Enabling 21st Century Cancer Research: Update DUKE-PKU Cancer Program

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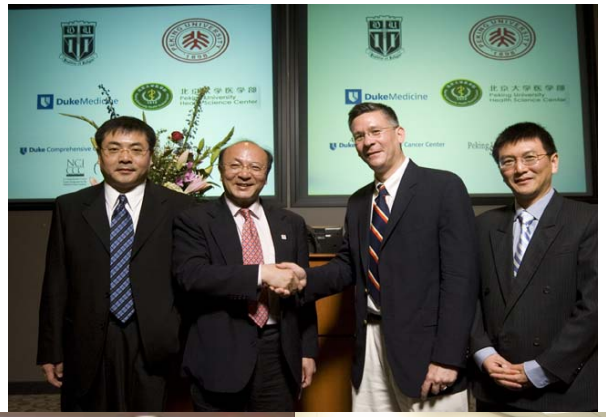
DUKE-PKU Cancer Program

- Signed the MOU on 26 Apr. 2007
- CaBIG Workshop at Beijing on 6 Sep. 2007
- CaBIG Training at Duke From 30 Jan. to 16 Feb. 2008



caBIG at Duke

- **Developer**

—Cancer Central Clinical Participant Registry (C3PR)

— caTRIP

- Many elements part of other caBIG applications

— RProteomics

— VCDE Mentorship

— CTMS Knowledge Center

caBIG at Duke

- **Adopter**
  - **—Flagship C3D implementation**
    - Many trials in production, many more in development
  - **— C3PR multi-center pilot**
  - **— caAERS (CALGB and Duke) (in progress)**
  - **— caGRID**
  - **— caArray (in progress)**

Impact of caBIG at Duke

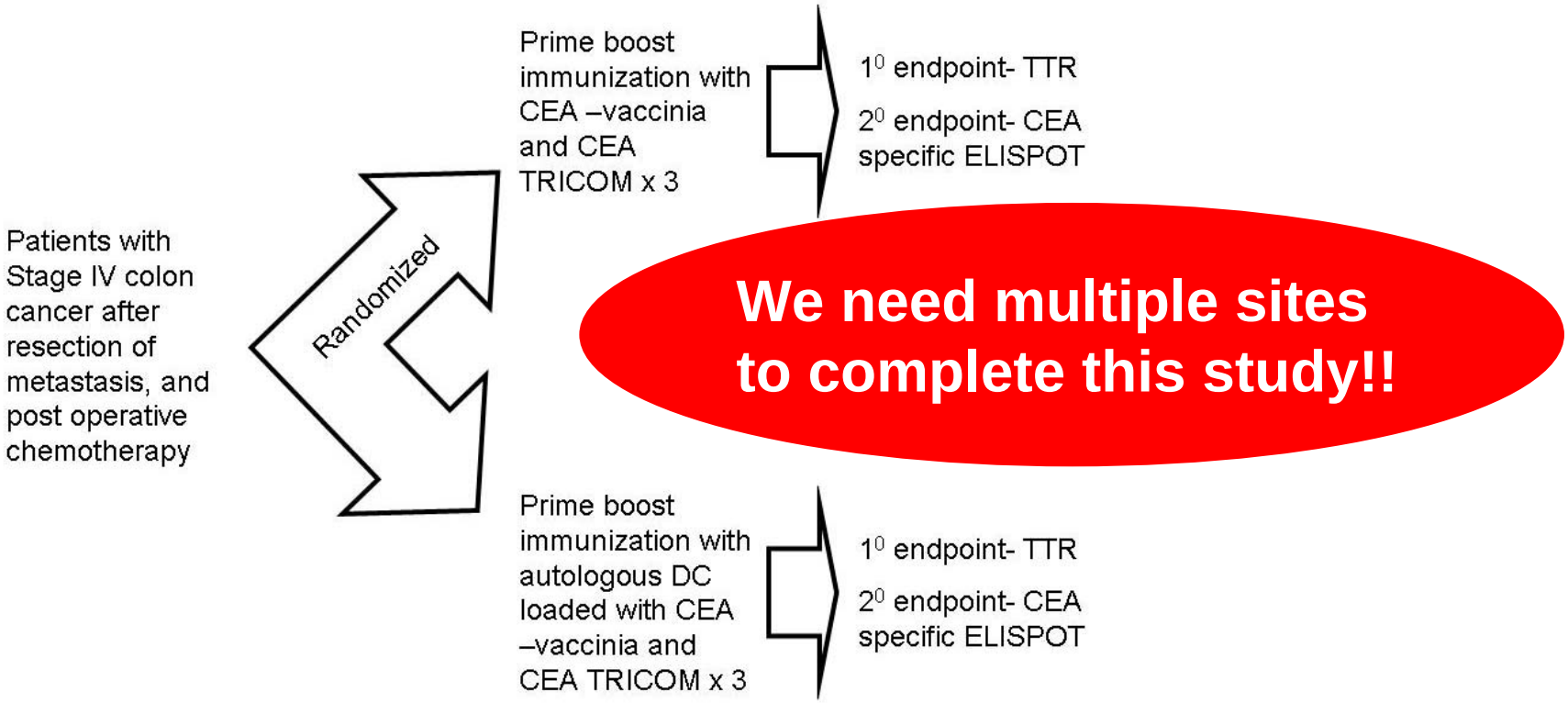
- Investment strategy and long term IT planning aligned with caBIG goals
- Enabling novel clinical trials between cancer centers
- Enabling biomarker intense (real time gene array based) clinical trials
- Improving access and services to underserved populations

