caBIG Program Update

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MESSAGE FROM NCICB

Since the caBIG Kickoff Meeting that took place in Washington, D.C. on February 19 and 20, the caBIG Workspaces and Working Groups have been making great progress. Over 40 teleconferences have been held with the various caBIG Workspaces and Working Groups, and all groups now have a regular meeting schedule established. Participants have undertaken further planning activities, generated documents, agreed to common principles, and organized their individual Workspaces and Working Groups to meet their objectives and needs. Cancer Centers have also begun to share their tools and data with the caBIG community.

Concurrent with these activities, NCICB and the caBIG General Contractor have been working hard to put contract mechanisms in place with participating Centers so funding can be provided for caBIG projects. All Centers have received the basic contract agreement template and are moving it through their internal review processes. Detailed discussions have been held with over 40 Centers about the contracting process, including a total of almost 80 individual calls or teleconferences. These discussions have been positive and productive. Once the basic agreements are signed by the Centers, task orders will be issued (based on agreed Statements of Work) and funded activities can commence.

In addition, NCICB and the caBIG Project Team have taken steps to bring you the most up to date information on caBIG activities. The website has been updated to include: a Calendar of Events, which currently lists meetings, demonstrations and webcasts scheduled through August of 2004; a new and improved Inventory section with additional tools provided by the Integrative Cancer Research Workspace; and a new section dedicated to the Strategic Level Working Groups – to name just a few areas. Additional work will be done on the caBIG website in upcoming months to ensure that it continues to be a useful resource for caBIG participants.

You may have also noticed a new newsletter sent to you weekly through the listserv entitled What's BIG This Week. This newsletter provides a snapshot of activities planned for the week, updates on contracting activities, and other areas of interest.

This edition of the caBIG Program Update offers an overview of key achievements in the caBIG Workspaces and Working Groups since the Kickoff meeting and touches on other important issues such as contracting activities and helpful resources.

Thank you so much for your continued support. It is very clear that with all your hard work and determination to date, caBIG is off to a fantastic start.

Sincerely,

Kenneth H. Buetow, Ph.D.

Director

NCI, Center for Bioinformatics

http://caBIG.nci.nih.gov

CONTRACTS UPDATE

Establishing contract mechanisms with participating Cancer Centers has been a priority for NCICB and the caBIG General Contractor so that participants can commence specific caBIG projects as soon as possible. To date, the contracting discussions with the Centers have been extremely positive and productive. Detailed discussions have been held with over 40 Centers about the contracting process, including a total of almost 80 individual calls or teleconferences.

As noted previously, a basic agreement template that sets out the general terms and conditions and creates a framework for the business rules of engagement was sent to all Centers (Contracts/Administration Office) in March 2004. Since then, the agreement has been revised to accommodate the particular concerns raised by Centers in the areas of works for hire, insurance and indemnification. The revised basic agreement was sent to all participating Centers last week. The General Contractor hopes that this will expedite the process and allow the process to move forward more quickly. Agreement in principle has been reached with two Centers, and the General Contractor is close to executing contracts with several other Centers.

Signing these basic agreements is a necessary first step before specific task orders for funding of particular caBIG project activities can be undertaken. Task orders will be based on Statements of Work (SOWs) generated by NCI for specific caBIG activities within caBIG Workspaces and Working Groups. Draft Statements of Work have been developed for many activities and are currently under review by NCI.

Another common question that arose during recent discussions with Centers is in regards to the distribution of resources for the caBIG initiative. At this stage, based on current projections it is expected that:

- Approximately 50% of resources for caBIG will go directly to Cancer Centers for focused development and adoption activities

- Approximately 15% of the resources will be dedicated to management and execution of caBIG - an amount which is very conservative for the coordination and oversight of a large software engineering initiative of this kind. Booz Allen Hamilton is providing coordination and logistics support for the caBIG effort, at both the Program level and General Contractor level

- Remaining resources will be committed to providing directed support for use of caBIG infrastructure and applications; resources will be available to Cancer Centers interested in assisting with these types of frontline support activities

Finally, the General Contractor is very eager to work through any concerns/questions of individual Centers to move things forward. It is imperative that all active caBIG participants from a Center, including technical representatives as well as contracts/administrative representatives, work collaboratively with the General Contractor to get the basic agreements in place. Centers are urged to contact the General Contractor directly with any questions/concerns through Denise Tingle at tingle_denise@bah.com.

