Lessons Learned from caBIG®

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National Cancer Policy Forum Workshop on
Informatics Needs and Challenges in Cancer Research
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National Cancer Institute

caBIG™ cancer Biomedical Informatics Grid™

Slides from a 2006 tutorial presentation, after caBIG launch in February 2004

Overview of The Cancer Biomedical Informatics Grid™ (caBIG™):

Connecting the Cancer Community

Health information tsunami

- overwhelming volume of data
- multitude of sources

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Informatics tower of Babel

- Each part of the health community speaks its own scientific "dialect" (e.g. lab values, genetic profile, clinical data)
- Lack of consensus on common standards and terms
- Lack of coordination across, and collaboration within, the cancer research enterprise
- Integration is critical to achieve promise of molecular medicine

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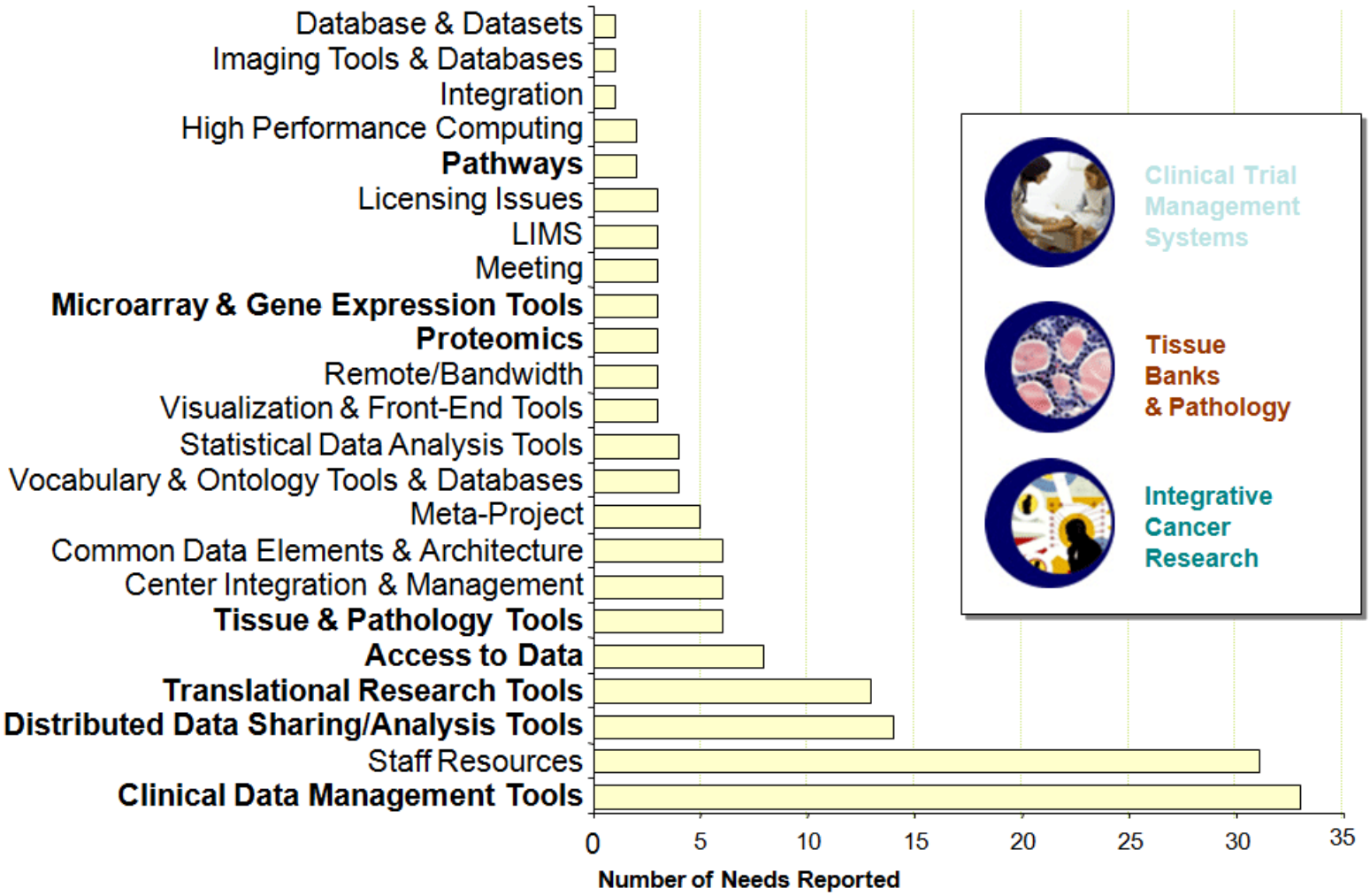
Common needs helped shape priority areas for the caBIG pilot activities