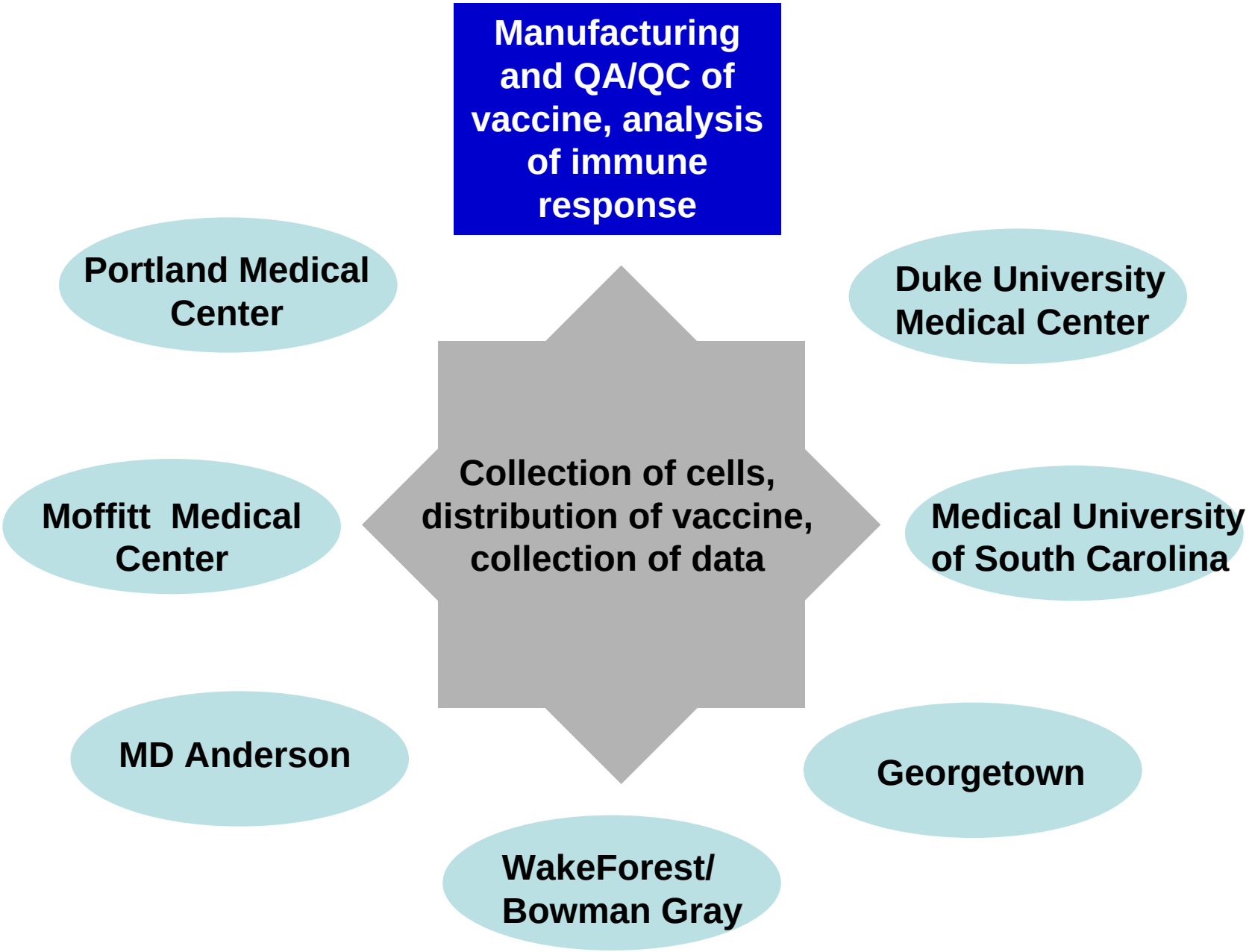
A randomized phase II trial

A) DC infected with rV-CEA(6D)-TRICOM followed by DC infected with rF-CEA(6D)-TRICOM

