University of Massachusetts Medical School

eScholarship@UMMS

May 16th, 10:15 AM

UMMS Biomedical Data Assets & D3Health

Jomol Mathew
University of Massachusetts Medical School

Let us know how access to this document benefits you.

Follow this and additional works at: https://escholarship.umassmed.edu/cts_retreat

Part of the Health Information Technology Commons, and the Translational Medical Research Commons

UMMS Biomedical Data Assets & D3Health

Jomol Mathew, Ph.D.
May 15, 2017

Disclosures:

I have no actual or potential conflict of interest in relation to this program/presentation.

University of Massachusetts is Uniquely Positioned to be a Game Changer in Healthcare

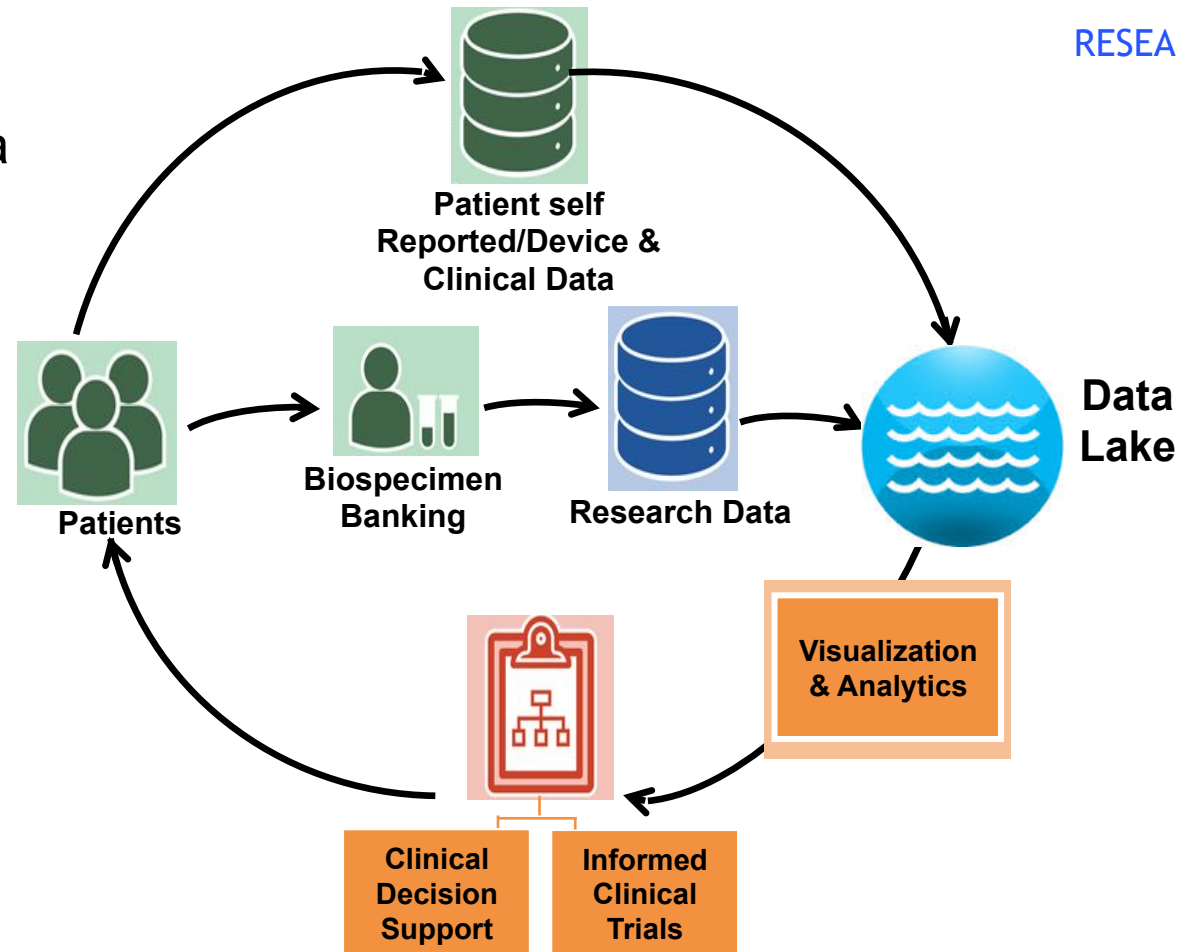# Patients generate useful data that is not available to health care providers

We will break down barriers to integrate data & make it available for clinical decision making

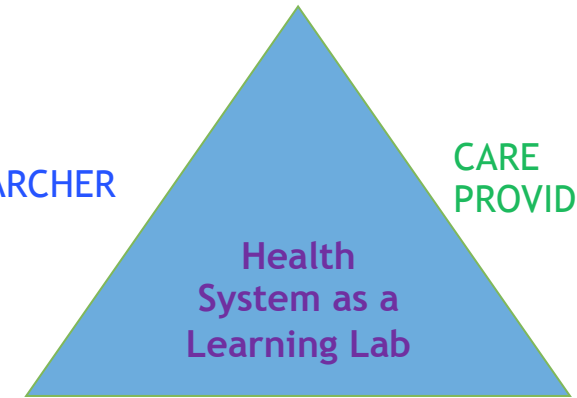# Our Clinical and Translational Research Data Ecosystem

Vision: Build an Integrative Clinical & Biospecimen Data Ecosystem to:

- Enable data driven research
- Enable translation of research findings to clinical care
- Make a difference in community and global health

