CAP Today Session: New Directions in Pathology Informatics:

Oncology Informatics as a Tool for Improving Surgical Pathology

Lab Infotech Summit – The Venetian, Las Vegas, NV
Wednesday, March 1st, 2006

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University of Pittsburgh School Medicine
Director, Center for Pathology Informatics
http://path.upmc.edu/cpi
Director, Benedum Oncology Informatics Center (Hillman Cancer Center)
http://www.upci.upmc.edu/internet/benedum/index.html
Course Co-Director, APIII or Advancing Practice, Instruction and Innovation through Informatics (http://apiii.upmc.edu)

Disclosures by MJB

- **Corporate Support for API and APIII**
  - **650K projected for 2006** [Cerner, Eleckta/IMPAC/Tamtron, Misys, IBM, GE/Triple G, Apollo, Ardais, Cisco, CAP Today, Definiens, De-ID Corp, Excelleris, Amersham, Applied Imaging, Chromavision, Nikon, Olympus, DakoCytomation, Ikon, General Data, Trestle, SCC Soft, Sysmex, Neural Ware, SNOMED, Pathology Outlines.com, PSA, Thermo Shandon and others]
- **Corporate Sponsored Research Agreements**
  - **1.5M in 2006** [Affymentrix, Amgen, Cerner, De-ID Corp, IBM, Intel, Nikon, Clinical Data (MJB founder), PathWorks, Stonebound, Trestle (MJB founder), Veridex]
- **Startup/Public Companies (Founder Equity - MJB):**
  - **Trestle Holdings, Inc.** (NASDAQ: TLHO; http://www.trestlecorp.com)
    - Provider of high speed/volume microscopic imaging/telepathology systems
    - Venture-MAVF, Birchmere & Cape Andover.
    - Ultrarapid digitization: Gb data transfers, terabyte storage and robotics
  - **Clinical Data** (NASDAQ:CLDA, formerly Icoria, Paradigm Genetics, TissueInformatics, merged 12/31/05, http://www.clda.com)
    - Becoming a leader in molecular testing and pharmacogenomics
    - Provides clinical chemistry and hematology equipment and reagents
    - Recent acquisitions include Genaissance Pharma (pharmacogenomics) and Lark Technologies (CRO) and Icoria (systems biology, metabolomics)

Outline

- **Introduction to Oncology Informatics**
  - Organizational and Strategic Goals
- **How Oncology Informatics can be leveraged in Surgical Pathology?**
- **Why Pathology Informatics has lagged and how we can fix it.**
  - Lack of focus on Specialty Labs, critical to Personalized Medicine
  - Funding issues
  - Training Program issues
- **Cancer Biomedical Informatics Grid Initiative (caBIG – http://cabig.nci.nih.gov**
  - Example of how to transform Oncology Informatics – NIH Roadmap
- **Conclusions**

Cancer Informatics Services at U Pitt

- **Software Solutions Supported and Deployed:**
  - **Clinical Trials Software – Developed at U Pitt = Clinical Trials Mgmt App**
    - » **Deployed at Hillman Cancer Center, UPMC Presbyterian/Shadyside**
    - » **Deployments underway at regional cancer centers and physician offices**
    - » **Deployments planned at Magee Women's, Children's Hospital**
  - **Cancer Registry Software – MRS system of IMPAC (formerly ImPath)**
    - » **Deployed in 12/18 hospitals (homogeneous consolidation); Outpatient rollout**
  - **Tissue Banking Info System (URL behind firewall) at 8 cancer centers**
  - **Organ Specific Databases (URL behind firewall) – identify tissue samples**
  - **Gene Expression Databases (public, see below) – at U Pitt only**
  - **Support of Clinical Systems:**
    - » **LIMS (Cerner, Affy and Amersham), Cerner CoPath (Anatomic Path), Misys (Clinical Path), Cerner (Electronic Medical Record)**
  - **Web Tools (including extensive web casting):**
    - » **UPMC Cancer Centers Website (see http://www.upmccancercenters.com)**
    - » **UPCI Website (see http://www.upci.upmc.edu)**
    - » **Bioinformatics (see http://bioinformatics.upmc.edu/index.html)**
- **Honest Broker for Tissue, Data and Outcomes Research (handout)**
  - **Certified Honest Brokers include:**
    - » **7 Tissue Bankers (Pathology Assistants and Support Staff), 5 Cancer Registrars & 3 Outcomes Researchers–Coordinator/Data Mgrs**

Component Technology – Pathology & Oncology Informatics

- Pathology Informatics
  - Anatomic Pathology
  - Clinical Pathology
  - Hematopathology & Molecular Diagnostics
  - LIMS for Genomics and Proteomics
  - Tissue Banking
  - Telepathology
  - Web Site Support
- Oncology Informatics
  - Cancer Registry
  - Clinical Trials
  - Organ Specific Program Support
    - Prostate, Melanoma, etc..
  - Telemedicine (for oncology)
  - Web Site Support
  - E-Health Initiatives

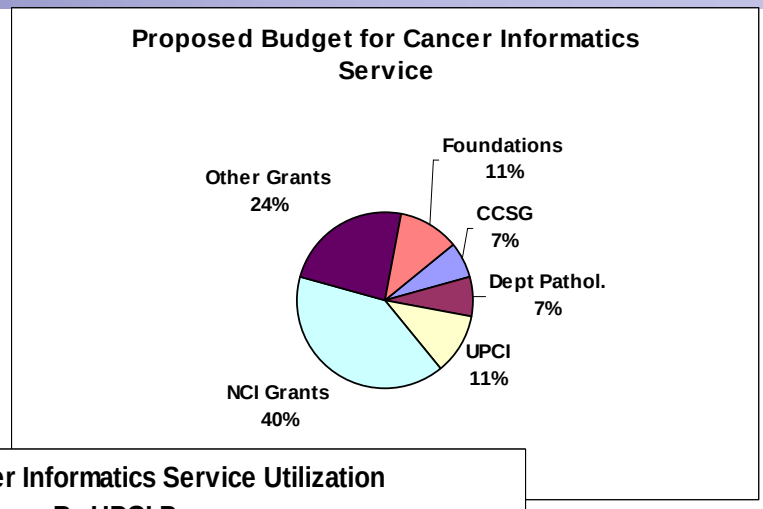
Strategic Approach – Why Oncology Informatics?

