

The Critical Role of Pathology (Bio-)Informatics in Translational Research

Lab InfoTech Summit 2007 - CAP Today Session

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**Advancing Practice Instruction and Innovation through
Informatics (APIII) - <http://apiii.upmc.edu> –
September 6-8th (Pittsburgh)**

**Association for Pathology Informatics
(API) - <http://www.pathologyinformatics.org>**

Disclosures/Conflict of Interest by MJB

- Corporate Support for API and APIII
 - **750K projected for 2007** [Cerner, Misys, IBM, IMPAC - Tamtron, Cisco, Verizon, CAP Today, Amersham, Apollo, Applied Imaging, Apollo, Ardais, Bacus, Carl Zeiss, Clariant, Data Access Technology, Definiens, De-ID Corp, DMetrix, Excelleris Tech, General Data, GE Medical Systems/Triple G, MediSolutions Inc, mTuitive, Nikon, Nuance Communications, Olympus, Pathology Outlines.com, SCC Soft, Sysmex, SNOMED, Stone Bond Tech, ThermoElectron, others]
- Corporate Sponsored Research Agreements
 - **1.8 M in 2007** [Amgen, Cerner, Clariant, dbMotion, Google, IBM, IMPAC, Intel & Misys]
- Public Companies (Consultant Equity - MJB):
 - **Clariant (NASDAQ: CLRT) formerly Trestle Corporation (NASDAQ: TLHO), formerly InterScope Technologies, Inc. - <http://www.trestlecorp.com> (merged 3/05)**
 - **Provider of high speed/volume whole slide imaging/telepathology systems**
 - Ultrarapid whole slide imaging: Gb data transfers, terabyte storage and robotics
- Consultancy
 - **Calgary Laboratory Service (CLS) (paid)**
 - **Misys – Strategic Planning Group and Physician Advisory Board (paid)**
 - **Pathology Education Consortium (PEC) with Bruce Friedman (volunteer)**
 - Sponsors of Lab InfoTech Summit (spring companion meeting to APIII)
 - **Provincial Laboratory Coordinating Office (PLCO) (paid)**
 - **Roswell Park Cancer Institute (RPCI) (paid)**
 - **ThermoElectron – Physician Advisory Board (paid)**
 - **Universities of AK, OK, MI and PA (paid); MD Anderson, Moffitt Cancer Centers**

Clinical and Translational Science Institute (CTSI) & Center for Clinical and Translational Informatics (CCTI)

- The Clinical and Translational Science Awards are part of a new NIH Roadmap Initiative – To transform current clinical research environment
- CTSA program emphasized the formation of new transformational structures
 - Center for Clinical and Translational Informatics (CCTI)
 - Pathology Informatics is key – structured
 - Tissue and Serum Banking is central to our strategy (U Pitt)
 - Patient Safety Informatics is one key area we are developing
- Twelve newly funded sites include: Duke, Mayo, U Penn, Yale – all have significant Pathology strength
 - Where is Pathology Informatics? No evidence yet...
 - How to get involved?
 - 48 more sites will be funded over the next 5 years
 - Pathology Informatics needs to get on board!!!

NIH Roadmap – <http://nihroadmap.nih.gov>



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 - [Clinical Research Policy Analysis and Coordination](#)
 - [Translational Research](#)

[What's New](#)

- ▶ **Notice:** [New Update to Frequently Asked Questions \(FAQs\): RFA-RM-07-004: Facilitating Interdisciplinary Research via Methodological and Technological Innovation in the Behavioral and Social Sciences \(R21\)](#)
- ▶ **Notice:** [Notice of Intent to Publish a Request for Applications for the NIH Director's New Innovator Awards](#)
- ▶ **New Roadmap Initiatives for 2008**
- ▶ **Notice:** [Solicitation of Compounds for High Throughput Screening \(HTS\) in the Molecular Libraries Screening Centers Network \(MLSCN\)](#)
- ▶ **PAR:** [Exploratory Collaborations with National Centers for Biomedical Computing \(R21\)](#)
- ▶ **PAR:** [Collaborations with National Centers for Biomedical Computing \(R01\)](#)
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CTSA Awardees – 12 fully funded, 52 planning grants

<https://www.ctnbestpractices.org/networks/nih-ctsa-awardees/>

Clinical and Translational Science Awards (Consortium)



The following CTSA grant awardees have agreed to post part of their application for public viewing. Click on the institution's name to view this information.

[▲ Up one level](#)

Last modified November 20, 2006 08:47 AM

NIH has created a national consortium that will transform how clinical and translational research is conducted, enabling researchers to develop new treatments faster and deliver them to patients more efficiently and quickly. Led by the National Center for Research Resources (NCRR), this new consortium, funded through Clinical and Translational Science Awards (CTSAs), begins with 12 academic health centers located throughout the nation. An additional 52 AHCs are receiving planning grants to help them prepare applications to join the consortium. When fully implemented in 2012, about 60 institutions will be linked together to energize the discipline of clinical and translational science. The new program draws on NIH's earlier initiatives to re-engineer the clinical research enterprise, one of the key objectives of the NIH Roadmap for Medical Research. The NIH News Release and the CTSA Questions and Answers offer additional information on the consortium.

[Columbia University Health Sciences \(New York, NY\)](#)

[Duke University \(Durham, NC\)](#)

[Mayo Clinic College of Medicine \(Rochester, MN\)](#)

[Oregon Health & Science University \(Portland, OR\)](#)

[Rockefeller University \(New York, NY\)](#)

[University of California, Davis \(Davis, CA\)](#)

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[University of Texas Health Science Center at Houston \(Houston, TX\)](#)

[Yale University \(New Haven, CT\)](#)