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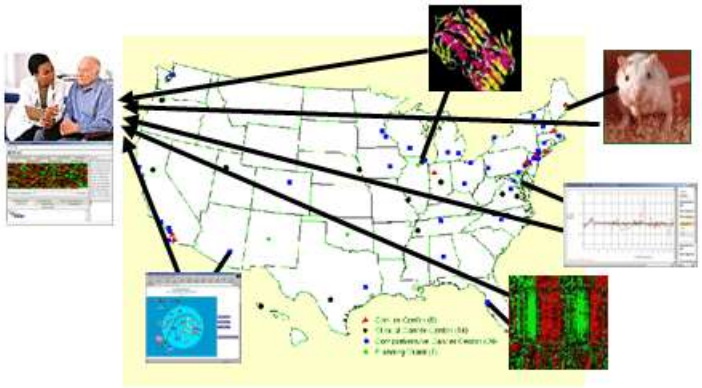
Cancer Biomedical Informatics Grid™ (caBIG™)



- Common, widely distributed infrastructure permits research community to focus on innovation
- Shared vocabulary, data elements, data models facilitate information exchange
- Collection of interoperable applications developed to common standards
- Raw published cancer research data is available for mining and integration

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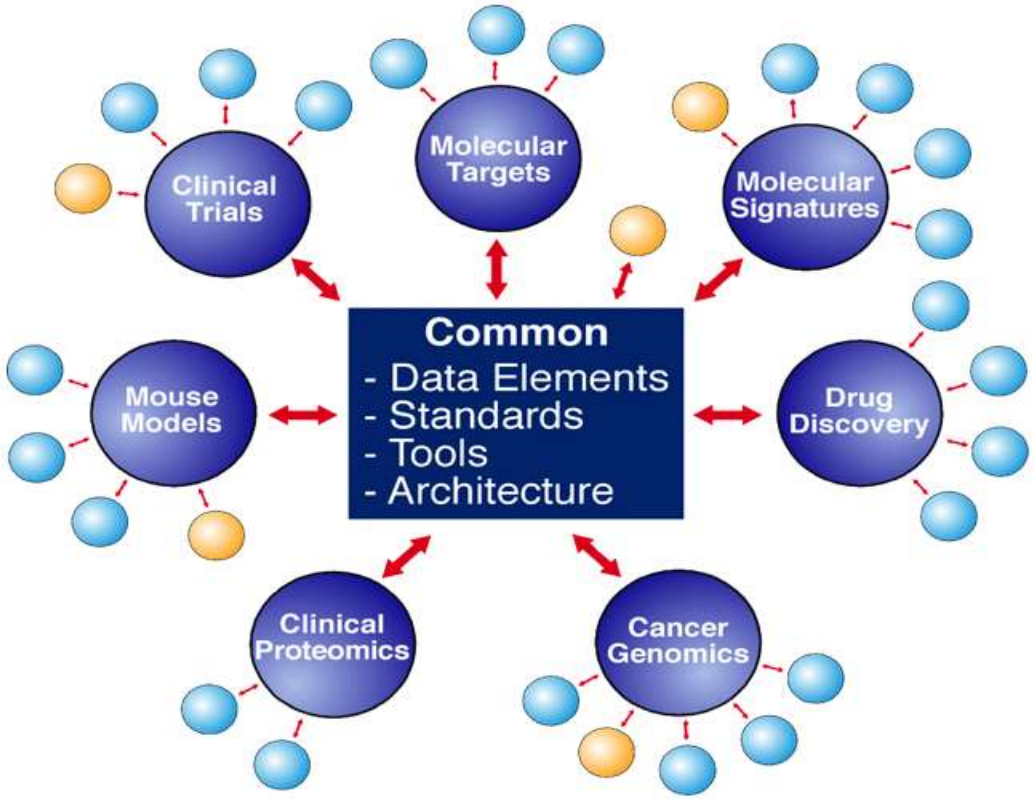
caBIG™'s Informatics Core



caBIG review group established Fall 2010

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Arul Chinnaiyan, M.D.*, Ph.D. *, University of Michigan

Geoffrey M. Duyk, M.D., Ph.D., TPG Biotech

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* NCI Board of Scientific Advisors Member

Review Group Conclusions March 2011

- Support for informatics tools and algorithmic advances is mission-critical for NCI
- Strong community support for original caBIG® vision and goals
- caBIG® successes offset by several serious problems
- Overall impact not commensurate with level of investment

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 data management system
  - Infrastructure tools
  - Community engagement
- Program administration, contracts management, and budget

Creation and Management of Standards for Data Exchange

- Greatest impact in this arena
- caBIG® 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

Conclusions, cont'd

- Main problems with caBIG ® approach
  - Cart-before-the-horse grand 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 the cancer research community.

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 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.**

NCI program management response

caBIG® Budget Adjustments

- Original FY 2011 appropriated budget was $45 million
- ARRA funding from FY 2009/2010 was $103 million
- New scope requires FY 2011 appropriated funding at $33 million
- ARRA funds reduced to $43 million
- Further adjustments of appropriated and ARRA funds are being evaluated
- Funding plans for future years will depend on NCI's budget level

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caBIG Oversight ad hoc Subcommittee Group Roster

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Lynn Vogel, Ph.D., MD Anderson

Jean Y. Wang, Ph.D., University of California, San Diego Cancer Center

Executive Secretaries: John Czajkowski, M.P.A. and Paulette Gray, Ph.D.

