Statement of Work

For

caBIG™ CTMS Developer – Patient Study Calendar Management Tool

1. Background

The National Cancer Institute (NCI) will deploy an integrating biomedical informatics infrastructure, the ***ca***ncer ***B***iomedical ***I***nformatics ***G***rid (caBIG), to expedite the cancer research community's access to key bioinformatics platforms. In partnership with the cancer research community, the NCI is creating a common, extensible informatics platform that integrates diverse data types and supports interoperable analytic tools. This platform will allow research groups to tap into the rich collection of emerging cancer research data while supporting their individual investigations.

The Clinical Trials Management Systems (CTMS) Workspace will provide tools and systems to enable integration and sharing of information among cancer researchers. These tools will facilitate the integration of data not only from different centers, but also data of different types, enabling translational and integrative research by providing for the integration of clinical and basic research data. Cancer Centers with experience in developing, integrating, or testing these tools are being asked to participate in the pilot program, leading to a well-documented and validated toolset for use throughout the research community. The Patient Study Calendar Special Interest Group (SIG) has been charged with defining the scope and requirements of a Patient Study Calendar module to be used to manage a clinical trial. Additionally the SIG is identifying touchpoints with other modules and areas of clinical trials management systems with the eventual goal of developing an object model that represents the Patient Study Calendar realm within a clinical trail.

A key need has been identified to develop a well defined and automated Patient Study Calendar that can be implemented in multiple clinical trial sites. Current processes to manage the study result in inefficient patient scheduling, which ultimately affect timely completion of the trial. These process are burdensome to study staff and can translate to data entry error which can adversely effect the trail. Additionally, there is a need to have the ability to forecast patient specific events including deviations to the patient schedule and appointments. The ability to allow for retrospective investigation of patient specific events should also be taken into account.

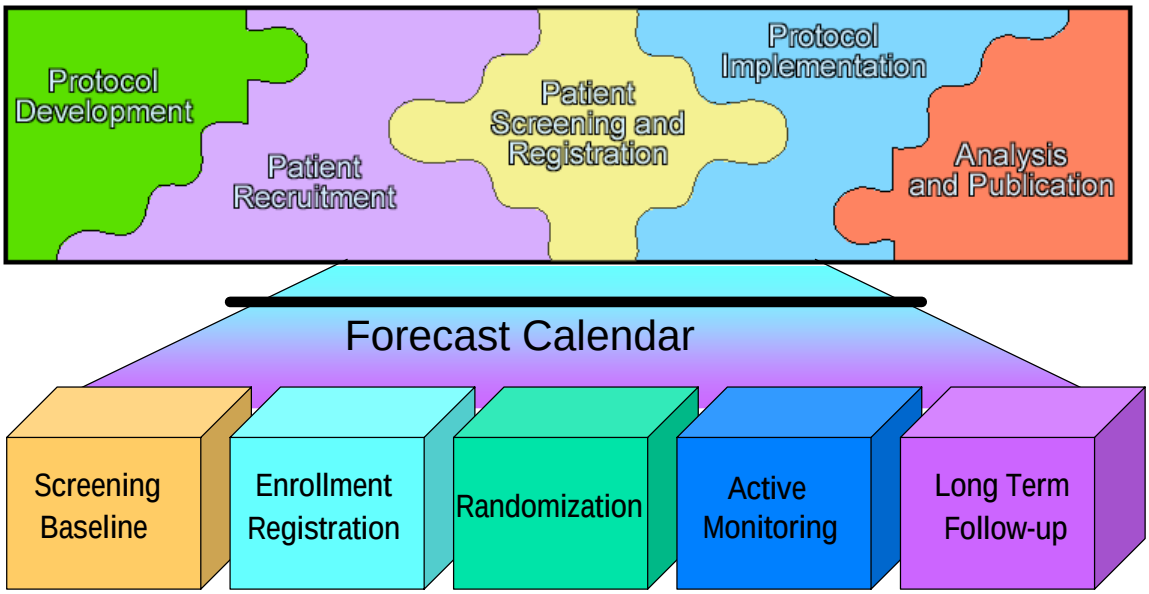

Figure 1: Protocol Lifecycle

A Patient Study Calendar module plays an important role in the protocol lifecycle, as shown in Figure 1. The implementation of a solution should facilitate the efficient coordination between various clinical study staff, including the clinical research coordinator, study nurses, pathologists, laboratory and administrative staff. The Patient Study Calendar model will accommodate epidemiological and population studies, observational studies, interventional studies.

