

Getting Connected with caBIG[™]

Implementation Plan Template

1 Executive Summary

This Implementation Plan is a product of the Center's participation in the *Getting Connected with caBIG[™]* project. The primary goals of this activity are to assess and implement the appropriate caBIG[™] components within the participating Center's informatics systems.

The Executive Summary should be fewer than 1,000 words and provide an overview of how the Center plans to execute and leverage the caBIG[™] infrastructure to become caBIG[™] compatible. This section should do the following:

- Include the Executive Summary from the Cancer Center caBIG[™] Goals document.
- Identify where the Center plans to adopt caBIG[™] software bundles and where it will adapt existing non-compatible tools. Also identify the support resources that will be needed to accomplish the adoption and the adaptation (both internal and external to the Center).
- Outline the plans for the Center's participation in the Data Sharing and Security Framework. Specify how caBIG[™] framework processes for managing data sharing and the associated regulatory, privacy, and legal issues will be incorporated into the Center's own processes and procedures. Outline data that the Center plans to share through the caBIG[™] infrastructure.
- Provide a general timeline for executing the *Getting Connected with caBIG[™]* Activities.

2 Overview of the Plan

Lists all sections in the document and provides a summary of each section.

3 Goals and Metrics

3.1 Getting Connecting with caBIG[™] Mission Statement

This section, copied from Section 2 of the Cancer Center caBIG[™] Goals document, should explain how the tools adopted or adapted are to support the research efforts across much of the Cancer Center.

3.2 caBIG™ Implementation Goals

This section, copied from Section 5, Implementation Goals, of the Cancer Center caBIG™ Goals document, should identify at a high level how the Center will implement the following three caBIG™ goals:

- Deploy a functional caGrid node that will connect to the national infrastructure to enable data sharing.
- Meaningfully deploy caBIG™ compatible tools and infrastructure through adoption and/or adaptation.
- Participate in developing the caBIG™ Data Sharing and Security Framework.

The ultimate goal of caBIG™ implementation is to use caBIG™ compatible infrastructure and tools to promote collaborative research within and between Centers. Please identify evaluation goals if the Center is planning to pilot a tool.

3.3 Measuring Project Success – Project Metrics

To ensure goals are met, a plan for measuring progress against the project's goals should be presented in this section. This section should identify specific, quantifiable metrics for each goal stated in Section 3.2. The metrics should be appropriate for the project based on whether the tool is a pilot or a complete installation. This section should outline the specific metrics that will be applied during the *Getting Connected with caBIG™* project to measure its success, including a plan for when they would be collected and how they would be propagated to the NCI and relevant Center stakeholders.

3.4 caBIG™ Center Goals Gap Matrix

This section should describe the capabilities of the Center and potential challenges that must be addressed for the Center to achieve its caBIG™ goals. Using Section 6, Managing Capabilities and Potential Challenges for caBIG™ Implementation, of the Cancer Center caBIG™ Goals document, as the basis, this section should discuss key gaps in terms of resources, capabilities, and Center knowledge/experience. References to the section in this Implementation Plan that addresses how each obstacle will be overcome should be included (probably as a table).

4 Implementation Activities

4.1 Functional Capability or Tool Name

After defining capability needs and evaluating tools, the caBIG™ project team should develop this Implementation Plan with specific activities for the tools selected for adoption/adaptation. This section of the plan should identify the tool or bundle component to be adopted (or the associated data standard to be used as the basis of adaptation of an existing Center resource to caBIG™ data standards). Repeat this section for each caBIG™ tool selected for implementation.

Adopt caBIG™ Tool

Fill in this section with an overview of the Center's adoption strategy if that is the strategy selected for that component. This strategy should include an overview of how the selected component fits into the Center's overall scientific, clinical, and information technology strategies. Indicate whether the tool will be evaluated as a pilot project or full installation. Describe what mechanisms will be used (messaging, interface standards, common data elements, vocabularies) to interface the software with the local users and external collaborators. Identify preparation work that will need to be undertaken (SOP changes/creation, workflow, training plans, etc.) and what roles will need to participate (domain experts, users, decision makers, communications, legal representative, IRB rep, etc.).