WORKSPACE/WORKING GROUP PROGRESS AND ACTIVITIES

A quick overview of progress and activities in the caBIG Workspaces and Working Groups is provided in the following sections. Please also look at the related materials and information on these activities on the caBIG Forum at http://ncicbforums.nci.nih.gov/cabigforum and the caBIG Website at http://caBIG.nci.nih.gov.

For more information on Workspaces, please visit: http://caBIG.nci.nih.gov/caBIG/workspaces. For more information on Strategic Level Working Groups, please visit: http://caBIG.nci.nih.gov/caBIG/working_groups.

Clinical Trial Management Systems Workspace (CT)

The CT Workspace is directing their efforts towards developing a comprehensive set of modular, interoperable and standards based tools designed to meet the diverse clinical trials management needs of the Cancer Center community. Tools developed will be configurable to meet the needs of Cancer Centers with little or no clinical data management systems in place as well as those with robust systems, and will take into account the diversity of clinical research activities and local practices that exist among these Cancer Centers. The caBIG core principles of open source, open access, open development, and federation of data sources will guide all new tool and product development. In particular for this Workspace, interoperability and modular develoment are key, as solutions are likely to consist of a flexible assembly of compatible tools pulled from a rich collection of tools developed by the Workspace, as well as existing commercial and locally developed solutions that have been made caBIG compatible by the community.

Through several teleconferences held by the CT Workspace since the February Kickoff Meeting, the following high priority areas have been identified by this Workspace:

· Adverse Event Reporting Module

· CTMS (Clinical Trial Monitoring Service) / CDUS (Clinical Data Update System) Reporting Module

· Laboratory Interfaces

· Financial/Billing Module

Other community needs to be addressed in the future include:

· Reporting to the FDA, IND Holder and hospitals

· Automatic grading of toxicities for CTC

· Support multiple destination formats for reporting

· Protocol management

· Data conversion tools

· Patient eligibility filtering and tracking

· Patient matching to clinical trials

· Systematic lay summaries

· Investigator registry

· Outcomes assessment

· Participant registry

· Summary 4 reporting

To date, the CT Workspace has made significant progress in the following areas:

· Draft Statements of Work (SOW): Draft SOWs have been created for Workspace Adopter and Developer participation, and are currently being reviewed by NCI

· C3D Demonstration: C3D (Cancer Central Clinical Database) was demonstrated as a possible solution for Cancer Centers without sufficient remote data capture and clinical data management systems. A recording will be made available to those who could not attend the demonstration. For more information on the C3D tool, please visit: http://trials.nci.nih.gov/projects/datamanagement/c3d

· Adverse Events meeting: City of Hope representatives were briefed on a possible architectural model to meet the adverse event needs of the community. Items discussed included the need

to involve Cancer Centers, leverage existing efforts, and discuss architectural requirements with the Architecture Workspace

Interactions with the other Domain Workspaces and Strategic Level Working Groups are anticipated. However, initial interactions have focused on the Cross Cutting Workspaces, including:

· Vocabularies and Common Data Elements Workspace: Liaisons from this Workspace will help coordinate activities to provide both short-term and long-term solutions for CDE curation

· Architecture Workspace: Liaisons from the Architecture Workspace will help resolve issues, such as security and rules engines modules

The CT Workspace will hold regular biweekly teleconferences on the second and fourth Tuesday of each month beginning May 25, 2004 at 12:00pm ET. Face-to-face meetings have not yet been established. For a complete listing of Workspace and Working Group meetings, please visit: http://caBIG.nci.nih.gov/caBIG/calendar.

Integrative Cancer Research Workspace (ICR)

Activities in the ICR Workspace are currently focused on defining projects and creating Developer-Adopter pairings through the formation of Special Interest Groups (SIGs). SIG meetings provide an important forum for Developers and Adopters to exchange information critical for moving forward with tool development. In addition to the SIG meetings, each Center has been meeting individually with the ICR Workspace lead to discuss specifics of their

projects with regard to scope and alignment with caBIG goals.

