

caBIG

cancer Biomedical
Informatics Grid



caBIG

OVERVIEW

WORKSPACE & WORKING GROUP
KICK-OFF MEETING
HANDBOOK

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NATIONAL
CANCER
INSTITUTE



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1. Introduction to caBIG

**Purpose of
this section**

This section provides an overview of the caBIG initiative as a whole and a description of caBIG's overarching vision, goals, and principles.

**Who should read
this section?**

All caBIG participants.



1. Introduction to caBIG

Overview of the caBIG Initiative

The caBIG pilot was initiated in July, 2003 by the National Cancer Institute (NCI), the Cancer Centers Program, and NCI's Center for Bioinformatics (NCICB) to test the feasibility of developing and deploying an integrating biomedical informatics infrastructure. The rapidly changing research environment, resource limitations, and the growing importance and demand for genomic data, expression profiling data, and other types of high-density biological information for biomedical research, has created a necessity for this type of open, unified bioinformatics infrastructure to support cancer research endeavors. The caBIG pilot is a novel and ambitious undertaking as no precedent exists for an initiative of this scale within the biomedical informatics and cancer research community.

At a foundational level, the caBIG pilot initiative seeks to provide members of the cancer research community with access to shared and enhanced data, applications, standards, and technologies. At an aspirational level, it is hoped that these improvements will facilitate enhanced biomedical research and better outcomes for patients and communities. As the caBIG initiative evolves, it also has the potential to support the activities of the broader biomedical research community, including intramural groups, industry groups, and existing National and International consortia and cooperative groups.

These caBIG goals directly address specific local needs of individual investigators and Cancer Centers for accessible, cost-effective, and consistent bioinformatics tools, standards, and unifying architectures. They also align with key HHS, NIH, NCI, National Cancer Advisory Board, and NCICB strategic priorities and policy directives.

The design and development of the caBIG pilot has been undertaken in close collaboration with the cancer research community (particularly NCI-designated Cancer Centers). Cancer Centers are currently the primary participants of the caBIG pilot. Over time, the type of participants will broaden and more members of the biomedical research community will be included. The current approach and structure of caBIG initiative reflects the specific needs, capabilities, interests, and priorities of the Cancer Center community and the NCI.



It is anticipated that the caBIG pilot phase will run for a three-year period. After that time, it is hoped that the caBIG effort will evolve into a self-sustaining community. Throughout the pilot phase, the NCI and NCICB will provide supervising coordination for the caBIG initiative.

Key caBIG Pilot Activities to Date – July 2003 to January 2004

To date, caBIG pilot activities have been primarily focused on outreach, information gathering, planning, and the establishment of an organizational structure. These activities have been critical to creating a solid foundation that ensures the ongoing success of the pilot initiative as well as fostering the collaborative partnership with the Cancer Center community. Key activities during this phase have included:

- Immediate-term and intermediate-term vision development, strategic planning and identification of key goals, priorities, and principles of participation (including technical principles—i.e., open source, open access, open development, and federated access)
- Informational seminars with NCI-designated Cancer Center members and other interested stakeholders (federal agency, industry)
- Cooperative Development Meetings conducted with 49 of the 61 National NCI-designated Cancer Centers to identify interests, needs and capabilities
- Selection and notification of pilot participants and identification of focal areas of pilot activities (e.g., project areas) based on needs and capabilities
- Conceptualization, formulation, and establishment of an organizational structure (including Workspaces, Working Groups, Developers, and Adopters) for the caBIG pilot
- Technical discussions regarding the grid and its compatibility with NCICB's existing platforms, standards, and technologies (e.g., caCORE, C3D, and other legacy systems)
- Ongoing communications with participating Cancer Centers.

All of these activities have resulted in the formation of a caBIG community of participants and the development of a robust structure for the caBIG initiative. Key next steps involve the initiation of the caBIG projects.

Additional information and program updates on the caBIG initiative are provided on the caBIG website, <http://caBIG.nci.nih.gov>.



caBIG's Vision

The caBIG pilot is being coordinated through the National Cancer Institute (NCI) and the NCI Center for Bioinformatics (NCICB) to support the following vision:

caBIG Strategic Vision

Provide cancer research infrastructure via a virtual web of interconnected organizations and individuals to leverage the combined strengths of Cancer Centers and investigators and enable the redefinition of:

- The methodology of cancer research
- The delivery of patient care
- The interaction and relationship of the patient/participant with the biomedical research enterprise

This will be achieved through the sharing of cancer research tools and cancer research data that meet common needs.

caBIG's Strategic Goals

The caBIG initiative aligns with key strategic goals and priorities of the Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the National Cancer Institute (NCI), and the National Cancer Institute Center for Bioinformatics (NCICB). The primary strategic goals of caBIG are highlighted below:

caBIG's Strategic Goals

- Illustrate that a spectrum of Cancer Centers with varying needs and capabilities can be joined in a common network or grid of shared data, applications, and technologies
- Demonstrate that Cancer Centers, in collaboration with NCI, will develop new enabling tools and systems that could support multiple Cancer Centers
- Demonstrate that Cancer Centers will actively use the network or grid and realize greater value in their cancer research endeavors by using the network
- Create an extensible infrastructure that will continue to be expanded and extended to members of the Cancer Research community

caBIG's Principles

The caBIG pilot initiative has adopted principles to guide caBIG activities. These include both principles of participation and technical principles.



caBIG's participants are encouraged to support the following principles of participation:

- Support the spirit, vision, and goals of the caBIG initiative as a whole
- Undertake activities with integrity and objectivity
- Perform activities in a collaborative and consensus driven manner
- Respect and capitalize on the skills and merits of individual members
- Act in accordance with caBIG guidelines and requirements.

caBIG's technical principles complement the principles that are the basis for NCICB's core bioinformatics infrastructure (caCORE). caBIG's technical principles are as follows:

- Open Source
- Open Access
- Open Development
- Federation.

2. caBIG Structure and Coordination

**Purpose of
this section**

This section describes the overall structure of the caBIG initiative including an overview of caBIG coordination and oversight roles.

**Who should read
this section?**

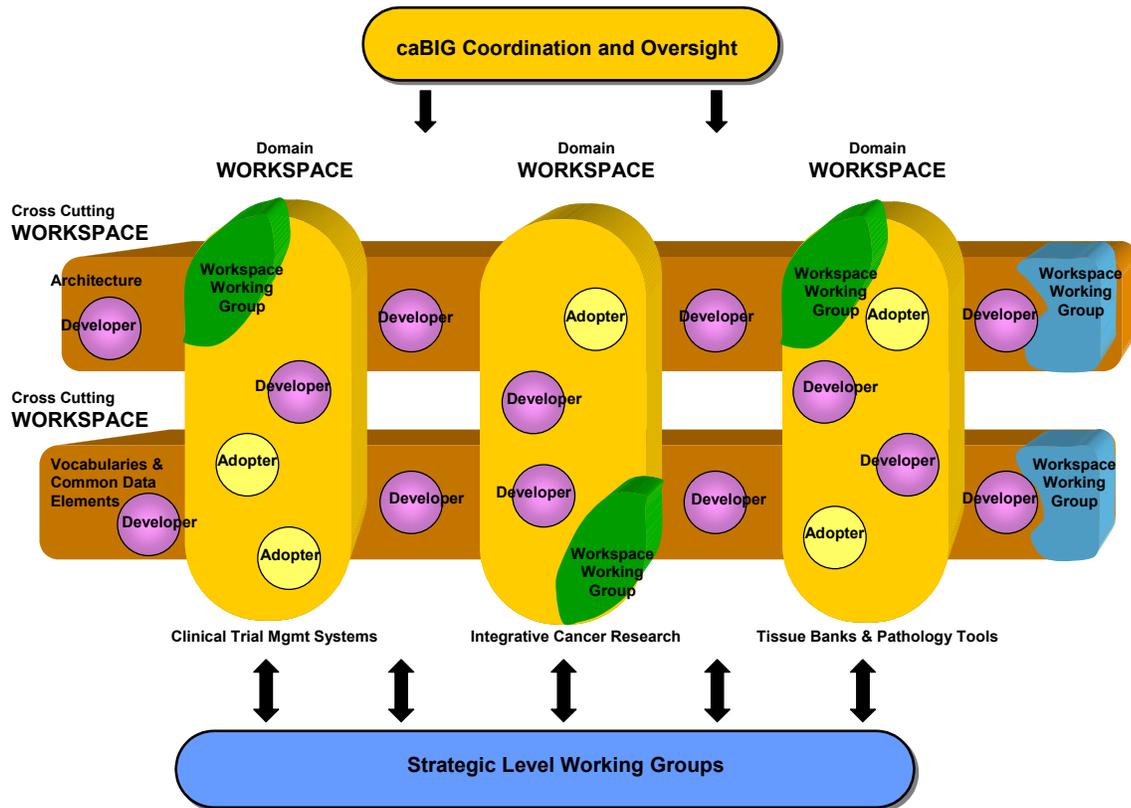
All caBIG participants.



2. caBIG Structure and Coordination

Overview

A high-level stylized diagram of the caBIG structure is presented below.



The central elements of the caBIG structure are the **Workspaces**. Workspaces are defined as areas or virtual environments where caBIG pilot activities are grouped. Each Workspace includes projects or activities with a common focus and addresses an area of need as identified by the Cancer Center community.

The Workspaces are divided into two groups according to their specific focus areas: **Domain Workspaces** and **Cross Cutting Workspaces**. A description of each of the Workspaces is provided in the following table:

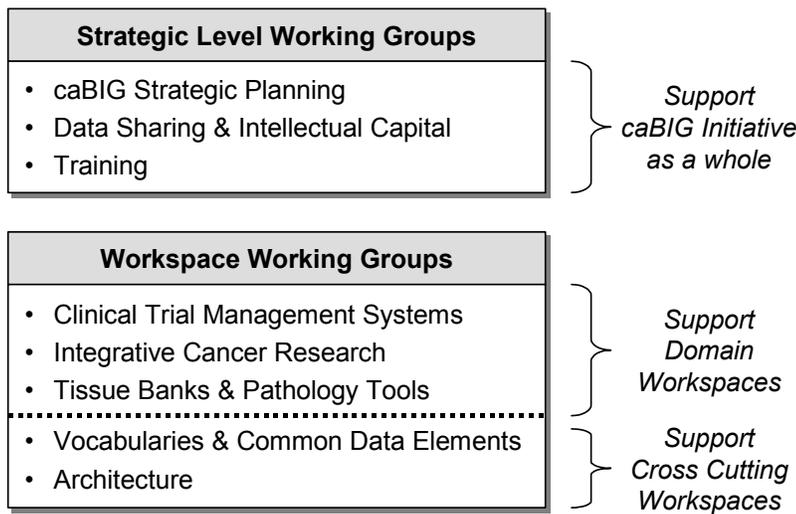


Workspace Types	Description of Workspace	Workspace Focus Areas
Domain Workspaces	Develop products or solutions that address specific areas of needs for the Cancer Center community and that can be used to test the feasibility of the grid.	<ul style="list-style-type: none"> • Clinical Trial Management Systems • Integrative Cancer Research • Tissue Banks and Pathology Tools
Cross Cutting Workspaces	Determine how areas of common concern across the various Workspaces and projects are captured and addressed. Cross Cutting Workspaces facilitate consistency and congruence of activities for the caBIG initiative.	<ul style="list-style-type: none"> • Vocabularies and Common Data Elements • Architecture

Within individual Workspaces, Cancer Centers participate in project level activities as **Developers** and **Adopters**. Based on the identified needs, specific software products and solutions (e.g., standards, documentation) are developed by **Developers** and tested, validated, and applied by **Adopters**. The final products or solutions are shared amongst the pilot group of Cancer Centers to test the grid or network.