The caBIG™ program is soliciting proposals for the development of an open-source, caBIG™ compatible solution to support the Patient Study Calendar within a clinical trial. In particular, the program is seeking proposals for solutions that are directly relevant to the broad goals in support of management of common milestones in the spectrum of clinical trial types. Offerors must engage the CTMS workspace as well as the Patient Study Calendar SIG during the requirements gathering and analysis phases of this project to address their specific requirements for Patient Study Calendar workflows. The resulting solution must be stand alone and Silver level compatible.

2. Objectives

The overall goal of this project is to build a management tool that can be adapted and extended to multi-site institutions to mange the Patient Study Calendar for a given protocol. Additionally the value and usability must be pilot tested in one or more cancer centers. All work performed for this project must be done in compliance with the caBIG principles of open source, open development, open access, and federation. Software that is used and/or developed in the context of this project must be caBIG™ compatible at the Silver level (https://cabig.nci.nih.gov/guidelines_documentation/caBIGCompatGuideRev2_final.pdf) and be made available to the community through resources provided by the General Contractor.

These objectives will be achieved by the following methodology, which is being used by all the participants in the caBIG™ project. The artifacts generated by this process will be the basis of the tasks and milestones associated with this contract.

- Work with the appropriate end user community to clearly define the scientific barriers to be addressed and to document the software functionality that will be used to address these barriers.
- Identify and manage risks that may affect delivery on time and on budget.
- Develop a plan to ensure that the information system functions according to the documented requirements.
- Implement the software according to the documented specification.
- Test the resultant information system to ensure that the functionality is consistent with the documented requirements.
- Ensure effective use of the application through appropriate documentation and training.
- Summarize the project outcomes, calling out "lessons learned" to support the improvement of subsequent projects.

The tool will provide several key functionalities:

- Allow the schedule of patient interactions proscribed by a study protocol to be described and incorporated into the protocol definition in the BRIDG model
- Development of a template schedule that can be easily adapted for a variety of protocols
- Prospective application to allow the capability to alert clinicians to schedule patient appointments
- Ability to record date, time and nature of the actual events, including deviations from the proscribed protocol schedule
- Ability to report to user upcoming events, create alerts for missed events and deviations and provide reports for study coordinators, investigators and administrators on patient accrual.

The tool is expected to take into consideration and appropriately plan for the general BRIDG/RIM compliant HL7 v3 message support needed for caBIG module interactions.

The tool would be expected to leverage the work of NCICB in the development of the HL7 SDK (http://trials.nci.nih.gov/projects/infrastructureProject/hl7_sdk) for content assembly.

3. Scope of Work

The overall role of the Developer in this project will be to create a Functional Requirements and Design Specification document for the Patient Study Calendar Management Tool project based on use cases, and to implement the requirements as high-quality software.

The following activities are for the Developer. See Section 5 for descriptions of acceptance requirements.

Task 1 – Project Management – Cancer Center Project Task Lead will manage Cancer Center level project activities.

- Task 1.1 - Use of General Contractor provided online tools for tracking of project deliverable, i.e., cancer Management Portal (caMP). The status of all deliverables must be maintained in caMP.

  Artifact: Project Management Plan

- Task 1.2 - The Cancer Center Project Task Lead will plan regular (and ad hoc) communications to share project information. Communications may include face-to-face meetings, teleconferences, videoconferences or use of the caBIG™ website and forums.
- Task 1.3 -The Cancer Center Project Task Lead will generate quarterly status reports and submit to the General Contractor not later than the 5th working day of each month.

Task 2 – Project Activities

- Task 2.1 - Risk Management Matrix: Identify the potential risks in the project and document the plan for managing these risks.