- **Why Oncology Informatics as the next step forward?**
  - **Higher profile in the clinical arena (70/70/70 rule)**
  - **No developed systems/people to support Onc Info**
  - **Unlike Path, Onc Informatics has significant $ support:**
    - » **Onc svc lines at most major med ctrs – very profitable, growing**
    - » **NCI has launched several strategic IT initiatives:**
      - **NCICB – NCI Center for Bioinfo (5 FTEs 5 years ago now >80)**
      - **caBIG – Cancer Biomed Info Grid Initiative – $100M (with NCICB)**
      - **NBN – Ntnl Biospecimen Network (NCI backed) – $100M**
    - » **Cancer Centers Program is highly supported by new director**
      - **Cancer Center Support Grants represent 20% of NCI funding base**
    - » **Part of the NIH Roadmap – Informatics key to research/clinical success**
    - » **Pathology needs to embrace this and move to "personalized" testing to support Oncology**

Support for Cancer Informatics Services

Overall Annual Budget

	Dollars	Percent
CCSG Request	$224,421	7%
Grants	$2,375,000	65%
Foundations	$350,000	11%
Institution	$578,000	17%
Total Facility Budget	$3,527,421	100%

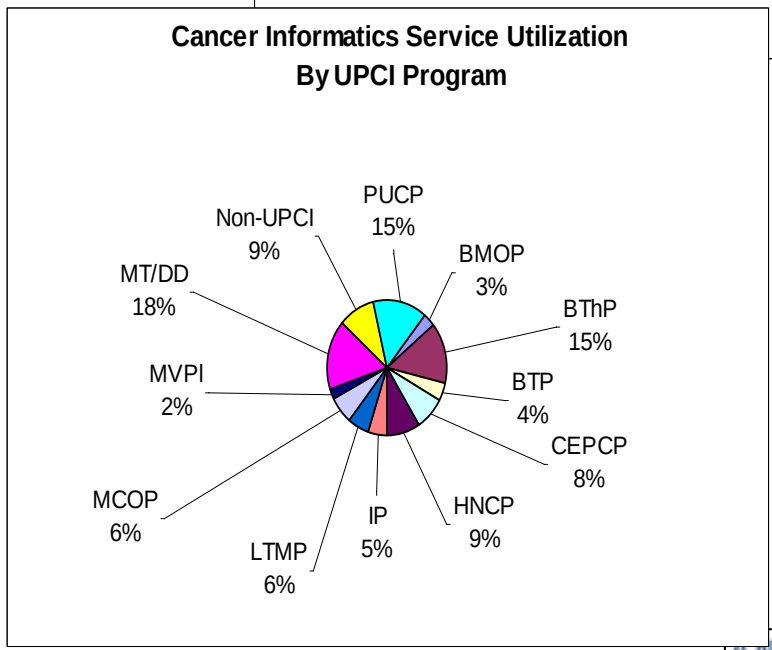


For CY 2005:

148 PIs used Clinical Trials Tools,
89 used Tissue Bank Info Svcs,
371 used Research Registry Info Svcs,
371 used the Honest Broker Services
161 Cancer Informatics server support.

Heaviest Users:

Molecular Therapeutics/Drug Discovery
Prostate Urologic Cancer Program
Biologic Therapeutics Program
Lung/Head & Neck SPORE Program



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Market Validation of Oncology & Pathology Value

- **Merger and Acquisition activity in 2000's – Validation?**
  - AP-, CP-Lab Information Systems (LIS) and Oncology Systems
    - » Elekta's purchase of IMPAC's after their purchase of Tamtron (AP-LIS) & MRS Registry (CR)
    - » LabCorp's purchase of Dianon/Urocor (AP and Clinical Trials)
    - » Misys's (CIS) purchase of Sunquest (CP-LIS)
    - » Cerner's (CIS) purchase of Dynamic Healthcare Tech. (APLIS-CoPath)
    - » Clinical Data's purchase of Icoria, Genaissance Pharma and Lark (CRO)
    - » Varian's purchase of Clinical Trials Software Company
    - » GE's purchase of Triple G
    - » Siemens purchase of Stentor
- **Biotech Startups – More Validation through VC & Mergers**
  - Icoria merger with TissueInformatics – Systems Biology approach combining Genomics with Tissue Based Image Analysis
  - LifeSpan Biosciences – Strategic Partnership with NEC (Japan) = CRO for tissue based discovery with high end imaging strategy
  - Ardais – >$20M VC – Tissue Banking for Pharma and Biotech
  - Aureon – >$20M VC – 'Gold Standard' Molecular AP Testing & Database
  - Pathogenomics – >$20M VC – Genomic Discovery on Tissue Bank
  - PathWorks - $10M – Genomic Discovery based on Cancer Signatures

Oncology Informatics and Relevance to Personalized Testing in Pathology

- **Oncology Informatics (3 faculty; JLW, VM & AT; and 20 staff)**
  - **17 of 20 hospital on one Cancer Registry (MRS, Eleckta)**
    - **Number of new index cancer patients per year: 10,000+**
  - **Clinical Trials Information System (developed by Oncology Informatics); being rolled out to enterprise**
  - **Genomics/Proteomics LIMS–GLP developmental labs**
    - **Genologics – making significant progress with Proteomics**
    - **Now funded by Onc Info due to funding pressure in Path Info**
  - **Specialized Cellular Therapies & Personalized Therapies**
    - **Stem Cell**
    - **Cellular Products (Immunotherapy)**
    - **Immune Monitoring of Cellular Therapies**
    - **All implemented now using Cerner's PathNet as a LIMS**
    - **Supported by Oncology Funding but managed by Pathology**
  - **Coagulation & Transfusion Medicine is an Opportunity!!!**

