

# Building a Non-mandatory Enterprise System Key Factors for Success

**February 9, 2011**

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# Seven Factors for Success

The Biomedical Translational Research Information System

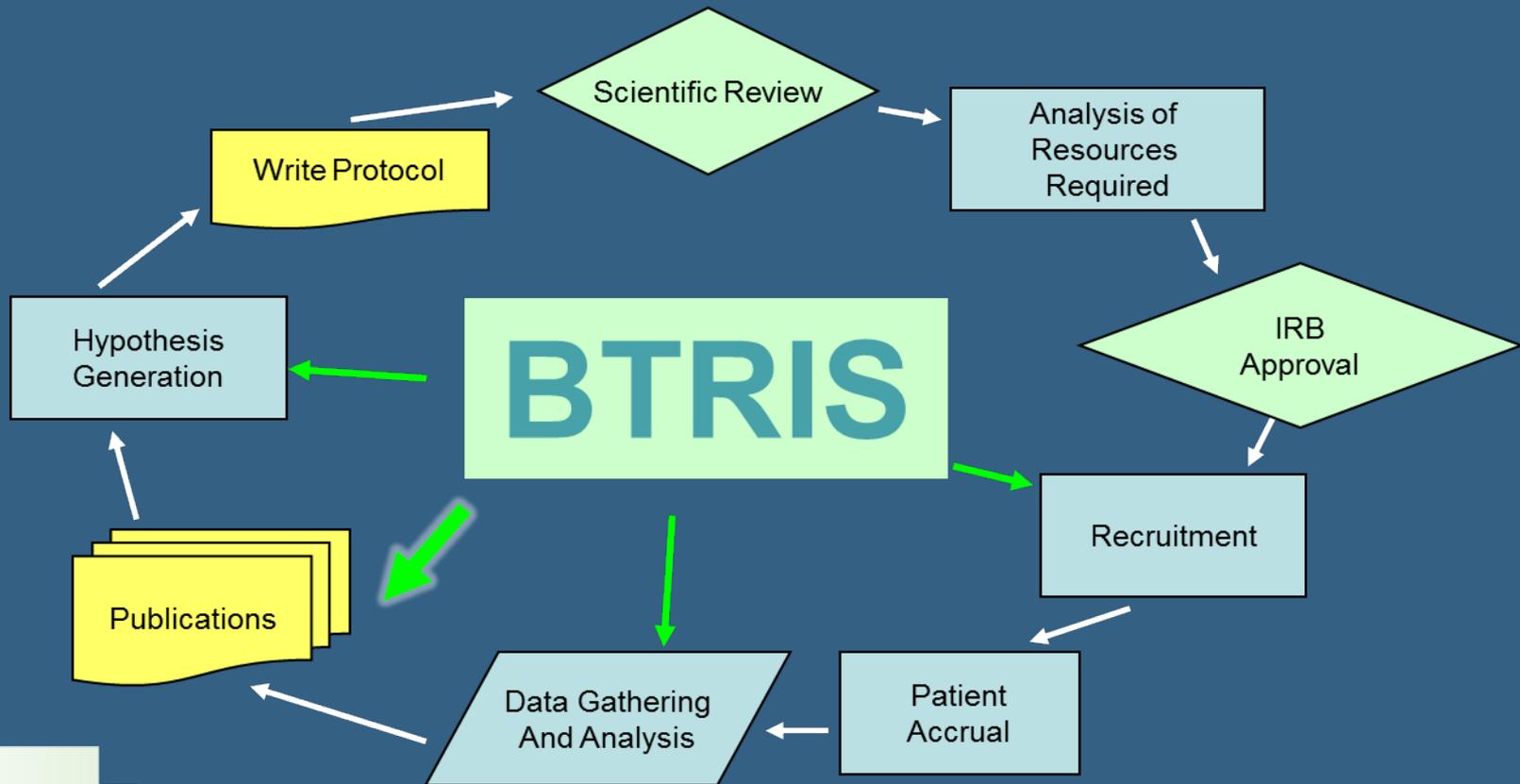
- 1) Define a clear purpose for the system
- 2) Create a system architecture that allows for optimum use of source data
- 3) Establish a data model that enables effective data storage and retrieval
- 4) Create an approach to terminology that allows utilization of data from disparate sources

# Continued

- 5) Develop a user interface that allows users to create their own queries
- 6) Establish clear policies and procedures for data use and data sharing that are accepted by institutional leadership
- 7) Ensure trans-institutional governance to ensure support and on-going funding for the system

# 1) Purpose of BTRIS

- How does the system contribute to the IC and NIH mission? *Create efficiencies in the research cycle.*

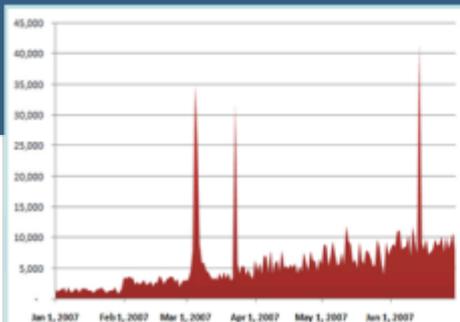
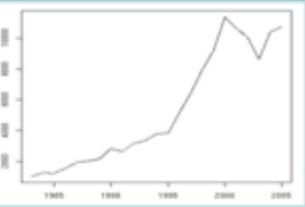
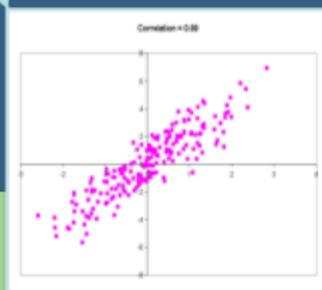
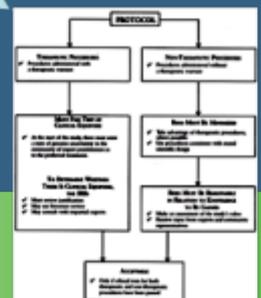
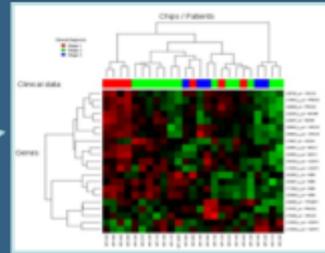
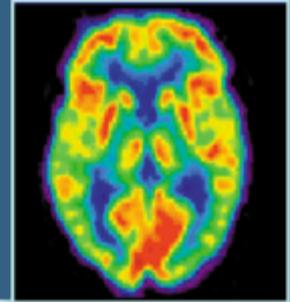