  Artifact: Risk Management Matrix

- Task 2.2 – **Develop Use Cases Document**

  The use case document will be developed in two phases, draft and final. The draft document does not require Adopter or Cross-Cutting WS sign-off prior to submission to NCI senior leadership for approval. However, the draft use case document will be circulated to the appropriate Adopter, Architecture and VCDE Workspace Reviewers to initiate the review process of this document. Submission of the Final Use Case Document to NCI senior leadership can not occur until the document has been reviewed by the Adopter, Architecture and VCDE Workspace Reviewers. The review process will be iterative in nature, resulting in the final reviewer-approved version of this document.

  - Task 2.2.1- Draft Use Case Document

    Artifact: Draft Use Case document

  - Task 2.2.2– Final Use Case Document

    Artifact: Final Use Case Document, approved by Adopter, VCDE and Architecture Workspace Reviewers

- Task 2.3 – **Develop Requirements and Specifications Document**

  The Requirements and Specifications Document will be developed in two phases, draft and final. The draft document does not require Adopter or Cross-Cutting WS sign-off prior to submission to NCI senior leadership for approval. However the draft Requirements and Specifications document will be circulated to the appropriate Adopter, Architecture and VCDE Workspace Reviewers to initiate the review process of this document. Submission of the Final Use Case Document to NCI senior leadership can not occur until the document has been reviewed by the Adopter, Architecture and VCDE Workspace Reviewers. The review process will be iterative in nature, resulting in the final reviewer-approved version of this document.

- Task 2.3.1 – Draft Requirements and Specifications Document
  Artifact: Draft Requirements and Specifications Document
- Task 2.3.2 – Final Requirements and Specification Document
  Artifact: Final Requirements and Specifications Document, approved by Adopter, VCDE and Architecture Workspace Reviewers

o Task 2.4 – **Develop UML model**

The information model will be defined in UML. If databases are utilized, Database Schema should be included. The UML model will be developed in two phases, draft and final. The draft UML model does not require Adopter or Cross-Cutting WS sign-off prior to submission to NCI senior leadership for approval. However the draft UML model will be circulated to the appropriate Adopter, Architecture and VCDE Workspace Reviewers to initiate the review process of the model. Submission of the Final UML model to NCI senior leadership can not occur until the model has been reviewed by the Adopter, Architecture and VCDE Workspace Reviewers. Additionally, the final version of the UML model will serve as the substrate for CDE creation (Task 2.6). The review process will be iterative in nature, resulting in the final reviewer-approved version of the UML model.

- Task 2.4.1-Draft UML Model
  Artifact: Draft UML Model
- Task 2.4.2 – Final UML Model
  Artifact: Final UML Model, approved by the Adopter, Architecture and VCDE Workspace Reviewers

o Task 2.5 – **Develop API**

The final API created will describe objects and is based on the UML model (Task 2.4). APIs for data services will need to document input and output data objects. The API documentation will be developed in two phases, draft and final. The draft API does not require Adopter or Cross-Cutting WS sign-off prior to submission to NCI senior leadership for approval. However the draft use case document will be circulated to the appropriate Adopter, Architecture and VCDE Workspace Reviewers to initiate the review process of this document. Submission of the Final API to NCI senior leadership can not occur until the document has been reviewed by the Adopter, Architecture and VCDE Workspace Reviewers. The review process will be iterative in nature, resulting in the final reviewer-approved version of this document.

- Task 2.5.1-Draft API
  Artifact: Draft API
- Task 2.5.2- Final API
  Artifact: Final API, approved by Adopter, Architecture and VCDE Workspace Reviewers

o Task 2.6 - **Generation of Common Data Elements (CDEs) from final UML model**

The final, approved version of the UML model (Task 2.4.2) will be used as the substrate for CDE creation. The UML model can be saved as an XMI file. Two tools supplied by the caCORE SDK (website) will be used to take the XMI file derived from the UML model and create CDEs in the caDSR. The Semantic Connector will be used to fully annotate the UML model (generated in Task 2.6.1). The UML Loader will be used to load the semantically annotated XMI file into the caDSR, thus creating CDEs from the original UML model.

- Task 2.6.1- Generation of semantically annotated XMI- The semantic connector tool will provide concept codes for descriptions of attributes in the model. Fully annotating the model will be an iterative process as there will be review and curation between the EVS team and the developer.