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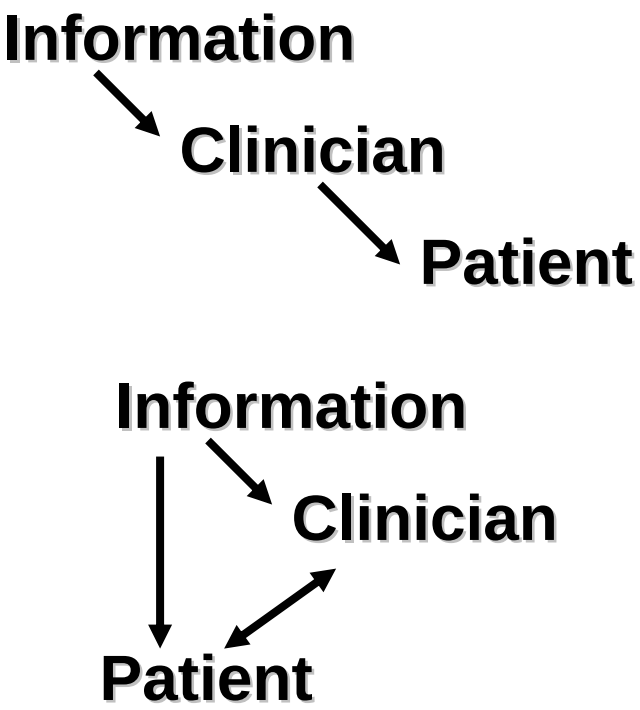
From John Gilbertson, MD
Now at Case Western University

InfoCentric Networks & Personalized Medicine

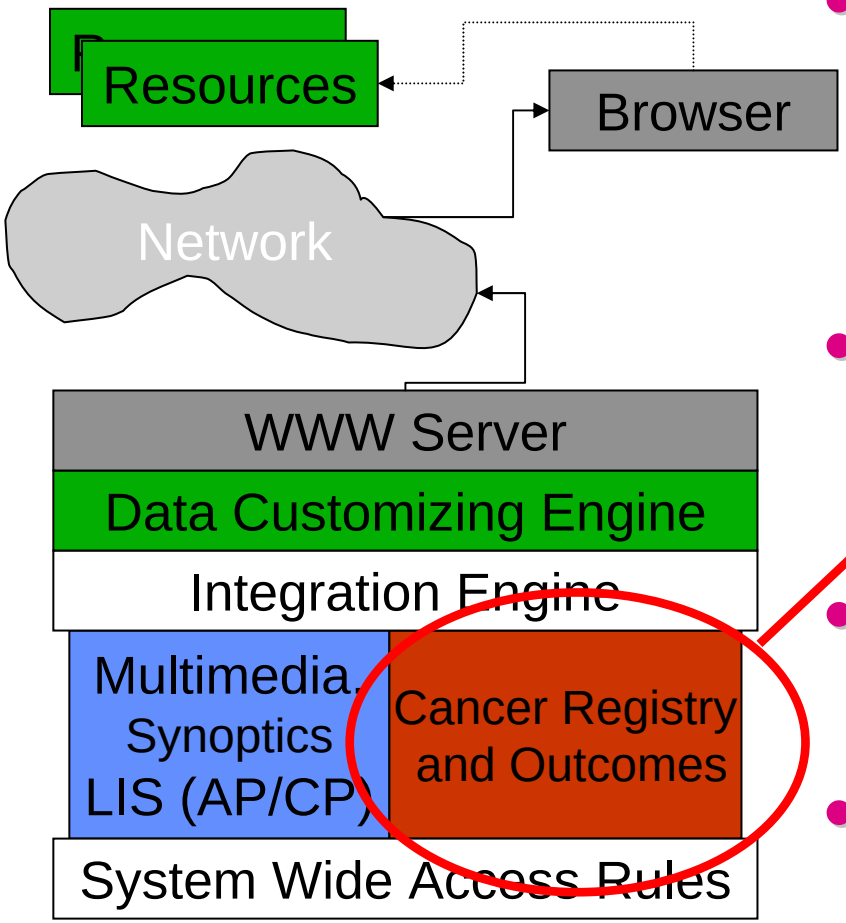


- **"Information relationships " in medicine are in silent upheaval. Ubiquitous access to information is changing the fundamental relationship between the physician and patient.**
- **This will impact pathology informatics.**
- **The way pathology, and its academic departments, position themselves now 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 informatics.**

Electronic Medical Repositories: The Value of Warehoused Lab Data

- Pathology is uniquely situated in medicine and provides objective and quantifiable data via electronic repositories
- Leverage the position we have (70/70 Rule) into leadership role in enterprise clinical datamining and datawarehousing
- As we enter the Post-Genome Era the time spent on actual testing will decrease and the amount spent on data analysis will increase
- This will place tremendous value on warehousing data and being able to efficiently datamine archives of Pathology data.
- Focus on changing system architectures and focus on reporting correlative information not individual values