# What is BTRIS?

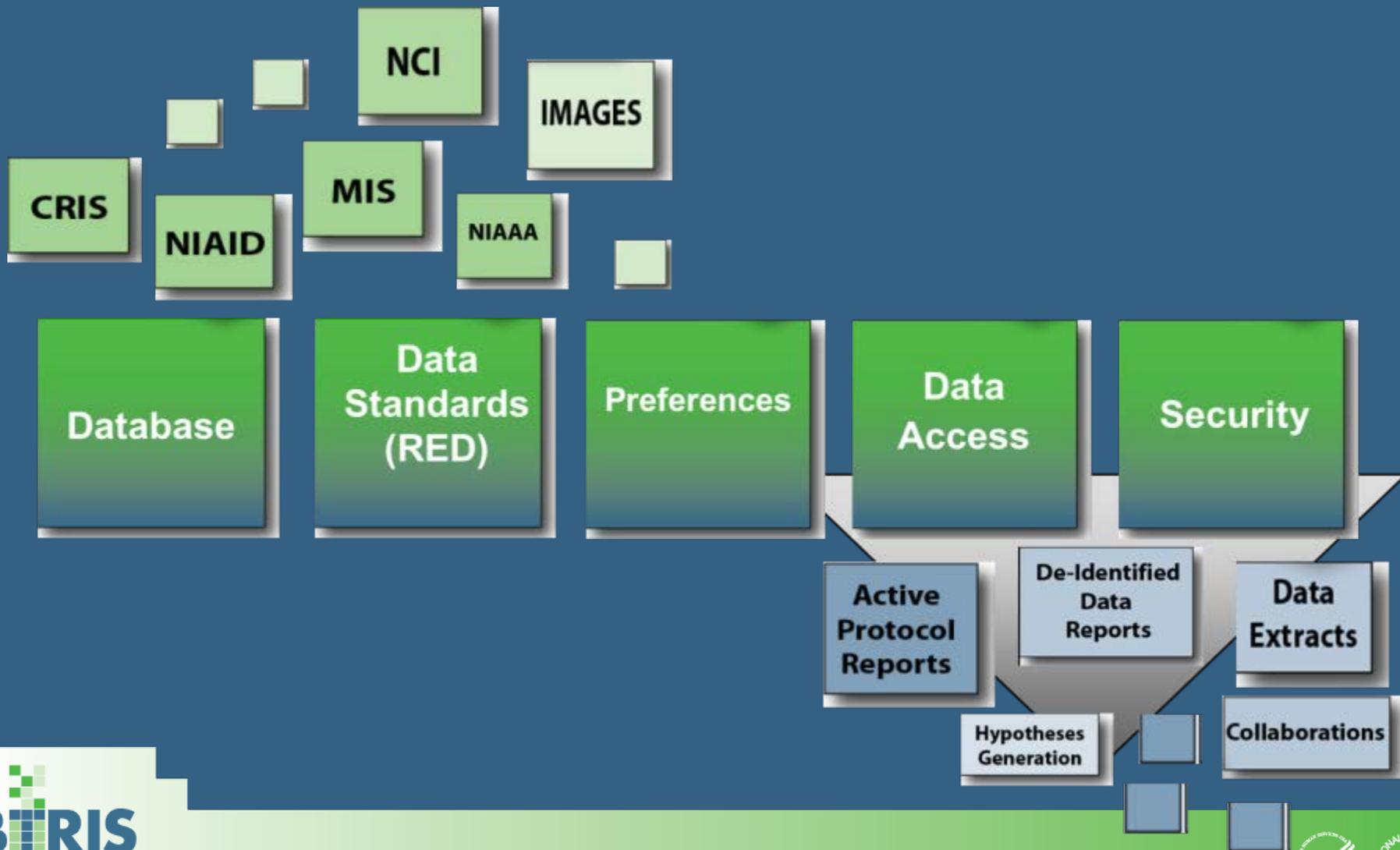


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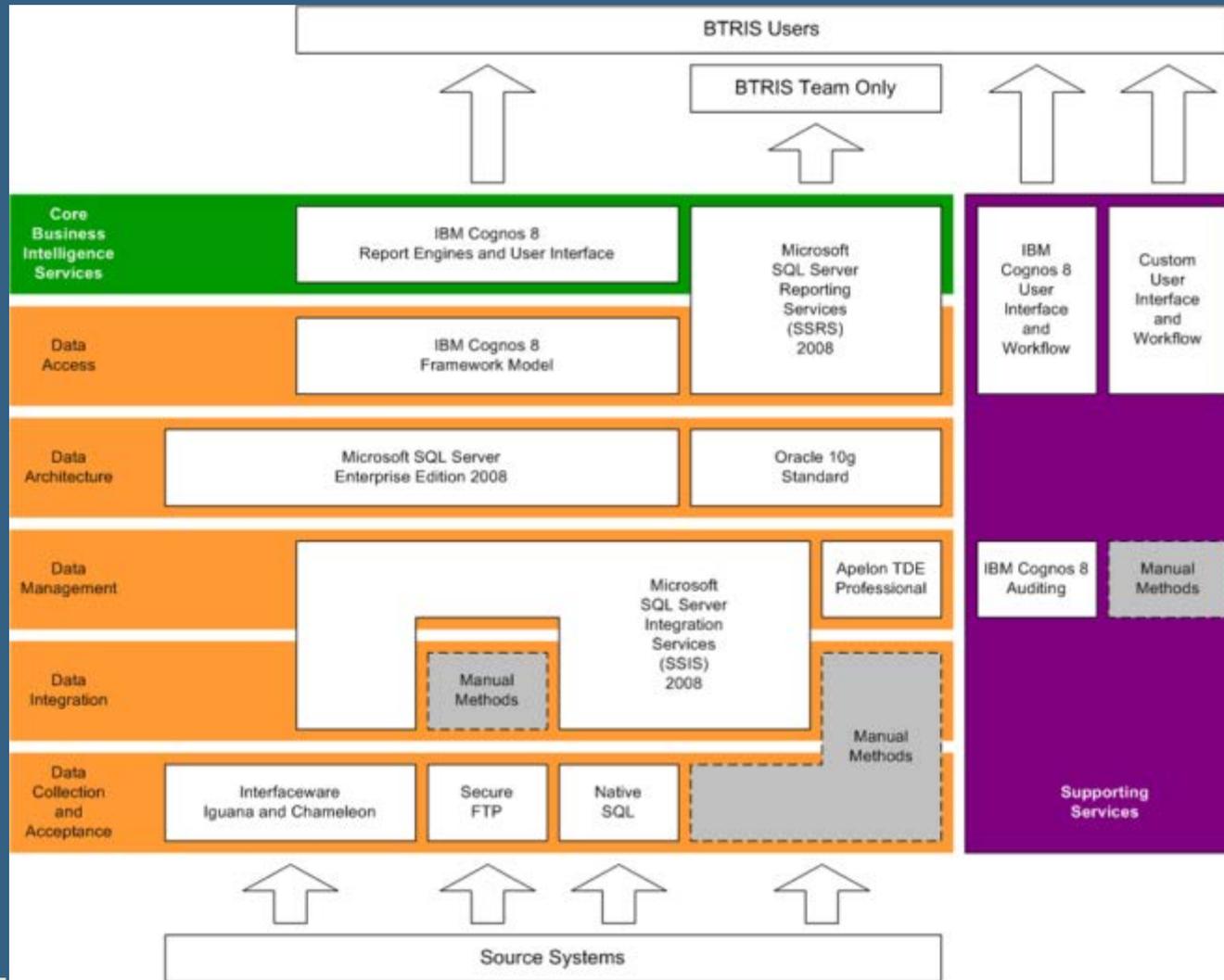
**Abstract**  
 The BTRIS (Bioinformatics Tools for Rapid Identification and Sequencing) pipeline is a novel approach to the identification and sequencing of DNA. It is designed to be used in conjunction with high-throughput sequencing technologies such as microarrays and next-generation sequencing. The pipeline consists of a series of steps that allow for the rapid identification and sequencing of DNA. The first step is the identification of