  Artifact: **Complete, Semantically annotated XMI file (XMI 1.2 format) describing the data system**
- Task 2.6.2- Generation of CDEs in caDSR- The UML loader tool will take semantically annotated XMI file and convert the objects of the model into CDEs. For a more detailed description of CDE creation from UML models please visit http://ncicb.nci.nih.gov/core/caDSR/Training. The CDEs created by loading the UML model into the caDSR will be on the staging server of the caDSR. The CDEs on the staging server will be reviewed by the caDSR team and the developer before they are moved to the production server of the caDSR. Once the UML model is loaded and the CDEs are on the caDSR staging server, the development team can submit an interoperability review package to the Cross-cutting WS (detailed in Task 2.7)

  Artifact: Full CDE Use Report

o Task 2.7 – **Develop Test Approach**: Document what approaches will be taken to assure requirements are met. Where appropriate, the Test Approach Document should define a validated test data set against which software will be regularly evaluated. The test approach document will be developed in two phases, draft and final. The draft test approach document does not require Adopter or Cross-Cutting WS sign-off prior to submission to NCI senior leadership for approval. However the draft test approach document will be circulated to the appropriate Adopter and Architecture Workspace Reviewers to initiate the review process of this document. Their comments will be incorporated into the draft document, resulting in the Final version of the Use Case Document. Submission of the Final Use Case Document to NCI senior leadership can not occur until the document has received approval from the Adopter and Architecture Workspace Reviewers. The review process will be iterative in nature, resulting in the final reviewer-approved version of this document.

- Task 2.7.1-Draft Test Approach Document

  Artifact: Draft Test Approach document

- Task 2.7.2-Final Test Approach Document

  Artifact: Final Test Approach document, approved by the Adopter and Architecture WS Reviewers

- Task 2.8 - Prototype:

  Artifact: Prototype code

- Task 2.9 – Final Code:

  Artifact: Final code

- Task 2.10 –**Compatibility Review Submission Package**: Various artifacts may be packaged together and submitted to the Cross-cutting Workspaces for final review and approval as a caBIG™ Silver Compatible application. Many of the deliverables listed below have been generated in previous tasks.
  - Task 2.10.1-VCDE Compatibility Review Submission Package includes the following artifacts:
    - Brief Description of the data system and its design
    - UML Model for the data system in Enterprise Architect Format (Task 2.4.2)
    - Semantically annotated XMI file describing the data system. This file must be in XMI 1.2 format with the Rose/Unisys extensions (Task 2.6.1)
    - Completed Semantic Connector report (Task 2.6.1)
    - UML Loader checklist (Task 2.6.2)
    - Value Domain Report (Task 2.6.2)
    - Vocabulary Report (Task 2.6.2)
    - Standards Report
    - Full CDE Use Report (Task 2.6.2)
  - Task 2.10.2-Architecture Compatibility Review Submission Package includes the following artifacts:
    - Software Architecture Document
    - Requirements and Specification Document (Task 2.3.2)
    - Implementation Document
    - Test Approach Document (Task 2.7.2)
    - UML Class Diagrams (EA .eap file-Task 2.4.2)
    - caBIG™ Compatibility Checklist
  - Task 2.11 – Technical/Architecture Guide – Describes architecture, systems requirements, APIs, and other tools that integrate with the software being developed as well as their implementation (https://cabig.nci.nih.gov/working_groups/Training_SLWG/Documents/working_groups/Training_SLWG/Documents/caBIG_programmers_manual_template_091405_jbh.doc); subject to caBIG™ Documentation and Training Review Process; The Technical/Architecture Guide will be developed in two phases, draft and final. The draft Technical/Architecture Guide should be submitted to the Training Working Group for review and feedback, but does not require Training Working Group sign-off prior to submission to NCI for approval.

However, the Final Technical/Architecture Guide does require review and approval by the Training Working Group prior to its submission to NCI leadership.

- Task 2.11.1 – Draft Technical/Architecture Guide

  Artifact: Draft Technical/Architecture Guide
- Task 2.11.2 – Final Technical/Architecture Guide; subject to the caBIG™ Documentation and Training Review Process.