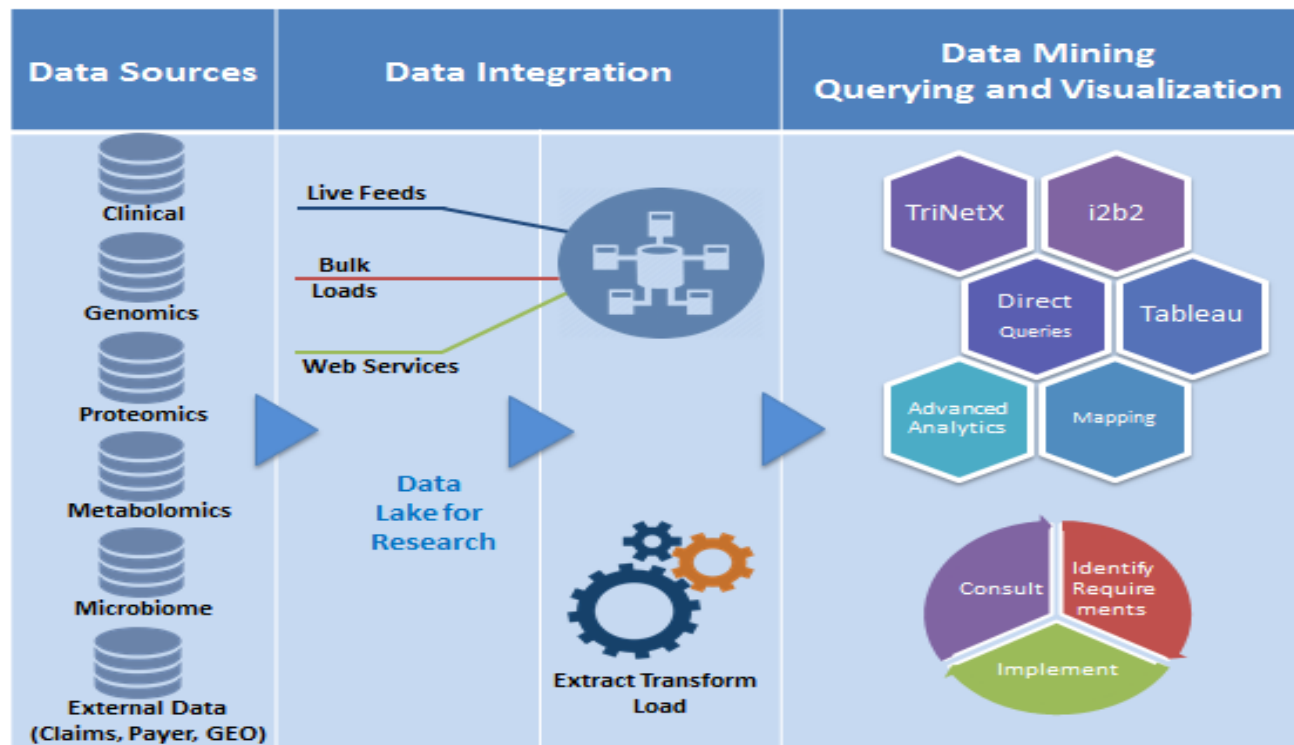Patient self Reported/Device & Clinical Data

Patients

Biospecimen Banking

Research Data

Data Lake

Visualization & Analytics

Clinical Decision Support

Informed Clinical Trials

RESEARCHER

CARE PROVIDER

Health System as a Learning Lab

PATIENT

UMMS Data Lake

Data Lake holds Clinical data from >2.5 Million patients representative of national diversity
- A rich source of data for studying chronic diseases (e.g. cardiovascular, diabetes)
- A useful tool to study genetic diseases (e.g. Cystic Fibrosis, Parkinson's)
- A mechanism to link biosamples, molecular data & digital health data to clinical data

D³Health: Integrating Biomedical Big Data, Analytics, & Decision Support
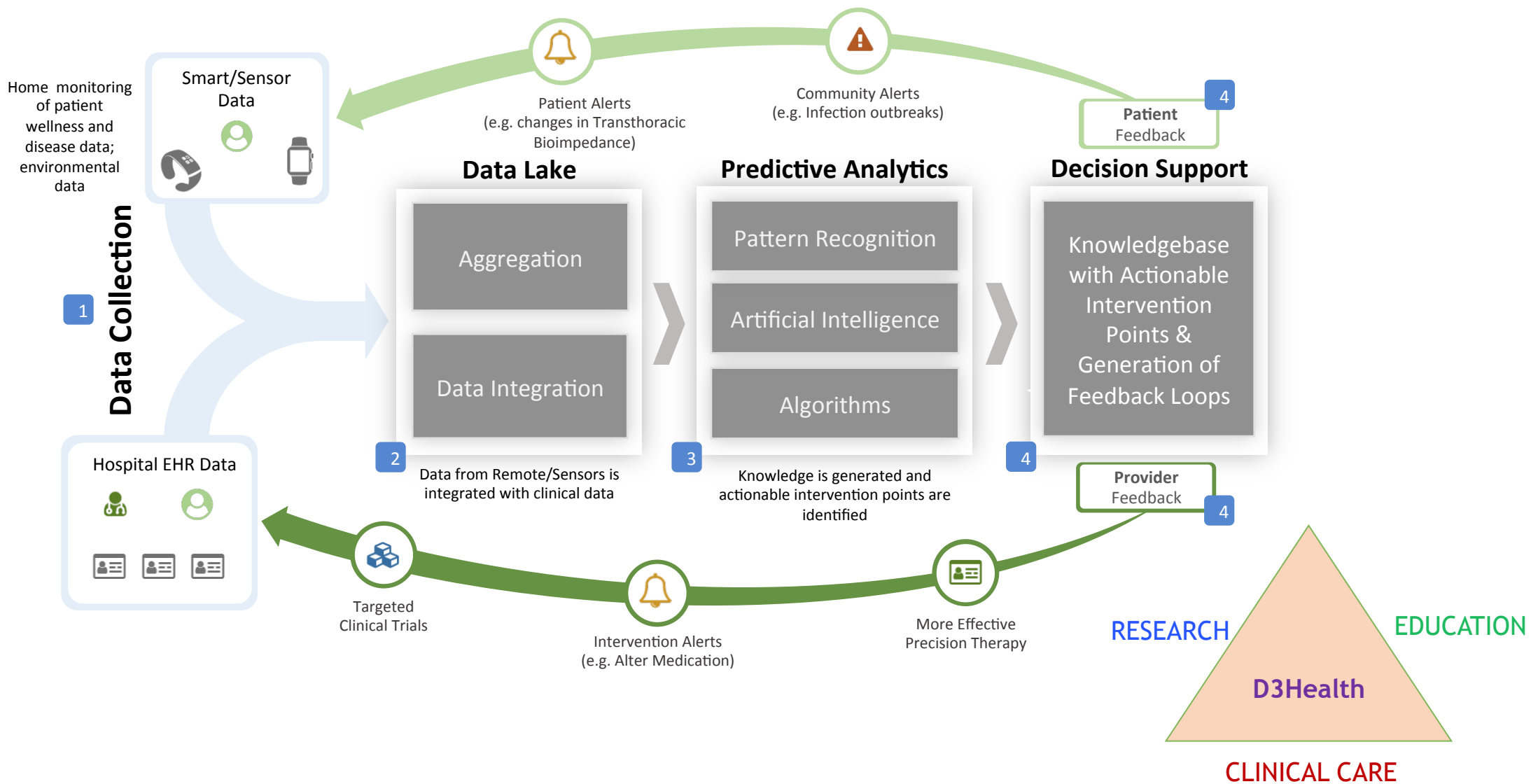
Data Lake & D3Health will helps us study
Diseases..... Continuum of care.....Continuous Learning Cycles...

