

***The Secure Digital Patient Record Repository:  
Virginia's Approach to HIPAA & Medical Research***

William A.Knaus M.D.  
Evelyn Troup Hobson Professor & Chair  
Department of Health Evaluation Sciences  
University of Virginia

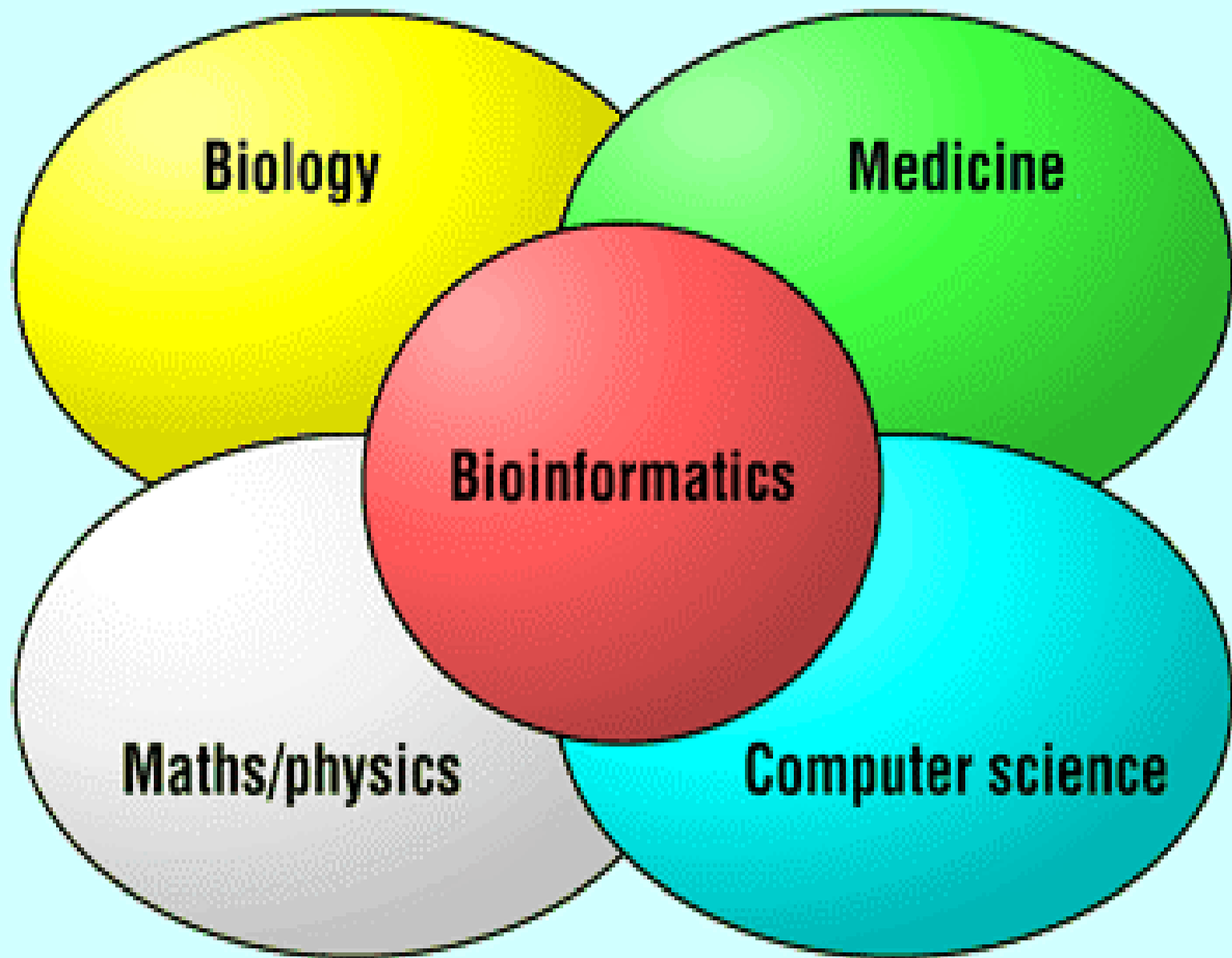
***Presentation to the Fifth National HIPAA Summit  
Baltimore, MD  
November 1, 2002***

Copyright UVA 2002

# NEW SCIENTIFIC KNOWLEDGE

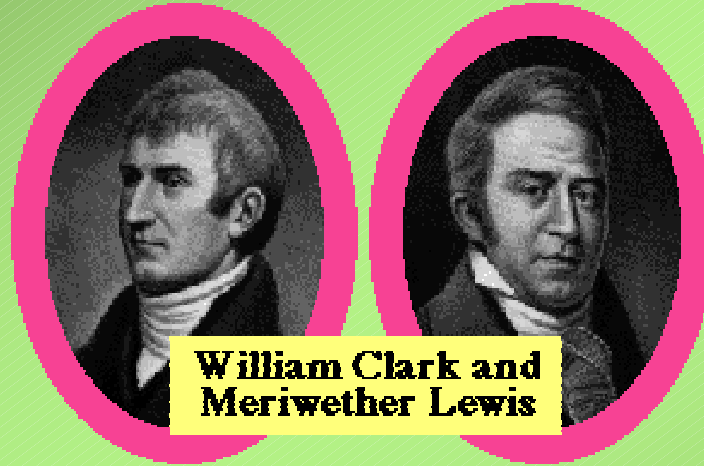
---

- Fundamental discoveries are leading to a new, comprehensive, and integrated theory of human function and life
- Genetic predisposition- protein function- cellular action-organ function-human representation
- Life will increasingly be based on a detailed understanding of molecular biology