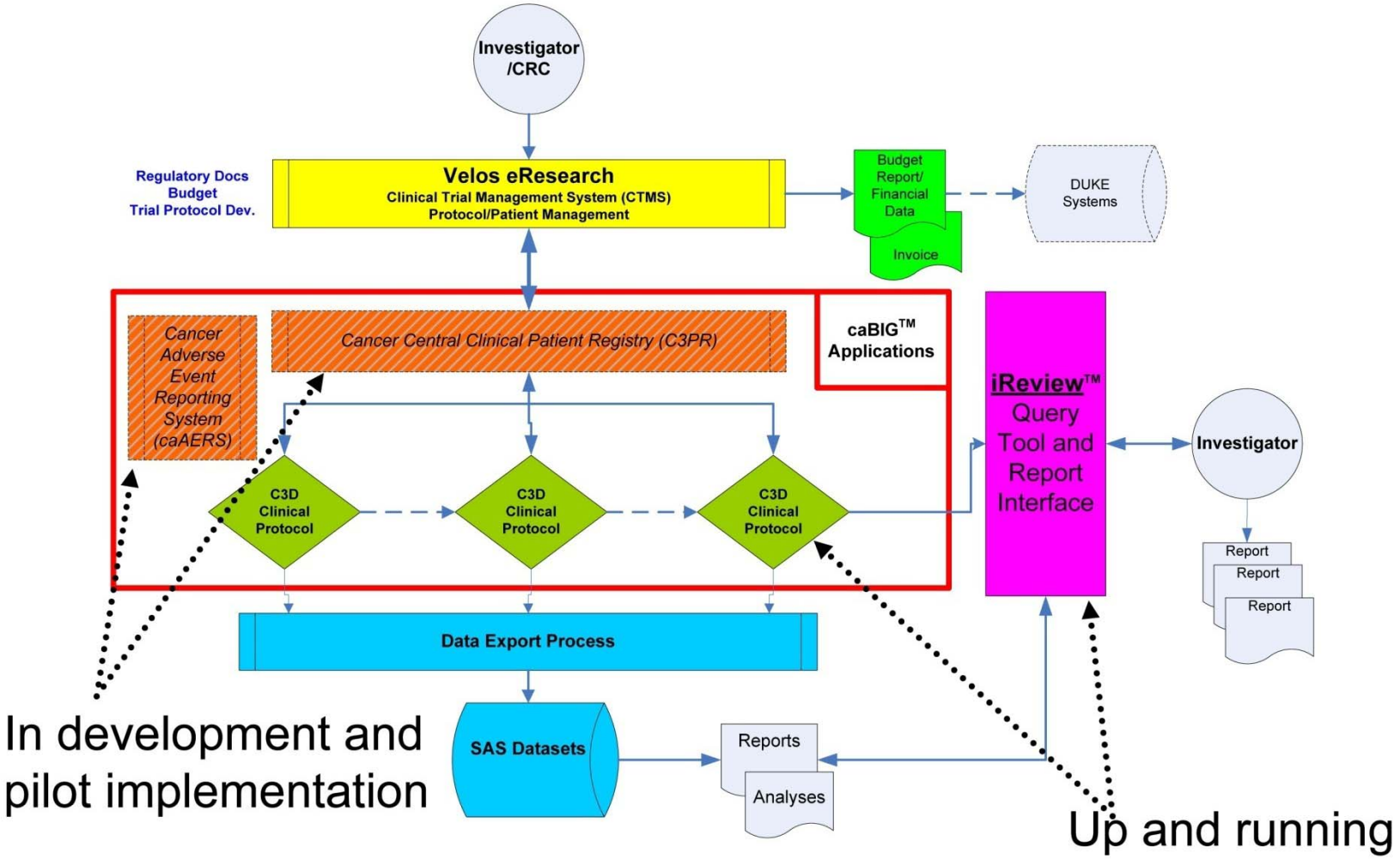
versus

B) rV-CEA(6D)-TRICOM followed by rF-CEA(6D)-TRICOM along with in situ GM- CSF following hepatic metastasis resection and adjuvant chemotherapy.



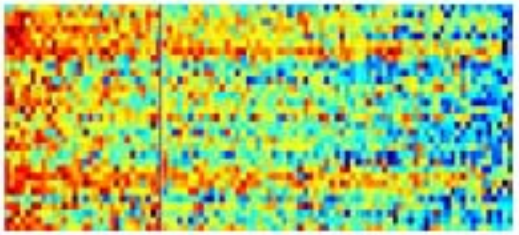

Manufacturing and QA/QC of vaccine, analysis of immune response
Portland Medical Center
Duke University Medical Center
Collection of cells, distribution of vaccine, collection of data
Moffitt Medical Center
Medical University of South Carolina
MD Anderson
Georgetown
WakeForest/ Bowman Gray

