caBIG Cancer Center Directors' Update

Welcome to the this issue of the caBIG Cancer Center Directors' Update. This newsletter provides an avenue for Cancer Center Directors to receive quick updates on key issues related to the caBIG initiative (cancer Biomedical Informatics Grid).

What's New – caBIG Compatibility Guidelines Announced

NCICB and the caBIG Project Team have developed preliminary guidelines outlining the requirements for caBIG compatibility. By providing a set of definitions that caBIG participants and interested stakeholders can use to measure the maturity level of potential caBIG applications, these guidelines represent the initial steps towards a community standard for interoperable biomedical informatics software. A sample scorecard is included which can be used to evaluate existing applications and the steps necessary to make an existing vendor or custom application caBIG compatible, and to create new applications at a specified level of maturity.

The guidelines define and describe caBIG compatibility in terms of specified maturity levels: Legacy, Bronze, Silver and Gold. The overall goal of caBIG is to have all caBIG compliant applications eventually attain the Gold Level of maturity. It is anticipated that, in the near term, new development activities undertaken as part of caBIG will meet the Silver Level of compliance. Bronze Level maturity will be applicable for allowing existing systems to meet the minimum level of maturity for caBIG compliance. This level of maturity is a transitional state along the pathway to the Silver and Gold Levels of compliance. In the immediate term, it may be necessary to retrofit existing legacy systems to achieve the Bronze Level of compliance. The natural progression will be to ensure that those existing applications meet the finalized Gold Level requirements once they have been fully defined by the caBIG community.

These preliminary guidelines have been developed in response to the caBIG community's request for guidance on what it means to be caBIG compatible and they reflect the Team's thinking that went into the founding and development of the caBIG pilot. Future versions of the guidelines will be a collective effort by the caBIG community, and will represent the needs and aspirations for the program. These efforts will be coordinated through the Cross Cutting Workspaces – Architecture Workspace and Vocabularies & Common Data Elements Workspace.

Where to find the Compatibility Guidelines document :

The Compatibility Guidelines can be found on the caBIG Website at: http://caBIG.nci.nih.gov/caBIG/cabiglfs/caBIG_Compatibility.pdf or via the Center Directors' Quick Links section of the website (http://cabig.nci.nih.gov/caBIG/cd/quicklinks).

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caBIG Progress to Date

caBIG project activities in the Workspaces and Working Groups are moving along at a strong and steady pace. In July, three Workspaces conducted face-to-face meetings for the first time since the February Kickoff Meeting in Washington, DC. These meetings provided an opportunity for intensive collaboration on projects being undertaken in these Workspaces. An overview of the key outcomes of these meetings is provided in the following sections.

Vocabularies and Common Data Elements (VCDE) Workspace Meeting

The VCDE face-to-face meeting was held July 19, 2004 in Bethesda, MD. The primary focus of this session was to establish a path forward in vocabulary governance, as well as deciding on the best way to carry out Common Data Element (CDE) training. An additional goal of the meeting was to decide how best to structure use cases that the VCDE Workspace would be receiving from the Domain Workspaces to ascertain their vocabulary and metadata needs.

Participants decided to use object-oriented modeling (UML Model) to represent data on the grid. Additionally, NCICB selected Enterprise Architect as the UML Modeling tool that will be used to construct these models. NCICB is going to secure a number of licenses for developers in the Workspaces to construct these object-oriented models.

The meeting concluded with several key outcomes including:

- Development of a vocabulary governance model
- Establishment of a training plan for CDE curation/administration
- Development of a set of guidelines for relationships between vocabularies, CDEs and data models
- Approach for gathering background and stakeholder use cases for vocabulary and metadata from the Domain Workspaces

Clinical Trial Management Systems (CT) Workspace Meeting

The Clinical Trial Management Systems Workspace met face-to-face on July 19 and 20, 2004 in Pittsburgh, PA. Representatives from six of the Special Interest Groups (SIGs) covering the financial, laboratory, clinical and interoperability/compatibility aspects of the CT Workspace attended the meeting and drafted and agreed upon several significant action items including:

- Performing surveys of existing systems (including areas such as patient enrollment, study calendar, adverse events reporting, and financial billing) to map work flows and functionality desired to build a modular, extensible and interoperable caBIG-compatible system that can be applied to diverse types of clinical trials
- Further defining caBIG compatibility guidelines (as part of the activities of the Compatibility Grading SIG that works closely with the Architecture Workspace) and creating a committee that will oversee the "benchmarking" or "certification" of systems for compliance with the interoperability standards developed by the Architecture Workspace

- Creating a best practices document or white paper that Cancer Centers can adopt to ensure that their clinical trials management systems are compliant with all applicable healthcare regulations such as HIPAA, and meet Institutional Review Boards (IRB) standards to ensure the privacy and confidentiality of protected health information

The issue of HL7 v3.0 compatibility was discussed and the CT Workspace decided that this was necessary to achieve semantic interoperability between systems that operate under the caBIG umbrella and that a cautious and step-wise approach to implementing HL7 v.3 based messaging was needed to ensure a smooth transition.

There were also several discussions on the CT Workspace Strategic Roadmap in regards to the life-cycle of the clinical trials process and what it may encompass. It was agreed that Financial Billing was not part of the clinical trials management system, but that protocol review and approval process should be part of the life-cycle. Going forward, the SIGs will be performing requirements gathering and analysis, including analysis of existing systems over the next several weeks to identify a complete set of needs for the community. Requirements will be further discussed, scoped and agreed upon in upcoming teleconferences.

Another important issue discussed was the differentiation between what is being performed as standard care within a patient study and what is being performed as research, and how the different procedures are covered (by insurance, by the sponsor, or neither). Associated with the issue of procedures is the concept of the study calendar where the individual procedures to be performed could be specified and defined clearly as standard care or research. The CT Workspace's position on this issue will help dictate the workflow of the Study Calendar module. Therefore, the Financial Billing SIG will be constructing and releasing a survey in the coming weeks to determine what existing systems are available, what parts are useful and what is still needed for a successful Study Protocol/Calendar module. Survey results, requirements and issues will be discussed, scoped and agreed upon in upcoming teleconferences. Next steps will be to create use cases and object models based on the agreed set of requirements.

Architecture Workspace Meeting

The Architecture Workspace met face-to-face July 27 and 28, 2004 in Columbus, OH. Software architecture experts from throughout the caBIG Community met and came to agreement on several key points for the caBIG initiative, including:

- Data exchange language will use XML supplemented by direct binary exchange for large or specialized data points, such as images, appropriately supplemented by XML bsed metadata

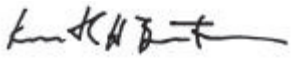
- Globus 3.2/OGSA-DAI will be the basis for the grid architecture. The Mobius group is working closely with the caGRID group to develop and document good standards

- Reference implementations incorporating these standards could be selected on the basis of use cases from the Workspaces

Additionally, standards and processes were proposed around abstract layers, software development kits (SDKs) and defined application programming interfaces (APIs) for grid implementation, a common security model and framework, and the use of a standardized UML modeling toolkit throughout the caBIG community.

Thank You

Thank you for your continued participation and enthusiasm for caBIG. If you have any questions or concerns, please feel free to reach out to Mark Adams on the caBIG Project Team at adams_mark@bah.com or 508-735-9950.



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