Oncology Informatics and SP Reporting: Future Reports

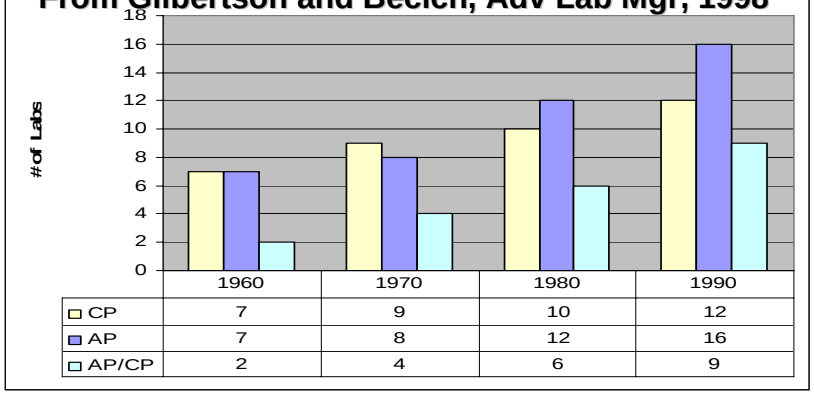


- **An integrated laboratory view of a patient.**
  - **Disease Based**
  - **AP, CP & Imaging information.**
  - **All Path Data & Disease Specific**
- **Knowledge Bases**
  - **Cancer Registry and Outcomes Data Warehouse communicated to patients and clinicians.**
- **Integrate pathology data and links to appropriate Patient/Physician resources depending on user.**
- **Report format based on user type (patient, physician or researcher).**
- **Provide identified and de-identified access to system.**

The AP/CP Integration Issue

- **Where does "The New Pathology" lead to:**
  - **Look at trends over the few four decades:**
    - **Increasingly specialty laboratories reporting needs are not being met:**
      - Tissue Typing
      - Hematopathology
      - Cytogenetics
      - Microbiology
      - Immunopathology
      - Molecular Pathology

Fig. 1 - Increase in Specialty Labs in Pathology
From Gilbertson and Becich, Adv Lab Mgr, 1998



	1960	1970	1980	1990
CP	7	9	10	12
AP	7	8	12	16
AP/CP	2	4	6	9

    - **Harder to distinguish which are CP (quantitative/numeric result driven) and which are AP-like (qualitative/text driven)**
    - **Vendors have largely not engineered this into their solutions**
- **Problem is that AP- &CP-LIS are not integrated.**
- **This is a basic flaw in pathology.**

Integration of Anatomic and Clinical Pathology Informatics

Lab InfoTech Summit, Las Vegas Wednesday, March 2nd, 2005

NOTE: Archived on Lab InfoTech Summit Website (http://www.labinfotech.org) at:

https://www.labinfotech.org/LIS2006/Presentations2005/Becich_las_Vegas_2005.htm

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Ad Hoc Councilor, Association for Pathology Informatics
http://www.pathologyinformatics.org

Pathology Informatics and Personalized Medicine

- Pathology Informatics (10 faculty; GB, MB, RC, RD, DGx2, DJ, SR,YY & 1 TBN; 85 staff; 3 open positions-CP,AP,R&D)
  - 20 hospitals – one anatomic laboratory information system (LIS = Cerner CoPathPlus and PathNet LIMS)
  - 16 of 20 hospitals - one clinical pathology LIS (= Misys)
  - Implementing Molecular Diagnostics LIS in 2006 – Helix from Cerner
  - One tissue banking plan (5 major tissue banks) and now linked to our Organ Specific Database program
- Critical Need – Specialty Lab Informatics Support to the vision of Personalize Medicine – happening in Oncology
  - Molecular Diagnostics
  - Cytogenetics
  - Hematopathology
  - Genomics and Proteomics

Pathology Informatics and Funding/Priority Issues

- Pathology Informatics has many issues to address:
  - Marginalization from Hospital IT investments due to EMR and "one system for all domains" strategy
  - Reimbursement pressure continues for Pathology
  - Systematic lack of investment by LIS companies
  - Lack of federal funding for Pathology Informatics (at least compared to Oncology Informatics)
  - Lack of significant investment in training (at all levels)
    - With LIS systems as a strategic IT asset
    - With prioritizing pathology informatics training (no funding to support)
- Critical Need – National Organizations must work together to address this – AACC, AABB, CAP, ASCP and USCAP
  - Association for Pathology Informatics (API) – see http://www.pathologyinformatics.org is making progress but needs your help. Please support API!!!

Association for Pathology Informatics (API)

http://www.pathologyinformatics.org

Search

Home Page

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.

API Membership Benefits to Individuals

- Recognition as member of Pathology Informatics professional discipline
- Discounts at APIII, Lab InfoTech meetings
  - Attending one meeting alone offsets cost of dues
- Members-only Listserv
  - Managed at ASIP (*advertisement-free*)
- Peer networking and education (real time)
- Professional development opportunities
- Access to open source tools:
  - TMA XML data exchange standard
  - Comprehensive abbreviations repository
  - Digital imaging standards efforts for pathology

Leveraging Our Hard Work in Pathology Informatics

- **Why Pathology Informatics has a lot to offer Oncology Informatics:**
  - **Advancing Practice, Instruction & Innovation through Informatics (APIII)**
    - **National Meeting focused on Biomedical Informatics (emphasis shifted to oncology informatics and bioinformatics from pathology informatics)**
    - **Over 2500 attendees to date over 8 years**
    - **Over 375 trainees to date over 8 years via CAP Foundation Program**
    - **Includes vendor community critical to long term support and R&D**
    - **Relationships with American Medical Informatics Association (AMIA), College of American Pathologist (CAP), in discussions with American Association for Cancer Institutes (AACI)**
  - **National Member Organizations (Hilliard)**
    - **Association for Pathology Informatics (API – see http://apiii.upmc.edu)**
    - **American Society for Investigative Pathology (ASIP)**
    - **American Telemedicine Society Special Interest Group in Telepathology**
  - **Training program coordinated centrally (Harrison)**
    - **APIII Travel Awardees – over 350 and CAP Technology in Training Informatics Awardees – 6**
    - **MS and PhD Students – 10**
    - **NLM Biomedical Informatics Fellows – 8 and Informatics Fellows - 13**
    - **Bioinformatics Trainees – 6**
  - **Web Properties – over 3M hits per month from over 350K unique visitors**