potential targets. This is done by comparing the target sequence to a database of known sequences. The second step is the sequencing of the target. This is done using a high-throughput sequencing technology. The final step is the analysis of the sequencing data. This is done using a series of bioinformatics tools. The BTRIS pipeline is a powerful tool for the identification and sequencing of DNA. It is designed to be used in conjunction with high-throughput sequencing technologies such as microarrays and next-generation sequencing.



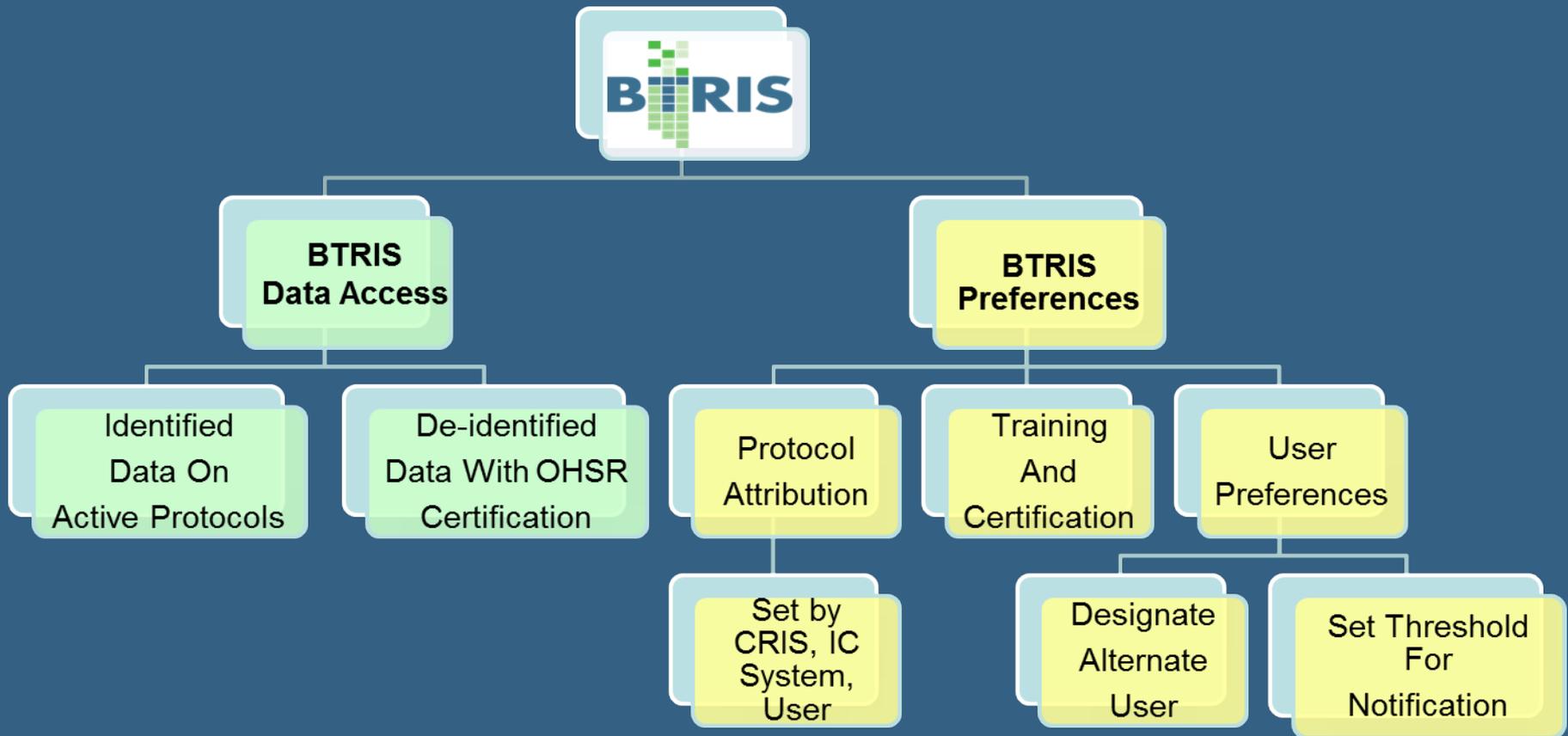
# What is BTRIS?