# The Secure Digital Patient Record Repository

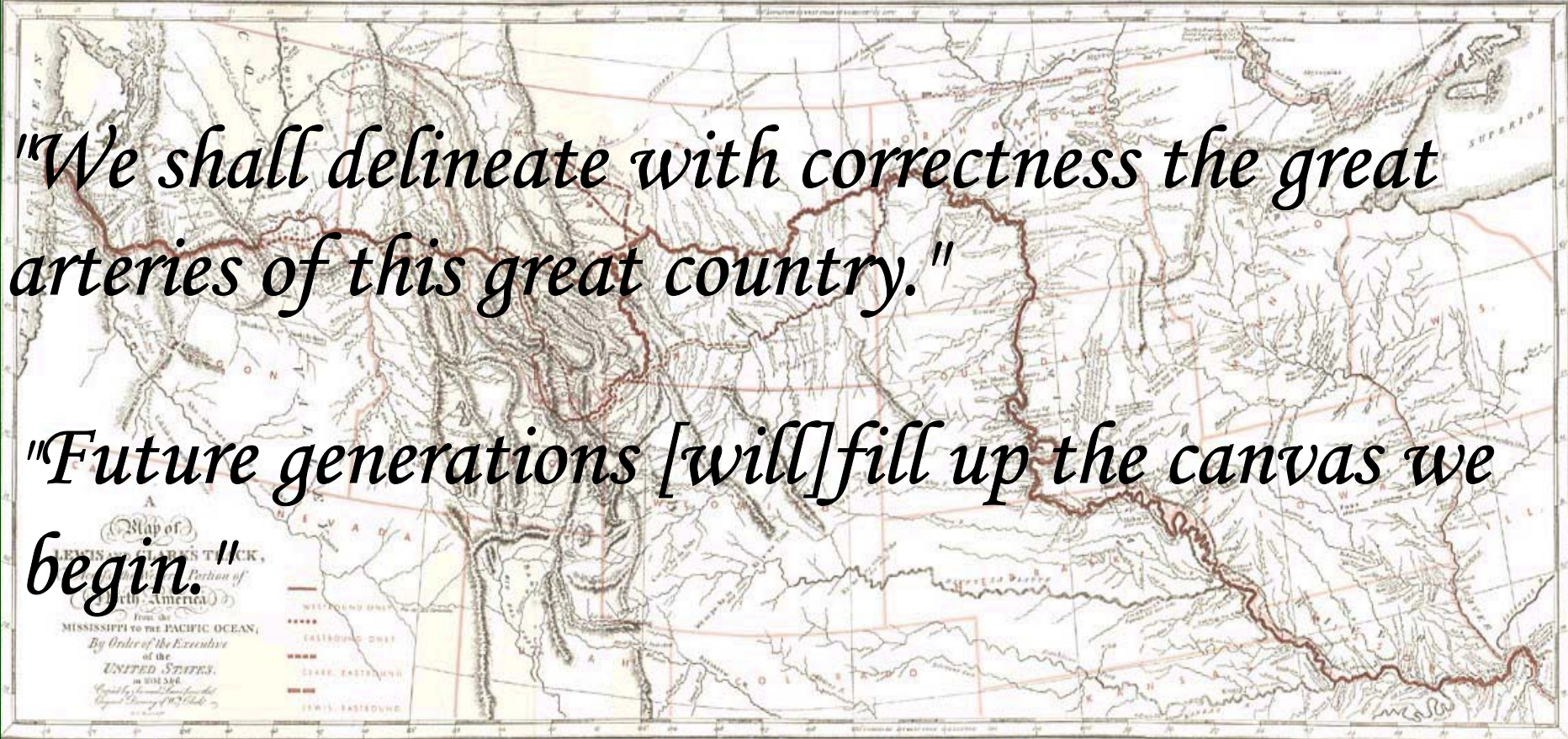
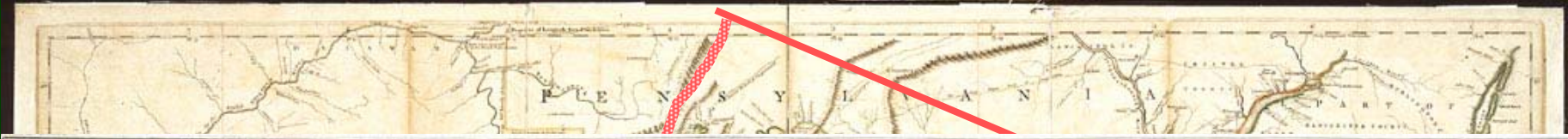
---



**William Clark and  
Meriwether Lewis**

## **Corps of Discovery**

**Initiative to map and combine biologic, demographic, clinical, behavioral, environmental, and outcomes data statewide to deliver better medical research, facilitate public health monitoring, and enhance individual decision-making.**



