

An Assessment of the Impact of the NCI Cancer Biomedical Informatics Grid (caBIG[®])

**Board of Scientific Advisors
Ad Hoc Working Group on caBIG[®]**

March 1, 2011

Working Group Charge

caBIG[®]'s mission: creating an information network enabling all constituencies in the cancer community (researchers/physicians/patients) to share data/knowledge.

Charge to the Working Group:

Advise the NCI Board of Scientific Advisors on the goals, accomplishments, challenges, and community outreach of the caBIG[®] program.

Help caBIG[®] achieve even greater traction in the cancer research community and identify stumbling blocks and areas that will require greater attention in the future development of the program.

caBIG[®] areas covered by the assessment:

- (a) clinical infrastructure,
- (b) analytical tools for the support of discovery based science,
- (c) research infrastructure, and
- (d) program administration, contracts management, budget.

Working Group Strategy

- Meeting with caBIG[®] leadership and primary contractors on November 2, 2010
- 16 teleconferences between November 22, 2010 and February 25, 2011
- caBIG[®] constituencies contacted by WG
 - NCI-designated Cancer Centers listed as caBIG[®] users by program
 - Leaders of TCGA labs
 - Cooperative clinical trials groups
 - Industry
 - Strong supporters and “constructive critics”
- 59 Investigators at 46 institutions interviewed

Institutions Interviewed

Amgen	Memorial Sloan Kettering Cancer Center	University of California at San Francisco Comprehensive Cancer Center
Baylor College of Medicine/Dan L. Duncan Cancer Center	Novartis	University of California at Santa Cruz
Case Western Reserve University	Ohio State University Cancer Center	University of Chicago Cancer Research Center
City of Hope National Medical Center/Beckman Research Institute	Oregon Health & Science University Cancer Center	University of Iowa/Holden Comprehensive Cancer Center
Dana Farber/Harvard Cancer Center	Roswell Park Cancer Institute	University of Medicine and Dentistry of New Jersey
Dartmouth Medical School	Salk Institute Cancer Center	University of North Carolina at Chapel Hill/Lineberger Cancer Center
Duke Comprehensive Cancer Center	Sanford/Burnham Institute for Medical Research	University of Pittsburgh Cancer Center
Eastern Cooperative Oncology Group	Stanford University	University of Southern California
European Bioinformatics Institute	The Broad Institute of MIT	University of Texas MD Anderson Cancer Center
ForteResearch	The Jackson Laboratory Cancer Center	University of Virginia Cancer Center
Fox Chase Cancer Center	The Wistar Institute	University of Wisconsin Madison/Paul P. Carbone Comprehensive Cancer Center
Fred Hutchinson Cancer Research Center	Thomas Jefferson University/Kimmel Cancer Center	Velos
Georgetown University/Lombardi Comprehensive Cancer Center	University of Alabama at Birmingham Comprehensive Cancer Center	Wake Forest University Comprehensive Cancer Center
H. Lee Moffitt Cancer Center and Research Institute	University of Arizona Cancer Center	Wayne State University School of Medicine/The Barbara Ann Karmanos Cancer Center
Inova Health System	University of California at San Diego/Rebecca and John Moores Cancer Center	Weill-Cornell Medical School
Johns Hopkins University/Sidney Kimmel Comprehensive Cancer Center		

Findings in Three Main Areas

- Creation and management of standards for data exchange and support of community-based software
- Impact and track record of caBIG[®] initiatives and tools
 - Life science/integrative cancer research tools
 - Clinical trial management system
 - Infrastructure tools
 - Community engagement
- Program administration, contracts management, and budget

Positive Findings

- Clinical and bioinformatics support is critical to achieve NCI goals
 - Prevention, diagnosis, and treatment of cancer
- Overwhelming agreement on value of caBIG[®] initial mission
 - Standards for data exchange and interoperability
 - Support of community-based tools supporting them
- Support of initial vision by caBIG[®] leadership
- Addresses a gap in current funding mechanisms

However.....

- Long-term Vision driven by technology advances rather than progress in cancer prevention, diagnostics, and treatment
 - Build it and they will come
- Lack of applications that demonstrate the value of caBIG[®] to clinical and basic science investigators
- Lack of independent scientific oversight (e.g. Peer review, SAB)
- Disconnect between caBIG[®] leadership and cancer research community resulting from heavy use of contractors to manage the program

Standards for Data Exchange and Support of Community-based Tools

- Considered caBIG[®]'s main contribution
- Catalyzed progress in 3 critical areas:
 - Development of community-driven standards for data exchange and interoperability
 - Development, maintenance, enhancement, dissemination of tools developed by academic researchers
 - Community dialog on interoperability of clinical and research software tools

caBIG[®] Life Science/ Integrative Cancer Research Tools

- Many Bench-to-Bench tools with varying development costs: Reactome (\$100K) → caARRAY (\$9.3M);
 - Surprisingly little correlation between investment and adoption
- Most tools were not widely adopted by the community
- Main reasons cited for lack of adoption:
 - Tools have been re-engineered too often
 - Tools over-designed and ambitious
 - Tools require significant technical knowledge and dedicated local informatics support/resources
 - Commercial tools available and easier to use
 - Some tools developed for narrow niches

Biospecimen Management Tools

- caTissue suite widely used in cancer centers
- Adoption facilitated by:
 - NCI mandate
 - Limited availability of commercial software
 - Two caBIG[®]-sponsored user meetings on caTissue deployment
 - Addresses a non-mission critical need for which legacy systems were not in place
- But needs considerable local customization, lacks needed functionality, only rigorously de-identified data, does not support CHTN standards