Clinical Trial Software Elements



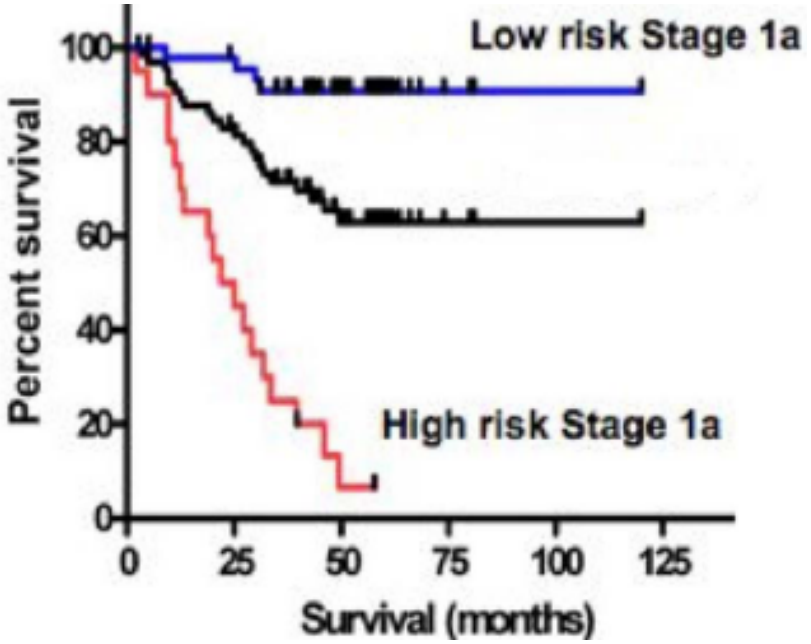
Lung Cancer Prognostic Markers

The NEW ENGLAND JOURNAL of MEDICINE



A Genomic Strategy to Refine Prognosis in Early-Stage Non–Small-Cell Lung Cancer

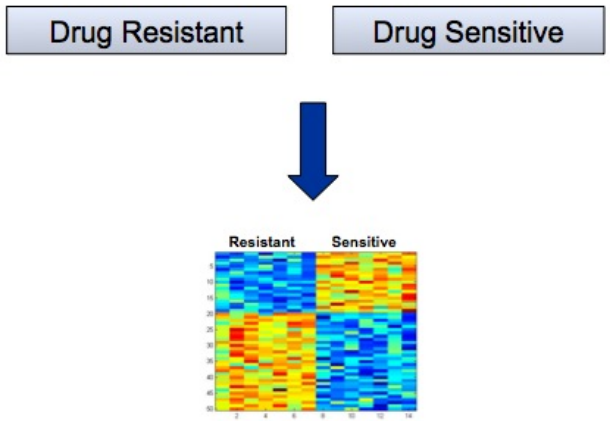
Anil Potti, M.D., Sayan Mukherjee, Ph.D., Rebecca Petersen, M.D., Holly K. Dressman, Ph.D., Andrea Bild, Ph.D., Jason Koontz, M.D., Robert Kratzke, M.D., Mark A. Watson, M.D., Ph.D., Michael Kelley, M.D., Geoffrey S. Ginsburg, M.D., Ph.D., Mike West, Ph.D., David H. Harpole, Jr., M.D., and Joseph R. Nevins, Ph.D.

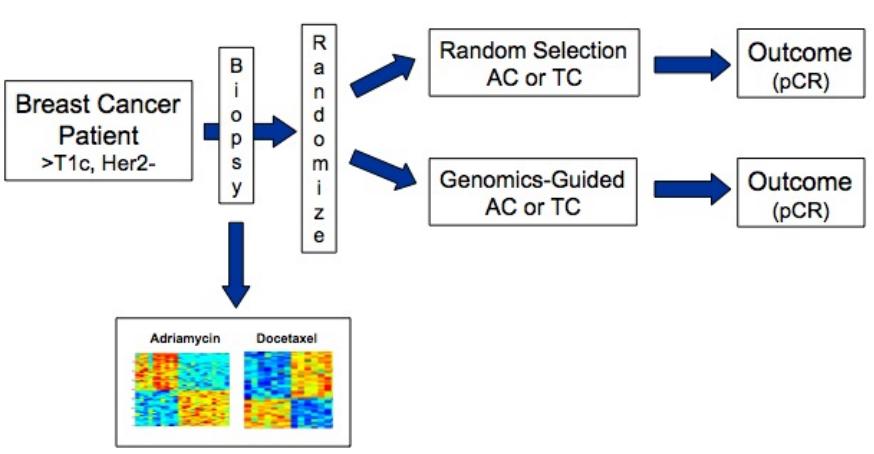


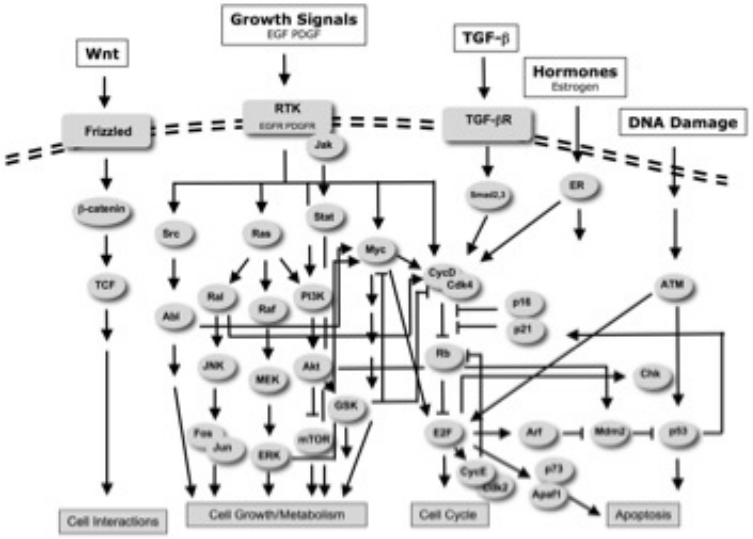
Predictive Markers-Chemotherapy

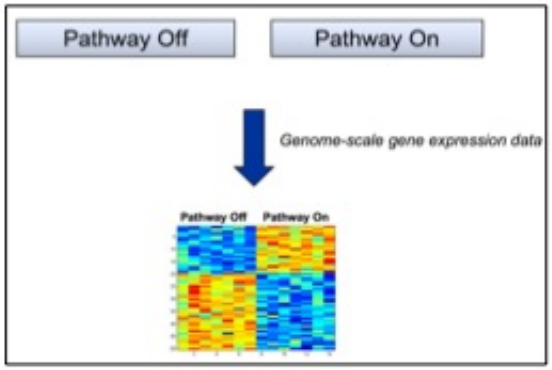
Potti, A., Dressman, H. K., Bild, A., Riedel, R. F., Chan, G., Sayer, R., Cragun, J., Cottrill, H., Gray, J., Marks, J., Kelley, M., Berchuck, A., Petersen, R., Harpole, D., Ginsburg, G. S., Febbo, P., Lancaster, J. M., and Nevins, J. R. (2006). A genomic strategy to guide the use of chemotherapeutic drugs in solid tumors. Nat. Med. 12, 1294-1300.