The supporting elements of the caBIG structure are the **Working Groups**. Working Groups provide guidance and support to the caBIG pilot Workspaces and to the initiative as a whole.

There are two main types of Working Groups: the **Strategic Level Working Groups** and **Workspace Working Groups**. Together the Working Groups play a synergistic role, even though the exact focus of each group varies according to its functions. Collaboration amongst the various Working Groups enhances their ability to support the goals of the caBIG initiative.





The **coordination and oversight** of the caBIG structure and activities is provided by a variety of different groups and individuals. A summary of the various roles is provided in the table below. Additional information on some of these roles is given in Section 6, Key caBIG Coordination and Oversight Roles.

caBIG Coordination Level	Group or Individual	Description of Role
Programmatic and Strategic Level Coordination	NCI and NCICB	<ul style="list-style-type: none"> Provide programmatic and strategic guidance for the caBIG initiative as a whole
	caBIG Oversight Board	
Operational Level Coordination	Program Management Team (Contractor)	<ul style="list-style-type: none"> Supports the NCICB and caBIG Oversight Board
	Master Contractor and Workspace Managers	<ul style="list-style-type: none"> Coordinate and monitor the operational activities of the Workspaces and Working Groups Report to the programmatic/strategic level on the progress of project activities and the alignment to caBIG goals and priorities.
	Working Group Facilitator	<ul style="list-style-type: none"> Lead Working Group functional activities
	Working Group Coordinator	<ul style="list-style-type: none"> Provide administrative and operational support to Working Groups
Cancer Center Level Coordination	Project Task Leads for Developers and Adopters	<ul style="list-style-type: none"> Manage Cancer Center level project activities (e.g., development of products, testing and application of solutions)
	Working Group Members (Workspace or Strategic Level)	<ul style="list-style-type: none"> Manage project-related tasks (e.g., Workspace Working Group activities) and cross-initiative tasks (e.g., Strategic Level Working Group activities) <p>(Note: Cancer Center participants are expected to support the guidelines and processes established at the programmatic/strategic and operational levels.)</p>

3. caBIG Workspaces

**Purpose of
this section**

This section provides an overview of the structure, activities, and scope of the caBIG Workspaces.

**Who should read
this section?**

caBIG participants undertaking the following roles in Domain or Cross Cutting Workspaces:

- Developers
- Adopters
- Workspace Working Group Members.



3. caBIG Workspaces

Workspace Principles of Participation

As part of the caBIG initiative, all Workspace participants are encouraged to:

- Support the spirit, vision, goals, and principles of the caBIG initiative as a whole
- Collaborate effectively with other Workspace participants and groups to support specific and overarching goals
- Collaborate effectively with other Workspaces and Working Groups (Workspace and Strategic Levels) to support specific and overarching goals
- Undertake activities with integrity and objectivity
- Perform activities in a consensus driven manner
- Respect and capitalize on the skills and merits of individual participants
- Support the caBIG Oversight Board and Master Contractor guidelines and processes

Workspace Definition

Workspaces are the central structures of the caBIG pilot initiative. Workspaces are areas or virtual environments where caBIG pilot project activities are grouped. Each Workspace encompasses projects or activities with a common focus and addresses an area of need as identified by the Cancer Center community. Products and solutions of various kinds will be produced by Workspaces, including tools, standards, data, and documentation. These products and solutions will be shared amongst the pilot group of Cancer Centers to test the feasibility of the grid and to facilitate congruence and consistency of pilot activities.



Workspace Types

Two different general types of Workspaces have been established as part of the caBIG pilot initiative:

- (1) **Domain Workspaces** – these integrate or develop informatics products or solutions that address areas of need for the Cancer Center community and that can be used to test the feasibility of the grid.

Each Domain Workspace has a specific focus or topic area, such as clinical trials management or integrative cancer research.

- (2) **Cross Cutting Workspaces** – these address issues of common concern across all the Domain Workspaces, such as architectural standards, vocabulary, and common data elements. Cross Cutting Workspaces produce documentation and tools to support greater consistency and congruence between domain areas.

The specific types of Domain and Cross Cutting Workspaces that have been established for the caBIG pilot are as follows:

- Domain Workspace – Clinical Trial Management Systems
- Domain Workspace – Integrative Cancer Research
- Domain Workspace – Tissue Banks and Pathology Tools
- Cross Cutting Workspace – Vocabularies and Common Data Elements
- Cross Cutting Workspace – Architecture.

Workspace Roles and Activities

Participants within each of the Workspaces play different roles. The success of the Workspace activities is dependent on effective collaboration between the various groups undertaking these roles.

During the pilot phase, the **key roles within each Workspace** are as follows:

Role	Definition
(1) Developer	An NCI-designated Cancer Center selected and funded by NCICB to participate in a specific Workspace to undertake software or solution development activities.
(2) Adopter	An NCI-designated Cancer Center selected and funded by NCICB to undertake formal testing, validation, and application of products or solutions developed by Workspace Developers.
(3) Workspace Working Group	A group of NCI-designated Cancer Center members (and other invited stakeholders) funded to provide guidance and support for Workspace activities. The Working Group includes representatives from the Developer and Adopter teams.



Note: Strategic Level Working Groups will also offer guidance for Workspace activities, but will focus on issues relevant to the caBIG initiative as a whole and will not be directly linked with an individual Workspace.

The high-level activities of the Workspace participants are summarized in the following table:

WORKSPACE PARTICIPANTS
General Activities
<ul style="list-style-type: none"> • Define project priorities, scope, specifications, deliverables, and schedules (within parameters set by Master Contractor and caBIG Oversight Board) • Negotiate funding (via contract vehicles) with the Master Contractor • Undertake projects (e.g., development of new tools, adaptation of existing tools, data sharing, production of standards or documentation) according to negotiated contracts and agreed Statements of Work • Test and apply solutions or products to ensure that they meet agreed specifications, as well as the needs of the grid and the Cancer Center participants • Comply with industry standard development practices to ensure the quality and rigor of products or solutions developed and tested. These guidelines are established by the Master Contractor (and caBIG Oversight Board) • Participate in activities to facilitate communication and sharing of information between Workspaces • Support strategic priorities, goals, oversight processes, and guidelines established by the Master Contractor and caBIG Oversight Board • Work collaboratively with Strategic Level Working Groups and Cross Cutting Workspace Working Groups to ensure Workspace activities are congruent with standards and policies delineated by these groups for the caBIG initiative as a whole

The specific activities of the Workspace participants are shown by role in the tables below:



Workspace Role	Activities
Developer	<ul style="list-style-type: none">• Implements, modifies or extends software or solutions according to the specifications and schedules set forth by the Workspace Working Group (as contracted by the Master Contractor).• Works with the Master Contractor to ensure that the requirements on which contracts are based adequately reflect the deliverables desired from the assigned Developer teams.• Documents software or solution development processes according to defined processes.• Carries out Quality Assurance and Quality Control activities, such as white-box and unit testing, during development process.• Carries out software defect reporting and responds to software defect reports from Adopter and testing activities at other sites.• Provides development support activities as required by the project, including hosting, systems administration, and database administration.• Communicates progress with the Workspace Working Group (and the Master Contractor and caBIG Oversight Board, as required) through the established collaborative mechanisms, including meetings, tele- and video- conferences, and websites.• Complies with formal software change control processes, as required by project.• Complies with defined Workspace processes and guidelines (e.g., from NCICB, caBIG Oversight Board or Strategic Level Working Groups) for project activities.
Adopter	<ul style="list-style-type: none">• Creates formal software or solution Test Plans according to defined processes.• Executes formal software or solution Test Plans, and documents the results, submitting defect reports into systems established for that purpose.• Creates and documents formal software or solution Validation (IQ/OQ/PQ) Plans, as required by project.• Executes formal software or solution Validation Plans (IQ/OQ/PQ), as required by project.• Integrates software or solutions into existing informatics systems at Adopter site.• Provides data for application through the importation of data sets from actual practice, both from Adopter site, and elsewhere.• Submits formal software or solution defect reports into systems established for that purpose.• Exports processed data where appropriate into systems and processes that reflect the use of the adopted software or solution in actual practice.• Creates End-User Documentation for finalized versions of software or solutions according to caBIG documentation standards and templates.• Complies with defined Workspace processes and guidelines (e.g., from NCICB, caBIG Oversight Board or Strategic Level Working Groups) for project activities.



Workspace Role	Activities
<p>Workspace Working Group</p>	<ul style="list-style-type: none"> • Defines, within the scope of the Workspace, the vision, goals, and priorities of that Workspace. • Prioritizes the Workspace goals, in terms of software, solution, and tool deliverables, creating a Workspace working plan. • Schedules the initial Workspace working plan based on the established development process. • Assigns deliverables using the available allocated effort from the Workspace Developer and Adopter resources. • Creates formal software or solution specifications for the assigned deliverables. These specifications are likely to take the form of use-cases, UML diagrams, and other high-level representations of the problem. • Works with the Master Contractor to ensure that the requirements adequately reflect the deliverables desired from the assigned Workspace Developer teams. • Provides for interactive Quality Control and Quality Assurance processes to ensure that the software or solutions developed by the Developers accurately reflects the intent of the Workspace Working Group. • Creates near- and medium-term strategies for general Workspace activities which reflect the overall goals of the Workspace. • Creates documentation around the adoption and implementation of standards within the context of the Workspace area, including formal Standards Documentation, White Papers, and general caBIG policy documents. • Participates in discussions with outside experts and groups focused on areas of similar interest and research germane to the Workspace area. • Complies with defined Workspace processes and guidelines (e.g., from NCICB, caBIG Oversight Board or Strategic Level Working Groups) for Workspace activities. • Communicates and shares information with Strategic Level Working Groups and other Workspaces to enhance the congruence and consistency of activities and priorities across the caBIG initiative as a whole.

Workspace Scope and Participants

This section describes the scope and participants of the three Domain Workspaces and the two Cross Cutting Workspaces established for the caBIG pilot, respectively. Each Workspace has a specific focus and possible project activities that will be addressed by participant Developers, Adopters, and Working Groups.

Clinical Trial Management Systems Workspace

The Clinical Trial Management Systems (CTMS) Workspace addresses the Cancer Center community need for consistent, open and comprehensive tools for clinical trials management. Enhanced tools in this area will improve clinical research productivity, sharing of de-identified data across trials and sites, and facilitate greater standardization of coding, vocabulary, nomenclature, and data collection methods used as part of clinical trials.



The table below lists the CTMS Workspace participants and group members according to their key roles for the pilot phase of the caBIG initiative, as of February 2004. The CTMS Workspace Working Group will conduct its activities according to an established charter. The CTMS Workspace Working Group Charter may be found in Appendix A of this Handbook.

Cancer Center Developers	Cancer Center Adopters	Workspace Working Group
<ul style="list-style-type: none"> University of Pittsburgh City of Hope 	<ul style="list-style-type: none"> Wake Forest University Duke University University of California Irvine – Chao Family Case Western Reserve University – Ireland University of Pennsylvania – Abramson 	<ul style="list-style-type: none"> University of California – San Francisco Yale University Northwestern University – Robert H. Lurie University of Nebraska – Eppley University of Iowa – Holden University of Minnesota University of Wisconsin Vanderbilt University – Ingram <p><i>Plus Representatives from each Developer and Adopter site</i></p>

The CTMS Workspace focuses on the specification, implementation, and integration of tools for clinical data management that are consistent with the caBIG technical specifications and design philosophy. It is likely that in the beginning, in order to provide useful tools quickly, Workspace effort will focus on already-available tools that can be modified to provide integration into the Grid through interface and data-exchange standards. Initial development activities will focus on specific tools and interface software required for caBIG integration of available tools and infrastructure. Ultimately, the efforts should result in a set of related and interoperable tools for clinical data management, arising from the efforts and specific interests of all the Workspace participants.