Overall Impact of caBIG[®] Life Science Tools

- Uneven adoption of tools
- Limited impact of most tools
- More impact from tools initiated or implemented by academic research institutions and developed at lower overall cost
- Less impact from caBIG[®] initiated tools with highest overall costs
- Data sharing and interoperability goals far from being achieved. “Bronze compatibility” not sufficient for interoperability.

caBIG[®] Clinical Trial Management System (CTMS)

- Tools for managing clinical data were highest priority for cancer centers
- Prior to caBIG[®], limited support within some cancer centers for advanced informatics tools
- Overall development costs of CTMS at least \$50M FY 2004-2010 + at least \$50M of ARRA money
- Few NCI cancer centers use CTMS tools - Commercial tools remain dominant
- CTMS tools support I-SPY trial and Duke/China Trial

Main Reasons Cited for Not Adopting caBIG[®] CTMS Tools

- Existence of critical legacy systems
- Tools incomplete, too generic, overly complex, “buggy” and require workflow modifications
- User interfaces require extensive customization
- High maintenance costs for unnecessary features
- Tools do not link to AdEERS or MedWatch
- Interfaces vary across tools
 - Awkward linkages
 - Tools do not interoperate

caBIG[®] Infrastructure Tools

- Standard vocabularies and data models constitute a valuable caBIG[®] effort. However:
 - Process takes too long
 - Process does not take adequate advantage of widely adopted standards
 - Resulting standards are very complex and change too rapidly
- Imaging tools are only viable tools for exchange of image metadata
 - Adoption in commercial workstations and ACRIN trials

caBIG[®] Infrastructure Tools: caGRID

- Did not address need perceived by cancer centers
- High development cost (~\$9M)
- Main reasons cited for not adopting
 - Very complex, difficult to maintain, needs resident experts in Java
 - No GUI for basic admin/configuring tasks
 - “Software churn” in grid architecture/tools
 - Not adequately security tested
 - Inadequate harmonization of tools into single architecture, tools don't interoperate well

caBIG[®] Community Engagement

- Broad range of activities
- Mixed reactions by community
- Deployment Lead program and Knowledge Centers generally viewed positively
- Annual meetings viewed as “marketing”
- Perception that feedback from community not incorporated

caBIG[®] Program Administration, Contracts Management and Budget

- caBIG[®] managed by NCI Center for Bioinformatics and Information Technology (CBIIT)
 - Two main contractors
 - Booz Allen Hamilton: program management office
 - SAIC-Frederick: technical operations, software development
 - Internal Program Oversight Board – CBIIT senior staff advised by contractors
- Subcontracting process for caBIG[®] projects and initiatives does not require concept clearance
 - BAH or SAIC-F issues RFP, evaluates proposals, selects and monitors subcontract awards

caBIG[®] Program Administration, Contracts Management and Budget

- Strong consensus among interviewees
 - Overly complex management structure
 - Considerable overhead costs: 25 – 30% of total costs, >\$60M in FY 2004-10 + more for ARRA projects
 - Contractors experts in technology, not science
 - Internal decision-making/funding decisions are not transparent, not peer reviewed
 - Potential conflict of interest if same contractors set standards and write/market software
 - Perception that caBIG[®] favors “in group”

Conclusions

- Support for clinical informatics tools and algorithmic advances is mission-critical for NCI
- Strong community support for original caBIG[®] vision and goals
- caBIG[®] accomplishments in data standards offset by limited success in other areas
- Overall impact not commensurate with level of investment

Conclusions

- caBIG[®] impact compromised by implementation approaches
 - “Cart-before-the-horse” vision
 - Technology-centric approach to data sharing
 - Unfocused expansion
 - One-size-fits-all approach
 - Unsustainable business model for both NCI and users
 - Lack of independent scientific oversight

Immediate Tactical Recommendations

1. **Institute an immediate moratorium on all ongoing internal and commercial contractor-based software development projects** while initiating a mitigation plan to lessen the impact of this moratorium on those using existing caBIG[®] tools.
2. **Institute a one-year moratorium on new projects, contracts and subcontracts by caBIG[®].**
3. **Provide a one-year extension on current caBIG[®]-supported academic efforts** for development, dissemination, and maintenance of new and existing community-developed software tools

Immediate Tactical Recommendations

4. **Establish an independent oversight committee,** representing academic, industrial, and government (NCI, NIH) perspectives **to review ongoing and planned initiatives** for scientific merit and to recommend effective **transition options** for current users of caBIG[®] tools.
5. **Conduct a thorough audit of all aspects of the caBIG[®] budget and expenditures** to recover unspent funds for reprogramming to implement the other recommendations and other NCI priorities.

Longer Term Strategic Recommendations

6. **Create an independent Scientific Advisory Group (SAG) for NCI biomedical informatics efforts and initiatives** that includes scientific, technology and informatics expertise to advise NCI on appropriate informatics priorities, initiatives, business model(s), and resource allocations. It may be appropriate that this group be a subcommittee of the BSA.
7. **Refocus caBIG[®] on its original mission** and discontinue all strategic efforts to develop and maintain its own brand of software tools, either directly or indirectly through commercial contractor efforts.

Longer Term Strategic Recommendations

8. **Separate the clinical informatics and bioinformatics components of the caBIG[®] program.**
9. **Use usual and established channels and mechanisms for concept clearance and peer review of NCI biomedical informatics initiatives in the future.**
10. **Promote interoperability and data sharing by making them key review criteria for grant and cooperative agreement applications and R&D contracts and as requirements for awards**

Working Group Members

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