# EVENTS

# TECHNIQUES INFORMATION

# INTEGRATION

Copyright UVA 2002

DNA



## Genomics

Large-scale sequencing

Sequence Database

Transcription



mRNA

## Genomics

DNA Microarray

Gene Expression Database

Translation

Protein



## Proteomics

2-D Gel Electrophoresis  
Mass Spectrometry  
Protein Array

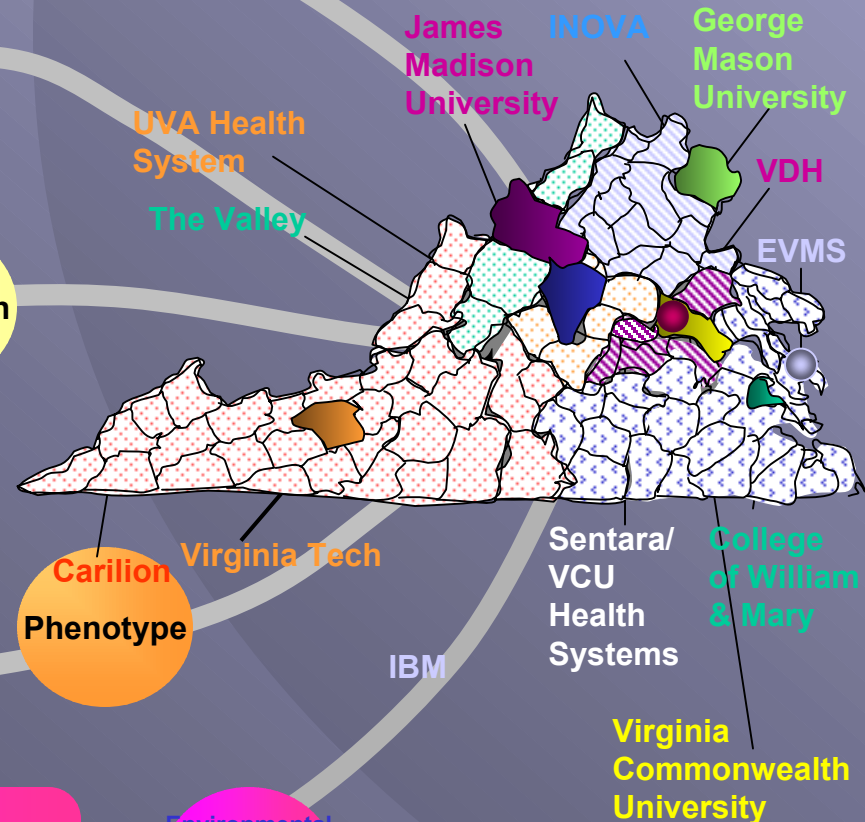
Protein Expression Database

Post-translational Modifications

## in vitro Testing

## in vivo Testing

Gene therapy  
Transgenic Mice

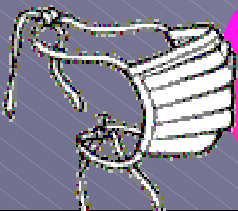


Physiologic Responses

Exposures  
Disease  
Outcomes

Epidemiology  
Surveillance  
Public Health Reporting

Environmental  
Clinical  
Population  
Databases



# NEW SCIENTIFIC & BUSINESS OPPORTUNITIES

---

- **Biotechnology**-dramatic improvements in precision and implications for biologic knowledge driving development of new products and services
- **Bioinformatics**-Fundamental changes in dissemination and access to medical data
- **Biomedicine**-Individually targeted diagnostics-**biomarkers** & treatments

# **The Promise of Biotechnology Requires Improved Access to Information**

## **OLD**

- **Discovery was personal & random**
- **Subjective diagnosis-treatment based on judgment/intuition**
- **Results uncritically accepted**

## **NEW**

- **Planned & corporate discovery**
- **Objective and data driven assessments**
- **Greater societal & personal accountability**



# Large Volumes of Multidimensional Integrated Data are a Key Resource

---

- Virginia is at the forefront of integrated, internet-based information technology & has targeted this sector for development
- Wide spread & low cost access to information technology has changed other industries
  - Banking & Finance & Commerce
- Biotechnology will also restructure medical research & patient care
  - Development of a comprehensive integrated research repository (“map”) is one key to progress

# Two Perspectives on Biotechnology & Integrated Data

---

- Great Potential through free markets, deregulation, and minimal government interference
- Great Problems with privacy and ethical concerns requiring strict control & government regulation

# The Secure Digital Patient Record Repository Could Begin To Address These Issues

---

- “The debate on biotechnology has to move beyond polarization....(and) begin to look concretely at what kinds of institutions (and solutions) would be needed for society and individuals to take advantage of biotechnology’s advances. -Francis Fukuyama *Our Posthuman Future*
- **Solving problems by working through the process**

# *Harvard Business Review*

---

**“The health care industry today is trying to preserve outmoded institutions. Yet the history of disruptive innovations tells us that those institutions will be replaced, soon enough, with new institutions whose business models are appropriate to the new technologies and markets.”**

# The Secure Digital Patient Record Repository “Business Model”

---

- **Obtain Raw Materials**-comprehensive & large *integrated* biologic, clinical, demographic, environmental, and outcomes databases **with patient privacy preferences recorded**
- **Select & Develop Storage/Data Mining Tools**-small & large scale approaches to quality control, standardization, analysis & interpretation
- **Securely Transport Raw & Processed Data**-among research, clinical, government, citizen & commercial entities with **match between patient privacy preference & researcher request**

# Principles for Obtaining Data

---

- **First**-recognize that the data belongs to individual citizens-their rights, desires, and privacy needs must be primary concern
- **Second**-accept that high quality standard data and sample collection will require widespread process changes
- **Third**-acknowledge that effort must be as open and as comprehensive as possible

# The Digital Patient Record Repository

## Four Initial Steps 2001-2

---

- **Developed draft of data model (Departments of HES & Systems Engineering & Institute for Practical Ethics) FOR Uva-PUBLIIC**
- Pilot data integration across two large academic medical centers ( VCU, UVA, IBM) *CIT*
- Established initial process for standardizing biologic samples-Virginia Bioinformatics Consortium ( VCU-GMU-UVA-VT) *CTRF*
- Organized initial meeting to discuss how we might approach issue statewide *VTSF*
  - Wintergreen September 20/21st 2002

# **THE VIRGINIA *PUBLIIC* PROJECT**

---

**Project to Understand Biomedical information, Learn to Integrate,  
Interpret, and Control**

**MISSION: Integrate bioinformatic and  
clinical informatic databases university  
wide, improve management approaches  
within an centered, open-architecture,  
large-scale university-government-  
industry collaborative environment**



# The Virginia *PUBLIIC* Project

## Rationale

---

- *With appropriate design and attention to ethical and privacy concerns, the biomedical revolution could serve as a new basis for public health monitoring and personal health management*
- **The information revolution could serve as a new basis for public control over data privacy and protection**

# **The Virginia *PUBLIIC* Project**

## **Specific Tasks**

- **1-Requirements Analysis**
- **2-Architecture Design**
- **3-Data Modeling**
- **4-Gap & Audit**
- **5-Ethics & Consent**
- **6 Pilot Integration**
- **7 Education & Economics**

# The Digital Patient Record Repository

## Four Initial Steps 2001-2

---

- **Developed draft of data model (Departments of HES & Systems Engineering & Institute for Practical Ethics) Uva-PUBLIIC**
- **Pilot data integration across two large academic medical centers ( VCU, UVA, IBM) *CIT***
- **Established initial process for standardizing biologic samples-Virginia Bioinformatics Consortium ( VCU-GMU-UVA-VT) *CTRF***
- **Organized initial meeting to discuss how we might approach issue statewide *VTSF***