# 2) Logical Architecture

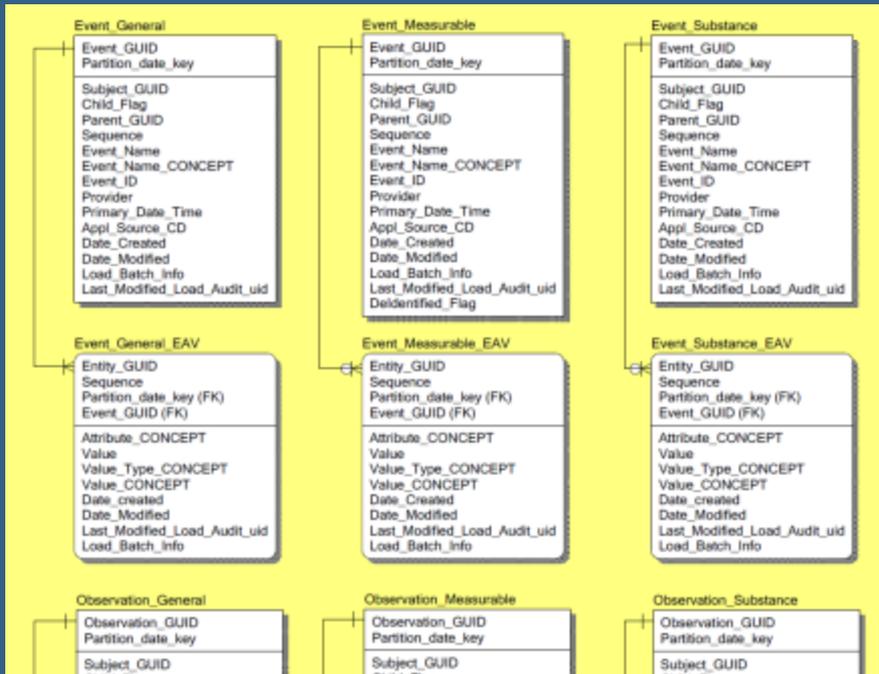


# BTRIS Applications



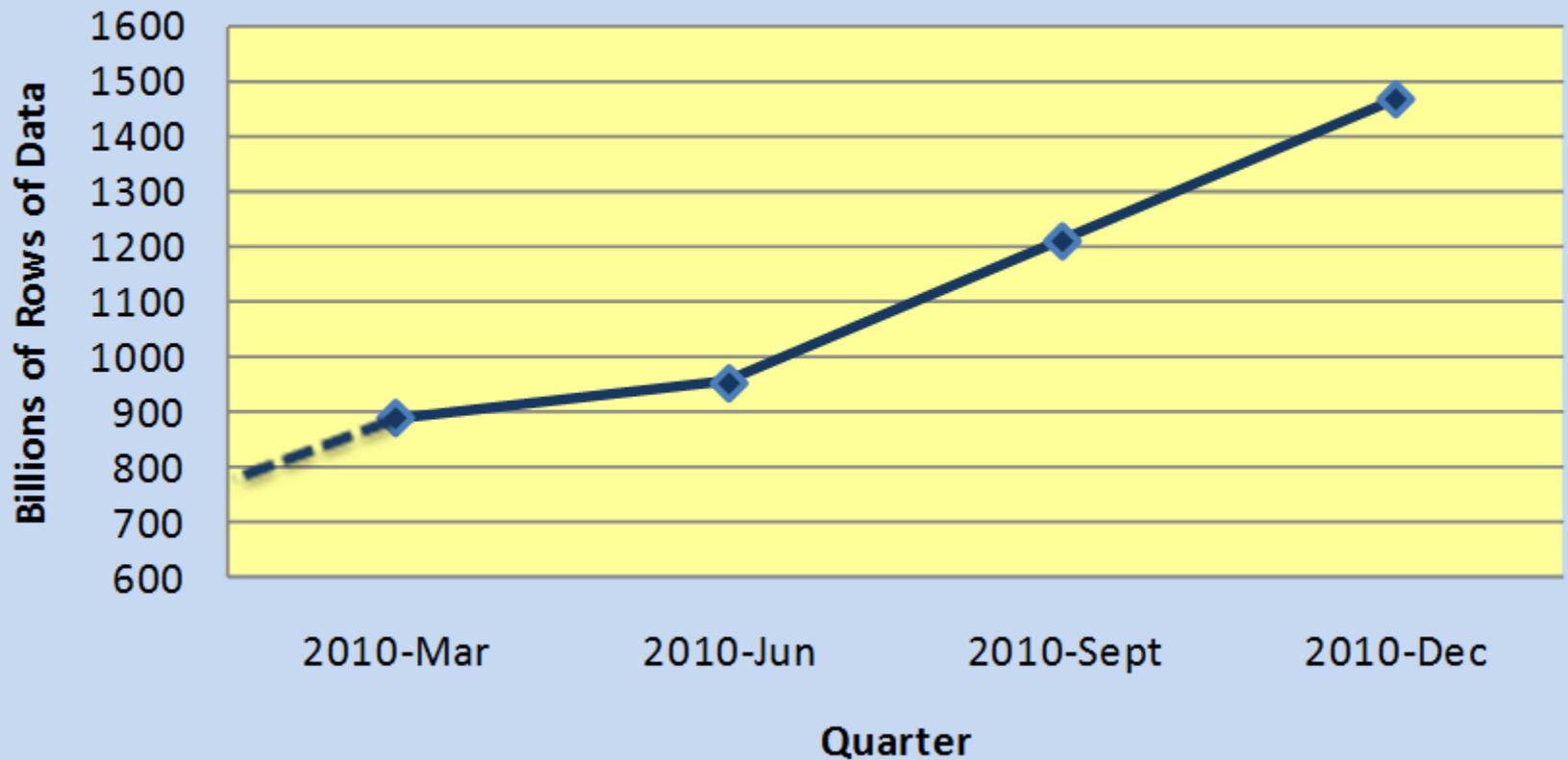
# 3) Data Model

- Hybrid model
- Traditional tables and columns
- Entity Attribute Value (EAV) for unique source specific data