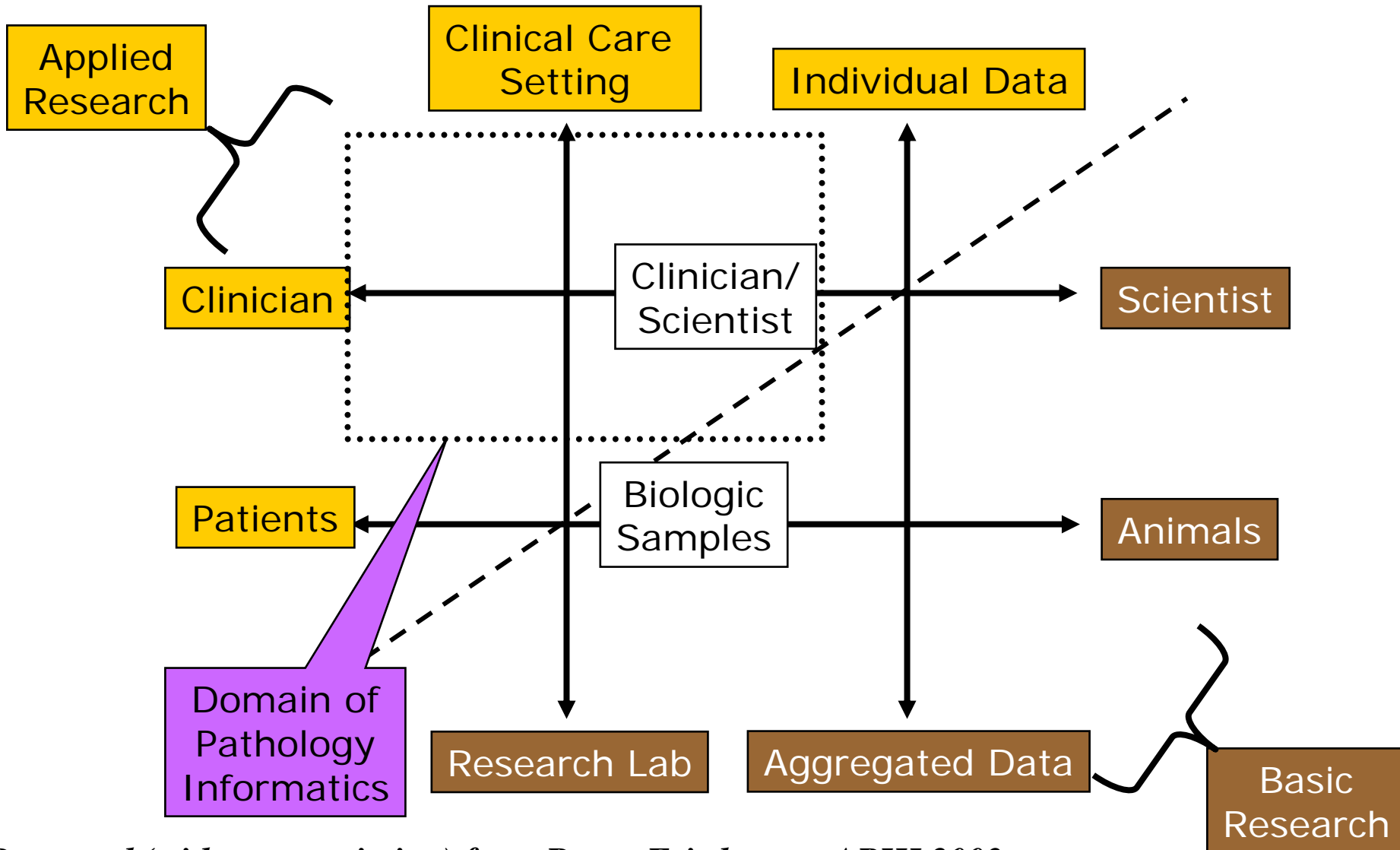


Brief Chronologic History of Two Decades of Pathology Informatics

- **Early 1980s:** Tom Lincoln & Don Connelly define theoretical & technical basis for pathology info as subdiscipline of medical info
- **1987:** Ralph Korpman proposes that the pathologist can/should serve as ideal individual to fill role of “medical info specialist”
- **1990:** Bruce Friedman coins term “pathology informatics” (PI); proposes that it should be viewed as 3rd subdiscipline with AP&CP
- **1993:** Greg Buffone & Bob Beck propose subspecialty of path info & define major goal as optimization of info systems
- **2002:** Bruce Friedman hosts first meeting focusing on “pathology bioinformatics” & begins to define subdiscipline as offspring of PI

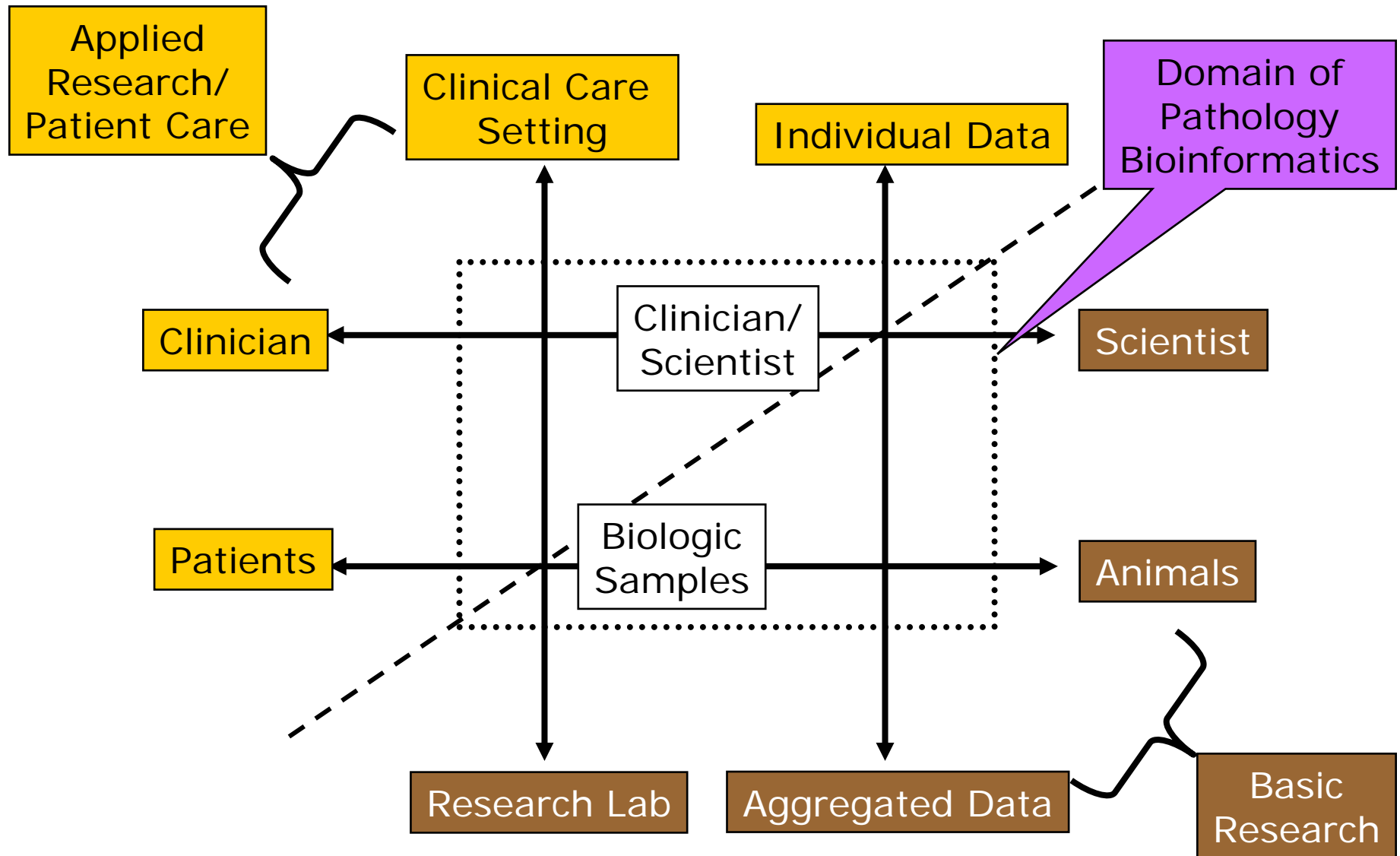
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Domain of Pathology Informatics and Its Skew toward Service & Applied Research