  Artifact: Final Technical/Architecture Guide

o Task 2.12 – Installation Guide – Outlines the supported configurations and technical installation instructions for a software application; subject to caBIG™ Documentation and Training Review Process. The Installation Guide will be developed in two phases, draft and final. The draft Installation Guide should be submitted to the Training Working Group for review and feedback, but does not require Training Working Group sign-off prior to submission to NCI for approval. However, the Final Installation Guide does require review and approval by the Training Working Group prior to its submission to NCI leadership.

- Task 2.12.1 Draft Installation Guide

  Artifact: Draft Installation Guide
- Task 2.12.2 Final Installation Guide

  Artifact: Final Installation Guide

o Task 2.13 – Administration Guide – Describes process for updating and maintaining the application, importing and deleting data, creating authorization for users and user groups (https://cabig.nci.nih.gov/working_groups/Training_SLWG/Documents/working_groups/Training_SLWG/Documents/T5aTemplateforcaBIGApplicationSystemInstallation-AdministrationReferenceManualv050.doc); subject to caBIG™ Documentation and Training Review Process. The Administration Guide will be developed in two phases, draft and final. The draft Administration Guide should be submitted to the Training Working Group for review and feedback, but does not require Training Working Group sign-off prior to submission to NCI for approval. However, the Final Administration Guide does require review and approval by the Training Working Group prior to its submission to NCI leadership.

- Task 2.13.1 – Draft Administration Guide

  Artifact: Draft Administration Guide
- Task 2.13.2 – Final Administration Guide

  Artifact: Final Administration Guide

o Task 2.14 – Release Notes – Lists new features and functionalities, known bugs, and their status, etc.

- Task 2.14.1 – Release Notes

  Artifact: Release Notes

o Task 2.15 – Lessons Learned Document

Artifact: Project Lessons Learned

The General Contractor will provide necessary standard operating procedures to support project activities. Templates for the Technical/Architecture Manual, Installation Guide, Administrative Guide, and Release notes are available at:
https://cabig.nci.nih.gov/working_groups/Training_SLWG/Documents/index_html/document_view

4. Deliverables

In responding to this RFP, the offeror should structure the proposed deliverable schedule, dues dates, and total costs using the deliverable schedule template provided in the RFP Package. Each artifact described in Section 3 should be included in the deliverable schedule unless the exclusion is explicitly justified in the Technical Proposal. Moreover, additional deliverables may be suggested by the offeror – these should be justified in the Technical Proposal and included in the Deliverable Payment schedule.

5. Inspection and Acceptance Requirements

All reports and deliverables are subject to the final approval of the NCI. General quality measures identified below will be applied to each work product received from the Workspace under this statement of work and of requirements documents completed as part of this statement of work.

- **Accuracy** - Work products shall be accurate in presentation, technical content, and adherence to accepted elements of style.
- **Clarity** - Work products shall be clear and concise. Any and all diagrams shall be easy to understand and be relevant to the supporting narrative.
- **Consistency to Requirements** - All work products must satisfy the requirements of this statement of work.
- **File Editing** - All text and diagrammatic files shall be editable by the Workspace Manager.
- **Format** - Work products shall be submitted in electronic media in CVS.
- **Timeliness** - Work products shall be submitted on or before the due date specified in this statement of work or submitted in accordance with a later scheduled date determined by agreement between the Workspace and General Contractor.
- **User acceptance** - User acceptance for CTMS software products will be documented by stakeholders signature(s) on software design documents and test plan, as well as completed software user testing documentation. The intent of involving stakeholders at all stages of design and testing is to ensure that the software both performs as per their specific needs, but that it also meets the documented design requirements. These signatures will represent that the relevant stakeholders have participated in the requirements generation, test design and user testing, ensured the software performs

according to the parameters specified in the design documents, and properly executed the approved test plan carried out at their site.

- **Developer User Acceptance** – User acceptance for Workspace/Working Group software and solution development products will be documented by Developers' signature(s) on a sign-off page for source code. These signatures will represent that the Developers:
  - Conducted software or solution development according to defined processes
  - Conducted quality assurance and quality control activities (e.g., white-box and unit testing) during the development process
  - Conducted software defect reporting and responded to software defect reports from Adopters.

5.1 Review and Acceptance Processes

This section describes the review and acceptance processes to be implemented for all caBIG™ artifacts/deliverables. With the exception of status reports, all other deliverables are subject to draft and final review processes, and final approval/sign-off by the NCI.