Based on the expressed needs of Centers participating in the Center Development Meetings (CDM), several specific activity areas were highlighted for the CTMS Workspace. These areas will represent the starting points for efforts to develop and extend existing clinical trials infrastructure in order to make it suitable for caBIG use.

Proposed Workspace Project/Product Areas	
General Clinical Trials Data Management Platform(s)	<p>Examples:</p> <ul style="list-style-type: none"> Existing systems for clinical trials data collection and management New systems currently being developed for clinical trials data collection and management Planning and specifications to be followed by developers of new systems intended to be compatible with the caBIG



Proposed Workspace Project/Product Areas

- | | |
|-----------------------|--|
| Interoperable modules | <p>Examples:</p> <ul style="list-style-type: none"> • Adverse event monitoring and reporting • National registry for clinical trials in cancer for matching candidate patients and treatments • Systems for collecting research data on chemotherapy and patient management within clinical trials • Collection and data management of quality-of-life information • Study protocol design • Monitoring and reporting on ongoing studies • IRB management |
|-----------------------|--|

Integrative Cancer Research Workspace

The Integrative Cancer Research (ICR) Workspace provides tools and systems to enable integration and sharing of information among cancer researchers. These tools 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 data from “bench to bedside” and from “bench to bench.”

The table below lists the ICR Workspace participants and group members according to their key roles for the pilot phase of the caBIG initiative, as of February 2004. The ICR Workspace Working Group will conduct its activities according to an established charter. The ICR Workspace Working Group Charter may be found in Appendix B of this Handbook.

Cancer Center Developers	Cancer Center Adopters	Workspace Working Group
<ul style="list-style-type: none"> • Burnham Institute • Dartmouth – Norris Cotton • Duke University • Georgetown University – Lombardi • University of California – San Francisco • University of Chicago • University of Iowa – Holden • University of North Carolina – Lineberger • Cold Spring Harbor • Memorial Sloan-Kettering Fox Chase • Thomas Jefferson University – Kimmel • Washington University – Siteman 	<ul style="list-style-type: none"> • New York University • Memorial Sloan-Kettering • Oregon Health and Science University • Wistar • University of South Florida – H. Lee Moffitt • University of Pennsylvania – Abramson 	<ul style="list-style-type: none"> • Vanderbilt University – Ingram • Columbia University – Herbert Irving • Meyer L. Prentis – Karmanos • University of Michigan • Northwestern University – Robert H. Lurie <p><i>Plus representatives from each Developer and Adopter site</i></p>



The ICR Workspace focuses on the extension and implementation of tools to enable researchers to integrate and share data collected from a variety of heterogeneous sources, including de-identified patient clinical data and information collected from a variety of high-throughput research techniques. The intent is to caBIG-enable a wide range of tools particularly useful to cancer researchers, with a focus on enabling translational research and making data and analytical bioinformatics methods more useful to cancer researchers. Ultimately, the data and analysis should be capable of being shared with colleagues and transparently integrated with other related data.

Based on the expressed needs of Centers participating in the Center Development Meetings (CDM), several specific activity areas were highlighted for this Workspace. These areas will represent the starting points for efforts to develop and extend existing integrative cancer research infrastructure in order to make it suitable for caBIG use.

Proposed Workspace Project/Product Areas	
Translational Research	Examples: <ul style="list-style-type: none"> • Register clinical specimens linked to genomic data • Collaborative access to clinical/genomic tools and raw data
Microarray / Gene Expression	Examples: <ul style="list-style-type: none"> • Extend existing microarray tools to interoperate with caBIG • Integration of Zebra fish resources into caBIG
Statistical and Analysis	Examples: <ul style="list-style-type: none"> • Create tools to integrate standard statistics packages on to the caBIG network • Initiate development of methods using the caBIG platform which facilitate the combination of population datasets and exposure data
Pathways	Examples: <ul style="list-style-type: none"> • Incorporate existing pathway tools and databases into caBIG • Design and maintain mechanisms for feeding the biological pathways data from outside systems into caBIG
Proteomics	Examples: <ul style="list-style-type: none"> • Develop caBIG-interoperable systems for storage and processing of a variety of proteomics data
Data Sharing / Integration	Examples: <ul style="list-style-type: none"> • caBIG enable tools for linking data from mouse models to human data • Link experimental data of many types into caBIG framework

Tissue Banks and Pathology Tools Workspace

The Tissue Banks and Pathology Tools (TB&PT) Workspace provides for the integration, development, and implementation of tissue and pathology tools to enable sharing of data and [information](#) across sites.



The table below lists the TB&PT Workspace participants and group members according to their key roles for the pilot phase of the caBIG initiative, as of February 2004. The TB&PT Workspace Working Group will conduct its activities according to an established charter. The TB&PT Workspace Working Group Charter may be found in Appendix C of this Handbook.

Cancer Center Developers	Cancer Center Adopters	Workspace Working Group
<ul style="list-style-type: none"> • Washington University – Siteman • University of Pittsburgh 	<ul style="list-style-type: none"> • Northwestern University- Robert H. Lurie • University of North Carolina – Lineberger • Dartmouth – Norris Cotton • University of Pennsylvania – Abramson • Thomas Jefferson – Kimmel 	<ul style="list-style-type: none"> • Virginia Commonwealth University – Massey • Jackson Laboratory • Johns Hopkins – Sidney Kimmel • Indiana University • University of Arizona • University of Alabama at Birmingham <p><i>Plus representatives from each Developer and Adopter site</i></p>

The TB&PT Workspace focuses on the integration and implementation of tools for the collection and maintenance of tissue and pathology data. This will include the specifications and interface techniques allowing the creation and federation of repositories to be used by geographically and temporally dispersed clients throughout the Cancer Center community. The Workspace will initially work on identifying systems already developed by the Centers, and providing means for integration and federation of those resources, as well as providing specifications and guidance for the development of future software compatible with the caBIG.

Based on the expressed needs of centers participating in the Cooperative Development Meetings (CDM), several specific activity areas were highlighted for this Workspace. These areas will represent the starting points for efforts to develop and extend existing tissue banking and pathology research infrastructure in order to make it suitable for caBIG use.

Proposed Workspace Project/Product Areas	
General tissue database systems	Examples: <ul style="list-style-type: none"> • Specimen tracking and patient linking, HIPAA-compliant • Patient-owned tumor database • Virtual tissue and specimen repositories • Transparent data federation • Features supporting association with heterogeneous data
Tissue databases and repositories for integration into the caBIG	Examples: <ul style="list-style-type: none"> • High-quality repositories for specific cancers • Tissue repositories with associated environmental samples and information



Vocabularies and Common Data Elements Workspace

The Vocabularies and Common Data Elements (V&CDE) Workspace is responsible for evaluating and integrating systems for vocabulary and ontology content development, as well as software systems for content delivery. They are also responsible for developing standards for the representation of ontologies and vocabularies used throughout caBIG, as well as assessments of existing systems proposed for use within caBIG.

The table below lists the V&CDE Workspace participants and group members according to their key roles for the pilot phase of the caBIG initiative, as of February 2004. The V&CDE Workspace Working Group will conduct its activities according to an established charter. The V&CDE Workspace Working Group Charter may be found in Appendix D of this Handbook.

Cancer Center Developers	Cancer Center Adopters	Workspace Working Group
<ul style="list-style-type: none"> • Albert Einstein • Fred Hutchinson • Jackson Laboratory • Mayo Clinic • University of California – Davis • University of Hawaii • University of Pittsburgh 	<p>As this is a Cross Cutting Workspace, Adopter sites will be the Domain Workspaces in the caBIG initiative.</p>	<ul style="list-style-type: none"> • Albert Einstein • Fred Hutchinson • Jackson Laboratory • Mayo Clinic • University of California – Davis • University of Hawaii • University of Pittsburgh

The V&CDE Workspace focuses on software systems for the development and delivery of controlled vocabularies and ontologies of use to the Cancer Center community. Systems providing these functions will be modified whenever possible from those already in use to bring them into technical and design harmony with the caBIG structure. Additionally, Workspace members will participate in the planning, design, and implementation of Common Data Elements extending the caBIG-associated software systems.

During the initial pilot phase, some of the development projects in this Cross Cutting Working space may be proof of principle projects. Examples of products that this Workspace may produce include:



Proposed Workspace Project/Product Areas

Examples:

- Integration and implementation of software systems for vocabulary and ontology content development
- Integration and implementation of software systems for vocabulary and ontology content delivery
- The assessment of existing and newly-developed vocabulary and ontology content and recommendations for caBIG adoption and use
- The development, when necessary, of vocabularies
- Participation in the ongoing assessment and content development of common data elements

Architecture Workspace

The Architecture Workspace assists in bringing new architectural developments and standards to caBIG, acts as an interface to IT communities developing novel architectures, develops architectural white papers describing new opportunities, and provides architectural expertise and solutions to other Workspaces.

The table below lists the Architecture Workspace participants and group members according to their key roles for the pilot phase of the caBIG initiative, as of February 2004. The Architecture Workspace Working Group will conduct its activities according to an established charter. The Architecture Workspace Working Group Charter may be found in Appendix E of this Handbook.

Cancer Center Developers	Cancer Center Adopters	Workspace Working Group
Products from this Cross Cutting Workspace will support the consistency of architectural standards across the caBIG initiative.	Products from this Cross Cutting Workspace will support the consistency of architectural standards across the caBIG initiative.	<ul style="list-style-type: none"> • Cold Spring Harbor • Duke University • Georgetown University – Lombardi • Fred Hutchinson • Ohio State University – Arthur G. James/Richard J. Solove • University of Chicago • University of Pittsburgh • University of Wisconsin • Washington University – Siteman

During the initial pilot phase some of the development projects in this Cross Cutting Working space may be proof of principle projects. Examples of products that this Workspace may produce include:



Proposed Workspace Project/Product Areas

Examples:

- Standards documents
- White papers
- Reference implementations, where appropriate
- Ongoing assessment and evaluation of other Workspace products, optimizing caBIG integration throughout the project areas

Coordination of Workspace Activities

Overall coordination of the Workspace activities is undertaken by the Master Contractor in alignment with the program-level and strategic guidance from NCI/NCICB and the caBIG Oversight Board. Workspace Managers will be appointed by the Master Contractor to support each Workspace.

Workspace participants are responsible for the coordination of their Center level caBIG related projects and activities according to agreed Statements of Work and contracts. All Workspace participants are expected to support processes established by the Master Contractor as part of ensuring the coordination of caBIG activities.

Other Workspace Issues

This section discusses a variety of other issues that caBIG Workspace participants should understand and consider.

Workspace Communication and Interactions with Other Workspaces and Working Groups

The success of the caBIG network relies on communication and coordination both within Workspaces and between caBIG Workspaces and Working Groups. The importance of this collaborative effort is highlighted in the caBIG vision, goals, and principles.

Mechanisms to enhance communications within the caBIG initiative will be established, including face-to-face meetings and electronically-based strategies such as e-zines, electronic Program Updates, and web-based tools.

In addition to these types of mechanisms, the Cross Cutting Working Groups and Strategic Level Working Groups are responsible for addressing issues of



common concern such as architecture, training, and strategic planning. These groups will be required to work actively across Workspaces.