To date, many of the Centers within ICR have existing tools that are available for immediate use while being further developed for caBIG compatibility. Some related NCI/NCICB tools are also included. A listing of these tools is available on the caBIG website at http://caBIG.nci.nih.gov/inventory/ICR_Tools. SIGs have also identified areas of research and resource development that will be of use to the entire cancer community. For example, the Translational SIG is developing guidelines for experimental design issues specific to translational studies.

Liaisons from ICR to the other Workspaces and Working Groups have been established to coordinate activities between other Workspaces and Working Groups. Liaisons are as follows:

· Tissue Banks and Pathology Tools Workspace: Washington University -- Siteman

· Clinical Trial Management Systems Workspace: University of Pennsylvania -- Abramson

· Architecture Workspace: Duke University

· Vocabularies and Common Data Elements Workspace: Vanderbilt University -- Ingram

· Data Sharing and Intellectual Capital Strategic Level Working Group: University of Iowa -- Holden

· Training Strategic Level Working Group: Institute for Cancer Prevention

· Strategic Planning Strategic Level Working Group: Fox Chase

Representatives from these Centers will be attending meetings for the Workspace to which they are liaisons and providing summary information to the ICR Workspace regarding the activities of the other Workspaces.

The ICR Workspace meets via teleconferences on the second Wednesday of each month at 2:00pm ET. There are seven SIGs within the ICR Workspace: Micorarray Repositories, Data Analysis and Statistics, Informatics for Proteomics, Gene Annotation, Pathways, Translational, Computational Genomics, and Collaborative Tools. These groups commenced their kickoff meetings the week of May 3 and will continue to meet via teleconferences on a monthly basis. Face-to-face meetings have not yet been established. For a complete listing of Workspace and Working Group meetings, please visit: http://caBIG.nci.nih.gov/caBIG/calendar.

Tissue Banks And Pathology Tools Workspace (TBPT)

The TBPT Workspace is focusing on developing a pathology information management system. The system will provide basic specimen inventory and tracking capabilities. For those centers with inadequate systems, a core version of the tool will be made available. In addition, the pathology information management system will provide many modules and tools including Software Development Kits (SDKs) and Application Programming Interfaces (APIs) to allow for those centers that currently employ robust pathology information management systems to leverage the caBIG network. The full suite will provide for unprecedented abilities to manage, query, retrieve and harness tissue specimen data and annotations across a federated infrastructure.

In order to develop the full pathology information management system, Workspace participants have identified the following high priority needs to address:

· Current pathology information management systems and interfaces

· Institutional needs and requirements for managing pathology specimens

· Institutional Review Board, Material Transfer Agreement, and general data sharing policies throughout the various Cancer Centers

· caBIG distributed Architectural specifications

· Identification and creation of pathology related standard vocabularies and common data elements

To date, the Developers have drafted a project plan to estimate the scope and level of effort required to develop the system. In addition, the Developers and Adopters have started developing use cases and are expected to have the high-level requirements identified by the end of May.

The TBPT Workspace has not yet identified liaisons to reach out to other caBIG Workspaces and Working Groups, though participants have noted the need to communicate immediately with the following Workspaces:

· Data Sharing and Intellectual Capital Strategic Level Working Group

· Vocabularies and Common Data Elements Workspace

· Architecture Workspace

Moving forward, the group has agreed to meet via teleconferences on Tuesdays at 12:00pm ET twice per month. Face-to-face meetings have not yet been established. For a complete listing of Workspace and Working Group meetings, please visit: http://caBIG.nci.nih.gov/caBIG/calendar.