5.1.1 General Review and Acceptance Process

5.1.1.1 Draft Review – Draft documents do not require Adopter or Cross-Cutting WS sign-off prior to submission to NCI senior leadership for approval. Upon submission, the draft document will be submitted to the appropriate Adopter, Architecture and VCDE WS Reviewers to initiate the review process. The review process will result in the Final, reviewer-approved version of the product.

5.1.1.2 Final Review – The final deliverable review process is an activity for the NCI Leadership to approve the production-ready product. This activity will be an efficient, relatively low level effort following an effective review process carried out by the Adopter, Architecture and VCDE WS Reviewers. Deliverables that have not completed the Review process and do not have the appropriate approval signatures will not be submitted to the NCI Leadership for Final Review. The NCI Leadership review will result in a sign-off indicating final approval of the product.

5.1.2 Cross-Cutting Review and Acceptance

5.1.2.1 Cross-Cutting Review - The review of development artifacts (use cases, requirements and specifications, UML models, APIs, and test approach documents) by the caBIG Architecture and Vocabularies and Common Data Elements Workspaces ("Cross-Cutting Workspaces") has been put in place to ensure that developers attain semantic and syntactic

interoperability in a timely and cooperative manner. The caBIG Compatibility Guidelines Document summarizes the approach taken within the caBIG program to ensure semantic and syntactic interoperability of data and services (see https://cabig.nci.nih.gov/guidelines_documentation/caBIGCompatGuideRev2_final.pdf). The cross-cutting reviews focus on the four areas addressed in this document which need to be considered for interoperability: APIs and messaging interfaces, vocabularies and terminologies, data elements and information models.

5.1.2.1 Interoperability Review – This specialized deliverable review process is an iterative process that involves the Architecture and Vocabularies & Common Data Elements (VCDE) Cross-Cutting Workspaces interoperability review processes. The goal is to be sure the development project achieves semantic and syntactic interoperability as outlined in the caBIG compatibility guidelines. The developer will submit a package to the Cross-Cutting Workspaces upon loading of the UML model into the caDSR. Only deliverables that require cross-cutting reviews are subject to this process. This process is managed by the Cross-Cutting Workspace Leads.

5.1.3 Status Reports

No formal review/approval process is required for Status Reports.

6. Travel and Other Direct Costs

1 All travel estimates will conform to the current Federal Travel Regulations (FTRs). All travel expenses should be included as part of the RFP bid.
2 Food, travel and lodging payments shall be based on the official government per diem rates found at http://www.gsa.gov/Portal/gsa/ep/contentView.do?contentId=17943&contentType=GSA_BASIC.
3 Any anticipated Other Direct Costs (e.g. reproduction, long-distance telephone, courier, and teleconference charges) may be included in the cost proposal.

7. Place of Performance

The majority of the work will be performed at the Offeror's facilities.

8. Period of Performance

The period of performance is six (6) months. The Offeror should submit a technical proposal that defines a scope that can be completed within the period of performance.

9. Data Use, Disclosure of Information and Handling of Sensitive Information

The caBIG grid must be built to share sensitive information from disparate data sources, meet the requirements of the Cancer Centers that participate in the pilot, as well as to include many additional Cancer Centers and other research stakeholders in future years. Therefore, the potential sensitivity of the information collected, information security issues, local Institutional Review Board requirements and the Health Insurance Portability and Accountability Act (HIPAA) of 1996 requirements will need to be addressed.

Final regulations issued by the Department of Health and Human Services provide privacy and security standards that must be observed in the handling of patient data resulting from biomedical research. HIPAA privacy standards will be used to establish safeguards and restrictions for the use and disclosure of research records. HIPAA security standards will be used to help Cancer Centers implement administrative, physical, and technical safeguards to protect electronic health information. Improper use or disclosure of sensitive information under the rules may be subject to criminal or civil sanctions prescribed in HIPAA.

Performance of caBIG tasks should be guided by the technical and operational principles of the caBIG program. Technical principles are defined in the caBIG Compatibility Guide, to be provided by the General Contractor. Overarching principles include:

1 Open source
2 Open access
3 Open development
4 Federation