## BTRIS

"BIOMEDICAL TRANSLATIONAL RESEARCH INFORMATION SYSTEM"





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#### WHAT IS BTRIS?



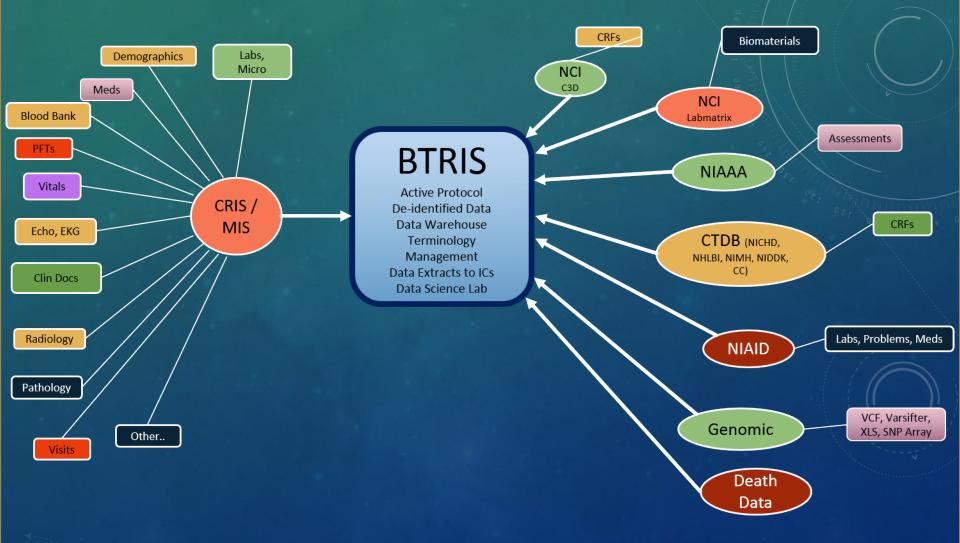
An enabling platform for research and patient care

39% of clinical protocols use BTRIS





## DATA WITHIN BTRIS



https://btrisportal.cc.nih.gov/pdfs/userGuides/BTRIS\_Data\_Availability.pdf







#### DATA WITHIN BTRIS

- EMR
  - o CRIS
  - Legacy MIS
- IC
  - Select case report form data
    - NCI, NIAAA, NICHD, NIMH, NIDDK,
  - Select Genomics data
  - NIAID CRIMSON Laboratory data, Problem lists, Medications
- Death Data SSA





## NOT ALL DATA ARE IN BTRIS

- Some data not in a format useful to research
  - IC systems send PDF reports to CRIS
  - **SOLUTION: Working with ICs to obtain raw data**
- No requirement to deposit all clinical research data to BTRIS
  - Some IC's have their own systems
  - All data sources must be individually negotiated
  - Lack of uniform Policy

**SOLUTION: NIH policy for data submission to BTRIS** 



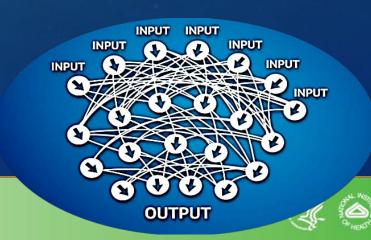




# WHAT IS BTRIS (CONT.)?

- Intramural clinical research support
  - Primarily protocol based
  - Secondary research, data reuse
    - OAI, Machine Learning
- Quality control / Quality assurance
  - Program / protocol
  - Hospital





#### **BTRIS IS NOT**

- A clinical care system
- A Clinical Trial Management System (CTMS)







## DIFFERENT FROM CRIS (CLINICAL RESEARCH INFORMATION SYSTEM)

- CRIS EMR-supports patient care one patient at a time
- BTRIS supports data across patients
  - **OCRIS** data downloaded daily
  - **Oldentified or Deidentified data provided**
  - **OSupports PI research data**