What causes this disease?

What are the treatment options?

How do I compare to other patients?

Is this condition genetically transferable?

Am I Eligible for a new study?

What is involved in the study?

What are the Potential Adverse Events for the new study?

What Treatment is Better for Me/My Patient?

What is the biological underpinning of this disease?

Are there sub-classes within this disease?

Why does the disease progress faster for some patients?

How does this Patient compare to other patients?

What is the best course of treatment?

Why do some patients develop resistance to drugs?

All there clinical trials targeting the specific genetic alterations found in this patient?

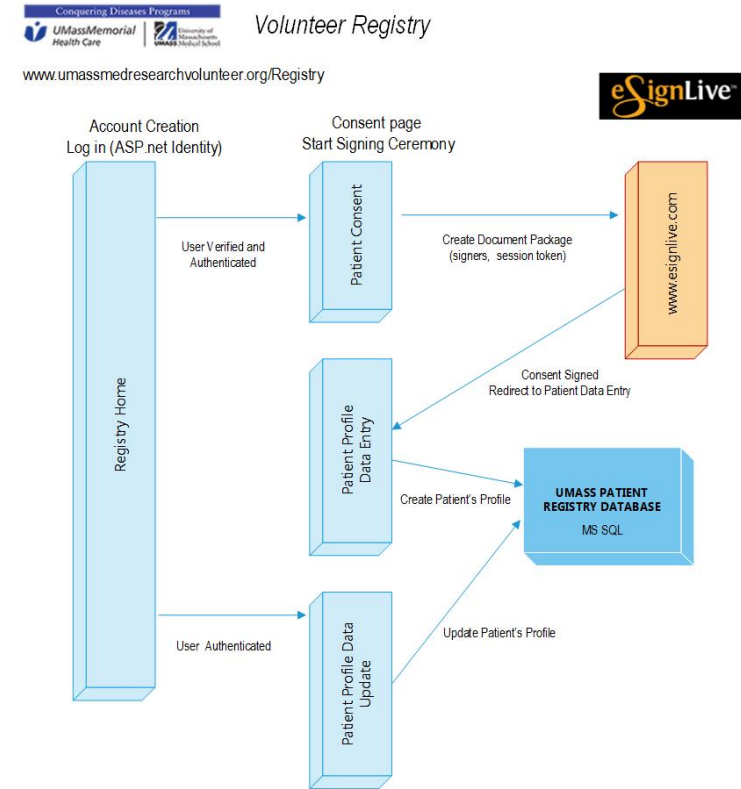Why do some patients respond well/poor to specific drugs?

- Enables Researchers to get a list of patients who have consented to be contacted about upcoming studies

Expanding via
  - Social media
  - Special population resource center
  - Direct to patient tools
  - Recruiting via EHR once EPIC in place

Data Ecosystem Components: OpenSpecimen for BioBanking

Single Shop for Biospecimens

- Consent, collect & barcode
- Create derivatives & keep lineage
- Search & find
- Scan & distribute
- Link to clinical data in Data Lake & facilitate query and request of biospecimens from central biobanks (blood, tumor, microbiome)
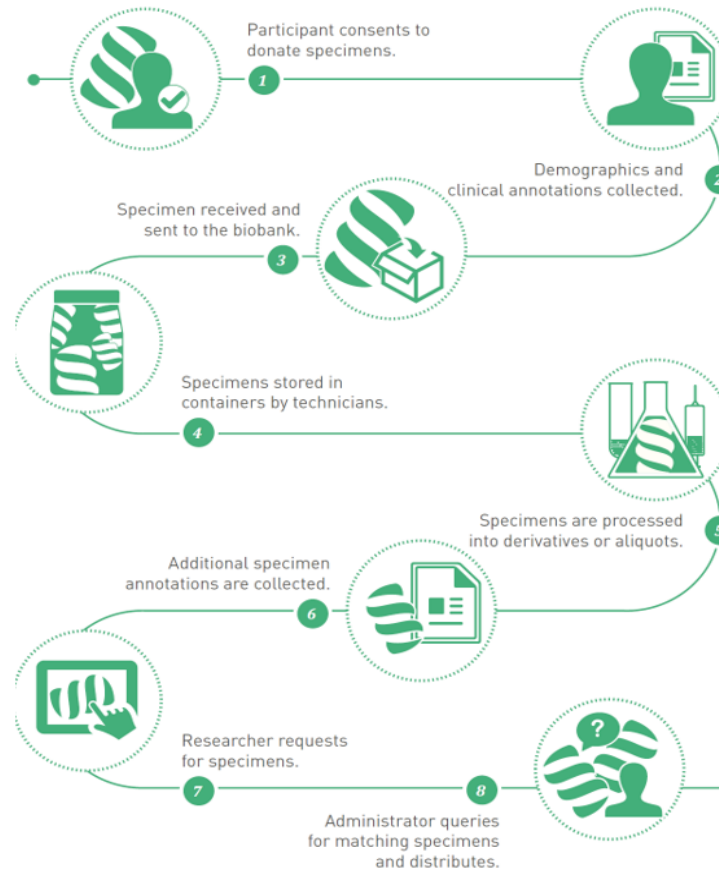
Data Ecosystem Components: LabArchives for Collection & Management of Research Data
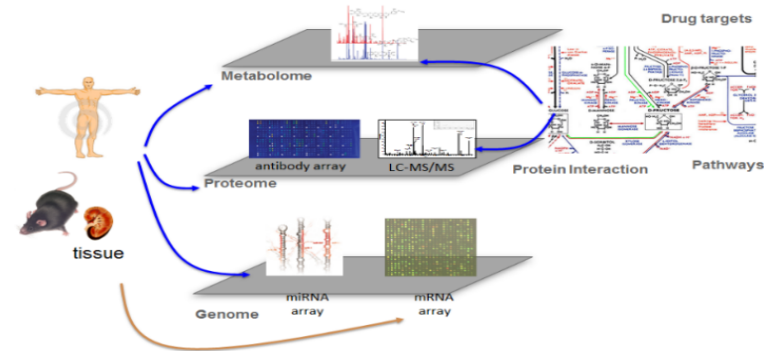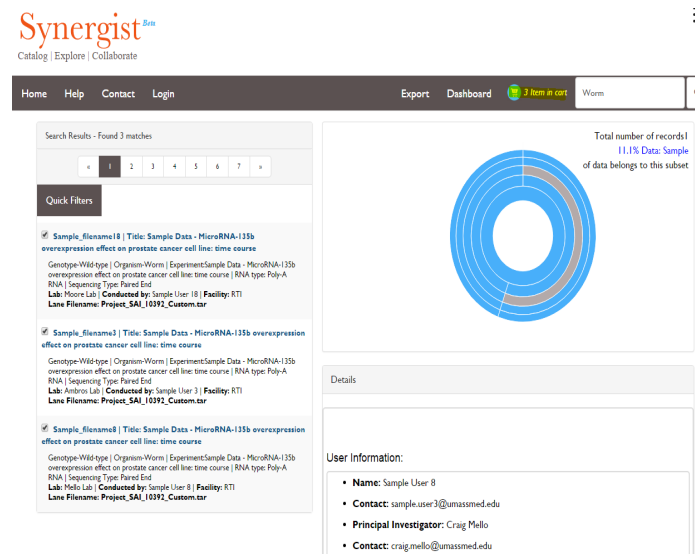
- Electronic Lab Notebook