– Wintergreen September 20/21st 2002 Copyright UVA 2002

# INTEGRATED DATA MODEL

## SECURE DIGITAL PATIENT RECORD REPOSITORY

**Biologic Databases**

**Clinical Databases**

Rules

Rules

Computational Biology

Decision Support Systems

Bioinformatics

Clinical informatics

Tools

Tools

**PATIENT PRIVACY PREFERENCES**

Copyright UVA 2002

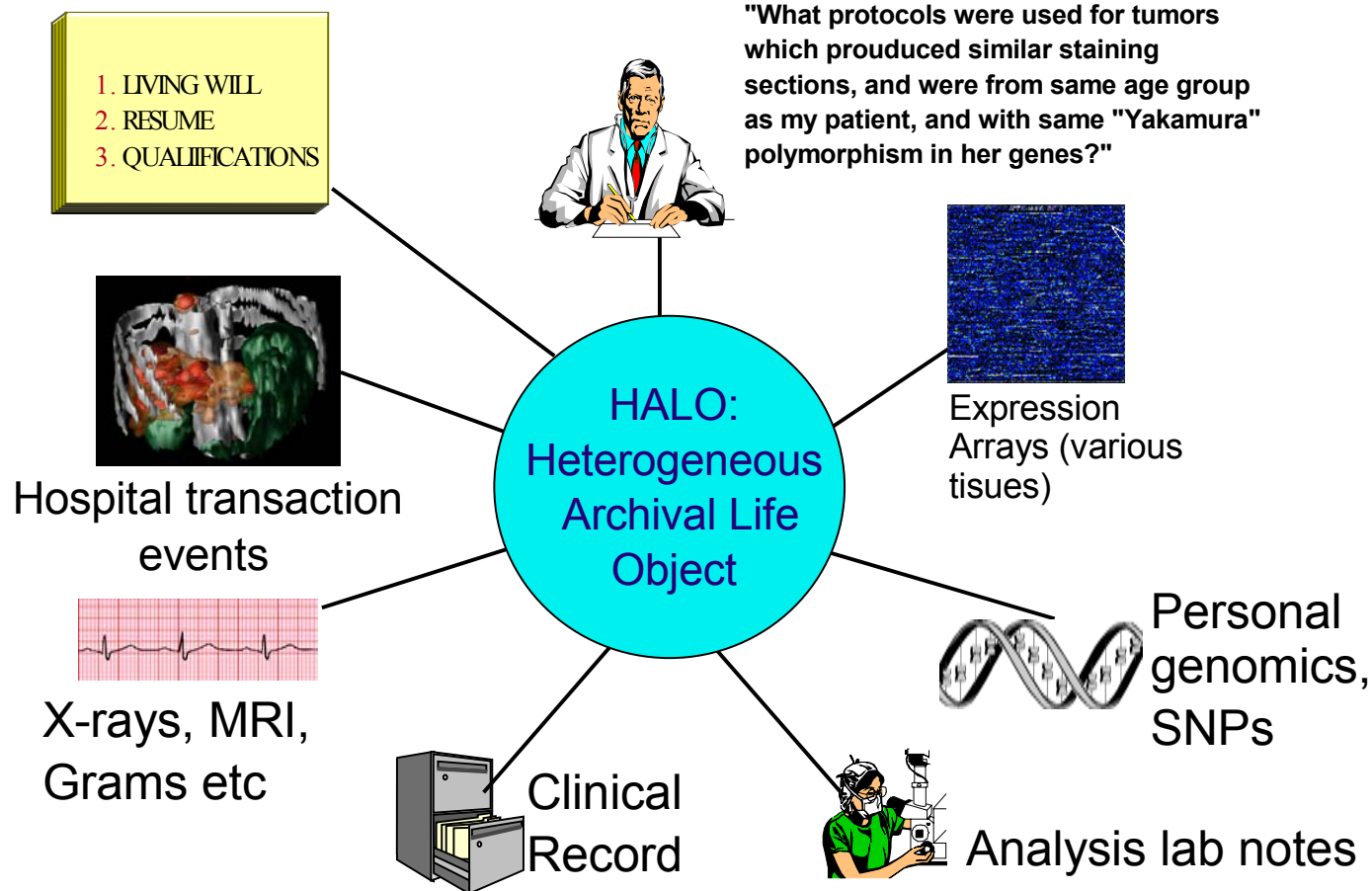
**Integrated Biologic Clinical Outcomes Data for Research**  
**Personal Preferences for Privacy**

Physiologic Systems  
Biological Systems & Dynamics  
Cellular Dynamics  
Drug Target Discovery (Pharmacogenetics)  
Proteomics  
Expression Array  
Structural Genomics  
Genome Sequence Comparison

Outcomes  
Response to Rx  
Practice Patterns  
Medical and Rx History  
Exposure - Lifestyle / Environment  
Tissue Samples  
Clinical Results  
Phenotype Description  
Family History

# SHAMAN: Secure Health and Medical Access Network

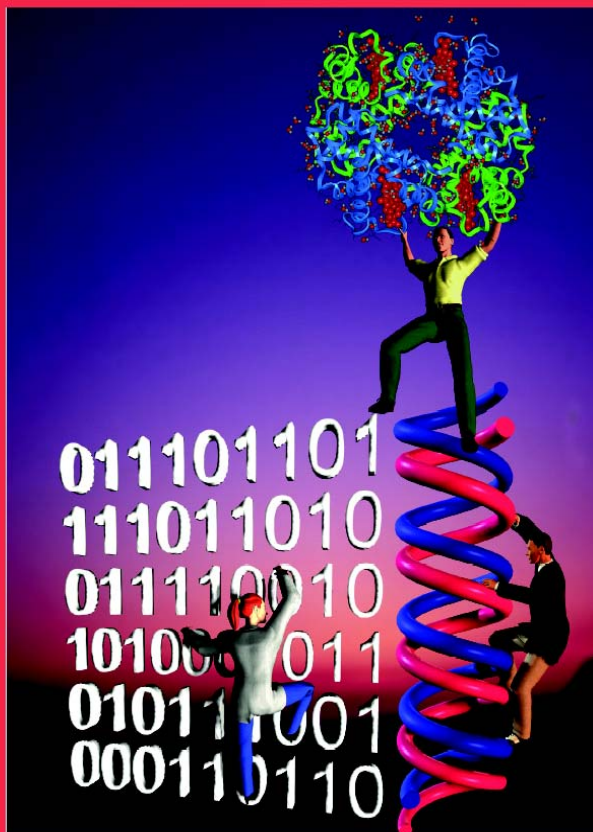
## The clinical record will be a complex heterogenous object