Performance of Workspace Activities

As part of undertaking Workspace activities, Workspace participants are expected to:

- Perform in accordance with their contracts and charters
- Meet agreed work plans, milestones, and deliverable schedules
- Support processes as stipulated by the Master Contractor, including those for performance planning, monitoring, and reporting
- Support programmatic and strategic guidance from the caBIG Oversight Board and NCICB and support the vision, goals, and principles of caBIG
- Perform activities within agreed scope and budget

Ownership of the Products and Solutions Developed from Workspace Activities

In keeping with the core values of the caBIG initiative, products and solutions developed as part of the caBIG Workspace activities will be designated under an open source / open documentation license. Throughout the pilot phase, it is envisioned that caBIG products will comply with NCI's open source model (additional information on this model can be found at <http://www.opensource.org>). As the caBIG initiative evolves, the licensing approach will be continually assessed and refined by the caBIG community, NCICB and the caBIG Oversight Board.

Introduction of New Workspace Participants and Projects

As the caBIG pilot evolves, new participants will be invited to join Workspaces either as Developers, Adopters, or Working Group Members. Invitation of new participants and spawning of new projects may be initiated at the NCICB or NCI level, or be the result of Working Group (Workspace or Strategic) or Project Group suggestions. New participants may include members of the Cancer Center Research Community or external groups that are in a position to make a strategic contribution to the caBIG initiative.



Conflict Resolution and Reporting of Concerns

Issues or concerns that arise within the Workspaces or that are associated with Workspace activities should be raised with the Master Contractor representative coordinating the Workspace. The Master Contractor is responsible for working with the individual or group that raised the concern and for ensuring that the issue is addressed. The Master Contractor may escalate the concern to the caBIG Oversight Board or NCICB for review and consideration. The caBIG Oversight Board and NCICB will be the final arbiters of any related decisions.

A Workspace participant can directly bring their concern to the caBIG Oversight Board if they feel that the Master Contractor is part of the issue they are raising and may impede resolution.

4. caBIG Project Processes

**Purpose of
this section**

Processes to guide caBIG project activities are discussed in this section.

**Who should read
this section?**

caBIG participants undertaking the following roles in Domain or Cross Cutting Workspaces:

- Developers
- Adopters
- Workspace Working Group Members.



4. caBIG Project Processes

Overview

Processes to guide Workspace level project activities have been established as part of the caBIG initiative. These processes accommodate the various types of possible caBIG projects, including software development, standards development, and efforts to share data. As caBIG evolves, these processes will be further developed and refined based on the input of caBIG participants.

These processes are not intended to be burdensome to caBIG participants. They should be considered as formal guidelines for the minimum amount of coordination and structure that is established for a given project.

These processes:

- Promote the use of industry best practice project management and development standards to enhance consistency and quality
- Facilitate effective management of project scope, schedule, and budget
- Enhance collaboration, cooperation, and integration between Workspace participants necessary to ensure the success of project activities
- Accommodate Cancer Center participants with varying needs and capabilities
- Enhance the creation and sharing of high-quality bioinformatics solutions between Centers and across the Cancer Center community
- Promote alignment of project activities with the broader goals of the grid and overall objectives of caBIG initiative.

Processes to guide project activities have been developed in the following key areas:

- Project Planning
- Implementation and Monitoring
- Testing/Adoption
- Documentation.



All caBIG project activities and processes must also be undertaken in accordance with caBIG’s technical principles:

- Open source
- Open Access
- Open development
- Federation.

caBIG Project Processes, Tasks and Activities

The Master Contractor will work in conjunction with the Workspace Project Leads and Working Groups to implement these processes. Templates, structures, and standards documents will be provided by the Master Contractor to assist the caBIG participants as they support the processes shown in the table below:

Project Processes	Tasks	Activities
Project Planning	<ul style="list-style-type: none"> • Project Plan Development 	<ul style="list-style-type: none"> • Estimate Project scope • Estimate Project effort, cost, and schedule • Establish/maintain estimates of work product & task attributes • Develop Project level Work Breakdown Structure
	<ul style="list-style-type: none"> • Requirements Management 	<ul style="list-style-type: none"> • Conduct requirements analysis • Generate/document requirements • Validate requirements • Develop requirements management process
	<ul style="list-style-type: none"> • Risk Management 	<ul style="list-style-type: none"> • Identify/analyze risks • Develop risk management process
	<ul style="list-style-type: none"> • Performance Management 	<ul style="list-style-type: none"> • Establish/maintain performance objectives • Define performance measures • Develop performance management plans
	<ul style="list-style-type: none"> • Confirmation Management 	<ul style="list-style-type: none"> • Identify/document configuration management items • Establish Change Control Board (CCB) to manage configuration items • Develop process for changes to configuration management items
Implementation & Monitoring	<ul style="list-style-type: none"> • Quality Assurance Management 	<ul style="list-style-type: none"> • Identify/document quality assurance items • Develop process for quality assurance monitoring
	<ul style="list-style-type: none"> • Project Plan Monitoring 	<ul style="list-style-type: none"> • Compare plan effort, cost, and schedule against actual • Generate regular status reports
	<ul style="list-style-type: none"> • Requirements Monitoring 	<ul style="list-style-type: none"> • Track requirements • Prepare/submit requests for changes to requirements • Address changes within project scope • Generate regular status reports for requirements



Project Processes	Tasks	Activities
	<ul style="list-style-type: none"> Risk Monitoring 	<ul style="list-style-type: none"> Mitigate risks Generate regular risk status reports
	<ul style="list-style-type: none"> Configuration Item Monitoring 	<ul style="list-style-type: none"> Track configuration management items Process changes to configuration management items Generate regular configuration item status reports
	<ul style="list-style-type: none"> Quality Assurance Monitoring 	<ul style="list-style-type: none"> Identify products and processes for QA audits Conduct regular QA audits Generate status reports with audit results Develop/execute corrective actions to resolve audit findings
	<ul style="list-style-type: none"> Performance Monitoring 	<ul style="list-style-type: none"> Compare actual performance against the plan Generate status reports with results
Testing/Adoption	<ul style="list-style-type: none"> Test Plan Development and Execution 	<ul style="list-style-type: none"> Develop Test Plan and Scripts Execute Test Plan and Scripts Generate Test Report
	<ul style="list-style-type: none"> Training 	<ul style="list-style-type: none"> Develop Training Materials Conduct User Training
	<ul style="list-style-type: none"> System Implementation 	<ul style="list-style-type: none"> Develop Implementation Plan Install System
Documentation	<ul style="list-style-type: none"> Documentation for Work Processes 	<ul style="list-style-type: none"> Project Plan Requirements Management Plan and Traceability Matrix Risk Management Plan Configuration Management Plan Quality Assurance Plan Test Plan and Scripts Standard and Ad Hoc Reports System Design Document Database Structure Application Source Code Training Plan User Manuals Performance Management Plan

Additional information on each of these processes, tasks, and activities will be provided as caBIG projects are initiated.

5. caBIG Working Groups

Purpose of this section

An overview of the structure and activities of the Strategic and Workspace Level caBIG Working Groups is provided in this section of the Handbook.

Who should read this section?

caBIG participants undertaking the following roles:

- Strategic Level Working Group Members
- Workspace Working Group Members.

Workspace Working Group Members should also read the caBIG Workspaces section of the Handbook.



5. caBIG Working Groups

Working Group Principles of Participation

As part of the caBIG initiative, all Working Group participants are encouraged to:

- Support the vision, spirit, and goals of the caBIG initiative as a whole
- Collaborate effectively with Workspaces and other Working Groups to support specific and overarching goals
- Undertake activities with integrity and objectivity
- Perform activities in a consensus driven manner
- Respect and capitalize on the skills and merits of individual members
- Support caBIG Oversight Board and Master Contractor guidelines and processes

Working Group Definition

Working Groups have been established to provide guidance and support to the caBIG pilot Workspaces and the caBIG initiative as a whole. Together, all Working Groups play a synergistic role, even though the exact focus of each Group varies according to its function. Group members will work collaboratively with the NCICB and the participating NCI designated Cancer Centers to facilitate the overall success of the caBIG pilot.

Types of Working Groups

Two types of Working Groups have been established to support the caBIG initiative:



Working Group Type	Role
(1) WORKSPACE Working Groups	<ul style="list-style-type: none"> • These Working Groups are specifically linked to each caBIG Domain Workspace and each Cross Cutting Workspace • These Working Groups provide expert guidance on Workspace and project activities, such as project priorities and tool specifications • Working Groups supporting Cross Cutting Workspaces provide leadership and content-related coordination for all caBIG Workspaces in their specific subject areas, so as to facilitate consistency and congruence for the caBIG initiative as a whole
(2) STRATEGIC LEVEL Working Groups	<ul style="list-style-type: none"> • These Strategic Level Working Groups assist the caBIG Oversight Board with strategic planning and vision development activities • These Working Groups also offer guidance on specific areas of concern to caBIG oversight groups or Workspace participants • Strategic Level Working Groups interact with external experts to ensure the adoption of appropriate standards and policies in the caBIG Workspaces

As described in previous sections, five Working Groups to support the Workspaces have been convened:

- (1) Clinical Trial Management Systems Working Group
- (2) Integrative Cancer Research Working Group
- (3) Tissue Banks and Pathology Tools Working Group
- (4) Vocabularies and Common Data Elements Working Group
- (5) Architecture Working Group.

Three Strategic Level Working Groups have also been convened:

- (1) caBIG Strategic Planning Group
- (2) Data Sharing and Intellectual Capital Working Group
- (3) Training Working Group.

Standing and ad hoc sub-groups, composed of Working Group members, may be established to perform specific functions on an as-needed basis.

Membership

Individuals from the NCI designated Cancer Centers form the core membership of each Working Group. Workspace Working Groups include both invited Center participants and Center participants who are directly undertaking Workspace project activities, such as Developers and Adopters.

The majority of Working Group members are funded participants. Support for membership on a Working Group is only provided for only *one* attendee from each Center represented. However, the same individual does not have to



attend all group meetings or undertake group activities. Depending on the nature of the activity, it is reasonable for different individuals to attend at different times based on their particular expertise or knowledge. Choice of which individual to attend a given Working Group meeting or activity is at the Center's discretion.

Members of the cancer research community who are interested in participating in a Working Group may request participation as an unfunded member. Ongoing participation of unfunded members is at the discretion of the caBIG Oversight Board and NCICB.

Stakeholders outside the NCI-designated Cancer Center community may be invited to participate in Working Groups on an ad hoc basis depending on their expertise or experiential knowledge.