- Enables easy access to data between lab members and collaborators

- Supports secure data trail (necessary for commercialization)

- ~ 300 Users are using LabArchives

Data Ecosystem Components: Synergist for Searching & Sharing Research Data

"Amazon" of Research data

- Catalog & Share Experimental Metadata
- Search and Discover Data & Collaborate
- Connect & Gain Insights
- Publish & Submit Data to External Data Banks

Data Ecosystem Components: OnCore Clinical Trials Management System

- A leading CTMS platform at Academic Medical Centers

- Integrates well with EPIC to
  - improve patient safety
  - Improve protocol compliance
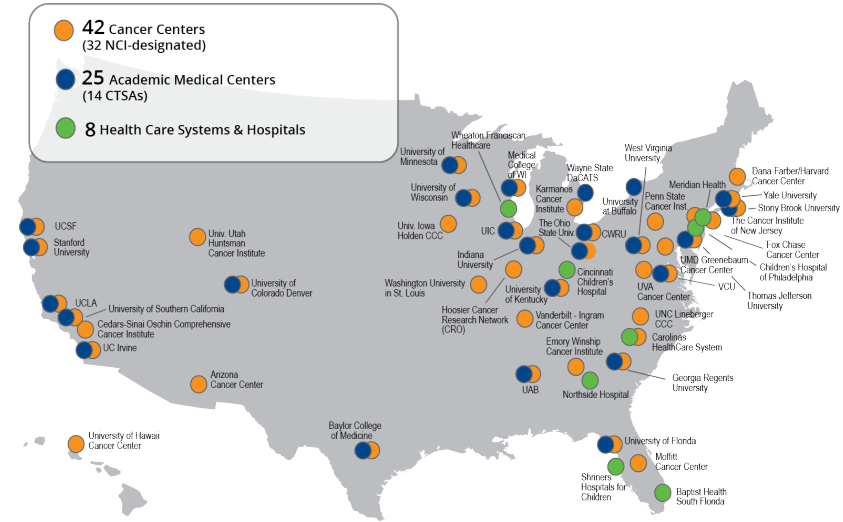
- Went live on 10/21/16
- Onboarding complete by 07/01/2017
- EPIC Integration & go-live by 10/01/2017

Data Ecosystem Components: ONCORE Clinical Trials Management System & EPIC Integration

EHR Primary Concerns:

Comprehensive management of a <u>patient</u> over time

Provide high-quality patient care

Patient safety

Clinical user efficiency and productivity

Research billing compliance (ability to separate clinical and research charges)

CTMS Primary Concerns:

Comprehensive management of a <u>study</u>

Catalogs and tracks all clinical trial processes
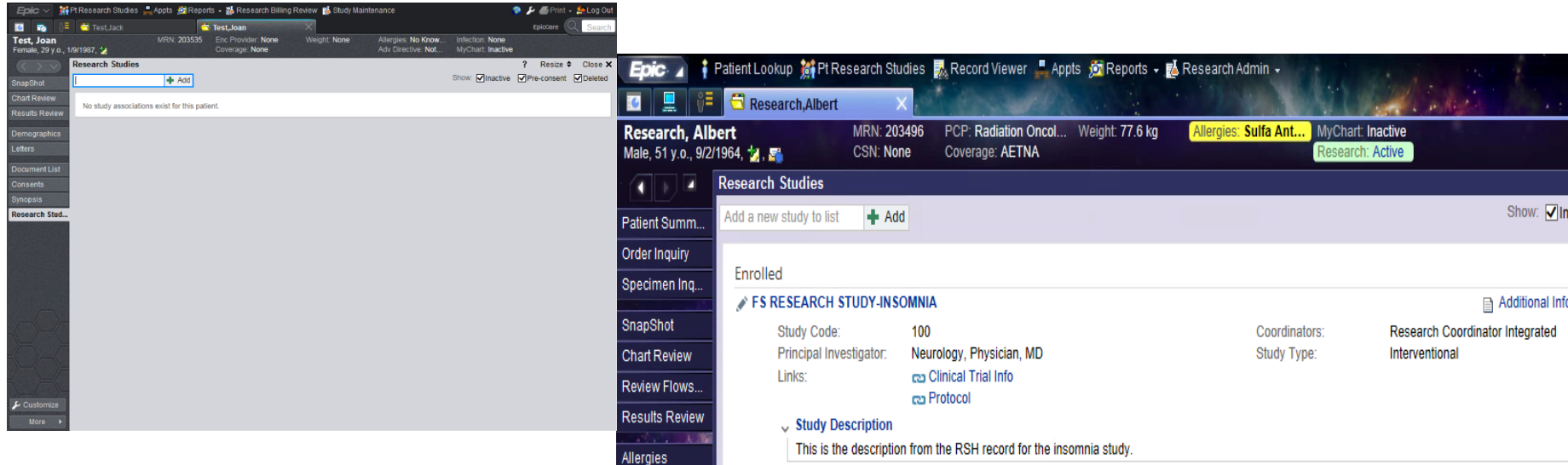
Administrative activities e.g., budgeting, approval tracking, study design, randomization

Investigator compliance to administrative requirements

Subject protocol compliance

Direct reporting to sponsors

EPIC
Patient-Centric

ONCORE
Study-Centric

<u>Overlapping Needs:</u>
- **Basic study information**
- **Patients associated with studies**
- **Research billing definition for study**

ONCORE & EPIC Integration: Empowers Research & Care

- Benefits for **Researchers**
  - Achieve better recruitment for trials
  - Study Teams can track the subjects
  - Streamline collection of biospecimens
- Benefits for **Care Providers**
  - See that a patient is on a clinical trial in the banner
  - Get detailed information on the protocol
  - Identify clinical trials for patients
- Benefits for **Patients**
  - Get access to latest care especially when options are limited