# BTRIS Data Growth

## BTRIS Data Growth



# Data in BTRIS

CRIS (Hospital Information System)		
1	Alert data	8/21/2004 - Current
2	Anatomic Pathology	3/01/1999 - Current
3	Blood Bank	1976 - Current
4	Clinical Documentation	8/21/2004 - Current
5	Demographics	8/21/2004 - Current
6	Diagnosis Codes	1989 - Current
7	Echo	6/21/2007 - Current
8	EKG	10/02/2000 - Current
9	Laboratory	3/01/1999 - Current
10	Medications	8/21/2004 - Current
11	Microbiology	3/01/1999 - Current
12	Radiology	8/21/2004 - Current
13	Vital Signs	8/21/2004 - Current
14	ADT	TBD
15	Allergy	8/21/2004 - Current
16	Orders	TBD
17	Other Observations	8/21/2004 - Current
18	Pain and Palliative Care	7/09/2007 - Current
19	Pulmonary Function Tests	8/21/2004 - Current
20	Radiology Images	TBD
21	Radiology and Diagnostic Images	8/21/2004 - Current

MIS (Legacy Hospital Information System)		
22	Blood Bank	1976 - 2/28/1999
23	Demographics	1976 - 8/20/2004
24	Laboratory	1976 - 2/28/1999
25	Microbiology	1976 - 2/28/1999
26	Vital Signs	1976 - 8/20/2004
27	Anatomic Pathology	1976 - 2/28/1999
28	Medications	1976 - 8/20/2004
29	Radiology	1976 - 8/20/2004
30	Other Reports	1976 - 8/20/2004
Protrak		
31	Protocol 1195	1962 - Current
NCI		
32	C3D Repository	2002 - Current
33	Lab Matrix	2005 - Current
NIAID		
34	Laboratory	1994 - Current
35	Medications	1994 - Current
36	Clinical Problem List	1994 - Current
NIAAA		
37	Clinical Assessments	8/30/2008 - Current

Since January 2010

# 4) Terminology

- Research Entities Dictionary or “RED”
- A controlled terminology
- Allows for common and unique concepts
- Each concept has a unique code
- Codes are in hierarchies to allow for class-based queries or leaf-node queries

# Biomedical Translational Research Information System

The screenshot shows the BTRIS website interface. At the top, the browser address bar displays <https://btrispreferences.cc.nih.gov/AuthFree/Welcome.aspx>. The page header features the BTRIS logo and the text "BIOMEDICAL TRANSLATIONAL RESEARCH INFORMATION SYSTEM" and "National Institutes of Health".

The main content area is titled "Welcome to BTRIS" and includes the following text:

The Biomedical Translational Research Information System (BTRIS) is a resource available to the NIH community that brings together clinical research data from the Clinical Center and other NIH Institutes and Centers. BTRIS provides clinical investigators with access to identifiable data on for the subjects on their own protocols, while providing all NIH investigators with access to de-identified data across all protocols.

BTRIS provides users with advanced search, filtering, and aggregation methods to create data sets to support ongoing studies and stimulate ideas for new ones. All investigators may review and update the lists of subjects attributed to their protocols using the BTRIS Preferences functions. Use of the BTRIS Data Access functions requires a license. Links for all of these and more may be found in the menu to the left.

The left sidebar contains a "Resources" section with links for "Training & User Guides", "Presentations", "Request Access to BTRIS", "Subject Attribution", and "Reference Materials". Below this is "BTRIS Customer Support" information, including a "Submit Comment" link, contact hours (M-F 8:30am to 5pm), phone number (301-827-8270), and email address ([BTRISsupport@nih.gov](mailto:BTRISsupport@nih.gov)). The page is dated "Updated: January 14, 2011".

The right sidebar features "System Updates" and "Research Entities Dictionary". The "System Updates" section lists "Data Available in BTRIS (21 KB)", "PC/MAC Browser Requirements (18 KB)", and "BTRIS Current Release Updates (74KB)". The "Research Entities Dictionary" section invites users to "Browse the Research Entities Dictionary (RED) for search terms and codes used in BTRIS queries." A large red arrow points from the diagram towards this section.

The central diagram illustrates the BTRIS system structure:

- BTRIS** (Root)
  - BTRIS Data Access**
    - Identified Data on Active Protocols
    - De-identified Data with OHSR Certification
  - BTRIS Preferences**
    - Protocol Subject Attribution
    - Designee Selection
    - Threshold for Notification