Adapt Local Infrastructure to caBIG™ Compatibility

Fill in this section with an overview of the Center's adaptation strategy if that is the strategy selected for that component. This strategy should include an overview of how the Center will extend existing software components to interface with caBIG™ tools, and how this activity relates to the Center's overall scientific, clinical, and information technology strategies. Indicate whether the tool will be evaluated as a pilot project or full installation. Describe the software component(s) to be extended and what mechanisms will be used (messaging, interface standards, common data elements, vocabularies) to provide that interface. Include a discussion of how the Center plans to work with the vendors to help with the necessary interfaces. Indicate the strategy that is being implemented to ensure that the

adapted system will interoperate with other caBIG compatible systems (use of common models, etc.) Also provide an overview of how the extended component will provide capabilities to local users and/or provide means to work effectively with external collaborators.

4.1.1 End-User Community

This section should identify the specific end-user community for the selected caBIG[™] tool or bundle. These end users should be the ultimate users of the tool/service, including (if possible) anyone who will be using the software as part of their work. Please include titles and roles, and estimate the number of users that will be interacting with the caBIG[™] tool or service. Note any special circumstances that will pose unique challenges and barriers for the users identified.

4.1.2 Deployment Goal

This section should state the key deployment goal(s) for the selected component. This goal should include the functionality(ies) to the end users (this can be drawn from the caBIG[™] tools documentation for program software or can be drawn from the existing tool/services processes for adaptation of existing resources), and provide a timeline for the implementation, validation, and deployment in production use. The aggregate goals for each of the selected components should roll up to the program implementation goals outlined in Section 3.2.

4.1.3 Component Name Metrics

This section should describe the specific metrics associated with the adoption/adaptation of the selected component. These metrics should be specific, measurable, and aligned with the overall metrics identified in Section 3.3.

4.1.4 Internal Deployment Support Resources

This section should list the local resources that will be required to support the adoption/adaptation activity. This resource information should include staff effort and additional software, hardware, and infrastructure needed to complete the task. Include the impact that adopting/adapting a specific component of the caBIG[™] bundle might have on associated departments, such as the legal team, the IRB team, and the security officer. This section should also provide an estimated level of effort (LOE) for the resources. This section should roll up into the overall internal requirements outlined in Sections 6.1 and 6.2.

4.1.5 External Deployment Support Resources

In this section, describe the implementation activities that external support resources will support in the adoption/adaptation of the tool. External support resources include contractors and consultants, external support providers, other academic groups, other caBIG[™] Cancer Center participants, and software developers. This section should also include an estimated LOE for the external resource. Data provided in this section will roll up into the overall external requirements outlined in Section 6.3.

4.1.6 Integration Plans

In this section describe the methodology for integrating the selected adopted/adapted component into existing systems and workflows. This should include technical methodology as well as the operational approach and any changes or adjustments that will be necessary to existing processes.

4.1.6.1 Modifications to Selected Software

Detail planned changes or modifications of existing software and systems to provide for integration to selected adopted components, or the specific activities planned for adaptation of existing software infrastructure to caBIG[™] standards including any changes required for interoperability with existing caBIG resources. This section should also specify any modifications to the adopted caBIG[™] compatible systems.

4.1.6.2 Legacy Data Upload

In the case of adoption (or adaptation, where the changes to enable caBIG[™] compatibility will require re-loading of existing data into the system), this section should describe plans for processing and loading any required legacy data into the system (data migration).

4.1.6.3 Changes to Processes and Responsibilities

This section should describe any changes that need to be made to existing standard operating procedures (SOP) and workflows or what new processes and procedures must be added to adopt/adapt the existing software to interface with caBIG[™] tools. This information includes process changes to maintain, operate, and support the tools. Clearly identify roles and responsibilities associated with the new processes and procedures. List the specific tasks that will need to be completed, the roles needed to accomplish them, and the timelines for achieving the planned goals.

4.1.6.4 Documentation and Training Activities

This section should describe how the newly adopted/adapted systems will be documented and how users will be trained. Describe how the materials from the Documentation and Training Workspace, supplied bundle tools, and training will be leveraged to provide this support.

4.1.6.5 Testing, Validation, and Verification

This section should describe how the testing, validation, and verification activities required by the Center will be carried out in support of the selected adopted/adapted component. Cross reference activities to the roles that will accomplish them and the associated timelines.

4.1.7 Data Sharing Plans

This section should outline the data sharing plan for the tool: describe the data that will be shared, including its source and the type of data in detail; the technical means by which it will be shared; the community with whom it will be shared; and the process for securing the necessary Center approvals for sharing the data. This data rolls up to Section 5.6. This section includes the following four distinct sub-sections that clearly outline the Center's data sharing plans.