RESEARCHER

CARE PROVIDER

Health System as a Learning Lab
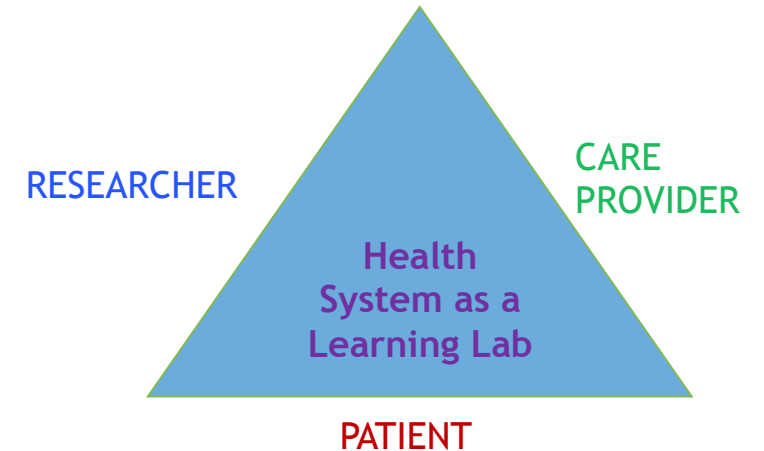
PATIENT

Quantifying Patient Experiences: Patient Reported Outcomes

- Patient Reported Measures
    - Compendium describing PRM use across UMass community to facilitate prioritization of Epic build
    - Domain Examples: QoL, mental health, physical functioning, pain, PTSD, Tobacco/Alcohol/Drug use, etc.
    - Settings: Inpatient, Outpatient, ED
    - Populations: Adults, Pediatrics, Psych

- PRM administration
    - Currently Collected using: REDCap
    - Working with Epic Team to prioritize and build

Honest Broker: Connect Research & Clinical Data
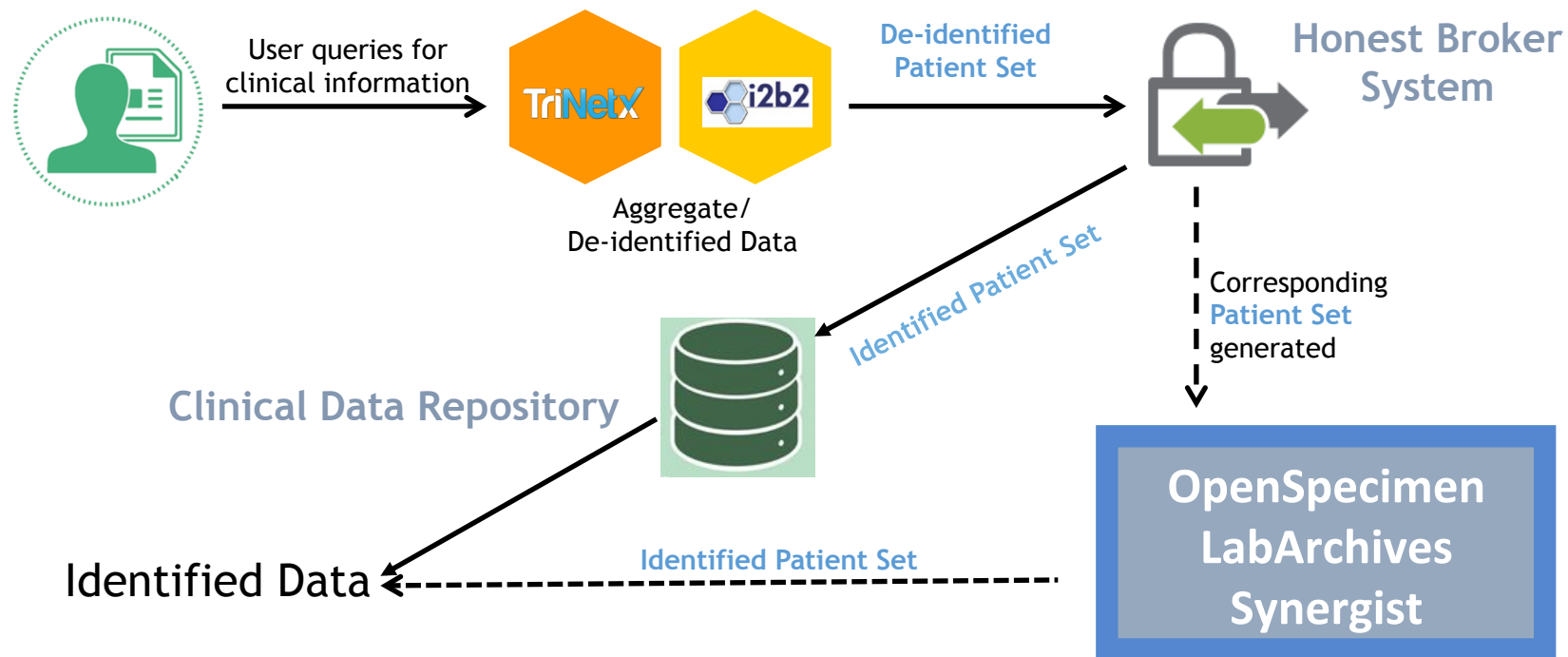
- Enables integrative queries & extraction
- Avoid duplication of data
- Full Traceability & Accountability
- Compliance with HIPAA & regulations

Rules for Diving into the Data Lake:
Data Access Policies and Processes @ UMMS

Data Sciences & Technology — Data Access Procedure

Request for Clinical Data

Aggregate Data
- Go to the Clinical Data Portal
- Complete the Aggregate Data Tools Account Request Form
- Select one or both systems you would like to access; TriNetX, MiCARD
- Once access is obtained, run queries and get aggregate numbers