API Focus Session
Oncology Informatics:
Organizational and Strategic Goals

Lab Infotech Summit – The Venetian, Las Vegas, NV
Friday, March 12th, 2004

NOTE: Archived on Lab InfoTech Summit Website (http://www.labinfotech.org) at:
https://www.labinfotech.org/LIS2006/Presentations2004/LIS_2004_becich_lecture.htm

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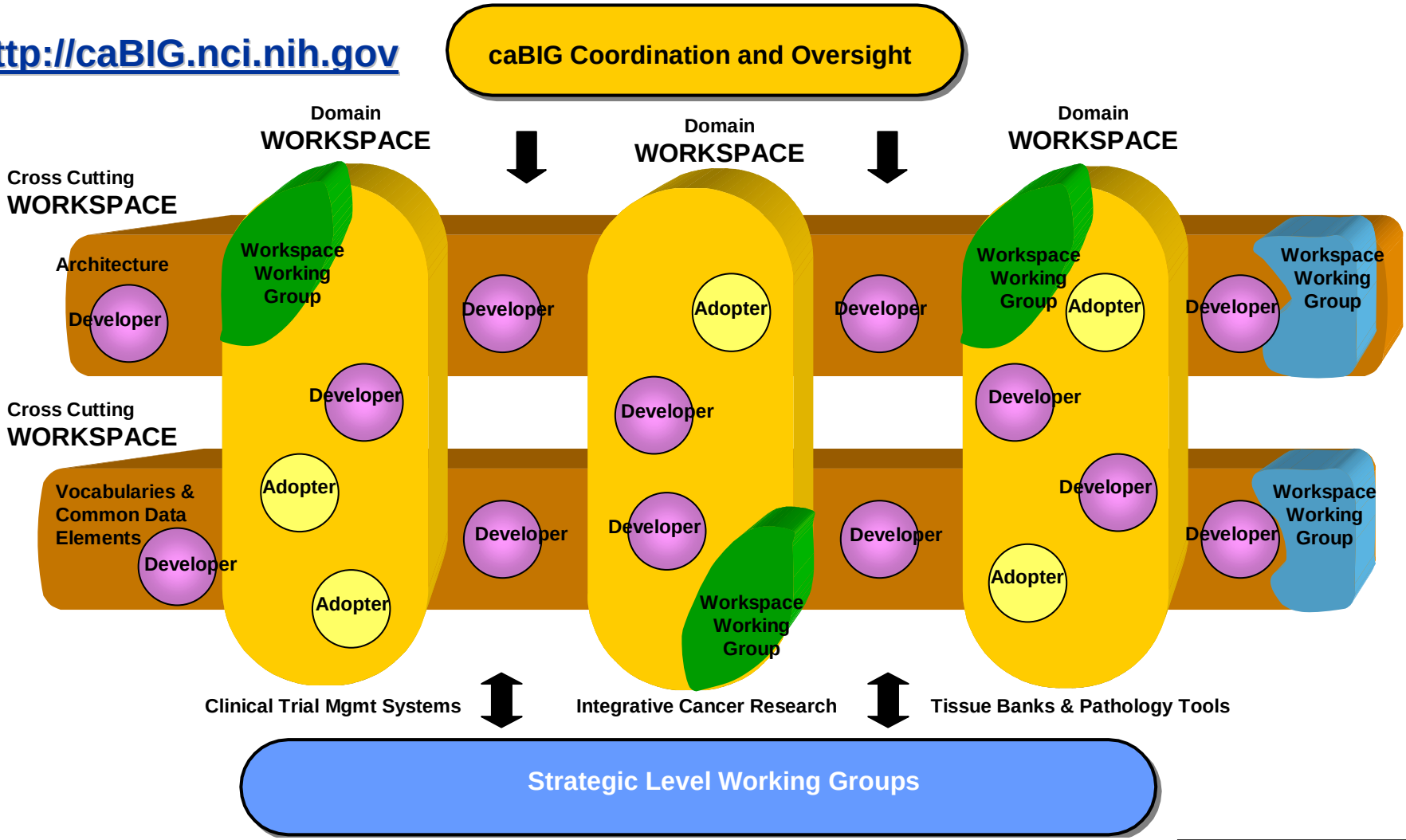
Cancer Center Needs Resulted in the caBIG "Grid"

http://caBIG.nci.nih.gov



A National Cancer Institute Designated Comprehensive Cancer Center NCI CCC

The Big Question(s):

WHERE IS PATHOLOGY IN ALL OF THIS?

WHY IS THERE NO SUPPORT FOR THIS KIND OF MAJOR UNDERTAKING FOR PATHOLOGY?

The bottom line:

WE MUST PARTNER WITH THESE BIG SCIENCE INITIATIVES OR WE WILL BE FURTHER MARGINALIZED IN THE MARCH TO PERSONALIZED MEDICINE.