# VIRGINIA BIOINFORMATICS SYMPOSIUM, JUNE 12

## BIOINFORMATICS & PHARMACOGENOMICS SYMPOSIUM 2002

### VIRGINIA BIOINFORMATICS CONSORTIUM



### P R O G R A M

## Schedule of Events

### WEDNESDAY, JUNE 12

Location: Omni Richmond Hotel  
James River Salon C

12:00-5:00 pm	<b>REGISTRATION</b>	James River Foyer	
1:30-1:45 pm	<b>OPENING REMARKS</b>		
	Introductory		Donald J. Abraham Gregory A. Buck
	Welcome		Thomas F. Huff
	<b>PLENARY LECTURE</b>		
1:45-2:30 pm	SHAMAN - the Secure Health And Medical Access Network: A Battleplan for Future Healthcare Including Genomics and Personalized Medicine		<b>Barry Robson</b> IBM
2:30-3:30 pm	<b>GENOMES AND GENOMIC ANALYSES</b>		
	Convener		Brad Windle
	The Cryptosporidium parvum Genome		Gregory A. Buck VCU
	The Genome of Streptococcus sanguis		Francis L. Macrina VCU
	Hereditary Disease Genes		David B....

### FRIDAY, JUNE 14

Location: Omni Richmond Hotel  
James River Salon C

7:00 am-9:30 am	<b>REGISTRATION</b>	James River Foyer	
7:30 am - 9:30	<b>CONTINENTAL BREAKFAST</b>	James River Foyer	
	<b>KEYNOTE ADDRESS</b>		
8:30-9:30 am	<b>INFORMATION TECHNOLOGY FOR THE LIFE SCIENCES</b>		<b>Joe Jasinski</b> BM
9:30-11:30 am	<b>INFORMATICS</b>		
	Convener		Donald J. Abraham VCU
	Considerations in Developing a Clinical Informatics Systems		Lynne T. Penberthy VCU
	Functional Genomics - a Medical Perspective		Carleton Garrett VCU
	Building a Computational Discovery System for the Application of Systems Biology to Clinical-Genomic Medicine		John P. Pestian U. of Cincinnati
	Whole Genome Analyses Tools and Applied Genomics		Don Seto GMU
	Development of an Extensible, Homogeneous Infrastructure for Distributed Bioinformatics Resources -An Update on the NIST/CTRF Project Incogen		Krista Miller
	Playing The Molecular Naturalist: Combining Human Insight With Computer Algorithms To View Both The Genomic Forest And The Trees		Jeff Elhai VCU
	<b>CLOSING REMARKS</b>		Gregory A. Buck