Committee Management Officer: Ms. Claire L. Harris

* BSA Member

Informatics project review criteria (10)

1. Does the activity, application or resource meet a well-articulated and attainable need of basic, translational or clinical researchers or cancer health care (ie., is there a ‘driving biological or clinical project’ and are the intended users members of the project team)?

2. How will success or failure be evaluated? Analogous to stopping rules for clinical protocols, what will be the stopping rules for ending the project if it either fails to meet its technical objectives or fails to be adopted even if technically successful?

Informatics project review criteria (10)

3. Will the activity, resource, or application, if successful, make some objectively measurable incremental progress toward an overall vision of interoperability of data and systems? Will it enable data sharing and make use of and/or enhance open international standards for research?

4. Is the activity, resource or application designed to anticipate change in a rapidly expanding knowledge base of science and practice? Flexibility and generalizability are important characteristics for longevity in an era of agile science.

Informatics project review criteria (10)

5. Is the intended deliverable of the project achievable in the time frame and budget proposed?

6. Will the output of the project be broadly implementable by organizations of varying size and sophistication? Will it be used broadly by organizations and institutions outside of NCI/Cancer Centers (e.g. other NIH centers or academic research organizations)?

Informatics project review criteria (10)

7. Is there a documented plan for long term maintenance, enhancement and fiscal sustainability of the activity, application or resource and its user base?

8. What is the user base and has there been a stakeholder assessment to assure that the activity, application or resource will indeed meet a currently unmet need or a reasonably anticipated future need?

Informatics project review criteria (10)

9. Is the project generalizable and likely to create value or address broad needs across the community of cancer centers and investigators? Or would this activity, resource or application be perceived as a “pet project” of an “in” group?

10. Does the activity, resource or application have enough market value to gain adoption without incentives, or if financial or policy incentives are required, are they justified?

Looking forward:
A three step approach to success in informatics innovation*

**With expert advice from:*

- *Isaac Kohane MD, PhD, developer of i2b2*
- *Paul Harris, PhD, developer of REDCap*
- *Paul Fearn, MBA, caBIG oversight committee member*

Step1: The Don'ts
Don't repeat the mistakes of the past

1. Do not try to solve all clinical and translational research IT problems in one framework.
2. Do not worship standards over functionality.
3. Do not try to have enterprise software adopted by fiat from above.
4. Do not try to buy adoption of software products (the costs will grow ever larger).
5. Organizations that cannot afford ongoing staffing and help desk functions for software should not be expected to adopt software, even if it is free or provides some income to the adopter.

Step 2: Understand the basic truth about IT complexity

- Increased functionality that is built at the expense of increased complexity is at risk of:
  - Delays in development
  - Inability of local implementers and users to understand how to implement and use it
  - Being overtaken by other approaches that have a better ‘price/performance’ ratio e.g., grid computing vs. web services

Step 3: Observe the Informatics R&D Do's

1. Solve one significant challenge at a time.
2. Use small nimble development teams.
3. Have R&D done by recognized domain experts and leaders.
4. Keep R&D-to-useable product intervals very short.
5. Deploy software that can solve at least one problem that users/adopters care about within 12 months of adoption.
6. Demonstrate success first with a smaller group of the most advanced sites and then let others follow.

Step 3: Observe the Informatics R&D Do's, cont'd

7. Create software that makes adoption of standards easier rather than harder than non-standardized alternatives.
8. Let the market prioritorize and vet the standards.
9. Invest in simple interfaces between applications, not architectures
10. Make interested healthcare organizations demonstrate willingness to invest their own assets and time for enterprise software.
11. Allow intra-organizational and inter-organizational needs and technologies to diverge as needed, to maximize productivity

Increasing the probability of successful adoption in cancer research

- Focus efforts on data sharing (both the standards for sharing, and the apps that share) on data for which there is a pre-existing *motivation to share*
  - i.e., where researchers really need one anothers' data
  - Ideally, scientific problems that simply cannot be solved within one lab or institution

Increasing the probability of successful adoption in cancer care

- Harder to succeed, given low penetrance of EMRs in US healthcare, and current economic pressures
- Therefore, align NCI efforts with fed govt. (ONC) incentives for EMR adoption
- A plausible transitional goal: make it easier in every oncology practice in America to take care of a patient on a clinical protocol than off protocol.
  - Precision medicine will necessarily be built on person-specific decision support within EMRs
  - Will need ‘public libraries’ of decision support tools that guide providers and patients through clinical protocols

Work in progress

- Ongoing review of existing caBIG projects and applications, sequenced by upcoming project deadlines.
- Search for new NCI senior staff leader for informatics activities
- Development of an NCI strategic plan for cancer informatics

Summary

- NCI commitment to computational infrastructure for basic, translational and clinical cancer research remains strong
- In an era of tightly constrained resources, focus will be on highest priority needs of science