BOP0701 – A Randomized Phase II Study to Evaluate the Capacity of Expression Signatures to Guide Neoadjuvant Breast Cancer Chemotherapy (DOD Breast Program)





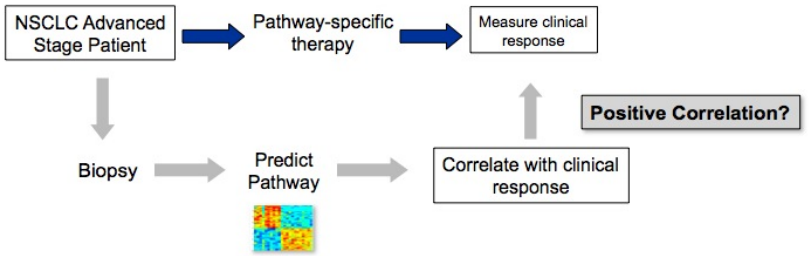




Nature 439, 353-357.

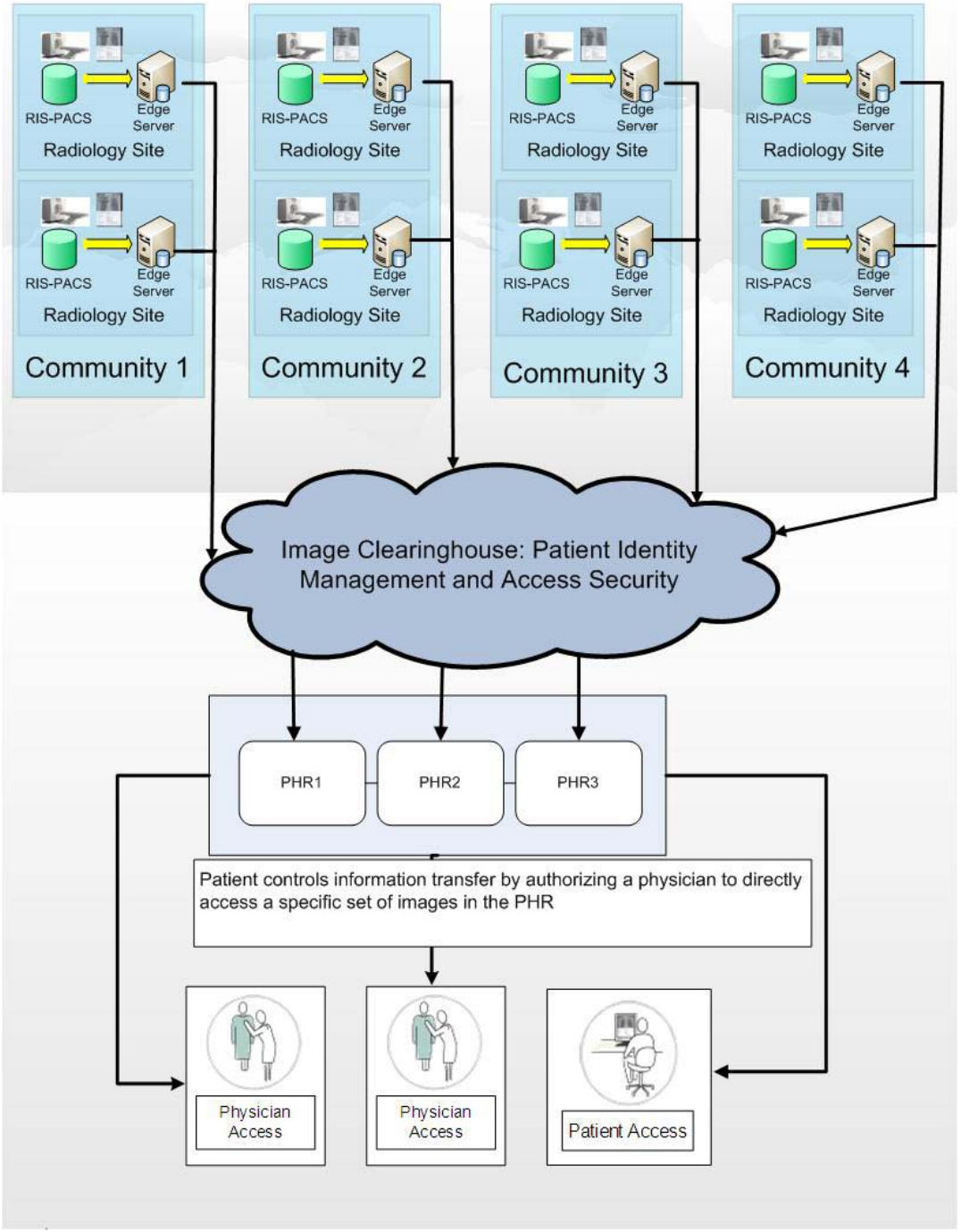
Can gene expression profiling demonstrate an activated pathway, suggesting that inhibition would predict response to a therapy?