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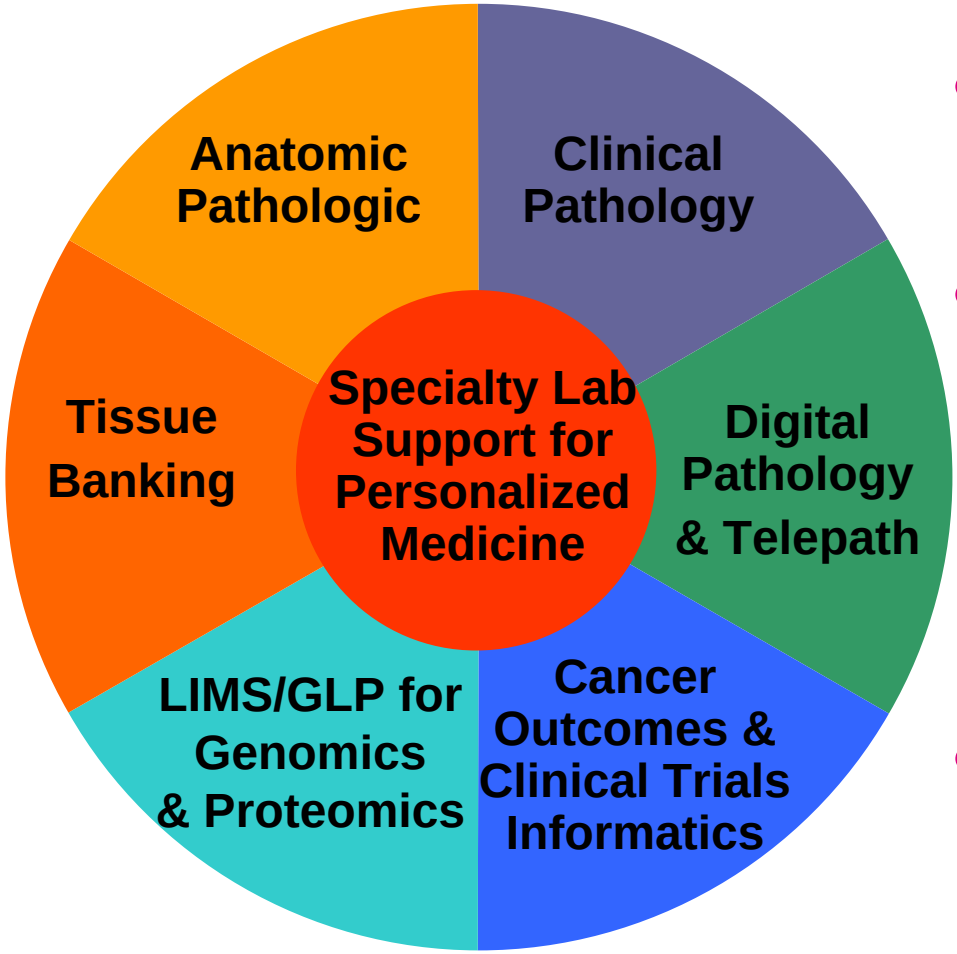
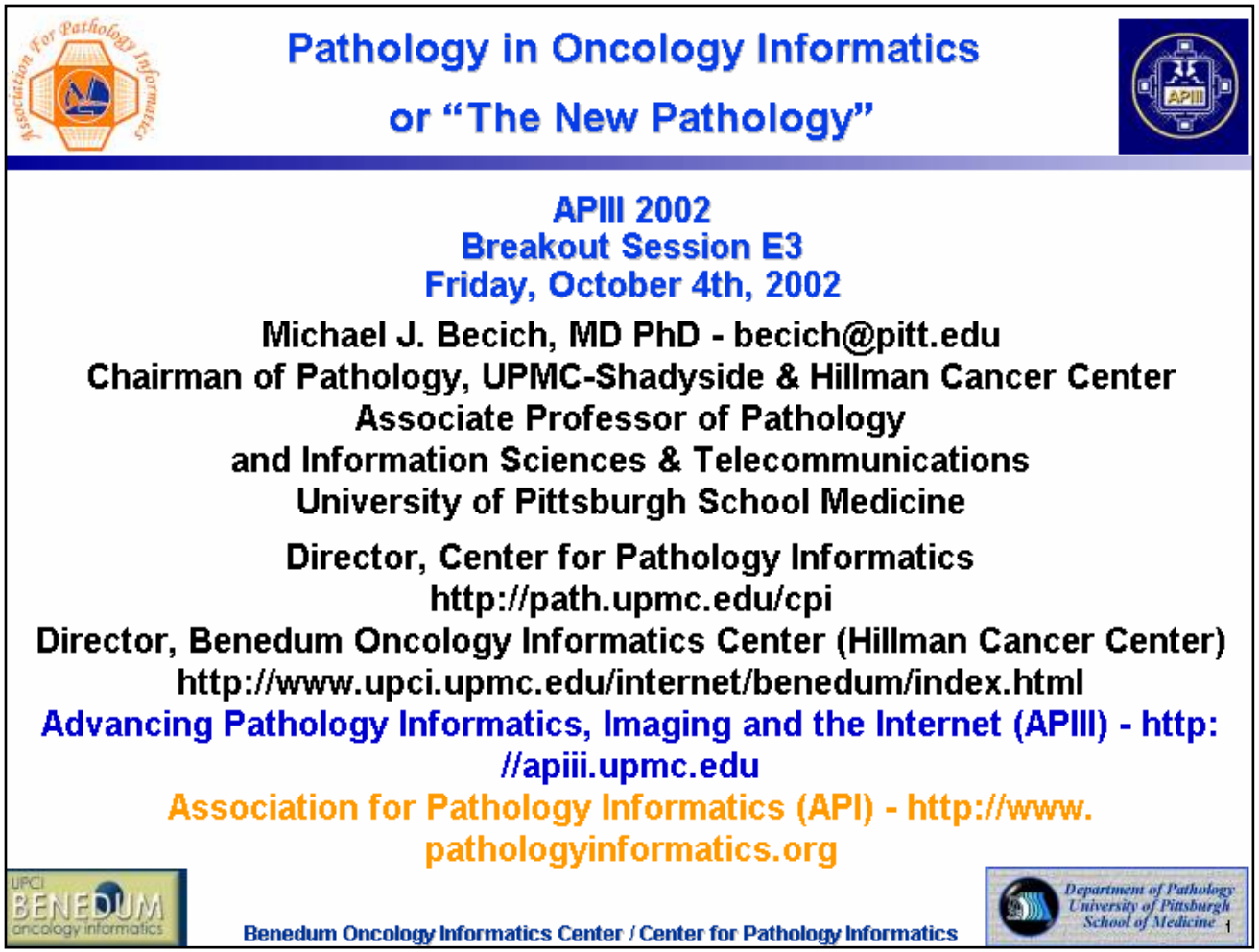
The Value of Oncology to Pathology Informatics and Pathology Practice



- 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?