De-identified Data
- Go to the Clinical Data Portal
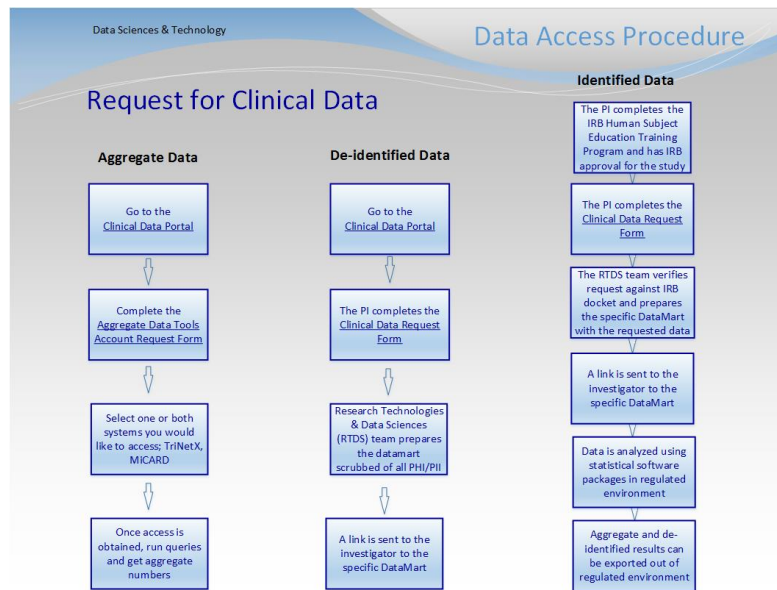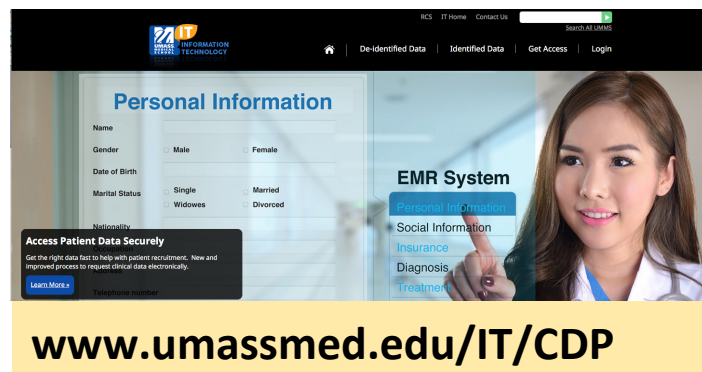- The PI completes the Clinical Data Request Form
- Research Technologies & Data Sciences (RTDS) team prepares the datamart scrubbed of all PHI/PII
- A link is sent to the investigator to the specific DataMart

Identified Data
- The PI completes the IRB Human Subject Education Training Program and has IRB approval for the study
- The PI completes the Clinical Data Request Form
- The RTDS team verifies request against IRB docket and prepares the specific DataMart with the requested data
- A link is sent to the investigator to the specific DataMart
- Data is analyzed using statistical software packages in regulated environment
- Aggregate and de-identified results can be exported out of regulated environment

Key Policies:
- **Aggregate or De-identified data**: No IRB approval required
- **Protected Health information (PHI**): IRB approval required
- BAA & Security clearance required while engaging third-party vendors

Who Can Access Data:
- Research
  - Faculty: Instructor or above
  - Any member of a research team
- Quality & Operations
  - Administrators and staff at UMMHC or UMMS

How:

www.umassmed.edu/IT/CDP

EHR Data for Clinical Trial Feasibility & Identify Cohorts

Using Electronic Health Records to Support Clinical Trials: A Report on Stakeholder Engagement for EHR4CR

Colin McCowan,[1,*] Elizabeth Thomson,[1] Cezary A. Szmigielski,[2] Dipak Kalra,[3] Frank M. Sullivan,[4] Hans-Ulrich Prokosch,[5] Martin Dugas,[6] and Ian Ford[1]

Author information ► Article notes ► Copyright and License information ►

37 structured interviewees in Germany, UK, Switzerland, and France indicated strong support for the proposed Electronic Health Records for Clinical Research (EHR4CR). **All interviewees reported that using the platform for assessing feasibility would enhance the conduct of clinical trials and the majority also felt it would reduce workloads.**

Electronic Screening Improves Efficiency in Clinical Trial Recruitment

Samir R. Thadani, MD, MEng,[a,f] Chunhua Weng, PhD, MS,[b,d,*] J. Thomas Bigger, MD,[a,c,d] John F. Ennever, MD, PhD,[e] and David Wajngurt, MD, MA[b]

Author information ► Article notes ► Copyright and License information ►

UMMS: DLR Can Help Researchers in Better design of Trials & Identify Cohorts

e.g. Botulinum Toxin for Pelvic Pain in Women With Endometriosis (NCT01553201)

- How does protocol design (exclusion/inclusion) impact recruitment?
- How can other sites selected for a multisite study?

INCLUSION CRITERIA:
- Female gender
- Age between 18 and 50
- History of endometriosis
- Persistent pelvic pain for at least 3 months
- Pelvic floor spasm
- Negative pregnancy test
- Willing to use reliable method of contraception for the month after botulinum toxin injection
- Willing and able to give informed consent
- Willing and able to comply with study requirements

EXCLUSION CRITERIA:
- Women with other causes of chronic pelvic pain including infectious, gastrointestinal, psychological disorders, fibromyalgia and chronic fatigue syndrome based on review of medical history within 1 year of first study visit*.
- Untreated severe cervical dysplasia or other gynecologic condition within the past year based on medical record review*.
- Significant abnormalities in the physical or laboratory examination including renal and liver function more than twice the normal range
- Hysterectomy and bilateral salpingo-oophorectomy
- Pregnancy
- Lactation
- Allergy to albumen or botulinum toxin
- Presence of antibodies to botulinum toxin or loss of response to previous injections for any indication
- A known neuromuscular junction disorder such as myasthenia gravis or Eaton-Lambert syndrome
- History of urinary or fecal incontinence
- Known pelvic prolapse