Architecture Workspace

As part of the recent activities of the Architecture Workspace, participants have agreed that the focus of caBIG should be to create a data-sharing infrastructure (or data grid) as distinguished from a processor-sharing infrastructure (or computation grid). These respective types of capabilities are not mutually exclusive, and computational grid features can be added if and when deemed a high priority. To address the many architectural issues surrounding the design and construction of a data grid, the Architecture Workspace will begin by partnering with liaisons from other Workspaces and Working Groups to develop specific use cases. The use cases that are needed can be grouped into a series of subtopic areas, of which, the Architecture Workspace has organized a corresponding set of subgroups to deal with these areas including:

· Interface Architecture

· Information Architecture

· System Architecture

· Security and Access Control

· Best Practices

· Reference Implementations

The scope for each of these subgroups have been defined and published on the caBIG Forums at http://ncicbforums.nci.nih.gov/cabigforum.

The Architecture Workspace, having a very strong cross cutting impact on all areas of the caBIG initiative, has established liaisons with each of the other Workspaces. These designated inter-Workspace liaisons will participate in inter-Workspace teleconferences and meetings. Each subgroup must send at least one liaison to these events. Liaisons will report back to the Architecture Workspace as a whole. The liasons are as follows:

· Clinical Trial Management Systems Workspace: Fox Chase, Fred Hutchinson, Ohio State University – Arthur G. James/Richard J. Solove, University of Pittsburgh

· Integrative Cancer Research Workspace: Duke University, Ohio State University – Arthur G. James/Richard J. Solove, Georgetown University – Lombardi, Fox Chase, Fred Hutchinson

· Tissue Banks and Pathology Tools Workspace: Duke University, Ohio State University – Arthur G. James/Richard J. Solove, Georgetown University – Lombardi, Washington University – Siteman

· Vocabularies and Common Data Elements Workspace: Fred Hutchinson, Ohio State University – Arthur G. James/Richard J. Solove

· Training Strategic Level Working Group: University of Pittsburgh

The Workspace will meet face-to-face twice a year and will hold teleconferences on a bimonthly basis beginning July 15, 2004. Subgroups will have more frequent calls to focus on the individual subgroup topics. For a complete listing of Workspace and Working Group meetings, please visit: http://caBIG.nci.nih.gov/caBIG/calendar.

Vocabularies And Common Data Elements Workspace (VCDE)

The primary objectives of the VCDE Workspace include the identification and evaluation of existing vocabularies, common data elements and relevant data standards resources for utilization in the caBIG context. In addition, the VCDE Workspace will assess further needs of the caBIG community for the creation, approval, management and delivery of additional vocabulary and CDE contributions from the other caBIG Domain and Cross Cutting Workspaces.

The VCDE Workspace members have identified several high priority tasks during recent meetings. Of critical importance is the attainment of Workspace consensus on the following:

· The governance model for the development, i.e. editing, curation and harmonization of common data elements (CDE) into the caBIG context

· The governance model for the development, review, approval, and delivery of additional vocabularies to the caBIG context

· Review, approval of integration tools, APIs, adapters for adoption by the caBIG community

· Adoption of relevant data standards from external organizations

With regard to the CDE Development Governance Model, the Workspace has recommended the following workflow elements:

· Cancer Centers in the caBIG community will be responsible for their own CDE concepts and creation

· Workspace Liaisons from the VCDE Workspace will train a select group in each Workspace to administer CDEs created by the individual Cancer Centers

· The VCDE Workspace, in conjunction with NCICB, will carry out final review and harmonization of CDEs

With regard to the Vocabularies Governance Model, the Workspace agreed to the following:

· A Use Case mechanism will facilitate the management of additional vocabularies

· The VCDE Workspace will develop a relevant Use Case template for use by the other Workspaces and the cancer community

· The Workspace will need to determine appropriate approval and harmonization of additional vocabularies for the caBIG context

One of the priorities of the Workspace is the information exchange, education and training of Workspace participants regarding software tools available under caCORE, and other products available from Workspace members in the caBIG community. The VCDE Workspace will explore additional means for providing education and training on these tools to the liaisons and other Workspace members and the cancer community

To date, demonstrations of EVS, caDSR Contents and Development, and HL7 have been provided by NCICB to Workspace members and liaison groups. The Mayo group at the May 20th meeting of the VCDE Workspace teleconference meeting will conduct a demonstration of the LexGrid system.