Phase II Studies to Evaluate a Src Pathway Signature as a Predictor of Dasatinib Response

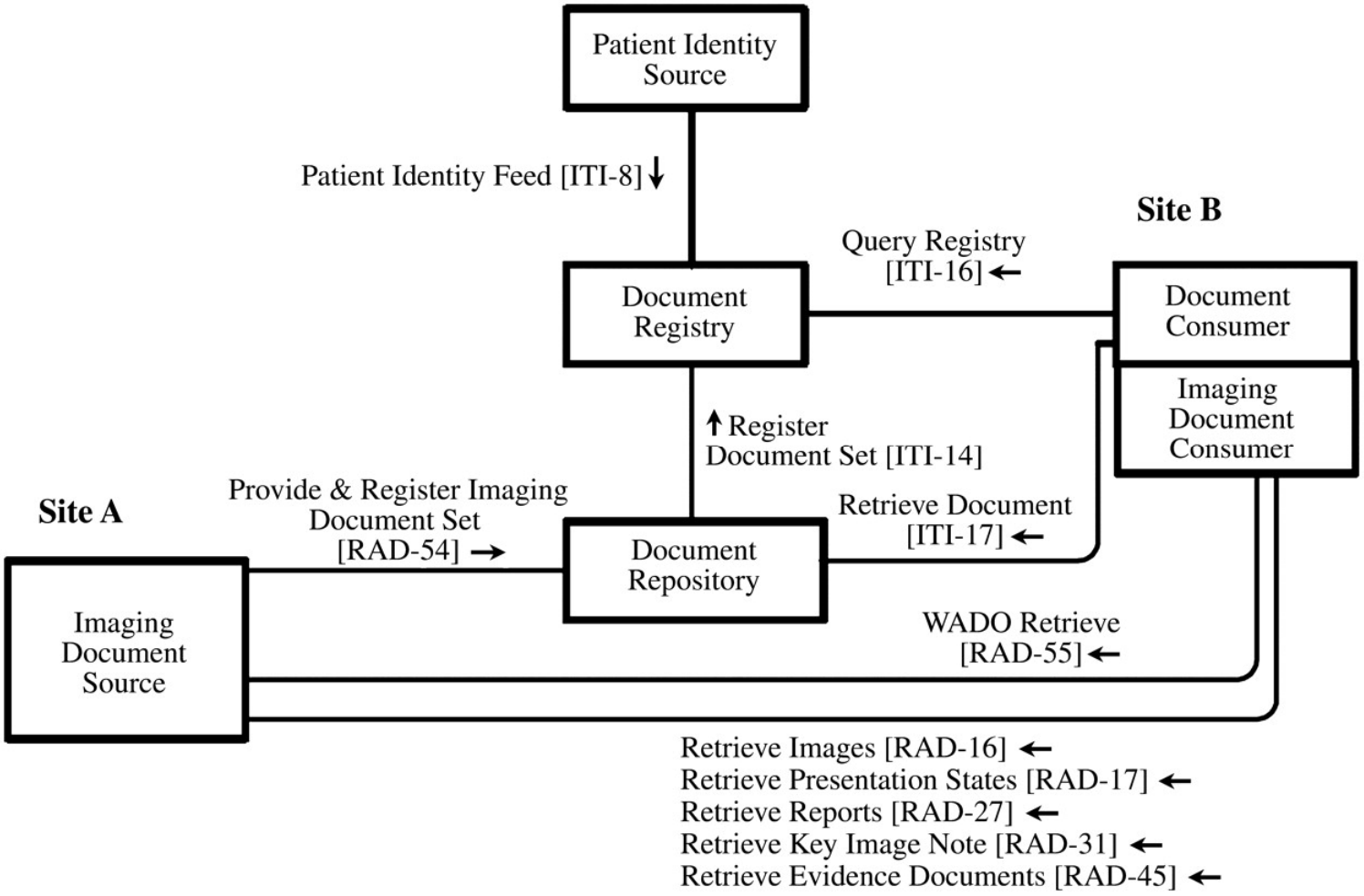


Patient-controlled Exchange of Breast Imaging Studies to Healthcare Providers

- **web-based system**
- **allows patients to access, download and transfer the DICOM files of all their imaging studies.**
- **makes them usable by medical care providers or researchers at any other medical center.**
- **improve health care**
- **reduce radiation dose from unnecessary duplicate imaging studies**
- **facilitate a wide array of research that requires data from images**


RIS-PACS
Edge Server
Radiology Site
Community 1
Community 2
Community 3
Community 4
Image Clearinghouse: Patient Identity Management and Access Security
PHR1
PHR2
PHR3
Patient controls information transfer by authorizing a physician to directly access a specific set of images in the PHR
Physician Access
Physician Access
Patient Access

Technical Architecture for Image Transfer



Duke University Medical Center

Duke Comprehensive Cancer Center

Collection of tumors collection of data

Gene expression analysis and generation of gene signature

Peking University Beijing Cancer Hospital

Other Clinics

中国肿瘤2008年第17卷第5期

网格技术在医学研究中的应用实例——caBig 简介

张　燕, 李　鸷　(北京大学临床肿瘤学院, 北京 100036)

An Example of caBig: Application of Grid in Medical Research // ZHANG Yan, LI Zhi

摘　要: 全文介绍美国国立卫生研究院(NIH)通向医学生物学未来研究路线图计划的试点项目癌症生物医学信息网格(caBig)的主要特点、目标和研究内容。NCI 认为 caBig 的出现将会改变癌症研究进行的传统方式, 全面推进恶性肿瘤医学领域各方面的研究。

关键词: caBig; 网格; 互联网; 肿瘤
中图分类号: R730.1; TP393　　文献标识码: C　　文章编号: 1004-0242(2008)05-0354-02

