Statement of Work for CSSI

Support for the Director and Deputy Director on activities within the Office of the Director of CSSI shall include the following tasks:

Task Area 1

1. Develop and plan senior scientific strategy that supports activities in multi-center, multi-agency committees and initiatives such as NCI-FDA Interagency Oncology Task Force (IOTF) and the Cancer Steering Committee of the FNIH Biomarkers Consortium. Activities include:

    a. Design and perform background research, participate in planning, develop relational databases and prepare draft white papers on topics relevant to the research and business needs of the initiatives and collaborations of the Director and Deputy Director of CSSI.

    b. Identify, qualify, and convene key participants for scientific workshops and conferences relevant to these initiatives; draft meeting agendas; participate in the meetings; draft meeting reports for internal use in project planning and for publication. Parties involved may include NCI, other NIH entities, FDA, academia, and industry.

    c. Design and perform literature/media research and prepare written summaries to keep the Director and Deputy Director of CSSI abreast of complementary research initiatives, both in the U.S. and worldwide.

    d. Develop and maintain research and business plans for projects undertaken by the Director and Deputy Director of CSSI. These plans shall emphasize the use of best practices and shall include:

        i. Definition of what will be measured and calculated;
        ii. Gap analysis to identify data needed to successfully complete a project;
        iii. Instruments or reagents to be used;
        iv. Standardized acquisition parameters for imaging, bioassay and tissue data;
        v. Drugs selected for use in protocols;
        vi. Clinical studies performed to validate biomarker assays and new technologies (including development and analyses of retrospective databases) and to evaluate the biomarker as a correlate of clinical status;

vii. Sites and investigators who will carry out the clinical studies;
viii. Governance plan for the project;
ix. Further data and analyses required to bring the biomarker, clinical trial process, *etc.* to routine use in drug development and/or other clinical settings, and publication of methods and results (including guidance from the FDA);
x. Business plans will include project timelines, projected resources and budget, and decision points for continuing or abandoning specific components of the plan or the entire plan.

e. Develop and review research protocols and analysis plans for projects carried out under the auspices of the Director and Deputy Director of CSSI. It is anticipated that many of the protocols will have novel and complex designs (*e.g.*, adaptive randomization, multiple investigational agents and/or devices) aimed at advancing the sciences of oncology drug development and management of cancer patients.

2. Design approaches and provide operational/documentation support to management of intellectual property and data sharing for multidisciplinary, multi-institutional projects carried out under the auspices of the Director and Deputy Director of CSSI.

3. Develop and maintain processes for multidisciplinary, multi-institutional projects:

a. Track project working groups, and define roles and responsibilities of individuals and working groups in carrying out projects.
b. Design and develop processes and systems for communicating and sharing information among project participants.

4. Develop science-based regulatory strategy and provide regulatory affairs support for studies sponsored by the Office of the Director of CSSI and its collaborators. Develop, submit and maintain regulatory documentation (*e.g.*, investigational device exemption (IDE) applications, 510(k) applications, investigational new drug (IND) applications and Master INDs, imaging charters, briefing documents, biomarker qualification packages). Manage safety data and reporting and Data and Safety Monitoring Board (DSMB) activities.

5. Manage operations for sponsored studies. For example, qualify sites for carrying out the studies; ensure manufacturing, tracking, and delivery of study materials to appropriate locations; assist in development of data management/bioinformatics systems; monitor study progress; and carry out quality assurance audits of study data and processes.

6. Prepare draft manuscripts, critical reviews, news releases, PowerPoint presentations and other graphics, *etc.*, as requested for publication of research results and plans. Assist in publication *via* a dedicated website, (government, if available, contractor, if not) as well as by preparing draft presentations for relevant scientific and trade association meetings, articles in the scientific and trade association literature, and news releases directly to the public or *via* other interested parties. Ensure that the required Government clearances/approvals are obtained prior to starting work and/or releasing/publishing these items.