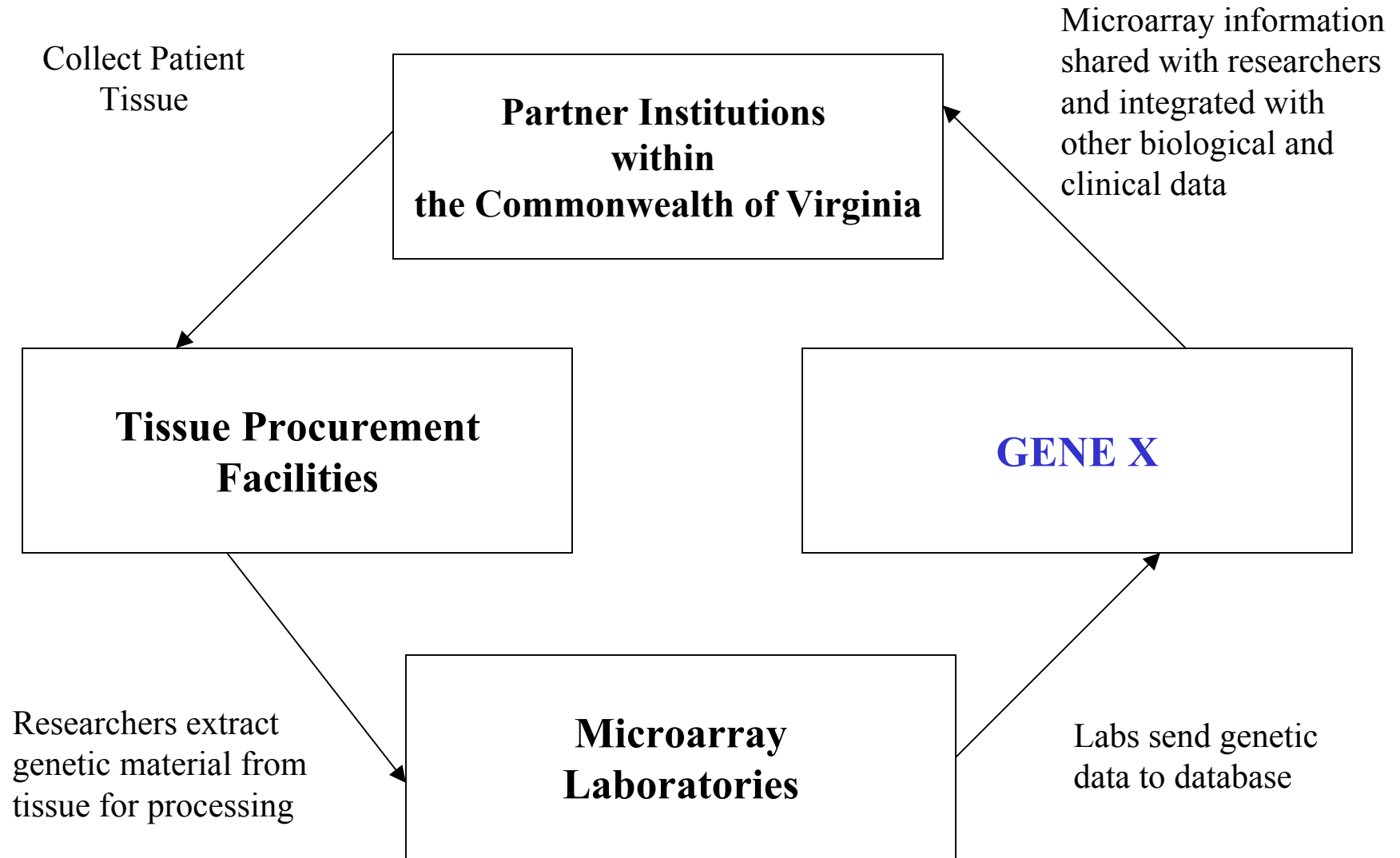
# The Digital Patient Record Repository

## Four Initial Steps 2001-2

---

- **Developed draft of data model (Departments of HES & Systems Engineering & Institute for Practical Ethics) Uva-PUBLIIC**
- **Pilot data integration across two large academic medical centers ( VCU, UVA, IBM) *CIT***
- **Established initial process for standardizing biologic samples-Virginia Bioinformatics Consortium ( VCU-GMU-UVA-VT) *CTRF***
- **Organized initial meeting to discuss how we might approach issue statewide *VTSF***
  - Wintergreen September 20/21st 2002

# ***VIRGINIA BIOINFORMATICS CONSORTIUM-VBC***





# The Digital Patient Record Repository

## Four Initial Steps 2001-2

---

- **Developed draft of data model (Departments of HES & Systems Engineering & Institute for Practical Ethics) Uva-PUBLIIC**
- **Pilot data integration across two large academic medical centers ( VCU, UVA, IBM) *CIT***
- **Established initial process for standardizing biologic samples-Virginia Bioinformatics Consortium ( VCU-GMU-UVA-VT) *CTRF***
- **Organized initial meeting to discuss how we might approach issue statewide *VTSF***
  - **Wintergreen September 20/21st 2002**

# The Digital Patient Record Repository

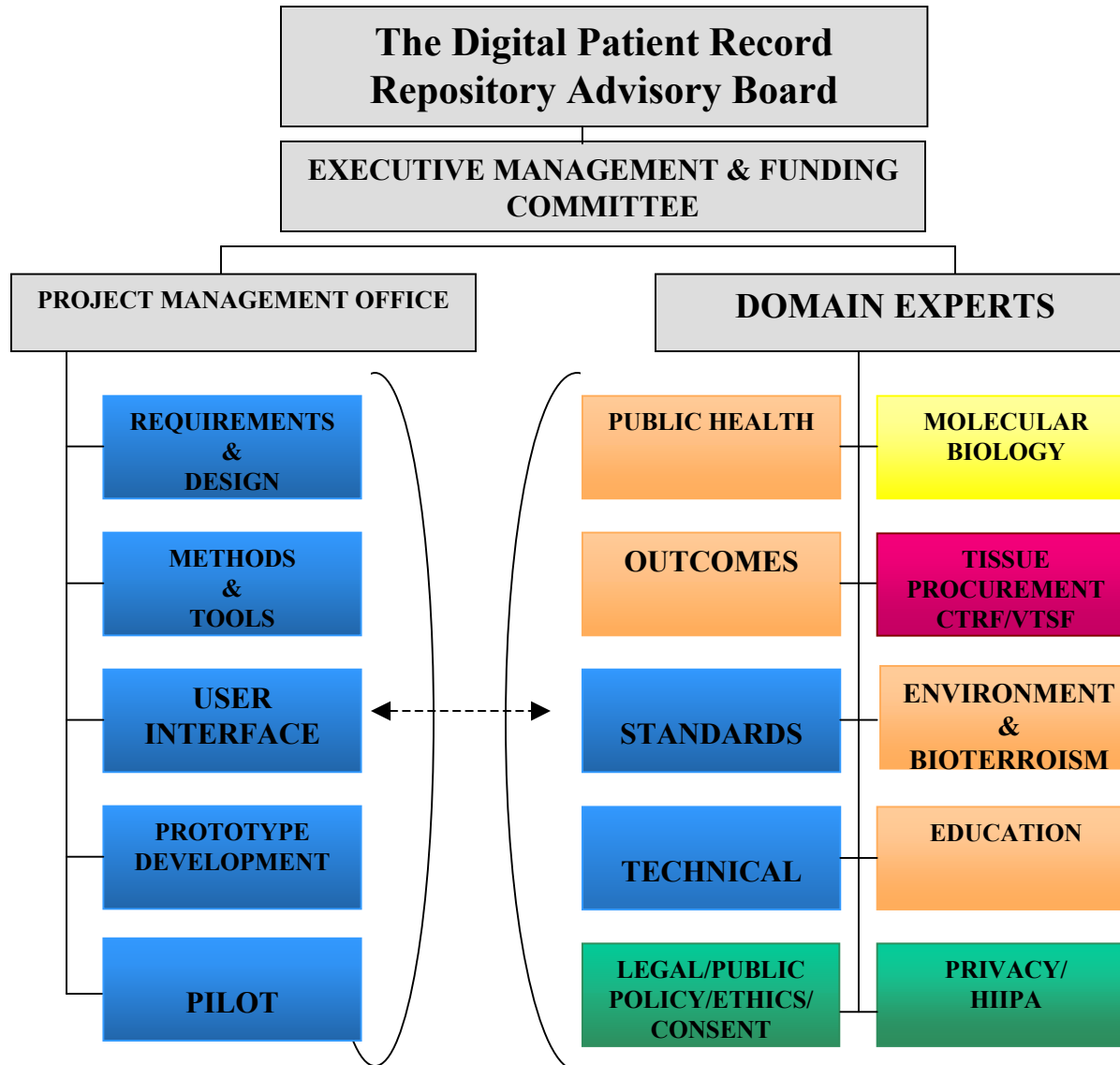
---

**Wintergreen Meeting** *Sept. 20 & 21*

- OBJECTIVES

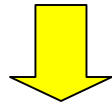
- Introduced participants & provided forum
- Discussed, reaffirmed, and revised vision & structure
- Provided status report & next steps
- Discussed possible long-range plans
- Provided opportunity for groups to meet
  - Executive Management Committee
  - Multidisciplinary/Multi-institutional task teams