The **funded members of each caBIG Working Group** are shown in the table below (current February 2004):

Workspace Working Group	Funded Members
Domain Workspace Working Group – Clinical Trial Management Systems	<ul style="list-style-type: none"> • University of California – San Francisco • Yale University • Northwestern University – Robert H. Lurie • University of Nebraska – Eppley • University of Iowa – Holden • University of Minnesota • University of Wisconsin • Vanderbilt University – Ingram <p><i>Plus representatives from each Developer and Adopter site</i></p>
Domain Workspace Working Group – Integrative Cancer Research	<ul style="list-style-type: none"> • Vanderbilt University – Ingram • Columbia University – Herbert Irving • Meyer L. Prentis – Karmanos • University of Michigan • Northwestern University – Robert H. Lurie <p><i>Plus representatives from each Developer and Adopter site</i></p>
Domain Workspace Working Group – Tissue Banks and Pathology Tools	<ul style="list-style-type: none"> • Virginia Commonwealth University – Massey • Jackson Laboratory • Johns Hopkins – Sidney Kimmel • Indiana University • University of Arizona • University of Alabama at Birmingham <p><i>Plus representatives from each Developer and Adopter site</i></p>
Cross Cutting Workspace Working Group – Vocabularies and Common Data Elements	<ul style="list-style-type: none"> • Albert Einstein • Fred Hutchinson • Jackson Laboratory • Mayo Clinic • University of California – Davis • University of Hawaii • University of Pittsburgh



Workspace Working Group	Funded Members
Cross Cutting Workspace Working Group – Architecture	<ul style="list-style-type: none"> • Cold Spring Harbor • Duke University • Georgetown University – Lombardi • Fred Hutchinson • Ohio State University – Arthur G. James/Richard J. Solove • University of Chicago • University of Pittsburgh • University of Wisconsin • Washington University – Siteman
Strategic Level Working Group	Funded Members
caBIG Strategic Planning	<ul style="list-style-type: none"> • City of Hope • Cold Spring Harbor • Duke University • Fox Chase • Fred Hutchinson • MD Anderson • St Jude Children’s Research Hospital • University of Alabama – Birmingham • University of Colorado • University of Iowa – Holden • University of Pennsylvania – Abramson • University of Pittsburgh • University of Southern California – Norris • University of Vermont • Washington University – Siteman • Yale University
Data Sharing and Intellectual Capital	<ul style="list-style-type: none"> • University of Arizona • City of Hope • Cold Spring Harbor • Fred Hutchinson • Jackson Laboratory • Johns Hopkins – Sidney Kimmel • Oregon Health and Science University • Thomas Jefferson University – Kimmel • University of Iowa – Holden • University of North Carolina – Lineberger • University of Michigan • University of Minnesota • University of Pittsburgh • Washington University – Siteman
Training	<ul style="list-style-type: none"> • Cold Spring Harbor • Institute for Cancer Prevention • Johns Hopkins – Sidney Kimmel • Mayo Clinic • Oregon Health and Science University • University of California Davis • University of Chicago • University of Iowa – Holden • University of Pennsylvania – Abramson • University of Pittsburgh



Working Group Activities

This section summarizes the activities of individual Working Group Members and Working Groups as a whole. *These activities are intended as a guide and not to restrict Working Group efforts.* Working Groups will have the opportunity to further develop and refine these activities as the pilot progresses.

Activities of Individual Working Group Members

The following tables present a summary of the activities of the individual Working Group Members for the Workspace and Strategic Level Working Groups.

Workspace Working Group Members	Activities of Individual Members
<p>Members of the Workspace Working Groups are Expected to:</p>	<ul style="list-style-type: none"> • Provide functional, technical, and experience-based, thought-leadership to assist the Workspaces in the development of targeted solutions that specifically address Cancer Center needs • Divide labor between Working Group members to reduce redundant activities and minimize workload • Contact and coordinate with functional experts and supporting staff at their own Institutions to assist with analysis and design of requirements • Collect and interpret requirements within and between Workspaces to ensure that they satisfy the needs of the Cancer Center community • Draft memos, white papers, and briefs to communicate findings and needs within and between Working Groups • Review deliverables, approaches, and work products for Developers and Adopters where necessary • Reference and introduce Standards Bodies and External Organizations to support specific choices for caBIG where necessary • Support the conduct of meetings to ensure that caBIG goals are met • Develop, draft, and edit Working Group reports to document accomplishments and activities • Maintain contact with other Working Group members and Workspace participants



Strategic Level Working Group Members	Activities of Individual Members
Members of the Strategic Level Working Groups are Expected to:	<ul style="list-style-type: none"> • Provide expertise and thought-leadership to develop guidelines and policies addressing critical cross-initiative Workspace and Working Group specific issues • Divide labor between Strategic Level Working Group members to reduce redundant activities and minimize workload • Collect concerns and develop proposals and solutions to address critical needs of multiple Cancer Center participants involved in caBIG • Draft memos, white papers, and briefs to communicate findings and approaches to resolve issues within and between Workspaces and Working Groups • Coordinate with Master Contractor and Working Group Facilitators to ensure that guidelines and policies are rapidly and widely distributed • Support the conduct of meetings to ensure that caBIG goals are met • Develop, draft, and edit Working Group reports to document accomplishments and activities

Activities of Working Groups as a Whole

The following two tables summarize the activities of the Workspace and Strategic Level Working Groups as a whole:

Workspace Working Groups

Activity	Sub-Tasks
Definition of Goals, Priorities and Scope for Workspace Projects	<ul style="list-style-type: none"> • Organization of initial meetings to define, within the delineated scope of the Workspace, detailed goals and targets of that Workspace • Assess and discuss feasibility of achieving Workspace goals with caBIG Oversight Board and Master Contractor • Prioritize defined Workspace goals, in terms of software, tool, or policy or standards deliverables • Record and submit to Master Contractor assumptions, needs, and risks the Working Group must address to succeed • Draft, revise, and submit a Workspace Vision and Goals document available to all caBIG participants



Activity	Sub-Tasks
<p>Establishment of Working Group Plans and Estimation of Required Effort</p>	<ul style="list-style-type: none"> • Assign roles and responsibilities within Working Group, based on availability, expertise, and willingness to adopt role (ensuring appropriate rotation and hand-offs where necessary) • Schedule and create a Working Group plan based on processes established by the Master Contractor as well as the Workspace scope and priorities • Work with the Master Contractor to ensure that the plan adequately reflects solutions/deliverables desired from the assigned Developers and Adopters • Record and distribute expected Working Group Level of Effort to Master Contractor to ensure that resources are appropriately coordinated • Review and coordinate schedule with Developers and Adopters • Using the available allocated effort from the Workspace Developer and Adopter resources, assign solutions/deliverables • Review Working Group plan with Developer and Adopters to ensure feasibility
<p>Coordination with Workspaces, Other Workgroups, caBIG Oversight Board, Master Contractor, and External Stakeholders</p>	<ul style="list-style-type: none"> • Adopt communication plan (in accordance with the caBIG Communication Strategy and Plan) and implement procedures where necessary • Review Working Group plan with Master Contractor and Facilitator to ensure that it matches needs and priorities of others • Solicit similar schedules from related groups to sequence inter-related activities • Validate and report schedule in the context of Workspace capabilities • Schedule time for interactive Quality Control and Quality Assurance (QC/QA) processes to ensure that the solutions developed by the Developers accurately reflect the intent of the project • Solicit and engage outside experts focused on areas of similar interest and research to the Workspace area
<p>Execution of Activities, Meetings, and Deliverables</p>	<ul style="list-style-type: none"> • Estimate complexity for high-level Workspace requirements • Iteratively collect strategic, technical, and administrative non-functional requirements and capture historical requirements from prior project efforts and prototypes from within own and related Workspaces • Categorize the requirements into groups to anticipate and mitigate implementation and design constraints • Where appropriate, create high-level models to logically organize and group the business requirements into functional modules (e.g., business process flow diagrams, context maps, and functional hierarchy outlines) • Review formal Software Specifications for solutions/deliverables generated by Developers. These specifications are likely to take the form of use-cases, UML diagrams, and other high-level representations of the problem



Activity	Sub-Tasks
Monitoring of Activities and Deliverables	<ul style="list-style-type: none"> • Agree with Master Contractor on appropriate project performance measures to ensure early conflict-resolution, if needed • Agree on thresholds that trigger the need to adjust schedule or work plan • Iterate progress reports and updates to ensure that projects are on track • Iteratively share planned schedule with other Workgroups to ensure coordination of schedules where required • Track activities, meetings, deliverables, and action items against planned measures together with Master Contractor to identify delays early • Solicit and track from Adopters resolution of QC/QA issues that were identified in QC/QA processes
Reporting of Findings and Work Products	<ul style="list-style-type: none"> • Provide adequate documentation of the Working Group’s activities • Solicit informal review from peers focused on areas of similar interest and research germane to the Workspace area • Report resolution of QC/QA issues that were identified in QC/QA processes to the Master Contractor • Create documentation around the adoption and implementation of standards, including formal Standards Documentation

Each Workspace Working Group will conduct its activities according to an established charter. These Charters are located in the Appendices of this Handbook:

- Appendix A – caBIG Clinical Trial Management Systems Workspace Working Group Charter
- Appendix B – caBIG Integrative Cancer Research Workspace Working Group Charter
- Appendix C – caBIG Tissue Banks and Pathology Tools Workspace Working Group Charter
- Appendix D – caBIG Vocabularies & Common Data Elements Workspace Working Group Charter
- Appendix E – caBIG Architecture Workspace Working Group Charter.

Strategic Level Working Groups

Activity	Sub-Tasks
Definition of Vision and Strategic Goals	<ul style="list-style-type: none"> • Publicize a Working Group vision and goals document available to briefly communicate strategic priorities to caBIG participants • Work in conjunction with caBIG Oversight Board and NCICB to define scope and goals for cross-initiative activities and how they pertain to individual Working Groups and Workspaces



Activity	Sub-Tasks
Review and Validation of Strategic Direction of Workspace Efforts	<ul style="list-style-type: none"> Solicit challenges and limits from Workspace Working Groups and Workspace participants to re-validate focus of the strategic analysis and to help identify which external experts to involve in future activities Identify Cancer Centers to involve in strategic discussions that may provide relevant insights and experiences
Incorporation of Functional Components, Solutions, or Standards from Other Working Groups, Workspaces, and Centers	<ul style="list-style-type: none"> Create formal documents illustrating goals and plans of caBIG that will be addressed by Developers and Adopters affected by the relevant issue(s) Identify Workspace-relevant standards and outline benefits, communicating these with White Papers and general caBIG policy documents. These standards will leverage existing standards and caBIO object models where possible Create documentation around the adoption and implementation of standards within the context of the Workspace area including formal Standards Documentation Create caBIG policy documents around issues relevant to the Workspace Working Groups. These policy documents are aimed at future caBIG activities Solicit and engage outside experts focused on areas of similar interest and research to the Workspace/Working Group area
Coordination with Other Working Groups, Workspaces, caBIG Oversight Board, Master Contractor and External Stakeholders	<ul style="list-style-type: none"> Coordinate with other Groups and outside experts exploring similar topics to ensure that the caBIG policy standards reflect those in current general usage where appropriate Report policy or standard-related changes together with the NCICB and caBIG Oversight Board with bulletins to ensure that other Working Groups have the opportunity to adjust to the changes
Consistency, Uniformity, and Establishment of Standards	<ul style="list-style-type: none"> Report on standards, vocabularies, and procedures in caBIG Workspaces and Working Groups and outline potential synergies or conflicts with existing Centers Report on foreseeable future standards-related developments Recommend resolution of internal standard or procedural conflicts within caBIG to foster uniformity of approaches, data, and policies Create a white paper outlining a draft policy on which standards should continue to be supported to ensure consistency across Workspaces
Reporting of Findings and Work Products	<ul style="list-style-type: none"> Prepare reports describing activities, findings, and unresolved issues

Each Strategic Level Working Group will conduct its activities according to an established charter. These Charters are located in the Appendices of this Handbook:

- Appendix F – caBIG Strategic Planning Group Strategic Level Working Group Charter
- Appendix G – caBIG Data Sharing and Intellectual Capital Strategic Level Working Group Charter
- Appendix H – caBIG Training Strategic Level Working Group Charter



Coordination of Working Group Activities

Coordination of Working Group activities is provided primarily by the Working Group **Facilitator** and the Working Group **Coordinator**.

A Working Group Facilitator will be appointed by the NCICB to each Working Group to lead the functional activities of the group. A Coordinator from the Master Contractor group will be appointed to each Working Group to provide administrative and operational support.

All Working Group participants are expected to support coordination and oversight processes established as part of the caBIG initiative.

Other Working Group Issues

Working Group Meetings

Working Group meetings will be held quarterly or more frequently, if required. The Working Group Coordinator will work with the Facilitator to ensure the meeting schedule meets the needs of the Working Group (and other affected caBIG groups) and enables them to effectively perform their role.

Where possible, quarterly meetings will be held on a face-to-face basis. Other appropriate avenues for meetings, such as teleconferences or videoconferences, will be identified with input from Working Group representatives.

The timing and frequency of Working Group activities, undertaken outside of group meetings (e.g., activities performed to help meet Working Group deliverables), will be determined by the Facilitator and Coordinator in conjunction with the other Working Group members.