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Domain of Pathology Bioinformatics within General Biomedical Research



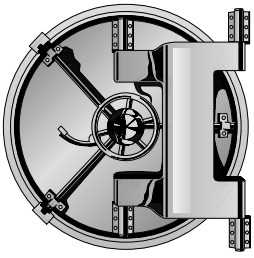
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Informatics Transformation Hypothesis: New Challenges Bridging Service/Research Chasm

- *Transformation hypothesis: Informatics disciplines that will develop unique identity must have following attributes:*
 - Critical pipeline across service/research chasm (e.g., new drugs passing through clinical trials & into practice)
 - Powerful financial drivers (e.g., research funding, big pharma)
 - Drive high-margin services which can be delivered in stand-alone clinics, thus depriving hospitals of big-ticket lucrative procedures
 - Mandated/unique data requirements (e.g., tumor registries, IRB)
 - Require high-level strategic informatics planning/oversight to meet reporting, patient care, and research requirements
- Classic medical disciplines (& informatics offshoots) not meeting these criteria must piggyback onto them in order to achieve influence/value

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Criticality of Information Technology in Development of Tissue Banks

- Pathology controls the flow of normal and diseased tissues and the handling of them when rapid processing is critical
- Physical storage minor component of creation & maintenance of tissue banks; data management critical value-add feature
- Development and maintenance of longitudinal databases, with images, also critical, and often neglected, components
- Tissue banking also provides opportunity for academic pathology departments to develop relationship with pharma research
- Web-based software with backend relational database can be used to present data/images on both service & research sides

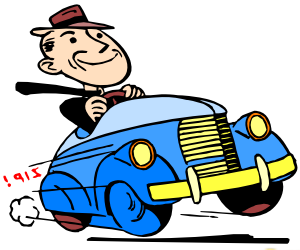
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Pathologists Need to Embrace/Pursue Data Sharing and Standardization

- Structured data entry and documentation in surgical pathology results in uncompensated & greater work burden for labs/pathologists
- However, integrated, retrievable, longitudinal clinical data provides new opportunities and new product lines for labs/pathologists
 - Compensated clinical laboratory consulting on the “service side” of pathology
 - Fundable translational research opportunities on the “research side” of pathology
- CP data is already fully integrated into the CPR using HL-7 and LOINC; these changes have been driven by demands from clinicians
- Next challenge is synoptic reporting and image capture and integration on the AP side; not just “marketing” issue which trivializes discussion

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Lecture Take-Home Lessons

- Pathology informatics evolved as a practical discipline with service responsibility for managing critical clinical information system
- Pathology bioinformatics differs from other “bioinformatics” because of linkage to service side of pathology and ready access to tissue specimens
- Pathology informatics becoming somewhat routinized/diminished by funding restrictions and growing influence of other informatics disciplines
- Oncology informatics, cardiovascular informatics, medical/theranostic informatics emerging as powerful informatics bridging disciplines
- Pathology informatics/bioinformatics need to link to these bridging disciplines; this will be easy because of criticality of “lab” information
- Complex sets of challenges still remain for pathologists to address; most important is the “integration” of genomic data into lab database

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Center for Clinical and Translational Informatics (CCTI)

Specific Aim 1 – Toolkit Development

Specific Aim 1 – “...to develop, implement & maintain the most advanced, integrated informatics tools to support research throughout the life cycle of translational research.”

- Integration of Pathology (Bio-) Informatics into CCTI
- Deploy a system wide tissue & clinical data annotation system
- Use of caBIG Tissue Banking Tools in non-cancer areas
- Embed **Clinical Trials tools** and **Tissue Banking tools** vetted by U Pitt OOR & UPMC CTO for “enterprise” use (including financial modeling and billing support)
- CCTI integrates **Clinical Research Information Service** which houses our clinical data repository (MARS, data from 1982-)
- **This is the ‘real’ IT goal of the CCTI transformation (from CTSI house analogy)**

Center for Clinical and Translational Informatics (CCTI)