#### BTRIS DATA SOURCES

#### 1976 - Present

- 6 TB
  - CRIS + retired records (MIS)
  - 11,000 Protocols / 2,200 active & 8,900 terminated
  - 500,000 + Patients
  - 15 M Observations
  - Semi-structured documents
    - Pathology, Radiology, Operative, Inpatient ...
- **Data held indefinitely**







#### BTRIS SERVICES

Analysis, manipulation & correlation of phenotype elements across pts

- Identified data within a protocol
- Deidentified across entire BTRIS data set (Intramural data sharing)





# BTRIS SERVICES (CONT.)

- Data
  - Analysis
  - Visualization
  - Organization / structure
  - Curation, organization, text mining
  - Exploration for hypothesis generation
  - Custom search for research and QA/QC





# BTRIS SERVICES (CONT.)

- Regulatory submissions
  - ClinicalTrials.gov
  - Center for International Blood & **Marrow Transplant Research** (CIBMTR)
- Patient consent management
- Data to IC systems







# QA / QC ACTIVITIES







# BTRIS QA/QC



- Perfect platform for data QA/QC
- Data mining does not impact patient care
- Fully explore all data from all patients
  - Ideal for research or hospital metrics







# BTRIS QA/QC

- Boutique services provided for each problem
  - Not turn-key
  - Presentation varies
  - Pulls data from multiple sources to single platform





#### RECENT PATIENT CARE QA/QC PROJECTS

- Glucometrics
- ICU Sepsis
- Pediatrics
  - Blood Draw Volumes
  - Pre-admission order set analysis
  - Heights
- Bone Marrow Transplant
  - o QA/QC
  - o GVHD
- Antimicrobial days' metrics
- Radiology







### RECENT PATIENT CARE QA/QC PROJECTS

- Bone Marrow Transplant
  - OQA/QC
  - **OGVHD**







## STEM CELL TRANSPLANT QA/QC

- Collated multiple protocols into a single view
- Robust data curation
- Simplified regulatory submission





#### **GVHD**

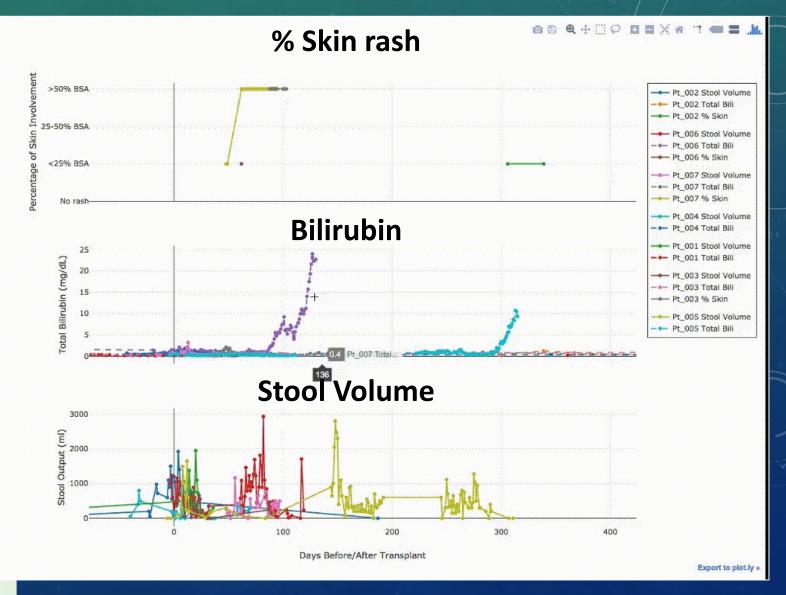
- Interactively visualized GVHD and engraftment markers across patients to quickly identify trends
  - Stool volume, % skin rash, bilirubin







## **GVHD INTERACTIVE MARKERS**









## **OUTCOME GVHD ANALYSIS**

- Visualize trends
- Modify protocol in real time
- Assist overall GVHD patient grading







#### **CHALLENGES**

Not all clinical or research data included or in a standard structure

- IC specific care summary not discrete data
- Protocol objectives not provided
   (would facilitate data curation for publication and <u>ClinicalTrials.gov</u> filing)
- No comprehensive research data policy