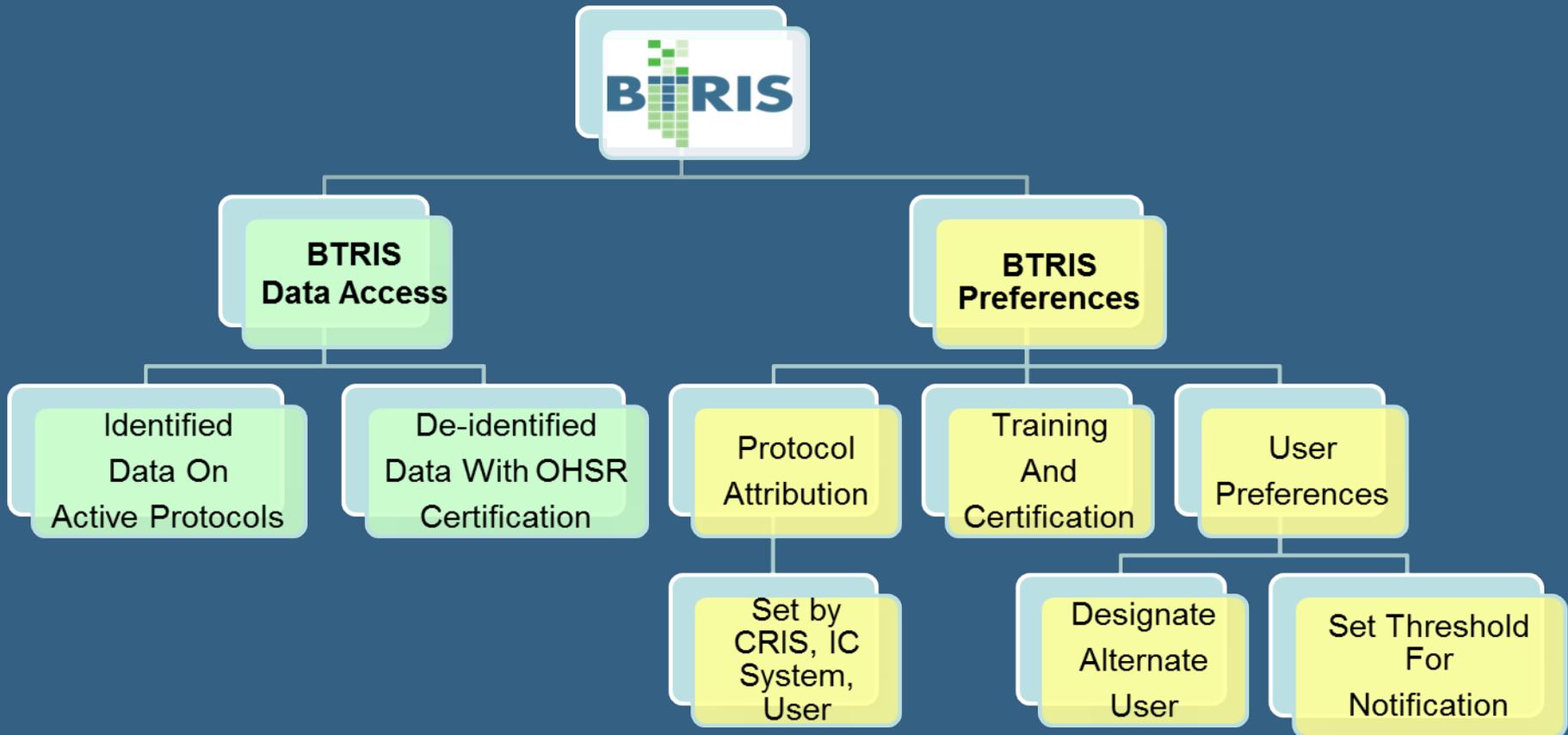
Below the diagram, a note states: "This graphic shows the two applications within BTRIS; BTRIS Data Access and BTRIS Preferences. BTRIS Data Access allows researchers to access identified data on active protocols, or de-identified data with approval from the Office of Human Subjects Research. BTRIS Preferences allows researchers to attribute subjects to their protocols, designate alternate users, and set thresholds for e-mail notifications."

A note at the bottom left states: "NOTE: PDF documents require the free [Adobe Reader](#)".





# 5) User Interface



# BTRIS Users

**297**  
BTRIS Users

+

**201**  
Non-  
BTRIS PIs

=

**498**  
BTRIS  
Beneficiaries

# Reports - Identified Data on Active Protocols

Select a report from the selections on the left side of screen. Report prompts and reports will display on right side of screen.

**Summary Reports**

Name ⇅

- IRB Inclusion Enrollment

**Subject Data Reports**

Name ⇅

- Alerts
- Clinical Documents
- Demographics
- Diagnosis
- Echocardiogram
- EKG
- CBC Panel
- Chem 20 Panel
- Laboratory Panel(s)
- Laboratory Test(s)
- Microbiology
- Pathology
- Medication Orders
- Medication Administration
- Radiology
- Transfusion
- Vital Signs

**Lists**

Name ⇅

- Laboratory Panel

[Back to default entry](#)

## **CBC with Differential Report**

Select "Protocol Number (s)" first (mandatory). All other prompts are optional. After completing desired prompts, click "Run Report" to begin running report.

Cancel

Run Report

**Please select one or more Protocol Number(s)**The number in ( ) indicates the verified subjects in the protocol. Reports will include data on ONLY verified subjects. You can verify, exclude or add subjects in [BTRIS Preferences](#)

**(Optional) Please Click 'Subject List' to Display and Select One or More Subject(s)/MRN(s)**

Subject List

- \* 08-H-0108 -- (224 of 225 verified)
- 09-CC-N202 -- No subjects identified
- 93-I-0119 -- (1297 of 1339 verified)**
- BTRIS-TEST-00 -- All 21 verified
- BTRIS-TEST-01 -- All 21 verified
- BTRIS-TEST-02 -- (1 of 23 verified)

[Select all](#) [Deselect all](#)

# Reports - Identified Data on Active Protocols

Select a report from the selections on the left side of screen. Report prompts and reports will display on right side of screen.

**Summary Reports**

Name ⇅

- IRB Inclusion Enrollment

**Subject Data Reports**

Name ⇅

- Alerts
- Clinical Documents
- Demographics
- Diagnosis
- Echocardiogram
- EKG
- CBC Panel
- Chem 20 Panel
- Laboratory Panel(s)
- Laboratory Test(s)
- Microbiology
- Pathology
- Medication Orders
- Medication Administration
- Radiology
- Transfusion
- Vital Signs

[Back to default entry](#)



**My Selections:**

Protocol(s) selected:	93-I-0119 -- (1297 of 1339 verified)
Collected Date Range selected:	From: All Dates To: All Dates
Number of Days Range selected:	From: All Days To: All Days

**Report Format**

\* Colors

**Subject Count:** 1,096

**Record Count:** 52,013

HH ■ H ■ N ■ L ■ LL ■ AA ■

Protocol Number	MRN	Subject Name	Initial Consent Date	Order Name	Collected Date	WBC Count (K/mcL)	RBC Count (M/mcL)	Hemoglobin (g/dL)	Hematocrit %	MCV (fL)	RDW %
93-I-0119	3	F F F	Jul 29, 1997	PANEL	Aug 4, 1997 9:30:00 AM	8.04	0	13.6	38.8	90	14.7
	3	Al Al	Jul 29, 1997	PANEL	Aug 4, 1997	6.29	0	14.6	41.5	90	14.1

# Radiology & Imaging Report

Select "Protocol Number (s)" first (mandatory). All other prompts are optional. After completing desired prompts, select "Finish" to begin running report.

Cancel

Run Report

**Please select one or more Protocol Number(s)**The number in

( ) indicates the verified subjects in the protocol. Reports will include data on ONLY verified subjects.