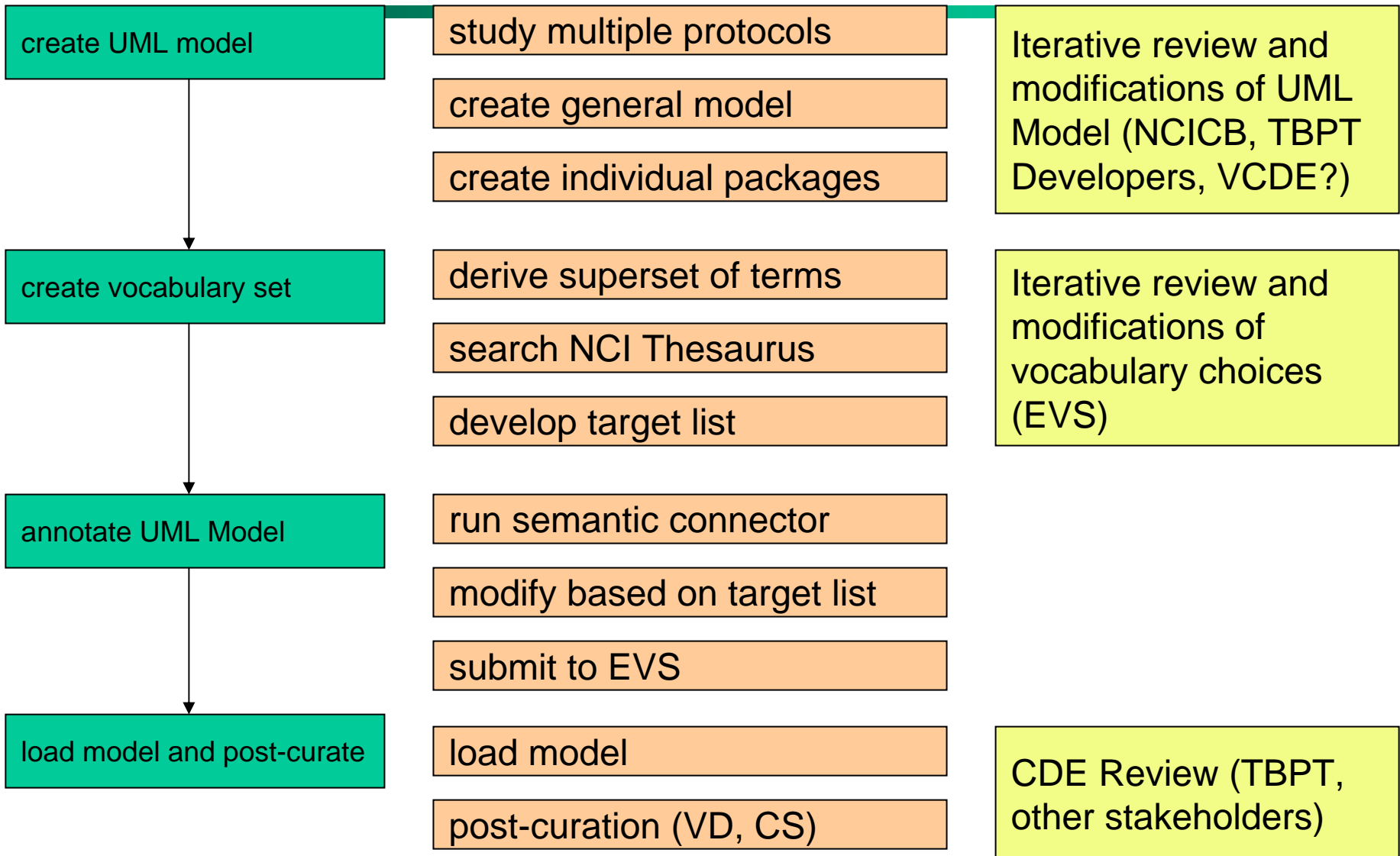
Tools for the Health Sciences – Tissue Banking Informatics

- caBIG caTISSUE Suite – Integrated suite of tools to manage all aspect of biobanking of blood, blood products, tissue, fluids
- caBIG – Cancer Biomedical Informatics Grid – see <http://cabig.nci.nih.gov>
- caTISSUE Components:
 - caTISSUE Core – Inventory management and interface to genomics and proteomics data
 - caTIES – Cancer Text Information Extraction System – allows millions of patient specimens in Lab Info Systems (LIS) to be automated coded and available for research query
 - caTISSUE CAE – Clinical Annotation Engine – currently allows pathology and cancer registry to automatically annotate specimens and will eventually do the same for radiology and EMR systems
- U Pitt has been key developers of these tools for caBIG

Using College of American Pathologists Cancer Checklists (Protocols) as Common Data Elements

- Define data elements expected in surgical pathology reports of cancer
- Defined by review of clinical/scientific merit
- 44 protocols describing wide range of tumors
- Represent a large fraction of all cancer cases
- Authored by committees of experts in the field
 - Required by American College of Surgeons Commission on Cancer (ACS CoC) for program accreditation for required data elements)
- Are CAP Protocols amenable to informatics modeling?
 - Grouped together in classification hierarchies
 - Excellent detail including value domains
 - Relatively precise definitions
 - References and explanatory material
 - Versioned

U Pitt Workflow for CDE creation



New Publication on caTIES implementation of caCORE

**BMC Medical Informatics and Decision
Making**



This Provisional PDF corresponds to the article as it appeared upon acceptance. The fully-formatted PDF version will become available shortly after the date of publication, from the URL listed below.

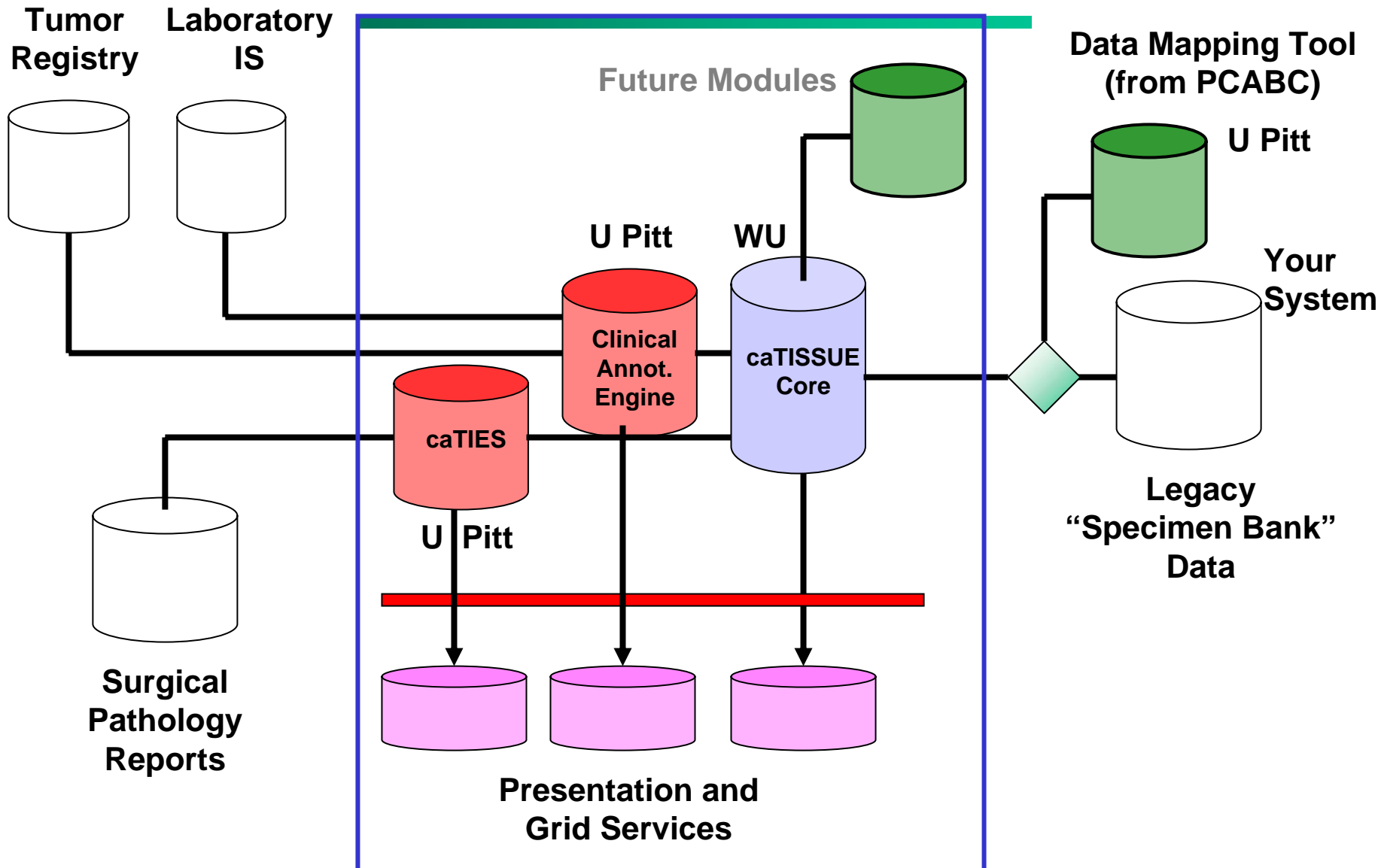
<http://www.biomedcentral.com/1472-6947/6/2>

