Information to Offerors

1.1.1 CPTAC Workflow:

The CPTAC program has a general workflow of tissue accrual to data generation. The workflow has many steps and generates terabytes of data from clinical and research centers all over the country. The next two paragraphs briefly describe the data flow for the purpose of highlighting the necessity for a QMS.

Tissue Source Sites (TSS) provide biospecimens (tumor and normal), along with clinical meta-data, to the Biospecimen Core Resource (BCR). The BCR is responsible for quality control (QC) prior to accepting the samples, and once accepted becomes the steward of the biological material, the subsequent derivative reagents, and the clinical meta-data. The BCR prepares the samples for proteomic and genomic analysis for the Proteome Characterization Centers (PCC) and NCI OTS contractor's Genome Characterization Centers (GCC). The GCC and PCCs produce an immense amount of digital information about the cancer and normal samples, which eventually end up at the Data Coordinating Center (DCC), the Comprehensive Data Resource (CDR), the NCI's Genomic Data Commons, and at the National Center for Biotechnology Information (NCBI). From here, the data are available for download by the public, but are further analyzed by the Proteogenomic Data Analysis Centers (PGDAC). Analyzed data are then uploaded to another partition of the DCC data servers and are also made available to the general public. Given the nature of the associated clinical meta-data, some information is considered personally identifiable information (PII) and is protected behind a secure firewall, as required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

The two (2) BCRs, CDR, and the DCC serve as the primary resource of the CPTAC biospecimens, clinical data, and molecular data, respectively. The QMS will need to be implemented at these four (4) institutions and be able to communicate with their Laboratory Information Management Systems (LIMS), their Clinical Data Management Systems (CDMS), and the CPTAC data repository to both ensure compliance and track and report conforming and non-conforming data. Additionally, the CPTAC QMS shall receive meta-data on a variety of performance and workflow metrics from the other grant funded institutions (PCCs, GCCs, PGDACs, PTRCs, and NCI OTS contractor's CDR) to support the program management duties.

1.1.2 Related QMS Guidelines:

The NCI is seeking to establish a QMS congruent with the guidelines described by the Clinical and Laboratory Standards Institute (CLSI) document QMS01-A4: Quality Management System: *"A Model for Laboratory Services; Approved Guideline – Fourth Edition*" (http://shop.clsi.org/quality-management-systems-documents/QMS01.html). CLSI document QMS01-A4 proposes Quality Management guidelines for organizations in the medical disciplines and these guidelines are based on a common set of 12 quality elements established by ISO 9001, typically referred to as Quality System Essentials (QSE). It is the intent of the Office of Cancer Clinical Proteomic Research (OCCPR) to employ a minimal QMS based on 10 of the 12 QSEs as outlined below. It will be the responsibility of the Contractor to define the

quality policies, processes and procedures around these ten (10) QSEs as they relate to the CPTAC program; however, the Contractor shall ***not*** attempt to make the CPTAC Program or any part therein compliant with ISO 9001.

The CPTAC QMS shall address the following QSEs:

In-Scope QSEs	Out-of-Scope QSEs
Documents and Records	Personnel
Organization	Facilities and Safety
Equipment	
Purchasing and Inventory	
Process Management	
Information Management	
Non-conforming Event Management	
Assessments	
Customer Focus	
Continual Improvements	

1.1.3 QMS Information Management and Reporting

A primary driver for this Statement of Work (SOW) is the amount of non-conforming data that is identified late in the CPTAC workflow. The amount of time and money spent per sample, to go from biospecimen to fully characterized sample, is substantial, and the identification of non-conforming data at the end of the workflow cycle is costly, time-consuming, and threatening to the success of the program. To overcome the late stage identification of non-conforming data, the QMS must have the ability to implement a variety of workflow throughput measurements and data quality checks across the BCR biospecimen repository, the clinical meta-data repository, and the data coordinating center. The Contracting Officer's Representative (COR) and CPTAC program management will require regular updates on the project's productivity and quality of the information at each of the information repositories.

To support the regular data quality checks, the QMS must, at a minimum, provide the means to identify, manage, and track both throughput of samples and available data (including non-conforming data). Ideally, the QMS information management system (IMS) shall also support automated functions to reach into the various CPTAC data repositories, perform a pre-defined list of data quality checks, capture the tests that passed and failed, and generate a summary report.

1.1.4 Compatibility

The new Contractor shall utilize some of the work done by the current Contractor (quality manual, information management system, etc.). Deliverables will need to be compatible such that they can incorporate information from the current Contractor.

The QMS Contractor will be required to implement an Information Management System (IMS) to support the execution of the QMS. The IMS will need to consume data from the Biospecimen and Clinical information systems from the Biospecimen Core Resources (BCR's) and the Comprehensive Data Resource (CDR), as well as specific meta-data from the Data Coordinating Center (DCC). The constraints on compatibility with these other systems are loose, as the means of consuming data from these entities is not of concern. Data may be consumed manually via spreadsheets or database dumps, system to system through Application Programming interfaces, or by other means. In this context, application programming does not include IMS configuration, system administration scripts, or related system maintenance/management activities.

1.1.5 Data Sharing

CPTAC is a large-scale public resource program. Participation in the program requires that centers performing proteomic characterization, sequencing and analysis agree that all data, analyzed data, analysis tools and computer code for analysis tools generated and/or developed for this project are made publicly available and are all open source. The data sharing plan and IP policies for this project are available through the project's website at https://cptac-data-portal.georgetown.edu/cptac/aboutData/disclaimer .

1.1.6 Disposition of Data

It is anticipated that the Contractor will need to enhance and/or modify the IMS employed for this project. The IMS may be either a COTS or Open Source tool. Any new development to either will be developed under the agreed upon Open Source license.