

Additional Business Proposal Instructions

The cost for work under section III in the SOW, **CCCT Scientific, Administrative and Logistical Meeting Support**, shall be provided as a separate budget as well as a category in the total estimated budget.

The cost for the phase-in transition shall be provided as a separate budget as well as a category in the total estimated budget.

For proposal purposes, the offeror shall propose based on the following budget assumptions:

1. Contract Transition (Phase-In)

- 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 CTIMS 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 10 calendar days of the 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 Contracting Officer's Representative (COR). The Final phase-in transition plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities.

2. Clinical Trials Information Support

- Support and attend a variety of weekly, monthly, and ad hoc meetings in support of NCI trials. Assume an estimated 4 regular weekly meetings approximately 1 hour and sometimes longer and up to 8 monthly meetings also lasting approximately 1 hour. Assume up to 3 ad hoc meetings may need to be set up weekly to manage clinical trials issues as they arise. Meetings are in-person at NCI Shady Grove and/or via teleconference with webinar support.
- Assume the attendance is needed at approximately 2 teleconferences per month and respond to approximately 20 emails per month to provide technical expertise for Common Data Element related projects.
- Information specialists ad hoc task requests: estimate 2 minor ad hoc requests per month and 1 major ad hoc request approximately every other month (i.e., requiring > 4 hours effort). This does not include ad hoc requests that fall within already approved activities.

3. Clinical Trials Project Management

- Approximately 30 new phase 3 clinical trial concepts are approved each year by CTEP and depending on length of the trial enrollment process, at any one time there may be up to 170 active treatment trials. Approximately 20% of trials have inadequate accrual and accrual need careful monitoring of data and additional accrual support is needed.
- It is anticipated that the Core Correlative Sciences Committee will hold one (1) monthly meeting conference call or Webinar lasting approximately two (2) hours and in-person meetings as needed would be held at Shady Grove.
- NCI is currently supporting four (4) nationally active or pending activation precision medicine trials and up to 2 per year are estimated to be developed The precision

medicine trials together require up to fifteen (15) weekly working groups and meetings.

- Assume there are expected to be up to 15 ETCTN agents that will require drug development project team support in 2015.
- Slow accrual tracking: Abstract 5 NCTN Group accrual reports per month for accrual milestones into database and tracking tools, and assess impact on slow accrual status.

4. CCCT Scientific, Administrative and Logistical Meeting Support

- The NCI currently supports sixteen (16) Scientific Steering Committees (SSCs) and one (1) Patient Advocate Steering Committee.
- It is anticipated that each steering committee will hold one (1) monthly meeting conference call or Webinar lasting approximately two (2) hours and in-person meetings as needed, usually one-two per year. Whenever possible the in-person meetings will be held in conjunction with a national scientific society meeting.
- Some Scientific Steering Committees (SSC) do not have any Task Forces (TFs), while others have as many as 6; the average is approximately three (3) TFs per SSC. It is anticipated that each task force will hold one (1) meeting per month by conference call/WebEx lasting approximately one (1) hour.
- The SC Chairs will have a minimum of three conference calls per year: Spring, Summer, and Fall.

5. Options:

- **Increased Capacity:** Assume an increase of 30% of base work costs per year through increased capacity options. Please include increased capacity option costs for each year as part of the proposed budget.

- **Phase-Out Transition:**

The Contractor shall prepare and submit a draft Phase-Out Transition Plan to the COR and the Contracting Officer 90 calendar days prior to the completion date of the contract. The plan shall describe the Contractor's strategy for transferring work from this contract to a successor contract, in the event a final transition would be required. The phase-out plan must include plans for transfer of policies and procedures; transfer of relevant files, records, materials, and data; transition of all activities, and transition of all applications, as appropriate.

6. Travel

- The following General Cost Assumptions apply to any travel to support the tasks in the Statement of Work: assume 12 trips may need to be taken for 8 staff members each year to attend, coordinate and support day long in person meetings of scientific committees. Estimate that the majority of meetings occur in Chicago, with at least 2 per year on the West Coast in San Francisco, one in San Antonio, Texas, and one in the south, Miami, FL.

7. General Assumptions

- Assume up to 3 personnel to be available to work on-site at the Shady Grove NCI location in Rockville, MD.