NCI Imaging & the caBIG Picture

C. Carl Jaffe, MD
NCI Cancer Imaging Program

Problem definition

- NCI spends ~ $750 M per year on cancer therapy research (mostly testing drugs)
- PhRMA spends far more
- Imaging is not a key element in trials
  - It's usually 'correlative' or a 2ndary end-point
- And only 2% of cancer patients are on formal clinical trials

The current model isn’t working

- Quantitative tools are deficient or lacking
  - And are not time-efficient or in common across sites
- Image acquisition protocols are diverse, ad hoc & often subtly violated
- Central reads are rare and expensive
- Images aren’t linked to clinical data & outcomes
- Access to primary images is limited or restricted
- Regulatory approval of drugs lacks ‘qualified’ imaging biomarkers
- CAD tool development community lacks ready access to images with clinical outcome data

Imaging Opportunities

- Lowering barriers to CAD development for quantitative therapy monitoring
- Validating and testing software algorithms
- Data transparency and data sharing
- Changing the culture/community of clinical trials to meet needs of CTWG
- Integrating imaging into bio-informatics

Integration Initiatives

- NCI:
  - Clinical Trials Working Group (CTWG)
  - Clinical Trials Evaluation Program (CTEP)
- ACR
  - Uniform Protocols in Clinical Trials (UPICT)
- Cancer Centers
  - Image Response Assessment Teams (IRATS)
- FDA, PhRMA Biomarker Consortium
  - ONCOLOGY BIOMARKER QUALIFICATION INITIATIVE (OBQI)
- NCICB
  - Ca Bioinformatics Grid (caBIG)

Report of the Clinical Trials Working Group of the National Cancer Advisory Board

Restructuring the National Cancer Clinical Trials Enterprise

http://integratedtrials.nci.nih.gov/ict/CTWG_report_June2005.pdf

June 2005

Summary Vision

Trials driven by advances in cancer biology will require robust clinical trial designs that necessitate comprehensive information sharing and close collaboration among clinical researchers and basic and translational scientists. Moreover, the evaluation of novel targeted therapies, designed to be effective against cancers with a specific molecular profile, depends on synergistic integration of treatment protocols with modern molecular diagnostic and imaging techniques. Such integration will require real-time, coordinated participation between clinical oncologists and experts in comprehensive molecular analysis and bioinformatics during the conduct of trials. Therapies appropriate for only a

Standardization Initiatives

- Create, in partnership with the extramural cancer research community, a national cancer clinical trials information technology infrastructure fully interoperable with NCI's cancer Bioinformatics Grid to improve cost effectiveness and comparability of results across trials and sites.

Where are we now ?
Existing image cores for clinical trials

- QARC
- ACRIN
- COG-Phase I
- PBTC
- CALG-B OSU
- ATC
- DCP

Common Imaging Needs of Cancer Groups

- **(Standardized study design for imaging)**
- **Image transfer from PI to group archive**
  - **DICOM archiving solution (software + hardware)**
  - **Network solution (secure transfer, HIPAA, ..)**
- **Online access to images to perform central review**
  - **Workstation to read images (software or hardware)**
  - **Ideal: Reuse personal DICOM Display workstation**
- **Annotate image data**
  - **CAD support to quantify image data (size, volume, perfusion, ..)**
  - **Ad-hoc interactive CAD at time of image reading**
- **Some Image Processing**

Cultures

- caBIG community
  - Technology driven
- Cancer Groups
  - Clinically driven

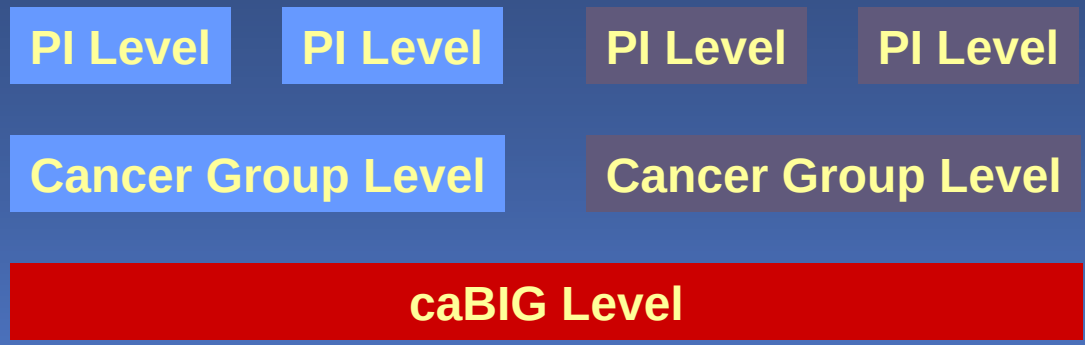
Demonstrate caBIG capabilities to match Common Needs