4.1.7.1 What Data Will Be Shared?

4.1.7.2 How Will the Data Be Shared?

4.1.7.3 With Whom Will the Data Be Shared?

4.1.7.4 What Is the Timeline for Making the Data Available?

5 Data Sharing and Security Implementation Activities

This section should outline how the Center will implement the Data Sharing and Security Framework Bundle and what kind of participation in the DSIC Workspace is planned.

5.1 Regulatory, Legal, and Privacy Requirements

This section should summarize how the regulatory, legal, and privacy requirements defined by the Center will be met. The project plan needs to specify how the appropriate groups within the Center (IRB(s)/HIPAA privacy boards, technology transfer/licensing offices, legal counsel, compliance officers, et al.) will be informed of the caBIG™ deployment and of the intention to use the caGrid to share data.

5.2 DSSF as Decision Support Tool

This section should outline how the Center will use the Data Sharing and Security Framework (DSSF) to assess the sensitivity of datasets to be shared in accord with the methodologies outlined in the Data Sharing Plans discussed in Sections 4.1.7 and 3.2.

5.3 Policies, Procedures, Best Practices, and Model Documents

This section should outline how the Center will implement the policies, procedures, best practices, and model agreements in the DSSF Bundle developed by the Data Sharing and Intellectual Capital (DSIC) Workspace in the *Getting Connected with caBIG[™]* activities. These documents include a Model Informed Consent, Guidelines for Preparing Data Sharing Plans and the Researcher Questionnaire, as well as other documents as they become available for implementation.

5.4 Security Policies and Procedures

This section should describe the processes and organizations involved for the Center to implement security policies and procedures for caGrid-wide authentication and authorization using the caGrid Level of Assurance (LOA) 1 and 2 NCI-caGrid Host Agreements, the LOA 1 and 2 Certificate Practice Statements, and other documents as they become available for implementation.

5.5 Participation in the DSIC Workspace

This section should describe how the Center plans to provide feedback on its implementation of DSSF tools to the DSIC Workspace into its workflow and identify any Center subject matter experts who plan to assist in developing and refining DSSF Bundle tools by actively participating in DSIC Workspace activities.

5.6 Data Sharing by Tool Matrix

This section should contain a matrix that identifies the data sharing plans shared by each tool. All of the Data Sharing Plans outlined in Section 4.1.7 should be included in this matrix.

6 Support Resources

6.1 Local Infrastructure

This section should outline the local infrastructure resources that are planned to support the *Getting Connected with caBIG[™]* project. Local infrastructure resources can include hardware such as servers or dedicated network hardware such as VPNs or firewalls; software resources such as databases; and network bandwidth (especially important if large amounts of data such as medical images will be transferred). If the project is expected to use other resources that the Center closely tracks, such as telephony or office space, that information should also be included in these infrastructure resources.

6.2 Local Center Staff

This section should identify the Center's local staff that is expected to be engaged in the *Getting Connected with caBIG[™]* project, specify their role in the project, provide a sentence detailing their qualifications, and note their estimated LOE. This information will help align the local staff efforts on the program with the project plan and ensure that sufficient local resources are available to

guarantee consistency with the program goals and success metrics outlined in Sections 3.2 and 3.3.

6.3 Existing or Local Contractors

This section should identify the Center's preexisting and/or local contractors expected to be engaged in the *Getting Connected with caBIG[™]* project in terms of the contracted company's name and its role in the project, provide a sentence summarizing each company's qualifications, and note each company's estimated LOE. It may help to identify contractor staff in aggregate and refer to the specific contract company's qualifications instead, especially if the specific individual resources may be difficult to identify in advance. This will help align the existing/local contractor efforts on the program with the project plan, and ensure that there are sufficient local resources to ensure consistency with the program goals and success metrics outlined in Sections 3.2 and 3.3.

6.4 Existing or Planned Software Vendors

This section should identify the software products and the vendors that are expected to provide the products and the associated installation, validation, and verification services.

6.5 Hardware Requirements

This section should identify any additional hardware requirements to enable the caGrid node, a caBIG[™] tool, or end-user requirements.

7 Timeline and Project Milestones

This section should provide a timeline with key project activities and major milestones described. The intent is to summarize the key points and estimated time spent on each element of this project plan. The timeline should provide an easy-to-understand overview of the overall project and the resources necessary to complete it.