History from APIII - 2002



Pathology in Oncology Informatics

or "The New Pathology"

APIII 2002
Breakout Session E3
Friday, October 4th, 2002

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http://www.upci.upmc.edu/internet/benedum/index.html

Advancing Pathology Informatics, Imaging and the Internet (APIII) - http://apiii.upmc.edu

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

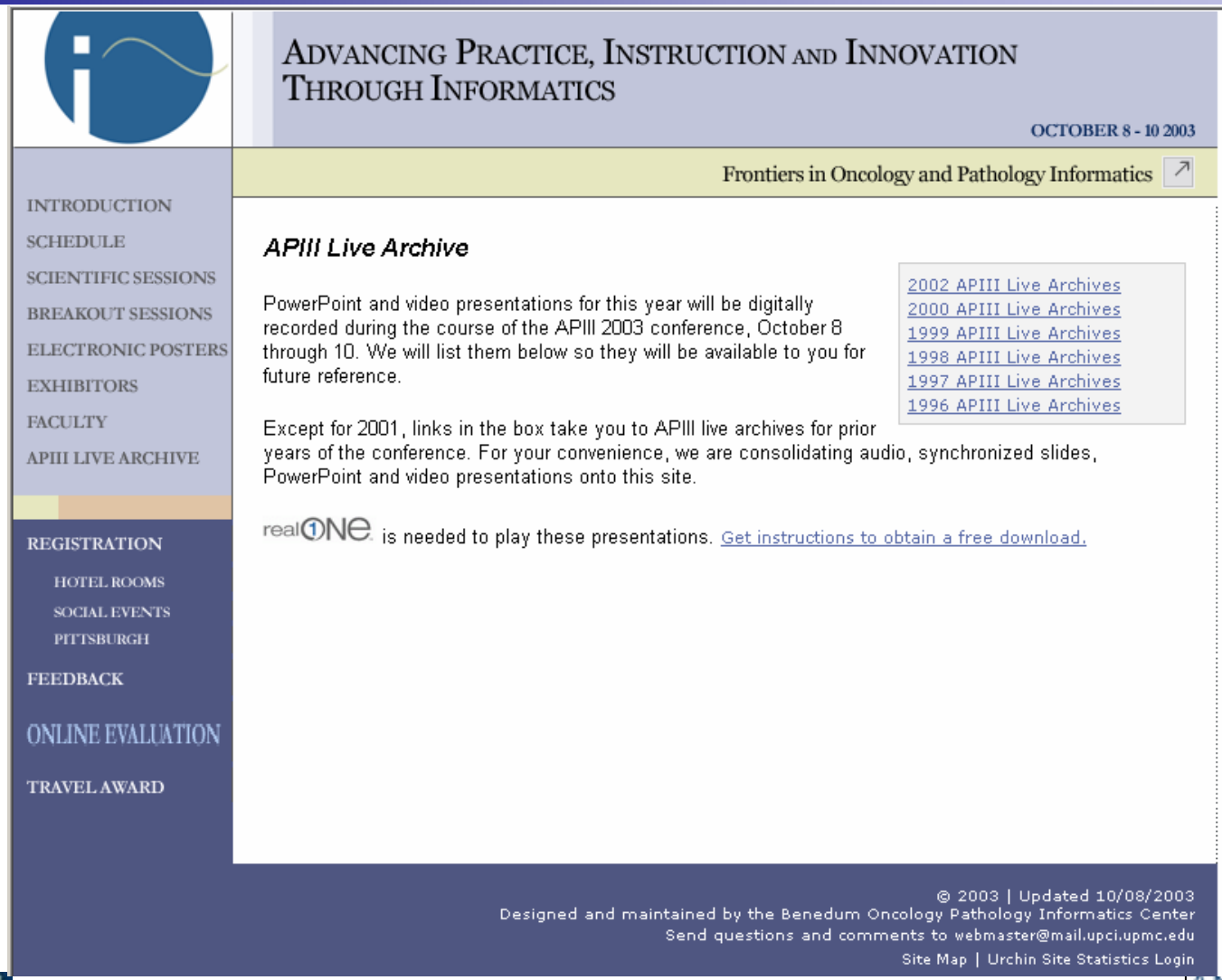
Benedum Oncology Informatics Center / Center for Pathology Informatics

Department of Pathology University of Pittsburgh School of Medicine

http://apiii.upmc.edu/archive/2002/Path-in-Onc-Info-APIII2002-MBv3-091802x.htm

APIII On Line Archive

http://apiii.upmc.edu/live/index.html



Benedum Oncology Informatics Center and Center for Pathology Informatics

Cerner CoPath AP LIS
- Bill Gross
- Anthony Piccoli
- Frank Losos
- Rick Nestler
- Lisa Devine
- Support staff of 12 (18 sites)

Misys FlexiLab CP LIS
- Gary Blank, PhD
- Jim Harrison, MD PhD
- Support Staff of 8 (12 sites)

Cerner PathNet LIMS
- Mike Sendek
- Jeff Schullo
- Support staff of 3 (5 labs)