7. Perform administrative coordination activities. Maintain contact information for working groups, committees, project teams, *etc.*; assist in planning business meetings and teleconferences; prepare agendas and minutes for same; maintain files of correspondence and other documentation as directed.

8. Facilities, staff, equipment and processes in place at start of contract. Including a relevant data management system that is caBIG capatible, and supports regulatory submissions, including preclinical and clinical data management, safety data, regulatory document tracking and background materials for IND/IDE maintenance.

9. The Contractor shall be readily available to attend meetings in person in Bethesda with one hour advance notice and respond to requests after normal business hours and on weekends.

Task Area 2

A. Senior scientific strategy development and support for research business planning specific to CSSI initiatives. Tasks shall include:

1. Conduct literature/media research and prepare written summaries for specific CSSI initiative(s) steering committees in support of high-priority initiatives.

2. Provide scientific literature research and review (including written summaries and databases) for selection of biomarkers, laboratory technologies and imaging modalities along with clinical settings providing the best possible opportunities for development of biomarkers, nano-based moieties and technologies, and proteomics-based technologies useful in oncologic drug development and improving the care of cancer patients; include information to address both scientific and economic criteria for qualifying candidate biomarkers.

3. Develop priority ranking of research efforts within CSSI initiative(s) by drafting criteria for determining their utility for developing new oncology therapies or new uses of approved therapies or other intended uses.

4. Prepare and maintain documentation for justifying CSSI initiatives and assisting with implementation with all stakeholders (e.g. academia, patient advocates, FDA, industry).

5. Prepare and maintain overall research and business plans for the Office of the Director of CSSI on CSSI initiative(s) projects, including elements listed above under Task Area 1, Task 1.d.

6. Under the direction of CSSI staff, develop, plan, support, and oversee physical, chemical, and biological assays required to support CSSI-sponsored studies.

B. Support grantees and other stakeholders in the initiatives of CSSI. It is anticipated that this support shall include tasks such as:

1. Assist in implementation of research plans. Activities include:

    a. Prepare draft documentation of the definitions and standards for review by CSSI and individual initiative committees, including review and assurance of standards adequate for data sharing among protocols.
    b. Draft clinical protocols and provide project management tools (*e.g.*, *via* Microsoft Project) for clinical protocols.
    c. Provide regulatory affairs support (see Task Area 1, Task 4).
    d. Provide quality assurance support (see Task Area 1, Task 5).
    e. Provide scientific and technical assistance for data analyses and documentation on clinical trials.
    f. Prepare draft manuscripts, PowerPoint presentations, news releases, *etc*. to assist in publication of the results of studies and research plans.
    g. Compiling and analyzing study data for use in drafting regulatory guidance and to support approval applications.

    Examples of specific tasks include preparation of a clinical development plan for a nano-based drug or drug delivery system; development and maintenance of specific clinical protocols and regulatory documentation (*e.g.*, IND, IDE, 510(k)) for the nano-based product in support of the clinical development plan or for proteomics assay; and

assisting in preparation of briefing documents and data packages for FDA validation and qualification of proteomics assays.

2. Prepare draft manuscripts, news releases, PowerPoint presentations, *etc.* Assist in publication *via* a dedicated website, (Government, if available, contractor, if not) as well as by preparing draft presentations for relevant scientific and trade association meetings, articles in the scientific and trade association literature, and news releases directly to the public or *via* other interested parties. Ensure that the required Government clearances/approvals are obtained prior to starting work and/or releasing/publishing these items.

3. Perform literature/media research and prepare written summaries to keep CSSI and the individual initiatives abreast of complementary research initiatives, both in the U.S. and worldwide.

4. Perform administrative coordination activities for grantees and the individual initiatives. Maintain contact information for members; assist in planning business meetings and teleconferences; prepare agendas and minutes for same; maintain files of correspondence and other documentation as directed by CSSI.