- **Image transfer from PI to group archive**
  - **DICOM to Grid transfer**
  - **HIPAA compliance**
  - **Audit trail**
  - **Light-weight deployment**
  - **Cohesive plan for all levels: User, Group Server, caBIG Server**
- **Online Access to images to perform central review**
  - **Access Authentication/Authorization (HIPAA, x.509)**
  - **Workstation support: Vendors and open-source, multi-platform**
- **Annotate image data**
  - **CAD example to quantify image data: e.g. MR perfusion**
  - **Persistent annotation support ?**
- **Develop a process for establishing 'qualified' imaging biomarkers**

Vision pathways

- **Image handling: Grid PACS**
  - **DICOM Image transfer from PI to group/caBIG archive**
  - **DICOM Image Grid access to serve as a substrate for qualified biomarker development**
- **Image knowledge retrieval:**
  - **CAD application to support review**
- **Image knowledge representation:**
  - **Ontology specific image annotation**

Tiered approach to data-sharing



1. PI Level:
   - Use existing hardware with caGRID image link
2. Cancer Group Level
   - Provide servers to store and retrieve domain specific images image with caGRID software
3. caBIG Level:
   1. First step: demonstrate / evolve NCIA as a resource
   - Next satep: Collect subset of de-identified, curated images in distributed storage sites

Advantages of a tiered approach when technologically mature

- Image ownership is with CG
- Frequent study related image access within domain (tire 1-2)
- Less frequent “expert” access between PI and caBIG (1-3 tire)

Starting Point: Image data must be treated with same rigor as clinical data

- Imaging Protocol should specify:
  - Image acquisition parameters
  - Image Quality Assurance procedures
  - Measurement procedures; data analysis
  - QA program for observer procedures, interpretations and measurements

Uniform Protocols for Imaging Clinical Trials

- Multi-societal, industry and gov't developing agreements on imaging methods for clinical trials – **ACR coordinated**

Update of OBQI Activities

- Framework for collaboration and initial project proposals completed and received approval from FDA, NCI and CMS leadership *(8/2005)*
- Tripartite MOU approved by FDA, NCI, CMS and HHS and being processed for full execution *(2/2006)*
- NIH/OD approved collaboration to occur independent of NIH-wide involvement: oncology focused, thus under NCI's purview
- 4 areas of focus identified under OBQI:
  - 1. Cancer Imaging: *diagnosing, assessing response to therapy, standardization*
  - 2. Molecular Assays/Targeted Therapies: *IVDs, assay panels*,
  - 3. Clinical Trials: *streamlining, standard setting, data generation*
  - 4. Data Mining: *electronic data, biospecimen*

1. Cancer Imaging

FDG-PET in NHL: Demonstration Project for OBQI

- Draft protocol for demonstration project: FDG-PET in NHL completed and approved for further development
- Industry agreed to fund FDG-PET in NHL project as 1st project under the PhRMA Biomarker Consortium, through the FNIH (11/2005)
- Possible NCI trial identified onto which these scans may be added to arm

ONCOLOGY BIOMARKER QUALIFICATION INITIATIVE (OBQI)
FDA - Janet Woodcock, MD

- An extension of activities under NCI's 21015 Goal & FDA's Critical Path Initiative
- Conducted under IOTF umbrella & in partnership with CMS
- A tripartite (NCI/FDA/CMS) Memorandum of Understanding (MOU) will establish framework for collaborations and launch initiative
- Many demonstration studies will be conducted as interagency collaboration or PPPs with multiple parties
- Project priorities will be set according to NCI, FDA and CMS (PPPs will be conducted with input of private parties)
- For projects conducted by independent partners, FDA, NCI & CMS will participate, in official capacities as Federal Liaisons

About caBIG
- caBIG Information
- Communication Tools
- 2005 Annual Meeting
- 2006 Annual Meeting

caBIG Participants
- Workspaces and Working Groups
- Events, Web casts, and Town Halls
- Online Forums
- Training
- Concurrent Versions System(CVS)
- caBIG Management Portal(caMP)

Progress and Products
- Program Milestones
- Inventory of Tools
- Compatibility Guidelines
- caGrid
- caBIG Papers

caBIG Communities
- Center Directors
- Industry Partners
- Public
- Media

Welcome to the caBIG™ Web site

2006 caBIG™ Annual Meeting

Click here for more details!

About caBIG™ - The **ca**ncer **B**iomedical **I**nformatics **G**rid, or ***caBIG™***, is a voluntary network or grid connecting individuals and institutions to enable the sharing of data and tools, creating a World Wide Web of cancer research. The goal is to speed the delivery of innovative approaches for the prevention and treatment of cancer. The infrastructure and tools created by caBIG™ also have broad utility outside the cancer community. caBIG™ is being developed under the leadership of the National Cancer Institute's Center for Bioinformatics.

caBIG™ Participants - Nearly 500 people from approximately 50 NCI-designated Cancer Centers and other organizations are working collaboratively on over 70 projects in a three-year pilot project. Workspace and Working Group specific information, materials and online forums can be accessed here.