Tobias J, Chilukuri R, Komatsoulis GA, Mohanty S, Sioutos N, Warzel DB, Wright LW, Crowley RS.

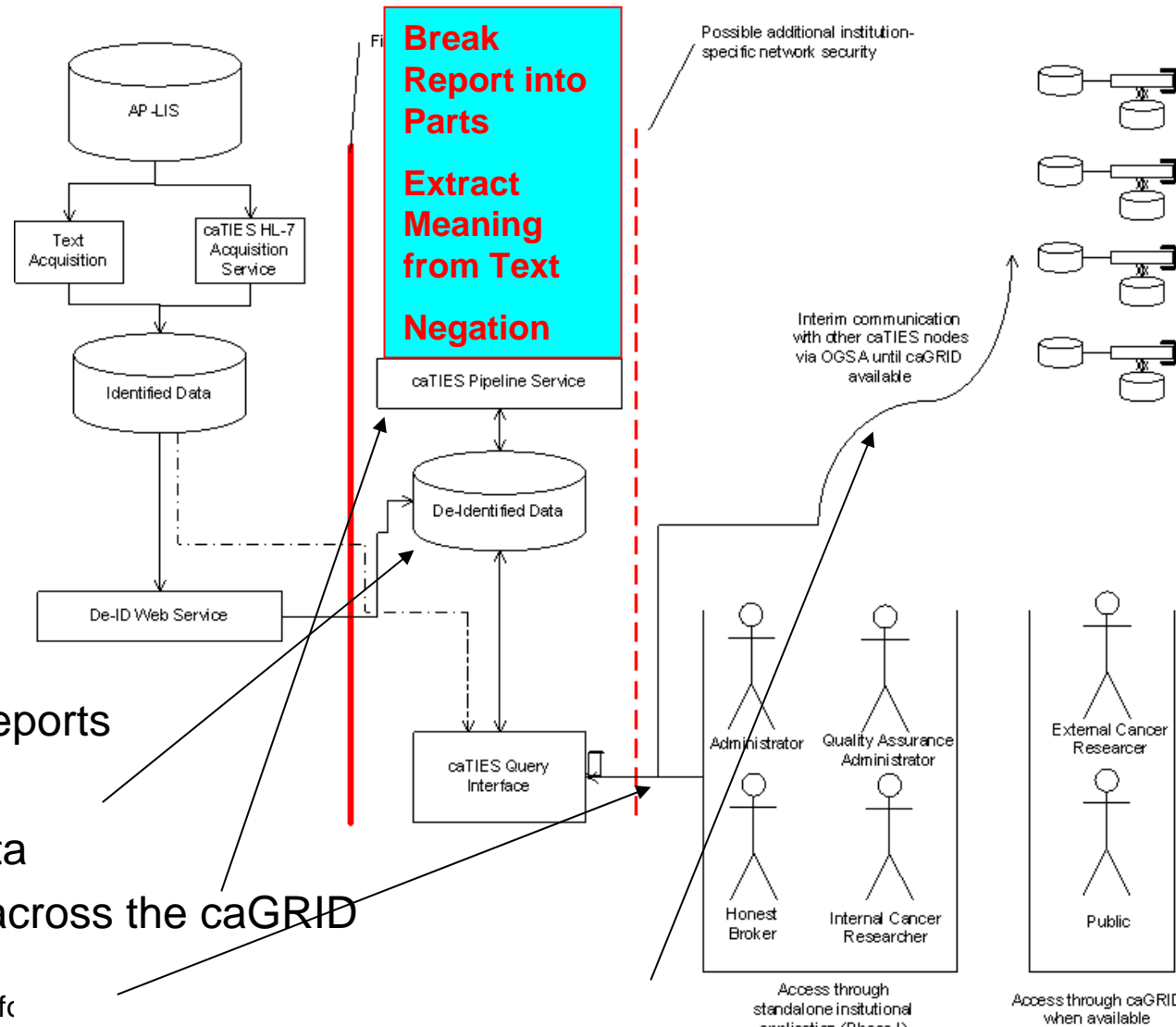
The CAP cancer protocols--a case study of caCORE based data standards implementation to integrate with the Cancer Biomedical Informatics Grid. BMC Med Inform Decis Mak. 2006 Jun 20;6:25.

NOTE: E-mail becich@pitt.edu for PDF

caTISSUE Components



caTissue Information Extraction System (caTIES)



- Load surgical pathology reports
- De-Identify the reports
- Annotate/structure the data
- Share the data for query across the caGRID

Example De-Identified Path Report

PATIENT HISTORY:
The patient is a **AGE<in 50s>-year-old white male.
PRE OP DIAGNOSIS: Prostate cancer.
POST OP DIAGNOSIS: Same.
PROCEDURE: Radical prostatectomy.