Liaisons between the VCDE Workspace and other Workspaces/Working Groups that have been identified to date are as follows:

- · Clinical Trial Management Systems Workspace: Mayo Clinic, University of California – Davis, NCI/OC/CIPS

- · Integrative Cancer Research Workspace: Fred Hutchinson, Albert Einstein, University of Hawaii

- · Tissue Banks and Pathology Tools Workspace: NCI, University of Pittsburgh

- · Architecture Workspace: Mayo Clinic, University of California – Davis, Fred Hutchinson, Albert Einstein, NCI/OC/CIPS

- · Strategic Level Working Groups: Mayo Clinic, Fred Hutchinson

VCDE Workspace teleconferences are held on a biweekly basis from 1:00-3:00pm ET beginning Thursday, May 20th. Additionally, a face-to-face meeting is tentatively scheduled for the month of July. For a complete listing of Workspace and Working Group meetings, please visit: http://caBIG.nci.nih.gov/caBIG/calendar.

Data Sharing And Intellectual Capital Strategic Level Working Group (DSIC SLWG)

The DSIC SLWG is addressing issues related to data sharing and intellectual capital associated with caBIG and developing recommendations for the caBIG community.

Since the Kickoff Meeting, the DSIC SLWG has been discussing and setting high priority areas to be addressed including:

- · Ownership issues created by preexisting agreements between cancer research institutions and the pharmaceutical/biotech industry. To understand the extent to which there is a problem imposed by proprietary restrictions, the DSIC SLWG plans to develop a one-page survey to identify problem areas in agreements that create third party rights in data and impose restrictions on data sharing by Cancer Centers

- · Establish relationships with representatives from pharmaceutical/biotech industry for advisory purposes on an ad hoc basis

- · Restrictions on data access and data sharing, where required to protect IP rights, will impact the architecture. Architectural features should be incorporated to allow partial access

- · Develop guidelines/best practices for data sharing

Liaisons to other Workspaces and Working Groups that have been identified are as follows:

- · Architecture Workspace: Fred Hutchinson, Ohio State University – Arthur G. James/Richard J. Solove

- · Training Strategic Level Working Group: Ohio State University – Arthur G. James/Richard J. Solove, University of Pittsburgh

- · Strategic Planning Strategic Level Working Group: University of Pittsburgh

- · Integrative Cancer Research Workspace: University of Iowa -- Holden

- · Clinical Trial Management Systems Workspace: University of Minnesota

- · Vocabulary and Common Date Elements Workspace: University of Pittsburgh

· Tissue Banks and Pathology Tools
Workspace: Washington University --
Siteman

The DSIC SLWG convenes regularly via teleconferences on the second and fourth Thursday of each month at 2:00pm ET. Face-to-face meetings have not yet been established. For a complete listing of Workspace and Working Group meetings, please visit: http://caBIG.nci.nih.gov/caBIG/calendar.

Strategic Planning Strategic Level Working Group (SP SLWG)

The SP SLWG, through a series of teleconferences, has identified the following high-priority focus areas for the group:

· Develop a caBIG strategic plan

· Identify venues for collaborative work environments, document sharing and on-line meetings

· Develop guidelines for caBIG interaction with external organizations and experts

· Develop usability and deployability guidelines for caBIG work products

· Create a framework to assess the adequacy of workspace goals

· Create a framework to assess progress of workspaces toward stated goals

This Working Group is actively pursuing the development of a caBIG roadmap detailing an overall strategy for caBIG over a 2, 3, 5 and 10 year period. A Strategic Plan subcommittee was established to draft this plan, and will meet May 21 at the upcoming BRIITE meeting. Ideas identifying short- and

long-term deliverables can be submitted to the SP SLWG forum, Strategic Plan Subcommittee thread, part of the caBIG online forum. The SP SLWG is also working to establish a collaborative work environment, document sharing and on-line meeting resources to facilitate caBIG activities. They have assessed a variety of products, compiled cost information, and are currently setting up the pilot testing of the top alternatives. This information will be shared with the other Workspaces and Working Groups.