Coming Soon………CTSA Recruitment RFP – Improve Recruitment using Data Lake

UMMS: How to do Feasibility/Recruitment? Use DLR & Aggregate Search Capabilities

CURRENT

INCLUSION CRITERIA:
- Female gender
- Age between 18 and 50
- History of **endometriosis**
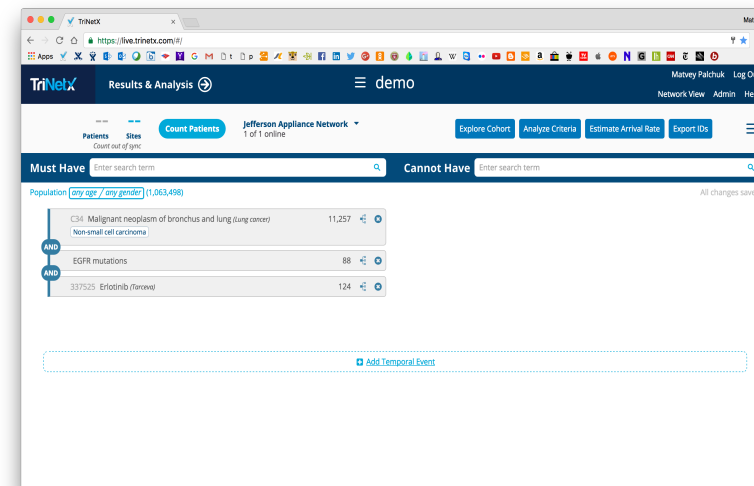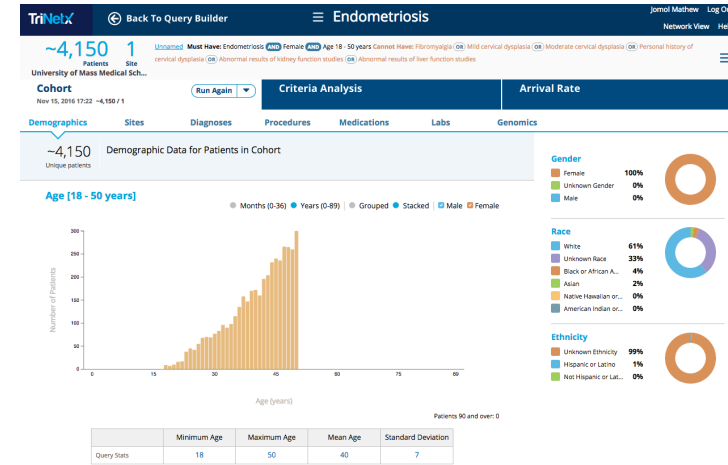
EXCLUSION CRITERIA:
- Fibromyalgia
- Cervical dysplasia
- Renal and liver function

Q2 2017

Integrated Clinical-Genomic Searches
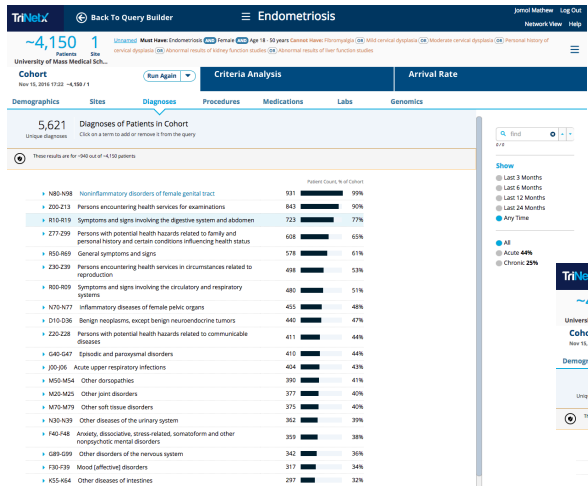e.g. Female, Asian, NSCLC with EGFR mutations receiving Tarceva

Q2 2017

- currently not on other trials
- consented for future contact
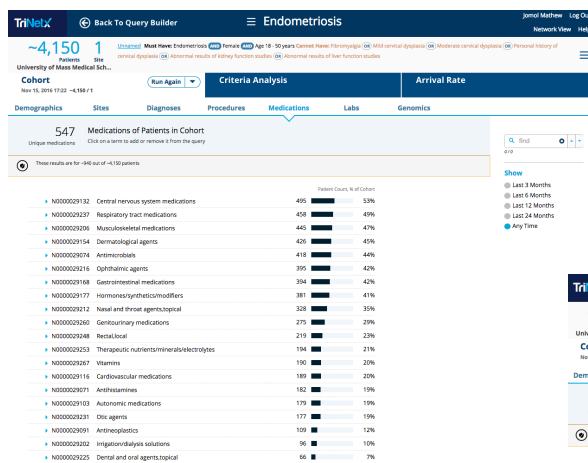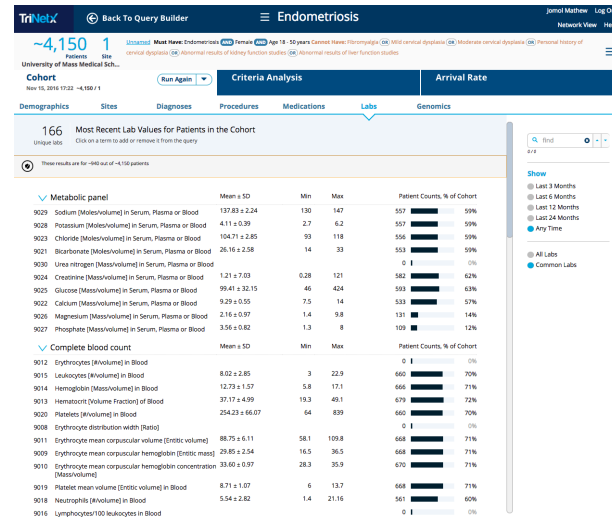

www.umassmed.edu/IT/CDP

UMMS: How to do Feasibility/Recruitment? Use DLR & Explore De-identified Data

Comorbidities

Concomitant Medications

Labs

EHR Data Can Enable Comparative Effectiveness Studies

Leveraging EHR Data for Outcomes and Comparative Effectiveness Research in Oncology

Frank J. Manion, MS, Marcelline R. Harris, PhD, RN, Ayse G. Buyuktur, MPH, MS, Patricia M. Clark, PhDc, RN, Lawrence C. An, MD, and David A. Hanauer, MD, MS

Author information ► Copyright and License information ►

ORIGINAL REPORT

Comparative effectiveness research using electronic health records: impacts of oral antidiabetic drugs on the development of chronic kidney disease

Andrew L. Masica[1]*, Edward Ewen[2], Yahya A. Daoud[1], Dunlei Cheng[6], Nora Franceschini[5], Rustam E. Kudyakov[1], James R. Bowen[2], Emily S. Brouwer[4], Dennis Wallace[3], Neil S. Fleming[1] and Suzanne L. West[3,5]

EHR Data Can help in Risk Prediction Studies

## Identifying primary care patients at risk for future diabetes and cardiovascular disease using electronic health records

Marie-France Hivert, Richard W Grant, Peter Shrader and James B Meigs ✉

Predicting Hospital-Acquired Infections by Scoring System with Simple Parameters

Ying-Jui Chang, Min-Li Yeh, Yu-Chuan Li 🄲 ✉, Chien-Yeh Hsu 🄲 ✉, Chao-Cheng Lin, Meng-Shiuan Hsu, Wen-Ta Chiu

EHR Data along with Biospecimens and Genomic data can aid in Pharmacogenomics studies

Research Article

Predicting warfarin dosage in European–Americans and African–Americans using DNA samples linked to an electronic health record