FINAL DIAGNOSIS:
PART 1: LYMPH NODES, LEFT PELVIC, LYMPHADENECTOMY
SIX BENIGN LYMPH NODES WITH NO EVIDENCE OF MALIGNANCY.
PART 2: LYMPH NODES, RIGHT PELVIC, LYMPHADENECTOMY
TWO BENIGN LYMPH NODES WITH NO EVIDENCE OF MALIGNANCY.
PART 3: PROSTATE AND SEMINAL VESICLES, RADICAL PROSTATECTOMY
A. INVASIVE MODERATELY DIFFERENTIATED PROSTATIC
ADENOCARCINOMA WITH A
COMBINED
GLEASON SCORE OF 3+3=6.
B. THE CARCINOMA INVOLVES BOTH RIGHT AND LEFT LOBES OF THE
PROSTATE,
HAVE THE GREATEST
NODULAR DIMENSION OF 0.6 CM, AND INVOLVES
APPROXIMATELY 10% OF THE PROSTATE TISSUE
EXAMINED.
C. BILATERAL SEMINAL VESICLES ARE FREE OF CARCINOMA.
D. FOCAL INVOLVEMENT OF CARCINOMA IS PRESENT AT THE APICAL
URETHRAL
RESECTION MARGIN.
(see comment).
E. NO EVIDENCE OF PERINEURAL INVASION IS SEEN.
F. HIGH GRADE PROSTATIC INTRAEPITHELIAL NEOPLASIA, MULTIFOCAL.
G. BENIGN PROSTATIC HYPERPLASIA.
H. PATHOLOGIC TNM STAGE: pT2d, N0 MX.
J. HISTOLOGIC GRADE: G2.

**INITIALS<QQQ/QQQ>
COMMENT:

In the apical periurethral resection margin there is focal involvement of the resection margin by carcinoma. The carcinoma consists of several cauterized glands present at the margin. No other evidence of surgical margin involvement is present within the remaining examined slides.

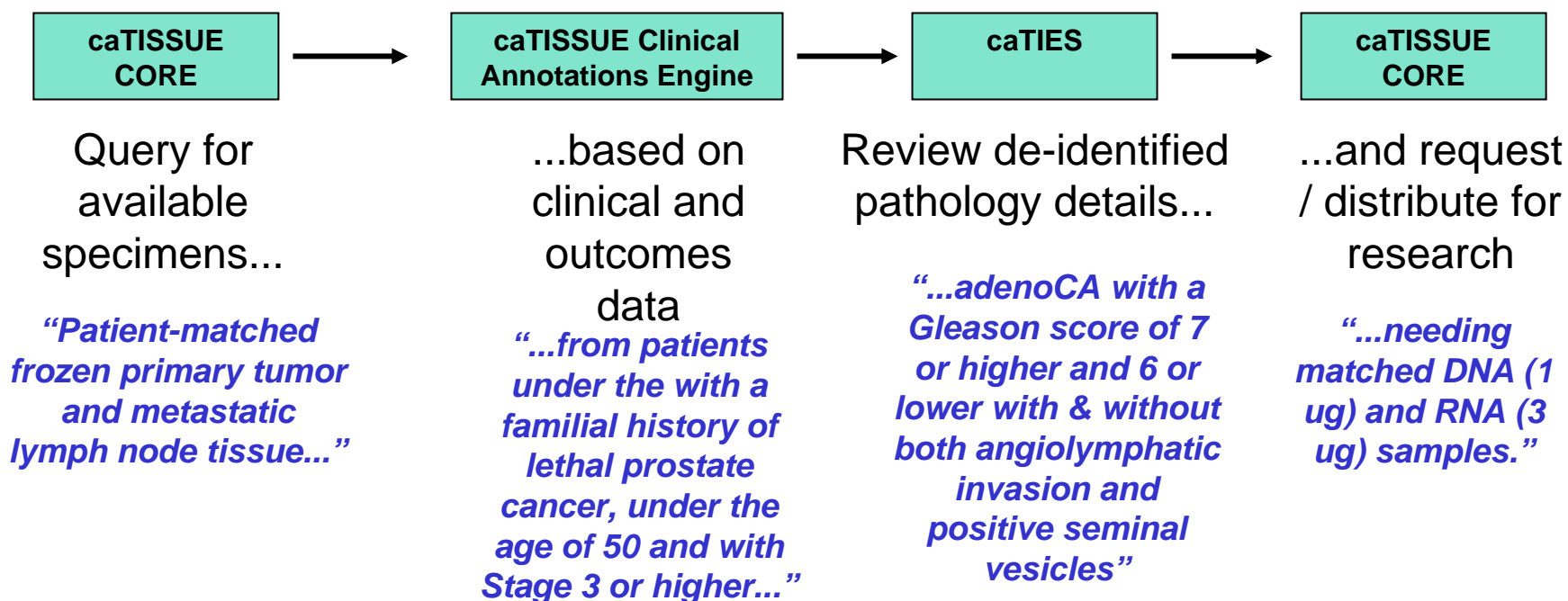
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**Removes HIPAA mandated
Personal Health Identifiers:
Ages
Report Numbers
Names
Initials
Locations
Dates (shifted not removed)**

**As well as 12 other PHI
data elements**

Simplified Use Case for caTISSUE Modules

Select Research Bank Specimens for Distribution Using caTISSUE Clinical Annotations Engine (CAE), caTISSUE Core and caTissue Information Extraction System (caTIES)



“Building” caTISSUE through 3 modules (caCORE, TIES and CAE)

- **Automatically load all patient demographics (tens of thousands) with pathology reports of biopsies and prostatectomies along with accession #, dates, etc... with caTISSUE CAE AP Lab Info System loader**
- **Automatically annotate all pathology reports (tens of thousands) with caTIES**
- **Import data from legacy systems with CAE Data Mapping Tools**
- **Manage inventory (thousands of patients) (e.g. paraffin blocks and frozen tissue, serum, RNA and DNA) of prostate tissue bank with caCORE**
- **Annotate biospecimen inventory (initially hundreds of identified cohorts) with therapy, progression and outcomes information with caTISSUE CAE**
- **Link research data (genomics, proteomics, etc...) with Experimental Annotation Module of caCORE**
- **Provide query to research community at large through caGRID with caTISSUE**

Center for Clinical and Translational Informatics (CCTI)

Specific Aim 2 – Infrastructure Development

Specific Aim #2 – “...share, implement and support the “open source” tools utilizing the core architecture in an interoperable grid by using tools developed by the Cancer Biomedical Informatics Grid (caBIG) program.”

