-AERS – CTEP Adverse Event Reporting System – A system through which any serious, fatal or life-

threatening adverse event that is thought to be drug or treatment related is reported immediately to the drug sponsor. Part of the CTEP-ESYS.

CTEP-ESYS – CTEP Enterprise System

CTMB – Clinical Trials Monitoring Branch, CTEP, DCTD, NCI

CTMB-AIS – CTMB Audit Information System. Part of the CTEP-ESYS.

CTMS – Clinical Trials Monitoring Service – Includes five components: (1) a central data management resource for DCTD and for clinical investigators conducting Phase I and selected Phase 2 clinical trials; (2) a on-site monitoring resource for DCTD to assure that institutions and clinical investigators conducting Phase I and selected Phase 2 clinical trials are in compliance with federal regulations, policies, and procedures and to verify submitted data and assure protocol compliance; (3) co-site visitation of Cooperative Groups and CCOP Research Bases as observers of peer audits to ensure adherence to CTMB’s Guidelines for Monitoring of Clinical Trials for Cooperative Groups, CCOP Research Bases, and the Clinical Trials Support Unit; (4) site visit monitoring of all other individual investigators conducting investigational drug trials; and (5) provision of training and administrative support for quality assurance programs of foreign groups/institutions who are collaborators in DCTD sponsored trials.

CTRP- Clinical Trials Reporting Program. This NCI Program is responsible for data management in ClinicalTrials.gov for CTEP sponsored trials and compliance with FDAAA.

CTSU – Cancer Trials Support Unit. This project coordinates participation in NCI-sponsored clinical trials.

DARTS – Drug Authorization, Review and Tracking System. Part of the CTEP-ESYS.

DCP – Division of Cancer Prevention, NCI – Another Division within NCI that focuses on cancer prevention research

DCTD - Division of Cancer Treatment and Diagnosis, NCI

DHHS – Department of Health and Human Services

DTP – Developmental Therapeutics Program, DCTD, NCI

Embedded Correlative Study – A trial that is incorporated into a larger trial. The embedded study is included as a sub-trial or secondary end-point of a larger trial (i.e. obtaining pharmacokinetics during a treatment trial). The embedded correlative study must be included as a separate sub-trial within the protocol document for the larger trial.

FDA – Food and Drug Administration

FDAAA- FDA Amendments Act

FISMA – Federal Information Security Management Act

Form FDA 1572 – Referred to as a “Statement of Investigator”; it is a requirement of section 505(i) of the Food,

Drug and Cosmetic Act and paragraph 312.1 of Title 21 CFR, that an investigator complete this form as a condition for receiving and conducting clinical trials involving investigational drug(s). It includes the investigator's training and experience and provides for legal certifications.

HHS – Health and Human Services

IDB – Investigational Drug Branch, CTEP, DCTD, NCI

IND – Investigational New Drug Application – An IND is a request for authorization from the Food and Drug Administration to administer an investigational drug or biologic product to humans.

IRB - Institutional Review Board – A IRB is an outside body composed of doctors and patient advocates that review research for human subject protections.

LOI – Letter of Intent – An idea for a phase I or phase II trial submitted for review by CTEP.

NCI – National Cancer Institute

NIH – National Institutes of Health

NSC # - National Service Center (anachronism)-Numbering system for study agents.

OEWG- Operational Efficiency Working Group. The OEWG has put forth recommendations on timelines for protocol activation.

PATS – Protocol Approval and Tracking System. Part of CTEP-ESYS.

PIO – Protocol and Information Office, CTEP, DCTD, NCI. The Protocol and Information Office is located at 9609 Medical Center Drive, Rockville, MD with CTEP.

PMB – Pharmaceutical Management Branch, CTEP, DCTD, NCI

PTMA- Project Team Member Application- An application to serve on an agent specific project team

PRC – Protocol Review Committee, CTEP – The committee within CTEP that meets weekly to review all new protocol submissions.

Protocol Related Documents – CTEP receives numerous types of documents used in the protocol development process. These documents include, but are not limited to, PTMAs, LOIs and Concepts representing pre-protocol ideas as well as the Protocol including revised protocols (changes made prior to final CTEP approval) and amendments (changes made after final CTEP approval). Protocol related documents also include protocol submission worksheets and change memos. Each type of submission (PTMA, LOI, Concept, Protocol, Revisions, and Amendments) require the use of a specific template or the addition of the protocol submission worksheet or change memo. The correct collection of documents submitted to CTEP based on the type of submission is what makes up a complete submission.

PRS – Performance Requirements Summary

PSW – Protocol Submission Worksheet – A worksheet used to organize various administrative aspects of a protocol to facilitate database abstraction.

QA – Quality Assurance

QASP – Quality Assurance Surveillance Plan

QOL – Quality of Life – A commonly studied aspect of clinical trials.

RAB - Regulatory Affairs Branch, CTEP, DCTD, NCI

RABITS – Regulatory Affairs Branch Information Tracking System. Part of the CTEP-ESYS.

RC – Resource Center – Off-site storage facility.

RUP – Rational Unified Process

SMARTS – Scientific Management of Agents Review and Tracking System. Part of the CTEP-ESYS.

Subgroup or stratum – A unique patient characteristic that is utilized to uniformly group or stratify patients for separate data analyses.

Submitter – An organization that conducts a CTEP sponsored clinical trial. May be a cancer center, ETCTN or NCTN group, consortium, NCI Clinical Center for Research, or other type of clinical trial delivery site responsible for interacting with CTEP.

TAC/TAD - Treatment Assignment Code/Descriptor – Standardized codes describing the various treatment options on a protocol.

References:

CTEP Home Page - <http://ctep.cancer.gov/>

Investigators Handbook - <http://ctep.cancer.gov/handbook/index.html>

CTEP Amendment Request Submission Policy -

<http://ctep.cancer.gov/protocolDevelopment/docs/requestsubmissionpolicyfinal.pdf>

Treatment Assignments Guidelines - <http://ctep.cancer.gov/protocolDevelopment/docs/TreatmentAssignment.pdf>

OEWG Information: http://ctep.cancer.gov/protocolDevelopment/OEWG.htm#oewg_timelines_sops