Specialty Labs Project Mgmt
- Mary Mueller

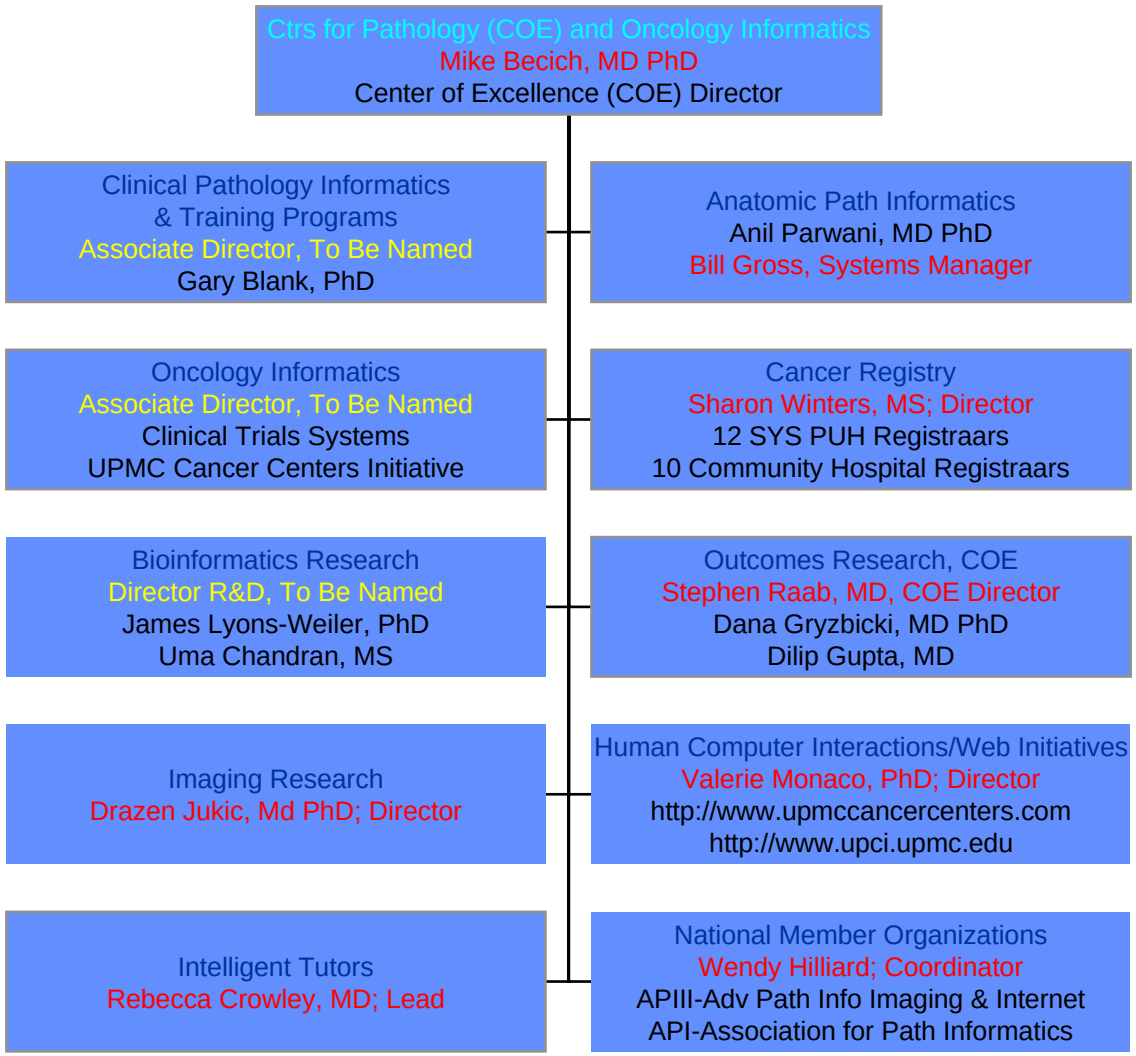
Programming Support
- Becky Boes
- Tom Harper
- John Milnes
- Kelli Richter

Web Services
- Valerie Monaco, PhD, MS HCI
- Aab Arnold
- Adrienne Weiss

Network and Server Services
- Gary Burdelski,
- Ryan Mitchell

Help Desk and Application Support
- Chuck Susanin
- Joel Young (Mac Support)
- Mark Michalski (PC support)
- Support staff of 8

Centers for Pathology and Oncology Informatics



Clinical Support & Training Programs

Pathology & Oncology Enterprise Research & Teaching Resources

Translational Research

Health Services/ Outcomes Research

National Teaching Organizations

A National Cancer Institute Designated Comprehensive Cancer Center NCI CCC

Recent Publications by Our Team – NOTE: Please e-mail me at becich@pitt.edu if you want PDFs

- Patel AA, Kajdacsy-Ball A, Berman JJ, Bosland M, Datta MW, Dhir R, Gilbertson J, Melamed J, Orenstein J, Tai KF, Becich MJ. The development of common data elements for a multi-institute prostate cancer tissue bank: The Cooperative Prostate Cancer Tissue Resource (CPCTR) experience. BMC Cancer. 2005 Aug 21;5(1):108.
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Invitation to APIII 2006
August 16-18th, Vancouver, BC

Advancing Practice, Instruction and Innovation Through Informatics

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Frontiers in Oncology and Pathology Informatics
Vancouver, British Columbia | August 16 - 18, 2006

- REGISTRATION
- ABSTRACT SUBMISSION
- INTRODUCTION
- SCHEDULE
- ABSTRACTS
- BREAKOUT SESSIONS
- APIII LIVE ARCHIVES
- EXHIBITORS
- FACULTY
- CME CREDIT
- TRAVEL AWARD
- ACCOMMODATIONS
- TRANSPORATION
- ABOUT VANCOUVER

The Advancing Practice, Instruction and Innovation through Informatics conference (APIII 2006) provides a broad overview of applications of biomedical informatics in pathology and oncology practice, education and research. APIII offers the opportunity to find answers to your informatics needs.

Who should attend

Anyone interested in learning how informatics is impacting and transforming pathology and oncology is encouraged to attend. APIII is designed for academic and practicing pathologists and oncologists, researchers in biomedical informatics, residents, fellows, graduate students, computer support personnel and lab/practice managers. Industry-related developers, engineers, and marketing representatives also comprise a significant portion of the attendees. Prior knowledge of informatics is not required.

http://apiii.upmc.edu

A National Cancer Institute Designated Comprehensive Cancer Center NCI CCC

End of Talk – e-mail me at becich@pitt.edu if you have questions/clarifications not covered in the discussion.

NOTE: Please e-mail me if you want PDFs of articles or presentation.

Thank you for the invitation to participate in the Lab InfoTech Summit.