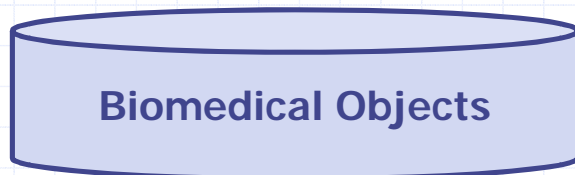
- Implementing an environment (network, hardware, software) to promote interoperability of translational informatics research tools:
 - Core Architecture – Vocabulary, Ontology, Interoperability
 - Tissue Banking, Clinical Research, Trials Tools that “talk”
 - This may be all caBIG architecture or may be more linked to UPMC Interoperability efforts (dB Motion – see recent press release) or probably a hybrid of both approaches
 - ***This is the ‘real’ Biomedical Informatics goal of the CCTI transformation***

caBIG and Interoperability

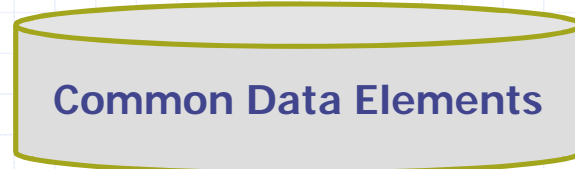
- **caBIG and Interoperability**
 - Common Data Elements, ISO11179 and Enterprise Vocabulary Services
 - Foundational or Reference Software Implementations
 - Modular Software Design designed to “fill gaps” in clinical trials, tissue banking and bioinformatics

What does caBIG offer in terms of interoperability?

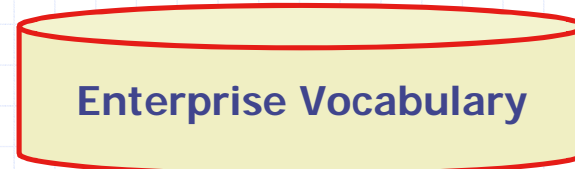
- Three common threads for caBIG (grid) development
 - #1 - Development of common data elements (CDEs) using Enterprise Vocabulary Services (EVS)
 - Depositing CDEs developed across systems in caDSR
 - caDSR – Data Standards Repository as a CDE management tool
 - **Key is to use a common concepts/terms for data interchange**



- 3 – “Information” objects enabled which can be deposited in caBIO



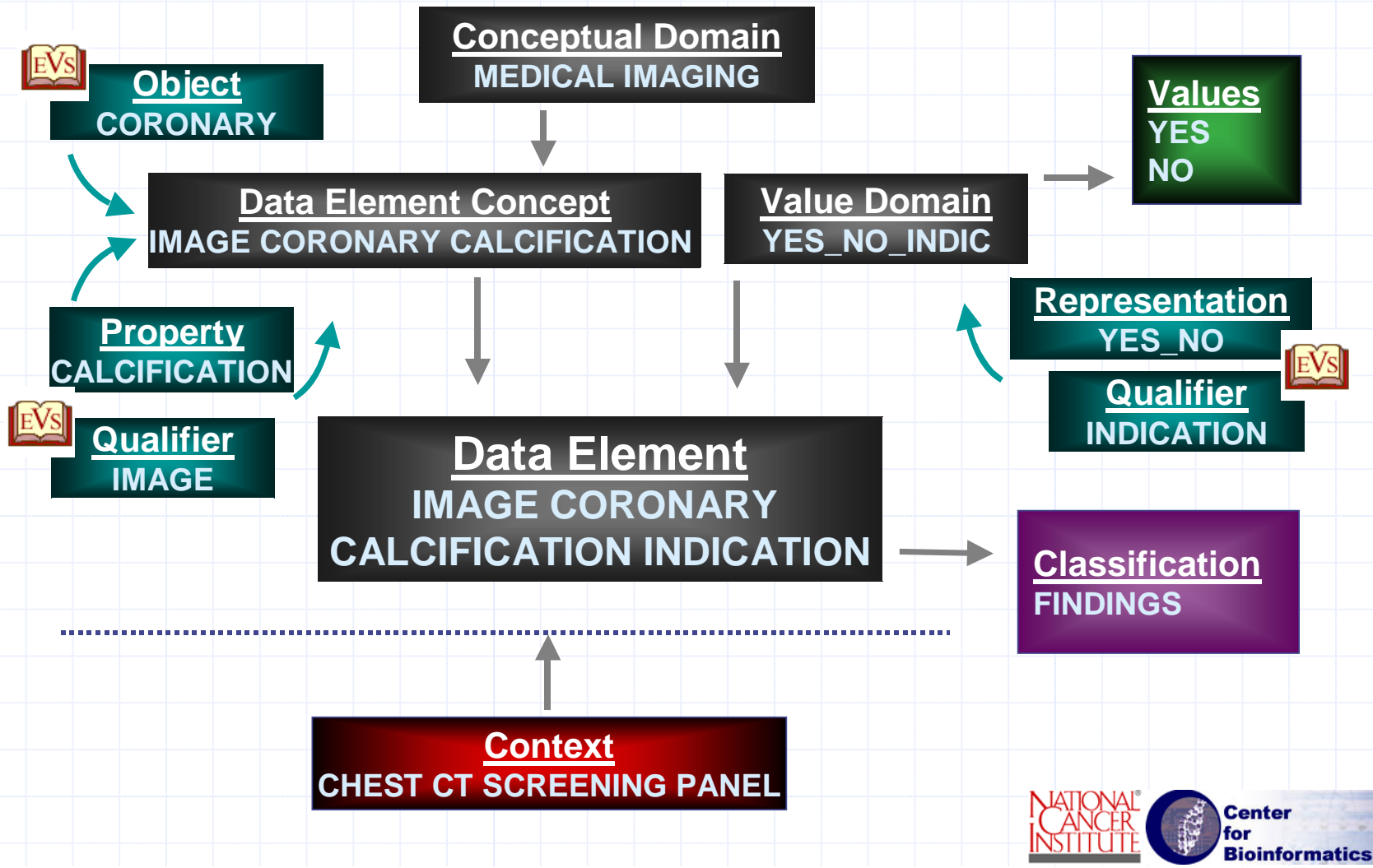
- 2 – Ensure data exchange via ISO11179 compliant CDEs



- 1 – EVS ensures all are “speaking” the same language

ISO11179 Metadata Standard

courtesy of Peter Covitz, NCICB



New Publication on caCORE

BMC Medical Informatics and Decision Making



This Provisional PDF corresponds to the article as it appeared upon acceptance. The fully-formatted PDF version will become available shortly after the date of publication, from the URL listed below.