Interactions with Other Working Groups

Effective communication between the Working Groups is critical to ensure the broader goals of the pilot grid are understood and achieved and the “lessons learned” from group activities are shared across the caBIG.

Communications and outreach mechanisms will be established as part of the caBIG initiative to support interactions between the various Working Groups.



Monitoring the Performance of Working Group Activities

As part of undertaking Working Group activities, Working Group participants are expected to:

- Perform in accordance with their charters
- Meet agreed work plans, milestones, and deliverable schedules
- Support processes established by the Master Contractor
- Support strategic guidance from the caBIG Oversight Board and NCICB and support the vision, goals, and principles of caBIG
- Perform activities within agreed scope and budget.

Conflict Resolution and Reporting of Concerns

Individual Working Group members may raise concerns regarding group activities to the Facilitator or Coordinator. If they feel that the problem has not been sufficiently addressed they may report concerns directly to the caBIG Oversight Board in accordance with established guidelines for reporting.

6. Key caBIG Coordination and Oversight Roles

**Purpose of
this section**

An overview of the activities and responsibilities of key caBIG coordination and oversight roles, including the caBIG Oversight Board, the Master Contractor, and Working Group Facilitators.

**Who should read
this section?**

caBIG participants interested in knowing more about the activities and responsibilities associated with these roles.



6. Key caBIG Coordination and Oversight Roles

This section of the Handbook provides additional information on the following key caBIG coordination and oversight roles:

- caBIG Oversight Board
- Master Contractor (including Workspace Managers and Working Group Coordinators)
- Working Group Facilitator

(Note: A full listing of caBIG coordination roles is provided in Section 2, caBIG Structure and Coordination.)

caBIG Oversight Board

The caBIG Oversight Board is the primary coordinating body for the caBIG initiative. It is comprised primarily of senior leadership from NCICB, as well as representatives from the NCI and NIH. The high-level activities, responsibilities and authority of the caBIG Oversight Board are summarized in the following table:

caBIG OVERSIGHT BOARD	
Activities and Responsibilities	Authority
<ul style="list-style-type: none"> • Provides strategic leadership and programmatic coordination for the caBIG initiative (in conjunction with NCI and NCICB) • Ensures effective operational coordination of the caBIG Initiative (via the Master Contractor) • Monitors the caBIG initiative (e.g., performance and risk management) • Facilitates communication and outreach activities for the caBIG initiative • Fosters accountability and provides conflict resolution mechanisms 	<ul style="list-style-type: none"> • Program level coordination of caBIG activities, groups, and participants. • The final arbiter of caBIG decisions including those related to overall scope, schedule, budget, and procurement.

The caBIG Oversight Board is supported by the Program Management Team (contracting team).



The caBIG Oversight Board will conduct its activities according to an established charter.

Master Contractor

The Master Contractor (contracting team appointed by NCICB) coordinates caBIG operational activities including Workspace and Working Group activities. The Master Contractor will appoint Workspace Managers to each of the five caBIG Workspaces to provide overall coordination for their respective Workspace. They will also appoint Coordinators to each of the Working Groups (Workspace and Strategic Level) to provide administrative support and coordination.

The Master Contractor works in close collaboration with the caBIG Oversight Board.

The high-level activities, responsibilities and authority of the Master Contractor are summarized in the following table:

MASTER CONTRACTOR	
Activities and Responsibilities	Authority
<ul style="list-style-type: none"> • Provides day-to-day coordination of caBIG operational activities, including Workspace, Working Group, and project activities • Provides funding to caBIG participants via contract mechanisms (as per programmatic guidance) • Ensures programmatic/strategic guidance and priorities are communicated to and implemented by the Workspaces and Working Groups • Monitors caBIG activities (e.g., performance and risk management) and reports on these to the caBIG Oversight Board • Facilitates communication and outreach activities at the Workspace and Working Group level to enhance consistency across caBIG • Fosters accountability and provides conflict resolution mechanisms • Works collaboratively with caBIG participants (e.g., Cancer Centers) to ensure their input into activities and guidelines is solicited and implemented 	<p>Operational coordination of caBIG Workspaces, Working Groups, and project activities</p> <p>In consultation with the caBIG Oversight Board:</p> <ul style="list-style-type: none"> • serves as the arbiter of any decisions related to project activities and Workspace/ Working Group funding • directs and manages budgetary allocations within Workspaces and Working Groups



The Master Contractor will conduct its activities according to an established charter.

Working Group Facilitator

Independent Facilitators will be appointed by NCICB to lead the functional activities of the Working Groups. If required, the Facilitator may appoint a representative to act on their behalf.

Facilitator responsibilities are detailed in the table:

The Facilitator is responsible for:

- Ensuring meeting discussions are balanced, fair, productive, and stay on task
- Honoring the consensus-driven nature of the Working Groups and ensuring that the skills and expertise of individual members are capitalized on as part of the effective functioning of the group
- Nominating members onto and off the group (in consultation with the Master Contractor, caBIG Oversight Board, and NCICB)
- Inviting ad hoc members to participate in meetings, as required, and soliciting written guidance on specific topics as required
- Ensuring that solutions development activities (e.g., applications, standards) are consistent with caBIG and NCICB, NCI and NIH requirements and priorities
- Monitoring that caBIG goals are pursued and that Working Groups are addressing tactical caBIG goals in support of Cancer Center needs
- Responding to programmatic and procedural questions of specific Workspaces relating to the content of caBIG
- Facilitating approval and review mechanisms for Working Group plans and deliverables with caBIG Oversight Board and Master Contractor
- Reinforcing the principles and values of collaboration within and between Workspaces and Working Groups by organizing meetings and soliciting feedback from other Facilitators and Workspace representatives relating to their activities
- Ensuring that group roles are appropriately rotated so that all Working Group participants can fully contribute during Working Group meetings
- Contacting Workspace participants between meetings for updates on project progress to provide pulse-checks for Working Group members
- Providing conflict resolution mechanisms and channels for reporting of concerns to the caBIG Oversight Board, the NCICB, as well as other Working Groups



Appendices

These Appendices provide additional information to support specific sections of this handbook and general information about the terms used herein. Appendices A-H present the caBIG charters of the Workspace and Strategic Level Working Groups. Appendix I provides a glossary of terms used in this Handbook.

- Appendix A – caBIG Clinical Trial Management Systems Workspace Working Group Charter
- Appendix B – caBIG Integrative Cancer Research Workspace Working Group Charter
- Appendix C – caBIG Tissue Banks and Pathology Tools Workspace Working Group Charter
- Appendix D – caBIG Vocabularies and Common Data Elements Workspace Working Group Charter
- Appendix E – caBIG Architecture Workspace Working Group Charter
- Appendix F – caBIG Strategic Planning Group Strategic Level Working Group Charter
- Appendix G – caBIG Data Sharing and Intellectual Capital Strategic Level Working Group Charter
- Appendix H – caBIG Training Strategic Level Working Group Charter
- Appendix I – Handbook Terms and Conventions



Appendix A – caBIG Pilot Initiative – Clinical Trial Management Systems Workspace Working Group Charter

DRAFT January 2004

Purpose

The Clinical Trial Management Systems Working Group supports the activities of the Clinical Trial Management Systems Domain Workspace of the caBIG initiative by providing expert guidance on project priorities and requirements. This Workspace addresses the Cancer Center community need for consistent, open, and comprehensive tools for clinical trials management.

Membership

Working Group members include invited NCI-designated Cancer Centers and representatives from the Developer and Adopter teams in the Workspace.

Funded Working Group membership (current as of January 2004) is as follows:

- University of California San Francisco
- Yale University
- Northwestern University – Robert H. Lurie
- University of Nebraska – Eppley
- University of Iowa – Holden
- University of Minnesota
- University of Wisconsin
- Vanderbilt University – Ingram
- *Plus representatives from each Developer and Adopter site.*

At the discretion of caBIG oversight groups, other members of the biomedical research community may participate in this Working Group on a funded, unfunded, or ad hoc basis.

Responsibilities and Authority

The general proposed responsibilities of this Working Group include:

- Definition of goals, scope, and priorities for Workspace projects
- Establishment of Working Group plans and estimation of required effort



- Coordination with other Working Groups, Workspaces, Master Contractor, caBIG Oversight Board, and external stakeholders
- Execution of activities, meetings, and deliverables
- Monitoring of activities and deliverables
- Reporting of findings and work products.

The specific proposed responsibilities of this Working Group are as follows:

- Establish overall structure and scope for initial clinical trials management projects
- Determine initial set of projects for Workspace
- Define requirements for clinical trials data management standards
- Propose integration requirements for “caBIG Compliant” clinical trials data management software and tools
- Define operational requirements and procedures for caBIG integration
- Prioritize tool and software development requirements
- Create specifications against prioritized tools and activities
- Develop test and validation requirement standards for Workspace software and tools
- Review completed tools and projects and evaluate against initial specification, test, and validation requirements.

This Working Group has the authority to work as a collaborative participant of the Clinical Trial Management Systems Workspace and to coordinate with other caBIG Working Groups and participants. The Group does *not* have the authority to direct budgetary allocations within Workspaces or the pilot as a whole.

Coordination and Oversight

The functional activities of this Working Group are led by an independent facilitator appointed by NCICB.



Administrative and operational oversight of Working Group activities is provided by a Coordinator representing the Master Contractor.

The Working Group is accountable to the Master Contractor and the caBIG Oversight Board for their activities and actions. The caBIG Oversight Board is the final arbiter of any caBIG decisions.

Meetings

Meetings are held quarterly or more frequently if required. Meetings may be face-to-face or undertaken via teleconference or videoconference.

Documentation

The plans, activities, and deliverables of this Working Group are documented and retained as part of caBIG initiative records. The Facilitator and Coordinator (Master Contractor representative) are responsible for ensuring effective documentation of Working Group activities.



Appendix B – caBIG Pilot Initiative – Integrative Cancer Research Workspace Working Group Charter

DRAFT January 2004

Purpose

The Integrative Cancer Research Working Group supports the activities of the Integrative Cancer Research Domain Workspace of the caBIG initiative by providing expert guidance on project priorities and requirements. This Workspace provides tools and systems to enable integration and sharing of information among cancer researchers to facilitate both “bench-to-bedside” and “bench-to-bench” integrative research.

Membership

Working Group members include invited NCI-designated Cancer Centers and representatives from the Developer and Adopter teams in the Workspace.

Funded Working Group membership (current as of January 2004) is as follows:

- Vanderbilt University – Ingram
- Columbia University – Herbert Irving
- Meyer L. Prentis – Karmanos
- University of Michigan
- Northwestern University – Robert H. Lurie
- *Plus representatives from each Developer and Adopter site.*

At the discretion of caBIG oversight groups, other members of the biomedical research community may participate in this Working Group on a funded, unfunded, or ad hoc basis.

Responsibilities and Authority

The general proposed responsibilities of this Working Group include:

- Definition of goals, scope, and priorities for Workspace projects
- Establishment of Working Group plans and estimation of required effort
- Coordination with other Working Groups, Workspaces, Master Contractor, caBIG Oversight Board, and external stakeholders



- Execution of activities, meetings, and deliverables
- Monitoring of activities and deliverables
- Reporting of findings and work products.

The specific proposed responsibilities of this Working Group are as follows:

- Establish structure and scope for initial integrative cancer research projects
- Determine initial set of projects for Workspace, based on current developer participant activities
- Select and develop standards for integrative cancer research data interoperability
- Propose standards for inclusion of tools and software in caBIG Integrative Cancer Research Workspace
- Determine roles of outside groups in the set of standards used in the Integrative Cancer Research Workspace
- Evaluate general mechanisms for data exchange in activities determined to be within the scope of the Integrative Cancer Research Workspace
- Prioritize tool and software development requirements
- Provide for use by Adopters of Workspace tools to offer their data on the grid
- Create specifications against prioritized tools and activities
- Develop test and validation requirement standards for Workspace software and tools
- Review completed tools and projects and evaluate against initial specification, test, and validation requirements.