# The Digital Patient Record Repository Draft Organizational Chart

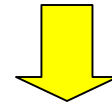


Prior attempts to integrate  
Clinical & Public Health Data  
have failed from both

## **Human & *Technical Challenges***



- **Intellectual Property**
- **Privacy Concerns**
- **Clashing Cultures**
- **Ethical Issues**
- **State, Institutional & Health Care Systems Priorities & Models**



- *Interfaces & Middleware*
- *Security & Monitoring Access*
- *Multidisciplinary Teams*
- *Regulatory Considerations*

# The Digital Patient Record Repository

## Unique Aspects

---

- **Bottom-up user & citizen based approach**
  - Build progressively but pragmatically
- **Systems engineering perspective**
  - Technical issues are addressed in other fields
- **Biomedical research orientation**
  - **Early & established legacy of sharing data**
- **Potential trusted agent relationship**
  - Structure exists primarily to protect data
- **Timing**
  - **HIPAA**
  - **Bioterrorism**
  - **Howard Hughes**

Search

[Limits](#) [Preview/Index](#) [History](#) [Clipboard](#) [Details](#)

### BLAST Info.

[BLAST overview](#)

[Frequently asked questions](#)

[BLAST program selection guide](#) **NEW**

[Description of BLAST services](#)

[BLAST Course](#)

[BLAST Tutorials](#)

[BLAST references](#)

[LinkOut](#)

## What's New in BLAST

March 5<sup>th</sup> 2002: New database linkouts from BLAST results. Results of a BLAST search will now link sequences from the BLAST results page.

### Nucleotide BLAST



- [Standard nucleotide-nucleotide BLAST](#)

### Protein BLAST



- [Standard protein-protein BLAST](#)

# HIPAA

---

- Health Insurance Portability and Accountability Act
- Specific provisions of HIPAA that directly affect the digital patient record project:
  - Privacy Standards
  - Security Standards
  - Transactions and Code Sets (+/-)
- Secure Digital Patient Record Repository could provide efficient & standardized “HIPAA Compliance” options for research

# Secure Digital Patient Record Reporting (SDPRR)

## Non-SDPRR

Does not participate by virtue of no contact with health care entities, or with entities that are not offering SDPRR authorizations

HIPAA notice and PHI authorizations handled case-by-case

Any resulting PHI or medical data collected *not* in SDPRR Database

No ability to track or monitor data releases

## Virginia Citizen SDPRR

Signs SDPRR authorization form (as part of receiving care at a SDPRR participating health care entity or as independent act)

SDPRR registration and preferences for PHI release/ additional requests for specific studies(options #1-#4) chosen

Unless revoked, all PHI requests by researcher with SDPRR user agreement can be referred to SDPRR. Data restricted to SDPRR participating institutions

Research request matched to individual preferences/ researcher receives data

Detailed record of releases maintained

## Refusal to Sign

Offered SDPRR registration but explicitly refuses to sign because of privacy/ other concerns

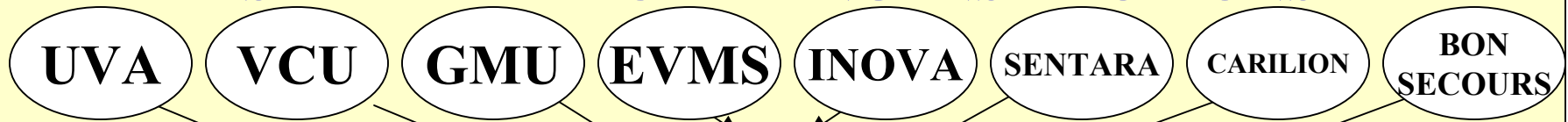
Individual's non-participation noted, de-identified data only maintained

All researcher requests for data result in de-identified data only, with notation that non-identified individual does not want PHI stored or released

Detailed record of de-identified releases maintained

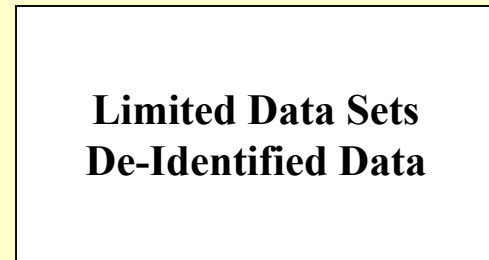
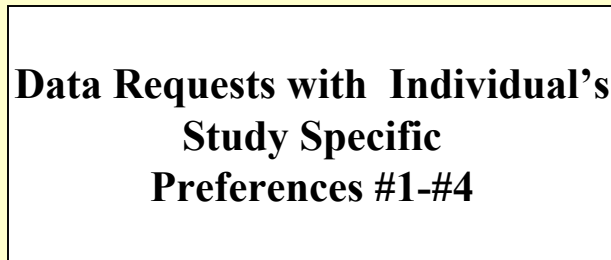
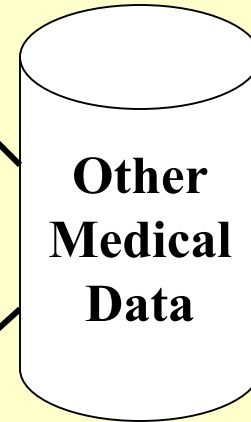
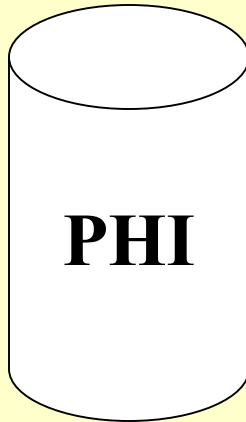
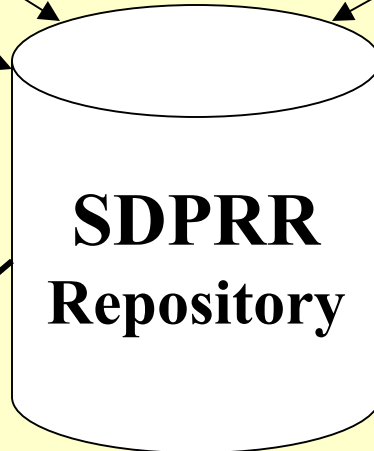


