caBIG cancer Biomedical Informatics Grid

Clinical Trial Management Systems Workspace

Vision Statement

The Clinical Trial Management Systems Workspace is 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. The 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 principles of open source, open access, open development and federation of data sources will guide all new tool and product development. The tools and standards developed will be shared with other programs that develop clinical trials, such as cooperative groups, SPORES and the NCI Division of Cancer Prevention. In particular for this Workspace, interoperability and modular development 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.

Who We Are

The Clinical Trial Management Systems Workspace is part of the larger caBIG initiative (cancer Biomedical Informatics Grid) that was announced in July 2003 under the coordinating supervision of the National Cancer Institute (NCI). caBIG is being developed in partnership with the Cancer Center community to create a voluntary virtual network (or grid) that links individuals and institutions both nationally and internationally, effectively creating a World Wide Web of cancer research. Researchers will be able to develop and share tools and data on the caBIG network according to agreed-upon, common standards. This initiative will allow biomedical researchers to answer research questions more rapidly and efficiently, thereby promising to accelerate progress in all aspects of cancer research.

Key to the success of caBIG is the development of solutions that are both semantically and syntactically inter-operable. This includes solutions newly developed for caBIG as well as existing commercial and locally developed applications. This involves the development of common models for Clinical Trial Management Systems Workspace areas of interest, agreement on a robust set of computable data types and terminology standards, and the development and/or adoption of messaging standards, interchange formats and common Application Programming Interfaces (APIs). By providing a set of semantically and syntactically interoperable tools, the caBIG Clinical Trial Management Systems Workspace project will ultimately provide the cancer research community with more choices, and a move towards modular and interoperable software architecture. Development of these solutions will be based on key needs and priorities identified by the Cancer Center community and will be developed, tested and validated by Cancer Centers participating in the caBIG initiative.

This modular development plan for the Workspace addresses the heterogeneous needs of the Cancer Center community. Cancer Center needs range from specific functionality required by Cancer Centers with existing systems, to a broad set of basic functionality required by Cancer Centers with no existing clinical trial management system in place. In addition, the specific practices and local environment at each Cancer Center varies, requiring a customizable approach to system implementation. By offering flexibility and adaptability, the modular and standards-based development approach offers the opportunity to address needs at each Cancer Center in this heterogeneous environment. Additionally, it will quickly generate a stream of tools and products as the Workspace marches to the ultimate long-term goal of providing a robust clinical trial management system that can be used not only by the Cancer Centers, but also the wider cancer research community, including cooperative groups, SPORES and the NCI Division of Cancer Prevention.

caBIG Workspaces & Working Groups:

- Clinical Trial Management Systems
- Tissue Banks & Pathology Tools
- Integrative Cancer Research
- Vocabularies & Common Data Elements
- Architecture

caBIG Strategic Level Working Groups:

- Strategic Planning
- Data Sharing & Intellectual Capital
- Training

For further information on this Workspace, please see http://caBIG.nci.nih.gov

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Progress to Date

The work began at the Kickoff Meeting in February of 2004. The Workspace participants reached agreements that began the journey to fulfill the ultimate Workspace vision. First among these were the Agreements in Principle for application development. These principles provide structure to the development process and continue to guide efforts within this Workspace. Agreements in Principle are as follows:

- caBIG General Principles: Apply an open access, open source, open development and federated approach to shared data and applications. All newly developed applications supported by caBIG resources will be open source.
- caBIG Architectural Principles: Use uniform Application Programming Interfaces (APIs) and appropriate standard message formats to make data and analytic services available.
- caBIG Data Standards: Use of data standards to achieve interoperability and comparability.
- Componentized Development: Apply componentized development principles for efficient support throughout the clinical trial life cycle and for compatibility across multiple existing clinical data management platforms. This strategy will also maximize interoperability with components built in other caBIG Workspaces.

List of Community Needs
* CDUS/CTMS reporting
* Adverse event reporting systems
* Laboratory interface modules
* Financial and billing systems
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

The participants agreed to a list of functions required by the community for effective clinical trial data management. After determining which of these needs are addressable through Workspace activities, the participants prioritized the list and identified four needs as the highest priorities (indicated in the table by asterisks). Although the Workspace intends to address the entire list of needs, as well as new needs as they are identified, the participants agreed to focus initial efforts on those highest priority needs.

All Clinical Trial Management Systems Workspace tools and products will be developed in a way that ensures all efforts remain focused on community needs and provide tangible benefit as quickly as possible. Many of the initial efforts will focus on clarifying specific baseline needs and requirements. Once these requirements are fully defined, existing software will be adapted where possible to meet the caBIG principles and to provide rapid fulfillment of immediate needs within the caBIG framework. Concurrently, new software will be developed where adequate solutions currently do not exist.

After the Kickoff Meeting, the group formed six Special Interest Groups (SIGs) to guide the prioritization of specific tasks within each area of focus. These SIGs include:

1) Adverse Event Reporting SIG
2) CTMS/CDUS Reporting SIG
3) Laboratory Interfaces SIG
4) Financial-Billing SIG
5) Structured Protocol Representation SIG
6) caBIG Compatibility SIG

The SIGs meet regularly to ensure steady progress in each area. Their work ultimately translates into specific projects that form the development and adoption activity of the Workspace.

In July, 2004 the Workspace held its first quarterly face-to-face meeting, hosted by the University of Pittsburgh. The highly productive two-day meeting enabled each of the SIGs to make substantial progress toward crisply defining the appropriate specific development activities to begin work on immediately. In addition, the group as a whole was able to revisit and refine our shared architectural vision, developing a roadmap to serve as a framework for all Workspace activities.