This Working Group has the authority to work as a collaborative participant of the Integrative Cancer Research Workspace and to coordinate with other caBIG Working Groups and participants. The Group does *not* have the authority to direct budgetary allocations within Workspaces or the pilot as a whole.



Coordination and Oversight

The functional activities of this Working Group are led by an independent facilitator appointed by NCICB.

Administrative and operational oversight of Working Group activities is provided by a Coordinator representing the Master Contractor.

The Working Group is accountable to the Master Contractor and the caBIG Oversight Board for their activities and actions. The caBIG Oversight Board is the final arbiter of any caBIG decisions.

Meetings

Meetings are held quarterly or more frequently if required. Meetings may be face-to-face or undertaken via teleconference or videoconference.

Documentation

The plans, activities, and deliverables of this Working Group are documented and retained as part of caBIG initiative records. The Facilitator and Coordinator (Master Contractor representative) are responsible for ensuring effective documentation of Working Group activities.



Appendix C – caBIG Pilot Initiative – Tissue Banks and Pathology Tools Workspace Working Group Charter

DRAFT January 2004

Purpose

The Tissue Banks and Pathology Tools Working Group supports the activities of the Tissue Banks and Pathology Tools Domain Workspace of the caBIG initiative by providing expert guidance on project priorities and requirements. This Workspace provides for the integration, development, and implementation of tissue and pathology tools to enable sharing of data and information across sites.

Membership

Working Group members include invited NCI-designated Cancer Centers and representatives from the Developer and Adopter teams in the Workspace.

Funded Working Group membership (current as of January 2004) is as follows:

- Virginia Commonwealth University – Massey
- Jackson Laboratory
- Johns Hopkins – Sidney Kimmel
- Indiana University
- University of Arizona
- University of Alabama at Birmingham
- *Plus representatives from each Developer and Adopter site.*

At the discretion of caBIG oversight groups, other members of the biomedical research community may participate in this Working Group on a funded, unfunded, or ad hoc basis.

Responsibilities and Authority

The general proposed responsibilities of this Working Group include:

- Definition of goals, scope, and priorities for Workspace Projects
- Establishment of Working Group plans and estimation of required effort



- Coordination with other Working Groups, Workspaces, Master Contractor, caBIG Oversight Board, and external stakeholders
- Execution of activities, meetings, and deliverables
- Monitoring of activities and deliverables
- Reporting of findings and work products.

The specific proposed responsibilities of this Working Group are as follows:

- Establish structure and scope for initial Tissue Banks and Pathology Tools Workspace projects
- Determine initial set of projects for focus by Workspace
- Select and develop standards for communication and storage of tissue and pathology data
- Evaluate existing tissue and pathology databanks for integration into caBIG
- Evaluate existing standards and mechanisms for tissue and pathology data exchange
- Prioritize tool and software development requirements
- Prioritize data source inclusion
- Create specifications for the development and inclusion of tissue and pathology tools and data sources into caBIG
- Create specifications against prioritized tools and activities
- Develop test and validation requirement standards for Workspace software and tools
- Review completed tools and projects and evaluate against initial specification, test, and validation requirements.

This Working Group has the authority to work as a collaborative participant of the Tissue Banks and Pathology Tools Workspace and to coordinate with other caBIG Working Groups and participants. The Group does *not* have the authority to direct budgetary allocations within Workspaces or the pilot as a whole.



Coordination and Oversight

The functional activities of this Working Group are led by an independent facilitator appointed by NCICB.

Administrative and operational oversight of Working Group activities is provided by a Coordinator representing the Master Contractor.

The Working Group is accountable to the Master Contractor and the caBIG Oversight Board for their activities and actions. The caBIG Oversight Board is the final arbiter of any caBIG decisions.

Meetings

Meetings are held quarterly or more frequently if required. Meetings may be face-to-face or undertaken via teleconference or videoconference.

Documentation

The plans, activities, and deliverables of this Working Group are documented and retained as part of caBIG initiative records. The Facilitator and Coordinator (Master Contractor representative) are responsible for ensuring effective documentation of Working Group activities.



Appendix D – caBIG Pilot Initiative – Vocabularies and Common Data Elements Workspace Working Group Charter

DRAFT January 2004

Purpose

The Vocabularies and Common Data Elements Working Group supports the activities of the Vocabularies and Common Data Elements Cross Cutting Workspace of the caBIG initiative. This Workspace is responsible for evaluating and integrating systems for vocabulary and ontology content development as well as software systems for content delivery. This Workspace is also responsible for developing standards for the representation of ontologies and vocabularies used throughout caBIG and for assessing existing systems proposed for use within caBIG.

As this Working Group supports a Cross Cutting Workspace, members are required to provide leadership and content-related coordination in their specific subject areas for all caBIG Workspaces so as to facilitate consistency and congruence for the caBIG initiative as a whole.

Membership

Working Group members include invited NCI-designated Cancer Centers and representatives from the Developer teams in the Workspace.* Funded Working Group membership (current as of January 2004) is as follows:

- Albert Einstein
- Fred Hutchinson
- Jackson Laboratory
- Mayo Clinic
- University of California – Davis
- University of Hawaii
- University of Pittsburgh

(*Note: Adopter sites are not included as representatives on this Working Group, as in the case of Cross Cutting Workspaces, Adopter sites are other Workspaces in the caBIG initiative.)



At the discretion of caBIG oversight groups, other members of the biomedical research community may participate in this Working Group on a funded, unfunded, or ad hoc basis.

Responsibilities and Authority

The general proposed responsibilities of this Working Group include:

- Definition of goals, scope, and priorities for Workspace Projects
- Establishment of Working Group plans and estimation of required effort
- Coordination with other Working Groups, Workspaces, Master Contractor, caBIG Oversight Board, and external stakeholders
- Execution of activities, meetings, and deliverables
- Monitoring of activities and deliverables
- Reporting of findings and work products.

The specific proposed responsibilities of this Working Group are as follows:

- Establish standards and platforms for caBIG activities in:
 - Vocabulary/Ontology Content development
 - Vocabulary/Ontology Content delivery
- Establish mechanisms for:
 - Content assessment and recommendations for caBIG adoption and incorporation of specific vocabularies and ontologies
 - Content development, when necessary
- Prioritize tool and software development requirements
- Evaluate, advise on, and test NCICB common data elements
- Develop reference implementations, software proof-of-principle implementations, skeleton applications, and other facilitators of CDE and Vocabulary use.

This Working Group has the authority to work as a collaborative participant of the Vocabularies and Common Data Elements Workspace and to coordinate with other caBIG Working Groups, Workspaces, and participants. The Group does *not* have the authority to direct budgetary allocations within Workspaces or the pilot as a whole.



Coordination and Oversight

The functional activities of this Working Group are led by an independent facilitator appointed by NCICB.

Administrative and operational oversight of Working Group activities is provided by a Coordinator representing the Master Contractor.

The Working Group is accountable to the Master Contractor and the caBIG Oversight Board for their activities and actions. The caBIG Oversight Board is the final arbiter of any caBIG decisions.

Meetings

Meetings are held quarterly or more frequently if required. Meetings may be face-to-face or undertaken via teleconference or videoconference.

Documentation

The plans, activities, and deliverables of this Working Group are documented and retained as part of caBIG initiative records. The Facilitator and Coordinator (Master Contractor representative) are responsible for ensuring effective documentation of Working Group activities.



Appendix E – caBIG Pilot Initiative – Architecture Workspace Working Group Charter

DRAFT January 2004

Purpose

The Architecture Working Group supports the activities of the Architecture Cross Cutting Workspace of the caBIG initiative. This Workspace is responsible for assisting with bringing new architectural developments and standards to caBIG, acting as an interface to IT communities developing novel architectures, developing architectural white papers, and providing architectural expertise and solutions to other Workspaces.

As this Working Group supports a Cross Cutting Workspace, members are required to provide leadership and content-related coordination in their specific subject areas for all caBIG Workspaces so as to facilitate consistency and congruence for the caBIG initiative as a whole.

Membership

Working Group members include invited NCI-designated Cancer Centers.* Funded Working Group membership (current as of January 2004) is as follows:

- Cold Spring Harbor
- Duke University
- Georgetown University – Lombardi
- Fred Hutchinson
- Ohio State University – Arthur G. James/Richard J. Solove
- University of Chicago
- University of Pittsburgh
- University of Wisconsin
- Washington University – Siteman

(*Note: At this stage, Developers and Adopters sites are not included as representatives on this Working Group, as in the case of the Architecture Cross Cutting Workspace, products developed by the Working Group will be used by other Workspaces and participants in the caBIG initiative.)

At the discretion of caBIG oversight groups, other members of the biomedical research community may participate in this Working Group on a funded, unfunded, or ad hoc basis.



Responsibilities and Authority

The general proposed responsibilities of this Working Group include:

- Definition of goals, scope, and priorities for Workspace Projects
- Establishment of Working Group plans and estimation of required effort
- Coordination with other Working Groups, Workspaces, Master Contractor, caBIG Oversight Board, and external stakeholders
- Execution of activities, meetings, and deliverables
- Monitoring of activities and deliverables
- Reporting of findings and work products.

The specific proposed responsibilities of this Working Group are as follows:

- Evaluate and establish architectural standards for future caBIG activities
- Create and distribute white papers and standards documents covering caBIG software architecture
- Provide project-wide coordination for software architecture between Workspaces, especially in areas where shared platforms and standards are required for communication or software integration
- Create and maintain a clearinghouse of information on applicable development and integration standards approved by Workspaces or NCICB for use in caBIG projects
- Assist the NCICB staff to modify, develop, adopt, and implement standards for use in the development of caBIG-related infrastructure.

This Working Group has the authority to work as a collaborative participant of the Architecture Workspace and to coordinate with other caBIG Working Groups, Workspaces, and participants. The Group does *not* have the authority to direct budgetary allocations within Workspaces or the pilot as a whole.

Coordination and Oversight

The functional activities of this Working Group are led by an independent facilitator appointed by NCICB.



Administrative and operational oversight of Working Group activities is provided by a Coordinator representing the Master Contractor.

The Working Group is accountable to the Master Contractor and the caBIG Oversight Board for their activities and actions. The caBIG Oversight Board is the final arbiter of any caBIG decisions.

Meetings

Meetings are held quarterly or more frequently if required. Meetings may be face-to-face or undertaken via teleconference or videoconference.

Documentation

The plans, activities, and deliverables of this Working Group are documented and retained as part of caBIG initiative records. The Facilitator and Coordinator (Master Contractor representative) are responsible for ensuring effective documentation of Working Group activities.



Appendix F – caBIG Pilot Initiative – caBIG Strategic Planning Group Strategic Level Working Group Charter

DRAFT January 2004

Purpose

The caBIG Strategic Planning Working Group supports the caBIG initiative as a whole by assisting the caBIG Oversight Board with strategic planning and vision development activities.

This Working Group functions at a strategic level and does not directly support individual Workspaces.

Membership

Core membership of this Strategic Level Working Group is formed by invited NCI-designated Cancer Centers.

Funded Working Group membership (current as of January 2004) is as follows:

- City of Hope
- Cold Spring Harbor
- Duke University
- Fox Chase
- Fred Hutchinson
- MD Anderson
- St Jude Children's Research Hospital
- University of Alabama at Birmingham
- University of Colorado
- University of Iowa – Holden
- University of Pennsylvania – Abramson
- University of Pittsburgh
- University of Southern California – Norris
- University of Vermont
- Washington University – Siteman
- Yale University

At the discretion of the caBIG Oversight Board, other members of the biomedical research community may participate in this Working Group on a funded, unfunded, or ad hoc basis.