Andrea H Ramirez, Yaping Shi, Jonathan S Schildcrout, Jessica T Delaney, Hua Xu, Matthew T Oetjens, Rebecca L Zuvich, Melissa A Basford, Erica Bowton, Min Jiang, Peter Speltz, Raquel Zink, James Cowan, Jill M Pulley, Marylyn D Ritchie, Daniel R Masys, Dan M Roden, Dana C Crawford & Joshua C Denny[*]

EHR Data Can Enable Drug Repurposing Studies

Validating drug repurposing signals using electronic health records: a case study of metformin associated with reduced cancer mortality

Hua Xu[1], Melinda C Aldrich[2,3], Qingxia Chen[4,5], Hongfang Liu[6], Neeraja B Peterson[7], Qi Dai[3], Mia Levy[5,7], Anushi Shah[5], Xue Han[4], Xiaoyang Ruan[6], Min Jiang[1], Ying Li[8], Jamii St Julien[2], Jeremy Warner[5,7], Carol Friedman[8], Dan M Roden[7,9], Joshua C Denny[5,7]

EHR Data Can Enable Quality Improvement Studies

AMIA Annual Symposium Proceedings Archive
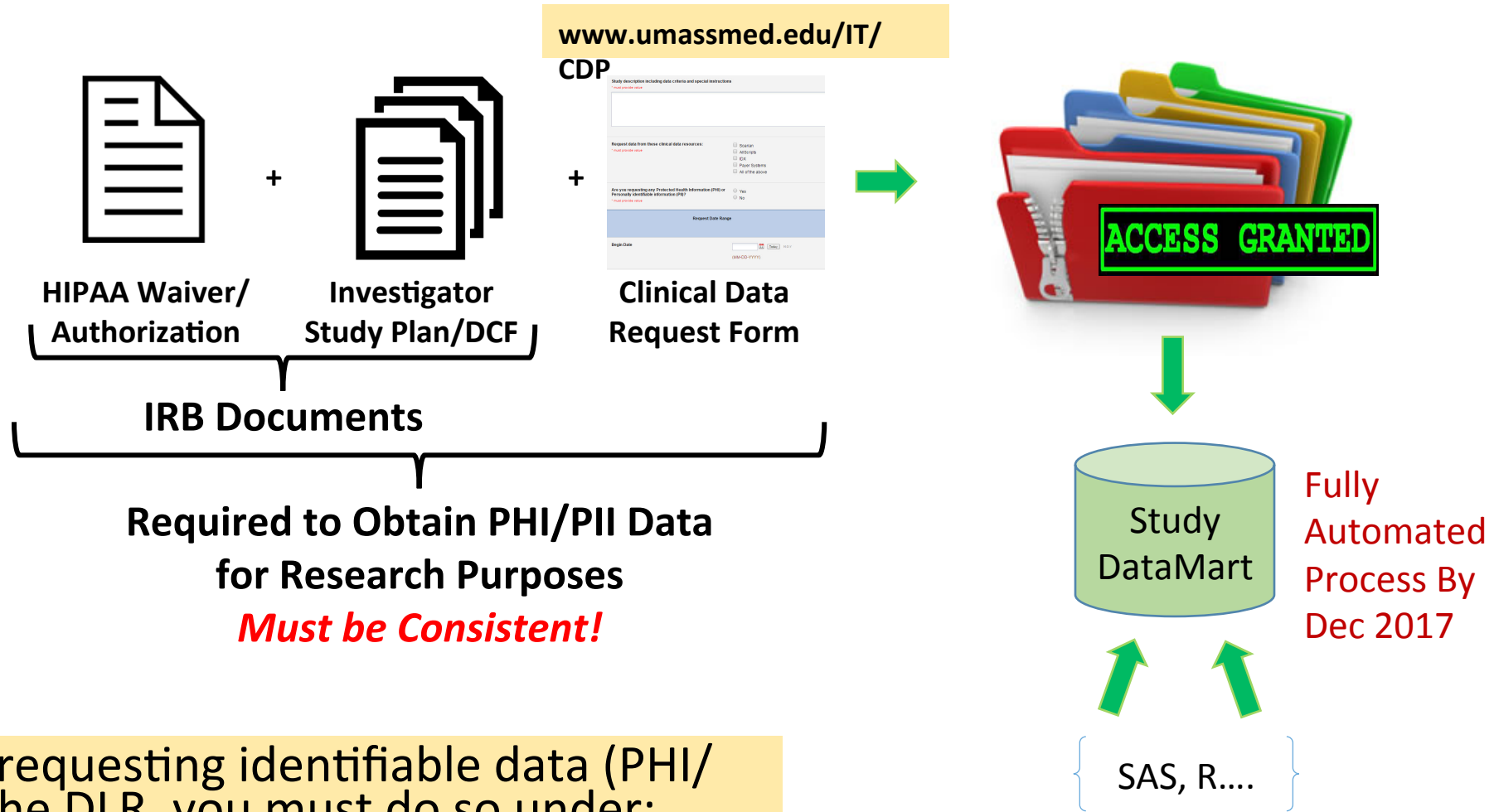
Secondary Use of EHR Timestamp data: Validation and Application for Workflow Optimization

Michelle R. Hribar, PhD,[2] Sarah Read-Brown,[1] Leah Reznick, MD,[1] Lorinna Lombardi, MD,[1] Mansi Parikh, MD,[1] Thomas R. Yackel, MD, MPH, MS,[2] and Michael F. Chiang, MD, MA[1,2]

Author information ► Copyright and License information ►

UMMS: Researchers can Obtain Detailed PHI/PII Data from DLR

www.umassmed.edu/IT/CDP

HIPAA Waiver/Authorization
+
Investigator Study Plan/DCF
+
Clinical Data Request Form

ACCESS GRANTED

IRB Documents

Required to Obtain PHI/PII Data for Research Purposes
Must be Consistent!

Study DataMart

Fully Automated Process By Dec 2017

SAS, R....

If you are requesting identifiable data (PHI/PII) from the DLR, you must do so under:
- A HIPAA Waiver and/or HIPAA Authorization
- Other appropriate documentation

Thanks to….

- *Advisory Committee (K. Luzuriaga, C. Kiefe, S. Corvera, M.Koziel, N. Hafer, G. Wolf)*
- *Clinical Research Task Force* (P. Muldoon & M. Koziel Chairs)
- *Clinical Trial Management Steering Group (*M. Koziel & J Mathew Chairs)
- *EPIC Research Integrated Work Group* (T. Houston & M. Koziel Chairs)
- UMMHC IT (T. Tarnowski & T.Eglin)
- **My Data Science & Technology Team**