<http://www.biomedcentral.com/1472-6947/6/2>

The caCORE Software Development Kit: Streamlining construction of interoperable biomedical information services

BMC Medical Informatics and Decision Making 2006, 6:2 doi:10.1186/1472-6947-6-2

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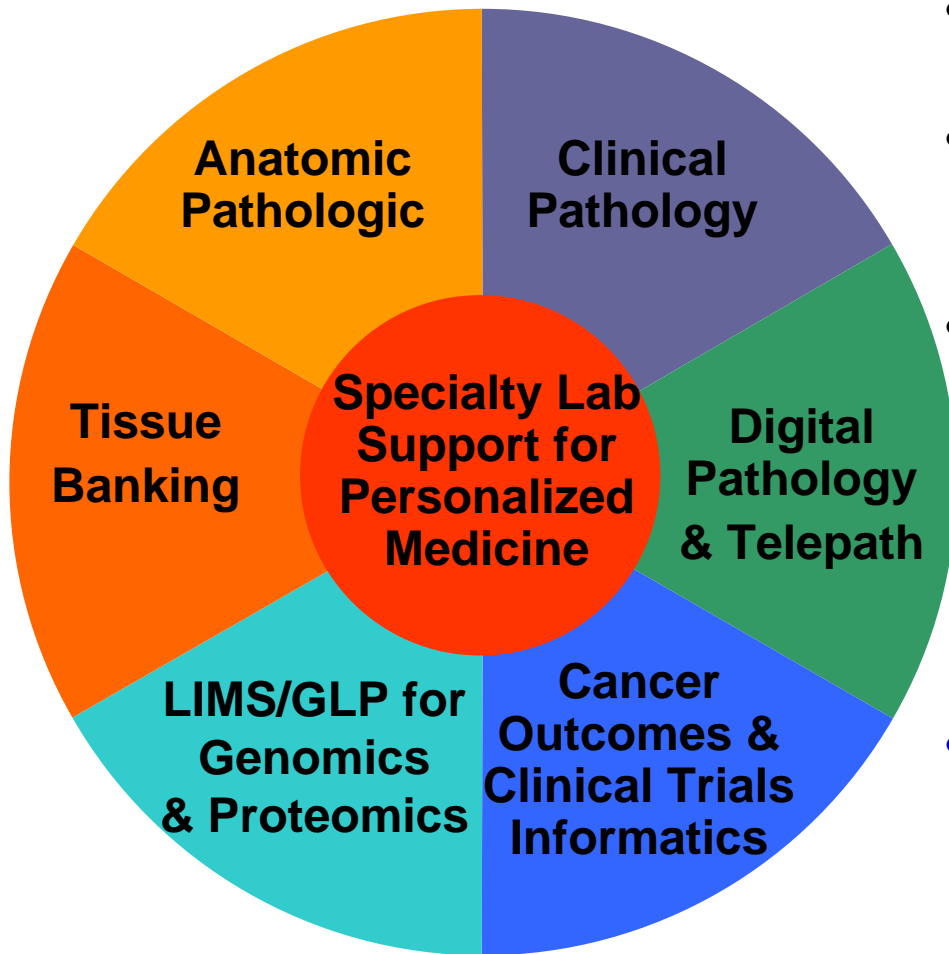
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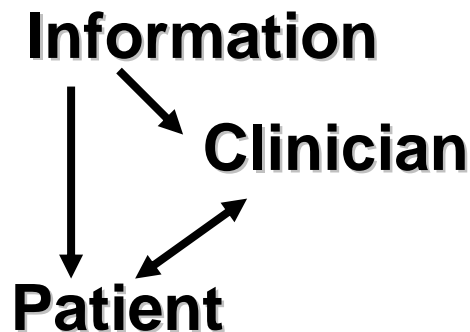
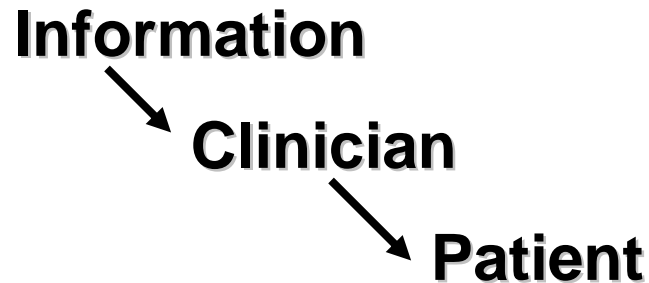
The Value of Pathology Informatics to Translational Medicine



- Pathology in partnership with Oncology has a great future.
- The importance of supporting Specialized Labs as distinct from AP and CP.
- Too many pathologists consider themselves “experts who look at glass slides and test values” not “experts in analysis of tissue/serum in disease and customized theranostics”. Need to change this!!!
- What could we accomplish if we could apply integrated data warehousing methods and standardized data capture to Pathology?

From John Gilbertson, MD (ala 1999) Now at Case Western University

InfoCentric Networks & Personalized Medicine



- “Information relationships “ in medicine are in silent upheaval. Ubiquitous access to information is changing the fundamental relationship between the physician and patient.
- This will impact pathology informatics.
- The way pathology, and its academic departments, position themselves now in this emerging infrastructure will determine the strength of our field twenty years from today.
- This can be one of the ways we reposition ourselves in pathology (through) pathology informatics.

Recent Publications by Our Team –

NOTE: Please e-mail me at becich@pitt.edu for PDFs

- Tobias J, Chilukuri R, Komatsoulis GA, Mohanty S, Sioutos N, Warzel DB, Wright LW, Crowley RS. The CAP cancer protocols--a case study of caCORE based data standards implementation to integrate with the Cancer Biomedical Informatics Grid. BMC Med Inform Decis Mak. 2006 Jun 20;6:25.
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Invitation to APIII 2007

September 9-12th, Pittsburgh PA



ADVANCING PRACTICE, INSTRUCTION AND
INNOVATION THROUGH INFORMATICS

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Anatomic Pathology Informatics and Imaging Support for Translational Medicine
Marriott City Center, Pittsburgh, PA | September 9 - 12, 2007

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Mark Your Calendars / Plan to Attend APIII 2007 Marriott City Center, Pittsburgh, Pennsylvania, September 9 - 12, 2007.

"Anatomic Pathology Informatics and Imaging Support for Translational Medicine"

The APIII educational conference provides a broad overview of biomedical informatics in pathology and oncology practice, education and research. As an attendee, you will gain knowledge of how informatics is impacting and transforming pathology and oncology. You will gain knowledge of new technology available to meet the informatics needs of the future. This year's conference will also highlight the evolution of digital pathology in the Armed Forces with speakers from various branches of the military sharing their experiences. APIII offers the opportunity to find answers to your informatics needs.

Who should attend?



<http://apiii.upmc.edu>

Association for Pathology Informatics (API)

<http://www.pathologyinformatics.org>



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Association for Pathology Informatics
a Division of the American Society for Investigative Pathology (ASIP)

...to advance the field of pathology informatics as an academic and a clinical subspecialty of pathology.

End of Talk – e-mail me at becich@pitt.edu if you have questions or need clarifications about the discussion.

NOTE: Please e-mail me if you want a copy of this presentation or contact info for connecting to our services – 412-623-3941

Thank you for the invitation to the LabInfoTech Summit CAP Today Session.