Responsibilities and Authority

The general proposed responsibilities of this Strategic Level Working Group include:

- Define Working Group vision and priorities
- Define scope and goals of cross initiative activities
- Review and validation of strategic direction of Workspace efforts
- Coordinate with Workspaces, other Working Groups, caBIG Oversight Board, Master Contractor, and external stakeholders
- Foster consistency, uniformity, and establishment of standards
- Execute activities, meetings, and deliverables
- Monitor activities and deliverables
- Report on findings and delivery of work products.

The specific proposed responsibilities of this Strategic Level Working Group are as follows:

- Provide recommendations for future caBIG Workspaces
- Offer reviews of current caBIG Workspaces, including recommendations for how to modify their processes to make them more effective
- Develop white papers evaluating the progress of outside initiatives, similar to caBIG, along with recommendations on how to proceed
- Develop a caBIG roadmap, detailing an overall strategy for caBIG over a 2,5, and 10-year period.

This Strategic Level Working Group has the authority to support strategic activities for the caBIG initiative and to coordinate with other caBIG Working Groups and participants. The Group does *not* have the authority to direct budgetary allocations.



Coordination and Oversight

The functional activities of this Working Group are led by an independent facilitator appointed by NCICB. This Group also works closely with the caBIG Oversight Board on functional activities.

Administrative and operational oversight of Working Group activities is provided by a Coordinator representing the Master Contractor.

The Working Group is accountable to the Master Contractor and the caBIG Oversight Board for their activities and actions. The caBIG Oversight Board is the final arbiter of any caBIG decisions.

Meetings

Meetings are held quarterly or more frequently if required. Meetings may be face-to-face or undertaken via teleconference or videoconference.

Documentation

The plans, activities, and deliverables of this Strategic Level Working Group are documented and retained as part of caBIG initiative records. The Facilitator and Coordinator (Master Contractor representative) are responsible for ensuring effective documentation of Working Group activities.



Appendix G – caBIG Pilot Initiative – Data Sharing and Intellectual Capital Strategic Level Working Group Charter

DRAFT January 2004

Purpose

The Data Sharing and Intellectual Capital Working Group supports the caBIG initiative as a whole by assisting the caBIG Oversight Board with activities related to data sharing and intellectual capital.

This Working Group functions at a strategic level and offers expert guidance to caBIG oversight groups and participants on specific areas of concern within their purview.

Membership

Core membership of this Strategic Level Working Group is formed by invited NCI-designated Cancer Centers.

Funded Working Group membership (current as of January 2004) is as follows:

- University of Arizona
- City of Hope
- Cold Spring Harbor
- Fred Hutchinson
- Jackson Laboratory
- Johns Hopkins – Sidney Kimmel
- Oregon Health and Science University
- Thomas Jefferson University – Kimmel
- University of Iowa – Holden
- University of North Carolina – Lineberger
- University of Michigan
- University of Minnesota
- University of Pittsburgh
- Washington University – Siteman

At the discretion of the caBIG Oversight Board, other members of the biomedical research community may participate in this Working Group on a funded, unfunded, or ad hoc basis.



Responsibilities and Authority

The general proposed responsibilities of this Strategic Level Working Group include:

- Define Working Group vision and priorities
- Define scope and goals of cross initiative activities
- Review and validation of strategic direction of Workspace efforts
- Coordinate with Workspaces, other Working Groups, caBIG Oversight Board, Master Contractor, and external stakeholders
- Foster consistency, uniformity, and establishment of standards
- Execute activities, meetings, and deliverables
- Monitor activities and deliverables
- Report on findings and delivery of work products.

The specific proposed responsibilities of this Strategic Level Working Group are as follows:

- Develop white papers on means of protecting intellectual capital while allowing for the exchange of scientific information among cancer researchers.
- Suggest software specifications for inclusion in systems providing federated data to the community
- Develop position papers on the role of intellectual property in the caBIG project
- Evaluate the effects of Federal privacy regulations (e.g., HIPAA Administrative Simplification provisions) on caBIG software products and databases
- Assist with data sharing issues raised by other Workspaces
- Structure discussions on how IRBs and Patient Consent can impact the aggregation, storage, and analysis of data from clinical trials.



This Strategic Level Working Group has the authority to support strategic activities for the caBIG initiative and to coordinate with other caBIG Working Groups and participants. The Group does *not* have the authority to direct budgetary allocations.

Coordination and Oversight

The functional activities of this Working Group are led by an independent facilitator appointed by NCICB. This Group also works closely with the caBIG Oversight Board on functional activities.

Administrative and operational oversight of Working Group activities is provided by a Coordinator representing the Master Contractor.

The Working Group is accountable to the Master Contractor and the caBIG Oversight Board for their activities and actions. The caBIG Oversight Board is the final arbiter of any caBIG decisions.

Meetings

Meetings are held quarterly or more frequently if required. Meetings may be face-to-face or undertaken via teleconference or videoconference.

Documentation

The plans, activities, and deliverables of this Strategic Level Working Group are documented and retained as part of caBIG initiative records. The Facilitator and Coordinator (Master Contractor representative) are responsible for ensuring effective documentation of Working Group activities.



Appendix H – caBIG Pilot Initiative – Training Strategic Level Working Group Charter

DRAFT January 2004

Purpose

The Training Working Group supports the caBIG initiative as a whole by assisting the caBIG Oversight Board with activities related to training.

This Working Group functions at a strategic level and offers expert guidance to caBIG oversight groups and participants on specific areas of concern within their purview.

Membership

Core membership of this Strategic Level Working Group is formed by invited NCI-designated Cancer Centers.

Funded Working Group membership (current as of January 2004) is as follows:

- Cold Spring Harbor
- Institute for Cancer Prevention
- Johns Hopkins – Sidney Kimmel
- Mayo Clinic
- Oregon Health and Science University
- University of California Davis
- University of Chicago
- University of Iowa – Holden
- University of Pennsylvania – Abramson
- University of Pittsburgh

At the discretion of the caBIG Oversight Board, other members of the biomedical research community may participate in this Working Group on a funded, unfunded, or ad hoc basis.

Responsibilities and Authority

The general proposed responsibilities of this Strategic Level Working Group include:

- Define Working Group vision and priorities



- Define scope and goals of cross initiative activities
- Review and validation of strategic direction of Workspace efforts
- Coordinate with Workspaces, other Working Groups, caBIG Oversight Board, Master Contractor, and external stakeholders
- Foster consistency, uniformity, and establishment of standards
- Execute activities, meetings, and deliverables
- Monitor activities and deliverables
- Report on findings and delivery of work products.

The specific proposed responsibilities of this Strategic Level Working Group are as follows:

- Develop templates and standards for caBIG software documentation
- Develop a modular caBIG training program framework, including standard curriculum for all program activities
- Plan and implement an electronic repository of training materials
- Develop White papers on the use of electronic and distance learning for training caBIG users
- Create a structure for caBIG workshops for presentations at National meetings
- Work with NCICB staff to create “beginner’s guides,” “hello worlds,” and software skeletons for existing and future caBIG/caBIO/caCORE software in order to jump-start outside development using those tools.

This Strategic Level Working Group has the authority to support strategic activities for the caBIG initiative and to coordinate with other caBIG Working Groups and participants. The Group does *not* have the authority to direct budgetary allocations.

Coordination and Oversight

The functional activities of this Working Group are led by an independent facilitator appointed by NCICB. This Group also works closely with the caBIG Oversight Board on functional activities.



Administrative and operational oversight of Working Group activities is provided by a Coordinator representing the Master Contractor.

The Working Group is accountable to the Master Contractor and the caBIG Oversight Board for their activities and actions. The caBIG Oversight Board is the final arbiter of any caBIG decisions.

Meetings

Meetings are held quarterly or more frequently if required. Meetings may be face-to-face or undertaken via teleconference or videoconference.

Documentation

The plans, activities, and deliverables of this Strategic Level Working Group are documented and retained as part of caBIG initiative records. The Facilitator and Coordinator (Master Contractor representative) are responsible for ensuring effective documentation of Working Group activities.



Appendix I – Handbook Terms and Conventions

This Appendix provides an alphabetical list of key terms/conventions and their definitions utilized in this Handbook.

Adopter

An NCI-designated Cancer Center selected and funded by NCICB to undertake formal testing, validation, and application of products or solutions developed by Workspace Developers.

caBIG

The **c**ancer **B**iomedical **I**nformatics **G**rid (caBIG) pilot initiative initiated by the National Institutes for Health (NIH), National Cancer Institute (NCI) and its Center for Bioinformatics (NCICB) to develop and deploy an integrating, common and extensible biomedical informatics infrastructure.

caBIG Oversight Board

The caBIG Oversight Board provides strategic and program level guidance for the caBIG initiative. The core membership of the caBIG Oversight Board is formed by NCICB leadership.

caCORE

caCORE is the NCI's and NCICB's informatics infrastructure. It is composed of three primary components:

- Enterprise Vocabulary Services (EVS)
- Cancer Data Standards Repository (caDSR)
- Cancer Bioinformatics Infrastructure Objects (caBIO).

Cross Cutting Workspaces

Cross Cutting Workspaces determine how areas of common concern across the various Workspaces and projects are captured and addressed. Cross Cutting Workspaces facilitate consistency and congruence of activities for the caBIG initiative.



Developer

An NCI-designated Cancer Center selected and funded by NCICB to participate in a specific Workspace to undertake software or solution development activities.

Domain Workspaces

Domain Workspaces develop products or solutions that address specific areas of needs for the Cancer Center community and that can be used to test the feasibility of the grid.

HHS

Department of Health and Human Services

Master Contractor

The Master Contractor is a contracting team appointed by NCICB to provide day-to-day oversight of caBIG Workspace and Working Group activities (e.g., project activities) in accordance with programmatic and strategic level requirements.

NCI

National Cancer Institute

NCICB

National Cancer Institute Center for Bioinformatics

NIH

National Institutes of Health

Program Management Team

The Program Management Team is a contracting team appointed by NCICB to provide additional support for the caBIG Oversight Board, the primary governing body of caBIG. This team will assist with activities related to the program management of the caBIG initiative.



Strategic Level Working Groups

Strategic Level Working Groups support the caBIG initiative as a whole by assisting with strategic planning and vision development activities and by offering expert guidance to caBIG oversight groups and participants. This type of Working Group does not directly support an individual Workspace.

Working Groups

Working Groups provide guidance and support to the caBIG Workspaces and the caBIG initiative as a whole. There are two types of Working Groups, Workspace, and Strategic Level. Group members work collaboratively with the NCICB and the participating NCI designated Cancer Centers to facilitate the overall success of the caBIG pilot.

Working Group Coordinator

A Coordinator is from the Master Contractor group and is appointed to each Working Group (Workspace and Strategic) to provide administrative and operational support.

Working Group Facilitator

An independent Facilitator appointed by NCICB to each Working Group to lead the functional activities of that group.

Workspaces

Workspaces are defined as areas or virtual environments where caBIG pilot activities are grouped. Workspaces are divided into two groups according to their specific focus areas: Domain Workspaces and Cross Cutting Workspaces. Each Workspace includes projects or activities with a common focus and addresses an area of need as identified by the Cancer Center community.

Workspace Managers

Workspace Managers are appointed by the Master Contractor to oversee each Workspace.



Workspace Working Groups

Workspace Working Groups are specifically linked to each caBIG Domain Workspace and each Cross Cutting Workspace to provide expert guidance on Workspace and project activities and leadership and content-related coordination for all caBIG Workspaces in their specific subject areas.