A Phase II Study of Abraxane® and Carboplatin as First-Line Treatment for “Triple Negative” (Demonstrating no Expression for Estrogen, Progesterone, or HER2 Receptors) Metastatic Breast Cancer

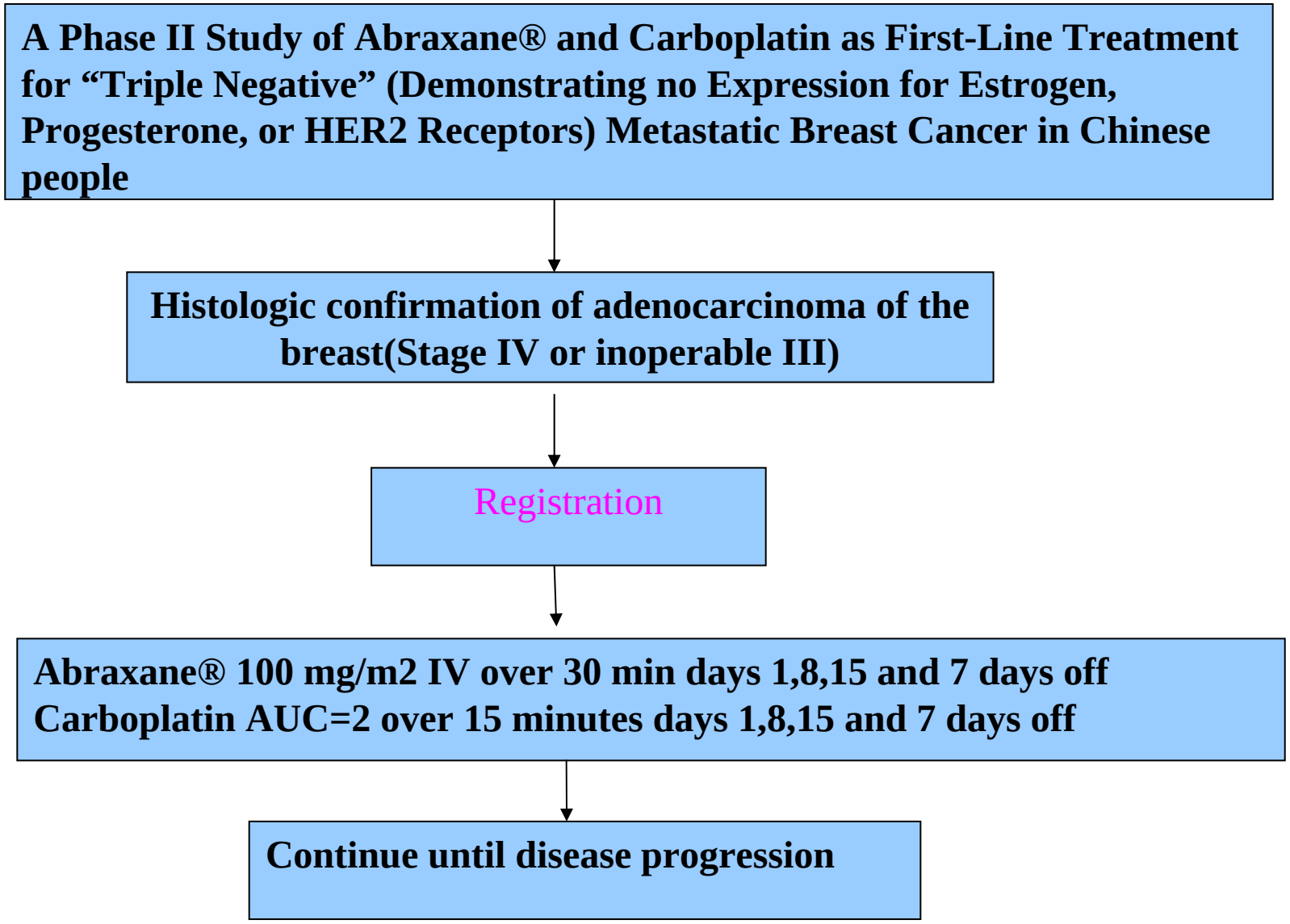
PI

DUKE: Kim Blackwell

Kim Lyerly

Peking:Jun Ren

SCHEMA


A Phase II Study of Abraxane® and Carboplatin as First-Line Treatment for “Triple Negative” (Demonstrating no Expression for Estrogen, Progesterone, or HER2 Receptors) Metastatic Breast Cancer in Chinese people
Histologic confirmation of adenocarcinoma of the breast(Stage IV or inoperable III)
Registration
Abraxane® 100 mg/m2 IV over 30 min days 1,8,15 and 7 days off
Carboplatin AUC=2 over 15 minutes days 1,8,15 and 7 days off
Continue until disease progression

OBJECTIVES

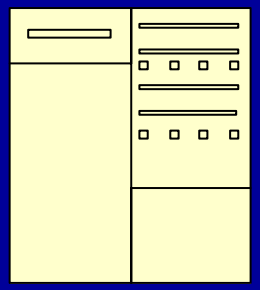
Primary Objective:

- To compare the PFS of this regimen in Chinese patients with that in American patients with "triple negative" Stage IV or inoperable Stage III metastatic breast cancer.