# SDPRR PARTICIPATING INSTITUTIONS



PHI's Medical Data

Personal Study-Specific Preferences for Release



Electronic Recording & Maintenance of All Requests Fulfilled

Answer Requests from Individual

Copyright UVA 2002

# **The Digital Patient Record Repository**

## **Funding Sources**

---

- **Virginia Tobacco Settlement Foundation**
- **State Government**
  - **CTRF- Virginia Bioinformatics Consortium**
  - **CIT-Gene Expression Integration**
  - **VDH-Registry Data**
  - **Governor's Advisory Board for Va Biotechnology**
- **Federal Government**
  - **NIH –NCI-NIAID-CDC-DOD-DHHS**
- **Industry**
- **Foundations-RWJF/Markle/Hughes**
- **Health Care Systems & Institutions**

# **The Digital Patient Record Repository**

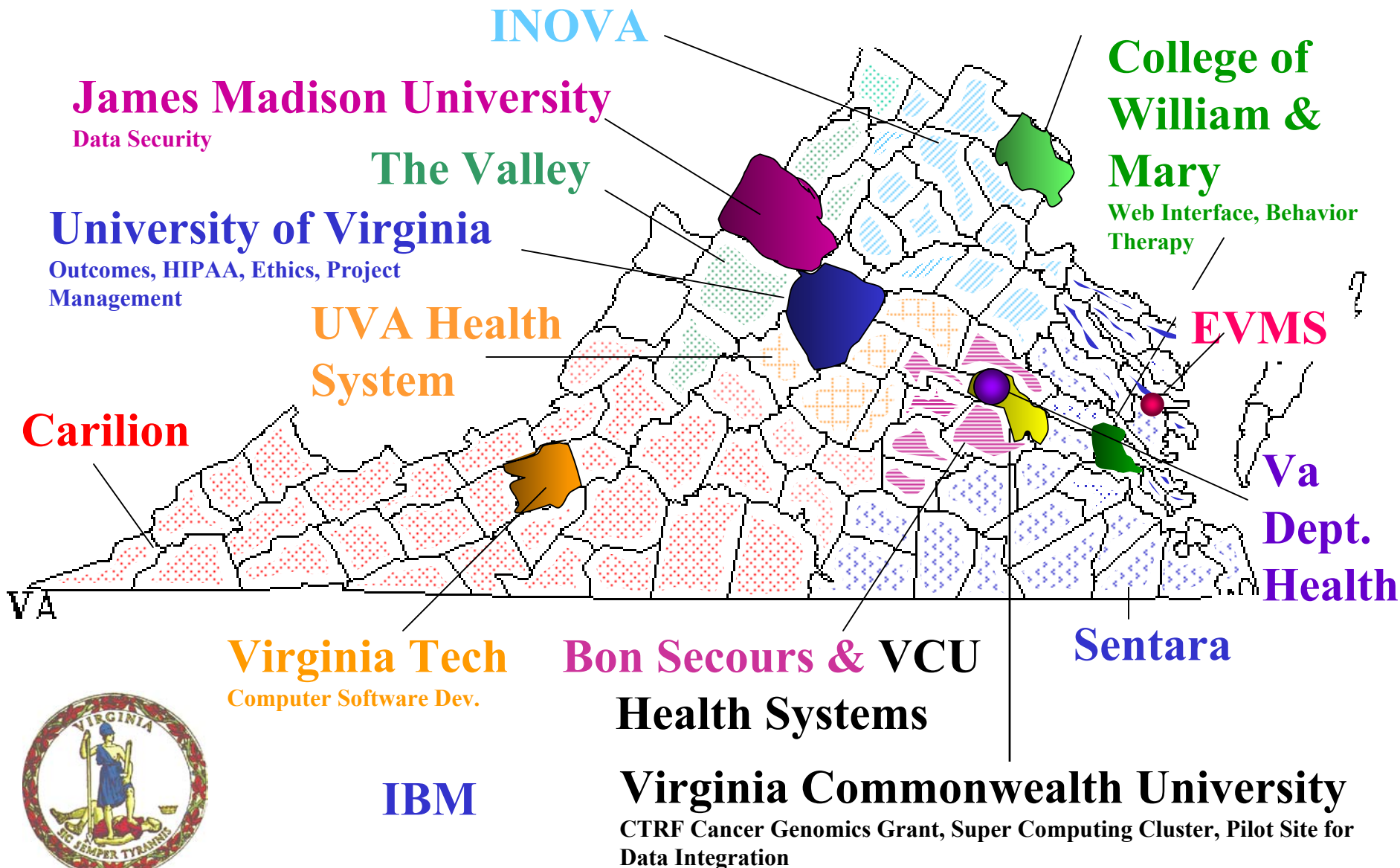
## **Leadership Opportunity**

---

- **First National Test-Bed**
  - **Integrated citizen-based HIPAA compliant research repository**
- **Potentially huge market- all research & service health care institutions will need this capability**
- **Synergistic with Virginia's unique strengths and regional priorities for research and economic growth**
  - **Information technology leader-N.Va.Internet**
  - **High-quality &majority state-affiliated universities/colleges-no big private players**

# George Mason University

Molecular Biology Submission Criteria, Privacy



**James Madison University**  
Data Security

**The Valley**

**University of Virginia**  
Outcomes, HIPAA, Ethics, Project Management

**UVA Health System**

**Carilion**

**Virginia Tech**  
Computer Software Dev.

**Bon Secours & VCU**  
Health Systems

**Sentara**

**College of William & Mary**  
Web Interface, Behavior Therapy

**EVMS**

**Va Dept. Health**

**IBM**

**Virginia Commonwealth University**  
CTRF Cancer Genomics Grant, Super Computing Cluster, Pilot Site for Data Integration