The SP SLWG would like to encourage other Workspaces and Working Groups to submit agenda items via the caBIG Forum (Strategic Planning forum, Agenda Items) and/or come and present issues to the Working Group.

The SP SLWG meets via teleconference biweekly on Mondays at 12:30pm ET. The SP SLWG will also schedule two face-to-face meetings each year. For a complete listing of Workspace and Working Group meetings, please visit: http://caBIG.nci.nih.gov/caBIG/calendar.

Training Strategic Level Working Group (Training SLWG)

The Training SLWG has identified pressing needs around developing training materials for developers, training and evaluation tools for adopters, and methods of communicating the caBIG message to participating Centers and their communities. As such, the Working Group has formed three subcommittees, which will meet every other week.

· Developer Training: Requiring tight interactions with the Architecture Workspace and the Vocabularies and Common Data Elements Workspace,

this committee has been formed with individuals acting as liaisons between the Workspaces and other Working Groups. The immediate tasks for this committee include: performing a needs assessment of developers, and developing a project plan around these needs with deliverables and milestones

· Adopter Training and Evaluation: Activities for this group are occurring in parallel to the Developer Training subcommittee. The immediate tasks for this committee include: identifying available training tools; developing a project plan with deliverables and milestones for developing additional necessary training tools; developing a protocol for evaluating and improving training tools; and developing a protocol for evaluating and improving caBIG applications

· Communication: This subcommittee works with the caBIG Communications Team to support aspects of the caBIG Communication Plan including: presentations internal to the Centers and external local and national meetings; and the creation of toolkits for use by the Centers to promote the caBIG initiative

A User Training Subcommittee will be formed in the future.

The Training SLWG has formed liaisons with the other Working Groups and Workspaces as follows:

· Integrative Cancer Research Workspace: Institute for Cancer Prevention

· Tissue Bank and Pathology Tools Workspace: University of Pennsylvania – Abramson

· Strategic Planning Strategic Level Working Group, Data Sharing and

Intellectual Capital Working Group, Architecture Workspace, and Clinical Trial Management Systems Workspace: University of Pittsburgh

· Vocabulary and Common Data Elements Workspace: Mayo Clinic

The Training Strategic Level Working Group meets via teleconferences every other Wednesday from 10 - 11:30am ET as of May 5th, 2004. Face-to-face meetings have not yet been established. For a complete listing of Workspace and Working Group meetings, please visit: http://caBIG.nci.nih.gov/caBIG/calendar.

http://caBIG.nci.nih.gov

caBIG Information and Resources

There are many ways to access additional information and resources on the caBIG initiative and activities. Following is a list current resources:

- caBIG Website:

  http://caBIG.nci.nih.gov

- caBIG Workspaces:

  http://caBIG.nci.nih.gov/workspaces

- caBIG Strategic Level Working Groups:

  http://caBIG.nci.nih.gov/caBIG/ working_groups

- Inventory of caBIG infrastructure, applications and datasets:

  http://caBIG.nci.nih.gov/inventory

- caBIG Interactive Overview (multi-media presentation on caBIG):

  http://www.nci.nih.gov/ directorscorner/caBIG

- National Cancer Institute Center for Bioinformatics (NCICB) homepage:

  http://ncicb.nci.nih.gov

In addition to these more general resources, a specific caBIG Forum has been established to provide a resource through which all of the caBIG participants can communicate and coordinate with other caBIG members. The forums are readable by anyone, but posting is limited to registered participants.

The caBIG forums can be reached at the following URL: http://ncicbforums.nci.nih.gov/cabigforum

If you do not yet have a login, and you are a registered participant in the caBIG project, you can get one by sending email to Leslie Derr at derrl@mail.nih.gov.

Raising Questions or Concerns

If you are a caBIG participant and you have any questions about caBIG Workspace and Working Group activities, please consider the following avenues to raise your questions:

- · The caBIG Forum at http://ncicbforums. nci.nih.gov/cabigforum

- · Workspace or Working Group Meetings

For specific, directed questions that you feel would be better addressed individually, please feel free to reach out to your respective Workspace/Working Group Coordinator from the caBIG Project Team, or Mark Adams at adams_mark@bah.com.