Secondary Objective:

- To explore the molecular biological mechanism reactive to his regimen,including the genomic and proteomic mechanisms.
- To assess the safety and tolerability of a combination regimen of weekly Abraxane® and carboplatin to treat Chinese women with "triple negative" Stage IV or inoperable Stage III metastatic breast cancer.

Independent Replication Processes

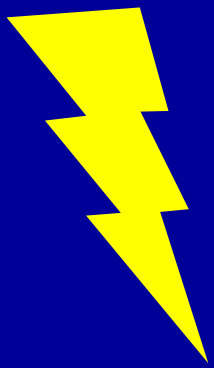


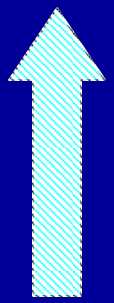
NCICB Master
C3D Instance

Export

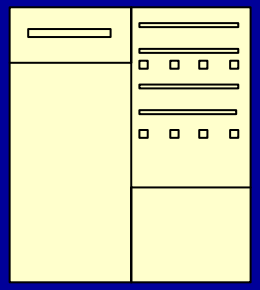
Export Global Library and Study into a file on the secured computer

Secured FTP





Optional
Data Export



Duke replicated
C3D Instance

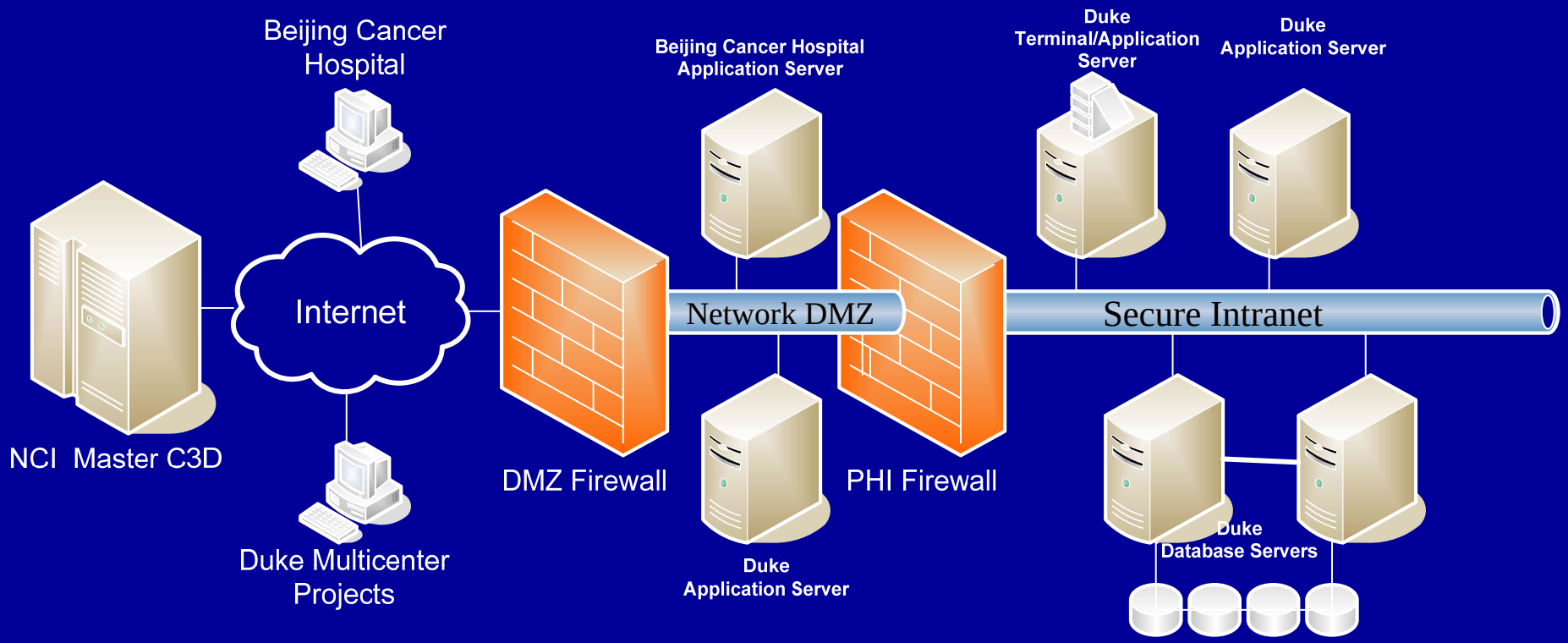
Beijing Replicated
C3D Instance

Import

File containing global library and study export is downloaded to the Duke Server via secured FTP.

C3D： Cancer Central Clinical Database

Internet/Intranet Security



- User connection to Application 128 bit encrypted
- Application server *to be* secured by Oracle Advanced Security option

Fulfill our needs

- Clinical Trial Management System (CTMS)
  - For the management of clinical trials
    - Documents (protocol, Consent, etc.)
    - Financial (Budget prep., invoicing, subcontracts)

- Clinical Data Management System (CDMS)
  - For the management of the clinical *research* data
  - eCRF, EDC
  - Unified format
  - International data standards

4 “S” of caBIG

- Start
- Share
- Standardize
- Speed

Potential caBIG solutions

- **Technical challenges can be addressed**
- **Standards for community providers from NCI**
- **Can address other issues that may have limited implementation of previous strategies:**
  - HIPAA (HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996)
  - Reporting concordant/non-concordant results (quality)
  - Billing
  - Liability


Thank you!
北京大学肿瘤医院
北京市肿瘤防治研究所