« December 2005 »

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news

- Two Data Standards for caBIG™ Review-Address and Organization Standards 2005-12-06
- Draft caBIG™ Conflict of Interest Policy: Request for Comments 2005-12-02
- caBIG™ Publication Policy, Final Draft: Request for Comments 2005-12-02
- Imaging Workspace Launch: Face-to-Face Meeting Planned 2005-11-28

Workspaces & Working Groups

Workspaces

Pilot Domain Workspaces

The four Domain Workspaces to date include:

Clinical Trial Management Systems

Purpose: Deploy and develop caBIG™ compliant tools to support data capture/analysis and management of clinical trials.

Integrative Cancer Research Workspace

Purpose: Assemble data, tools, and infrastructure that facilitate the cross silo use of cancer biology information to promote integrated cancer research.

NEW!

In Vivo Imaging Workspace

Purpose: To advance the field of imaging and, by extension, all clinical trials and research, by identifying new ways to extract and share meaning from in vivo imaging data and thereby improve outcomes for patients with cancer and enhance efforts in early diagnosis and prevention.

Tissue Banks and Pathology Tools Workspace

Purpose: Develop a set of tools to inventory, track, mine, and visualize tissue samples and related information from a geographically dispersed repository

National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov

NCIA National Cancer Imaging Archive

Search: Go

Site Map

HOME | Overview | Informatics | Download | Collections

- What's New
- NCIA Application
- Collaborators
- NCI Cancer Imaging Program (CIP)
- Cancer Therapy Evaluation Program (CTEP)
- Division of Cancer Prevention(DCP)

QUICK LINKS

- National Cancer Institute
- cancer Biomedical Informatics Grid (caBIG)
- NCI Center for Bioinformatics

WELCOME TO THE NATIONAL CANCER IMAGING ARCHIVE

National Cancer Imaging Archive (NCIA)

The in vivo image repository provides the cancer research community, industry, and academia with access to image archives that can be used for many purposes including the potential to assist in the development and validation of analytical software tools supporting: lesion detection and classification software, accelerated diagnostic imaging decision, and quantitative imaging assessment of drug response. The repository provides access to imaging resources that will improve the use of imaging in today's cancer research and practice by: increasing the efficiency and reproducibility of imaging cancer detection and diagnosis, leveraging imaging to provide an objective assessment of therapeutic response, and ultimately enabling the development of imaging resources that will lead to improved clinical decision support.

National Cancer Imaging Archive

Click here for Imaging Application.

Imaging Workspace: All Participants Teleconference

Every 4th Tuesday of the month.

Click here for more information.

National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov

NCIA National Cancer Imaging Archive

HOME | SEARCH IMAGES | MANAGE DATA BASKET | HELP | LOGOUT

SITE TOOLS

DICOM Image Viewers

MY DATA BASKET

View Contents
(0 Series in Basket)

MY QUERIES

View Saved Queries
(0 Saved queries)

View Query History

QUICK LINKS

NCIA NEWS

NCI HOME

NCICB HOME

CANCER IMAGING PROGRAM

Center for Bioinformatics

RSNA

NIBIB

WELCOME TO NATIONAL CANCER IMAGING ARCHIVE

SEARCH IMAGES
Choose to query the NCIA Image Server using a Simple Search or an Advanced Search.

MANAGE DATA BASKET
Manage the information in your data basket.

NCIA Updates

New Images available as of Feb 3, 2006

NCICB Application Support

Please contact NCICB Application Support group at (301)451 4384 or toll free (888)478 4423 or at ncicb@pop.nci.nih.gov for any questions and suggestions regarding this image repository.

SIMPLE SEARCH

SEARCH CRITERIA

Image Modality(ies)	Available: CT, DX — SELECT > / SELECT ALL >> / << REMOVE ALL / < REMOVE — Selected
Contrast	Either Enhanced or Unenhanced
Anatomical Site	
Image Slice Thickness	☐ I would like to filter by "Image Slice Thickness" > 0 mm AND <= 5 mm
Minimum Number of Studies	Baseline Plus
Number of Months between Baseline and Final Study	
Collection(s)	Available: RIDER — SELECT > / SELECT ALL >> / << REMOVE ALL / < REMOVE — Selected
Annotations	☐ Only include series that have annotations

Modality Manufacturer

Manufacturer Model Software Version	☐ All Manufacturers

DICOM

0008	103E	Series Description	

Basic objectives

- Insert appropriate imaging into clinical trials where meaningful
- Engage the oncology community
- Support quality-controlled, uniform acquisition and store digitally
- Assemble databases of images and clinical data as biomarker candidates
- Encourage development of quantitative tools
- Communication and dissemination effort