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Near-term Activities

The Workspace is focusing initial efforts on modules to meet the highest priority needs, while laying the foundation for the modular development approach that will provide the structure to meet the long-term vision for the Workspace. The initial modules include:

- **Adverse Events Module:** The adverse events module will be a comprehensive, highly automated, componentized solution for monitoring and managing adverse events that emerge during a clinical trial and generating reports for submission to internal and external regulatory monitoring organizations. Features will be developed in priority order based upon the requirements defined by the community, with the ultimate goals of improving patient safety, increasing productivity, streamlining processing, and facilitating sharing of adverse events information for research purposes.
- **Laboratory Interfaces:** A laboratory interface module will be developed that will allow laboratory data across multiple systems and in multiple formats to be translated into common standards. This will facilitate automated data submission to clinical trials systems components that rely on laboratory data in order to improve workflow and promote flexibility as systems are added to the Cancer Center.
- **CDUS/CTMS Reporting Module:** A regulatory reporting interface module will be developed to submit data electronically to NCI's CDUS (Clinical Data Update System) and the NCI's Clinical Trial Monitoring Service (CTMS). This module will capture relevant data from multiple systems and in multiple formats and translate them into the required formats. The process will be automated as much as possible to improve workflow and reduce manual operations. Additionally, this module will allow retention of data that is lost under current reporting mechanisms in order to facilitate internal analysis of ongoing studies.
- **Financial/Billing Module:** A financial/billing module will be developed to meet identified needs and requirements of the Cancer Center community. Features will be developed as community needs are prioritized, but will likely include capabilities to monitor plans versus budgets versus actual expenditures for clinical trials as well as to monitor financial/billing compliance for clinical trials.

To address some of the immediate needs for data capture and data management for groups that are in acute need or have no existing systems, a caBIG-compatible remote data capture solution (C3D), implemented using standardized vocabularies and common data elements, has been made available for adoption as either a web-accessible application service provider (ASP) solution hosted at the NCICB, or as a system entirely deployed at participating Cancer Centers. In addition, the Workspace anticipates other caBIG-compatible vendor solutions in this area. caBIG participants will be made aware of these alternative solutions as soon as they become available.

As a parallel effort, the Clinical Trial Management Systems Workspace is defining needs to provide the components of a comprehensive clinical trials solution over the long term. Providing a structured model for protocol representation is critical to this activity as everything begins with the protocol definition. A structured format enables improved interchange of this data among systems and system components. Developers in the Clinical Trial Management Systems Workspace will be working with various standards efforts to identify standard elements of a clinical trial protocol that can be further elucidated and codified to facilitate study design, regulatory compliance, project management, trial conduct and data interchange among consumers and systems. This may then be implemented as a Protocol Authoring Tool.

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Future Directions

To continue momentum toward the ultimate vision of providing a rich and comprehensive tool set for clinical trial management, the Workspace will perform activities to address all needs identified by the Cancer Center community. These needs will be prioritized by Workspace discussions, clarified by white papers, and defined by formal analysis. These activities will continue to lead the development of additional tools.

Supporting Activities

In the broader context, parallel and ongoing activities at the NCI and beyond will benefit the Clinical Trial Management Systems Workspace and caBIG. Other supporting activities include:

- As part of the broader IOTF (Interagency Operational Task Force), NCI and FDA are collaborating to streamline processing for electronic submissions of Investigational New Drugs (INDs), New Drug Applications (NDAs), Biologics License Application (BLAs), and amendments including serious adverse events as well as providing capabilities for a clinical investigator repository, leveraging existing solutions.
- NCI is collaborating with a consortium of pharmaceutical companies to develop solutions to meet regulatory reporting needs that include core infrastructure for identity management, privacy and security.
- HL7 standards activities: NCI is in the forefront of standards development for the RCRIM (Regulated Clinical Research Information Management) and has the opportunity with the support of members of the caBIG Clinical Trial Management Systems Workspace to drive convergence of CDISC and HL7 standards to a common model that meets the needs of the overall community.
- At the request of the Cancer Center Directors, the NCICB has created a world wide web portal for the registration of clinical trials. This information will be available through the caBIO infrastructure, which can be found at http://ncicb.nci.nih.gov/core/caBIO.
- The NCI is working with the Department of Health and Human Services to ensure that caBIG activities are fully integrated with the NIH roadmap and Department-wide information technology and integration efforts.
- NCI has created a working group of all stakeholders in clinical trials research with the goal of integrating its diverse activities. These various communities are providing coordinated input to the NCI, which will inform caBIG efforts.

Access to Tools

Existing clinical trials management tools being used to support caBIG activities (including NCICB resources), such as C3D (remote data capture and clinical trials database) and a portal for registering protocols, are already available on the caBIG website at http://caBIG.nci.nih.gov. As caBIG project activities continue and more clinical trial management tools, products and data become available, they will be accessible via the caBIG website.

Further Information

For additional information on the activities of the Clinical Trial Management Systems Workspace and caBIG in general, please see http://caBIG.nci.nih.gov.

Cancer Centers participating in this Workspace include:
* Case Western Reserve University—Ireland
* City of Hope
* Duke University
* Memorial Sloan Kettering
* Northwestern University—Robert H. Lurie
* University of California Irvine—Chao Family
* University of California, San Francisco
* University of Iowa—Holden
* University of Minnesota
* University of Nebraska-Eppley
* University of Pennsylvania—Abramson
* University of Pittsburgh
* University of Wisconsin
* Vanderbilt University—Ingram
* Wake Forest University
* Yale University
* Oregon Health and Science University

In addition, there are number of volunteer participants and affiliated organizations participating in this Workspace. For a complete listing, please go to http://caBIG.nci.nih.gov and click on Workspaces.

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