You can verify, exclude or add subjects in [BTRIS Preferences](#)

- 93-I-0057 -- (219 of 220 verified)
- 93-I-0063 -- (513 of 545 verified)
- 93-I-0086 -- (182 of 184 verified)
- 93-I-0106 -- (28 of 37 verified)
- 93-I-0119 -- (1297 of 1339 verified)**
- 93-M-0170 -- (1461 of 2180 verified)
- 93-N-0202 -- (2254 of 3412 verified)
- 94-AR-0066 -- (734 of 859 verified)
- 94-AR-0105 -- (858 of 1023 verified)
- 94-C-0074 -- (79 of 80 verified)
- 94-CH-0103 -- All 73 verified

[Select all](#) [Deselect all](#)

**(Optional) Please Click 'Subject List' to Display and Select One or More Subject(s)/MRN(s)**

Subject List

### (Optional) Please Select a Radiology Test

- Radiology and Imaging Procedure Observation
  - Imaging by Body Region
    - Abdomen & Pelvis, Imaging
    - Breast, Imaging
    - Chest, Imaging
      - Central Cardiovascular System, Imaging
      - CT BX - Mediastinum (CC, RADNET)
      - CT Chest (CC, RADNET)
      - CT Chest (High Resolution) (CC, RADNET)
      - CT Chest + Abdomen (CC, RADNET)
      - CT Chest, Abdomen + Pelvis (CC, RADNET)
      - CT Mediastinum (CC, RADNET)
      - DX Chest - Apical Lordotic (CC, RADNET)
      - DX Chest - Decub - Bilateral (CC, RADNET)
      - DX Chest - Decub - LT (CC, RADNET)
      - DX Chest - Decub - RT (CC, RADNET)
      - DX Chest - Inspiration / Expiration (CC, RADNET)
      - DX Chest - Oblique(s) (CC, RADNET)
      - DX Chest - PA + Lat (CC, RADNET)



## Radiology & Imaging Report

**My Selection(s):** Access to images is in DEMONSTRATION mode. Please direct all questions to [BTRISsupport@mail.nih.gov](mailto:BTRISsupport@mail.nih.gov)

Protocol(s):	93-I-0119 -- (1297 of 1339 verified)
Radiology Test(s):	Chest, Imaging
Test Date Range:	From: All Dates To: Current Date
Days Range relative to Subject Initial Consent Date:	Start: All Days End: All Days
Report Text Value	No search text values entered

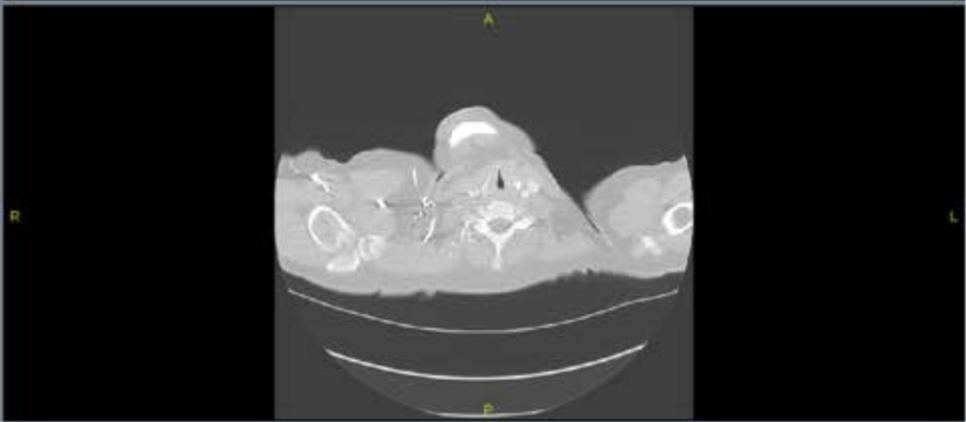
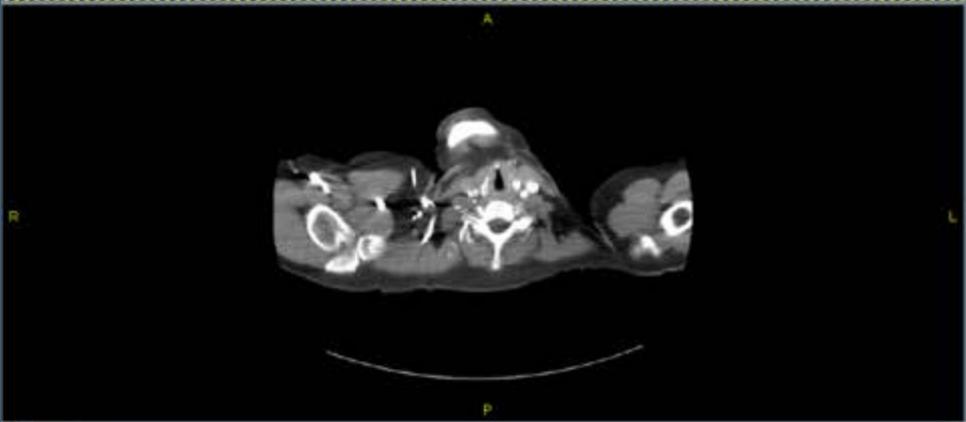
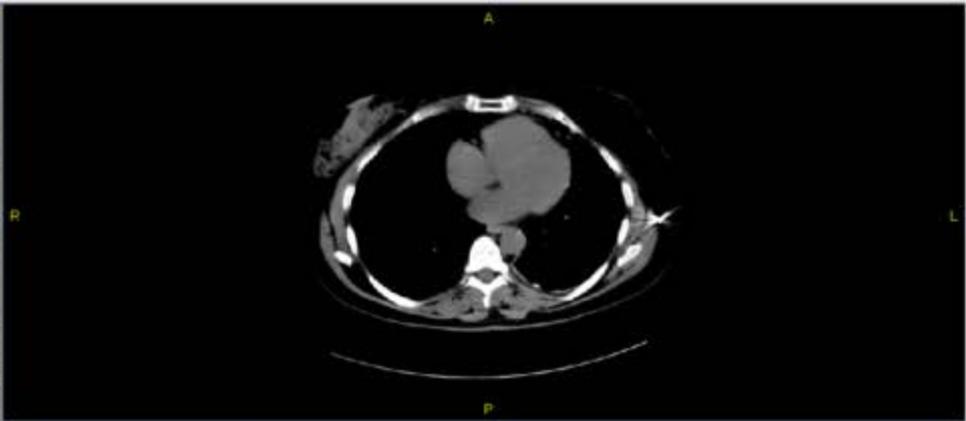
**Subject Count:** 536

**Record Count:** 6,522

Protocol Number	MRN	Subject Name	Result Date	Test Name	Report Text	Link to Image(s)	Status	Initial Consent Date	Data Source
93-I-0119	0 3	L V ,	Dec 8, 2006 6:14:45 PM	CT Chest	CT-06-163081066031 Exam: Exam Date: Accession #: CT Chest 12/7/06 CT-06-16308 3:17:57 PM Report: HISTORY: Suspected congenital contractural arachnodactyly with previous right upper lobe lobectomy, evaluate for possible underlying disease. FINDINGS:	<a href="#">CT0616308</a>	F	Nov 30, 2006	CC-Radiology



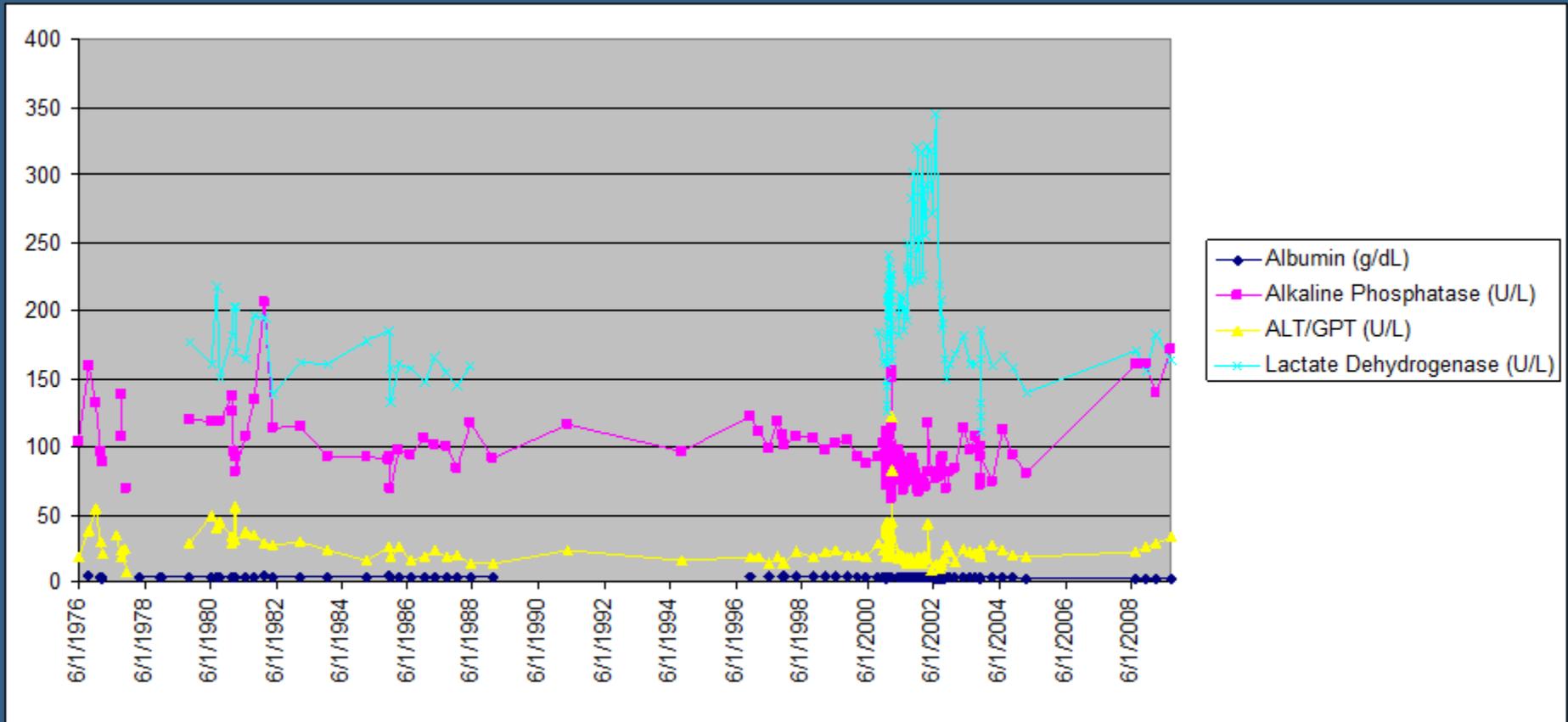
RemoteEye application window title bar and menu bar (File, Edit, View, etc.)



Series browser showing thumbnails for different image slices and a selected image.

Active tools and status information: Currently loaded, Current frame, Current zoom.

# 33 years of Data



# Data Extracts

- Data also available for extracts
- Three methods:
  - Run queries in Cognos
  - Direct database connection (ODBC)
  - BTRIS Web Access (BWA) – an HL7 data service
- NCI and NIAID using BWA
- Other IC's using ODBC

## 6) Establish Clear Policies and Procedures

- BTRIS Policy Committee composed of investigators
- Data sharing and use policies approved by Director, NIH
- Modified over the past two years to include new types of users

# 7) Project Governance

- CRIS Steering Committee governs project
- Entirely funded by ITWG
- Multiple sub-committees
  - Policy
  - Data Access
  - User Group
  - Clinical Trial Management Systems (new)
  - Hand Held Devices

# Accomplishments for 2010

- Images from the CC PACs now available in the BTRIS radiology report
- NCI research data from two systems is available to NCI researchers
- Created a web application for BTRIS data extracts to IC systems
- Subject attribution improving based on input from investigators
- User base increased from 120 to 297 over past year

# 2011 Development

- Add NHGRI from LabMatrix system
- Add NICHD data from CTDB system
- Develop pilot of ClinicalTrials.gov report

# Performance Metrics

- Enhanced user satisfaction compared to baseline
- Ability to access data needed for analysis
  - Data available (numeric, reports, images, specimens)
  - User requests to add data for increased functionality
- Utilization rates of targeted groups
- Efficiency improvements to research cycle (throughput)
- Impact on publications

# Challenges

- Adding additional data
- System performance
- User workflow
- Pressure to take on additional functionality