BU-CTSI Clinical Research Informatics Tools and Resources Update

December 15, 2021

William G. Adams, MD
Professor of Pediatrics
BU-CTSI Director of Biomedical Informatics Core

The Boston University Clinical and Translational Sciences Institute Biomedical Informatics Core (BU-BIC) seeks to work with the BU/BMC research community to improve access to and use of clinical data from Boston Medical Center, affiliated Community Health Centers, and other research institutions nationally and internationally. This webinar will provide an update on current data resources, tools and consultation services so that attendees will better understand what is available and how they can be used for research.

Note: This webinar is being recorded

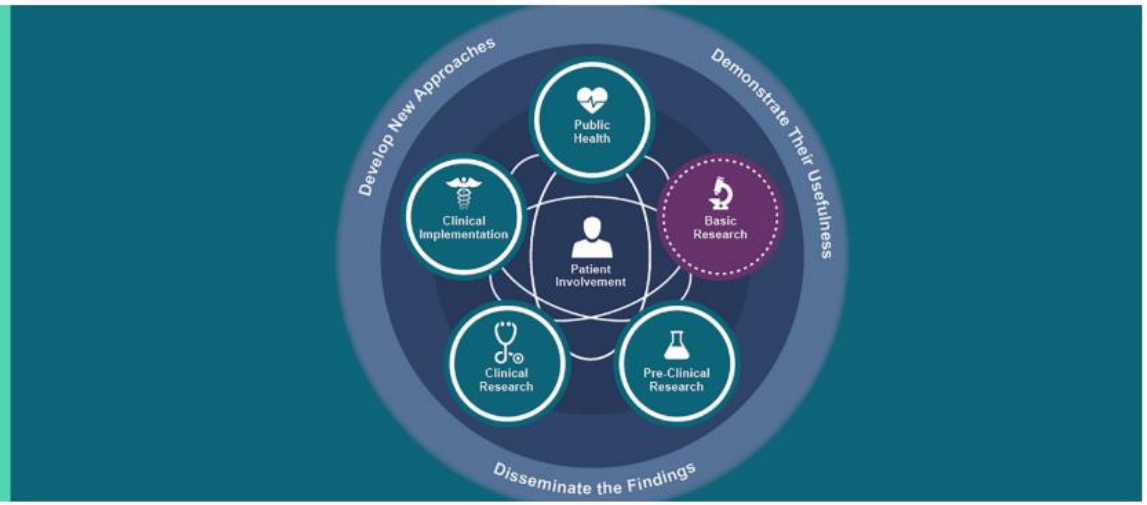
BU Clinical & Translational Science Institute

Tools CTSI Services BU Profiles Contact Us For Staff

News About Us Training & Education Support for Research Community Funding Program Evaluation

About Us

We provide tools, services, and resources to clinical investigators to maximize the impact of discoveries and speed the translation of research into improved patient care though collaborative approaches.



About Us →

What is Translational Science?

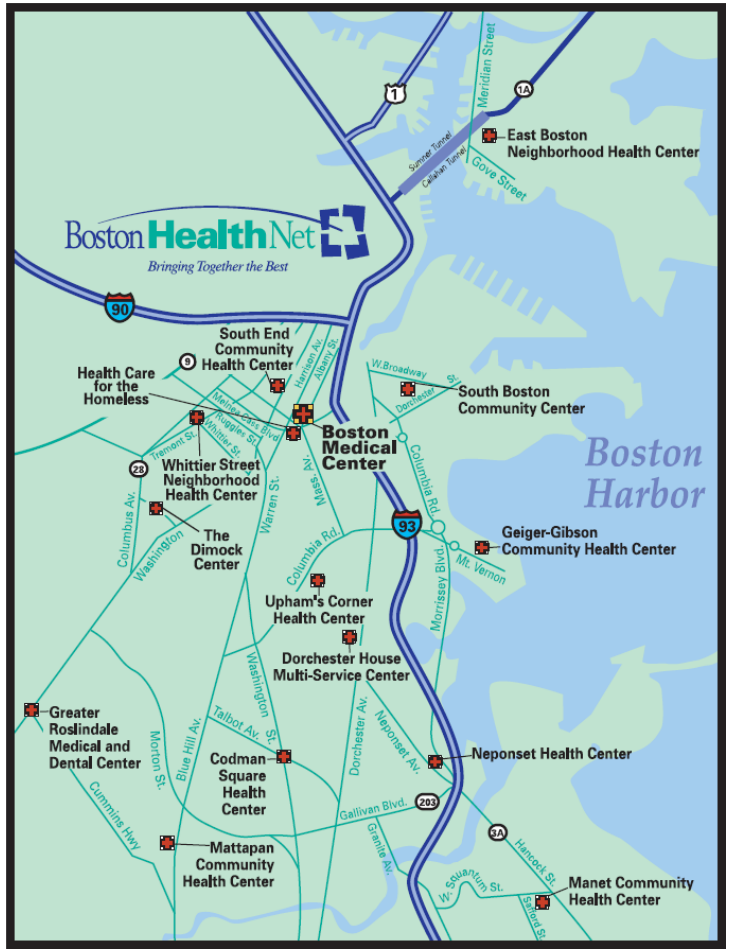
Accomplishments

https://www.bu.edu/ctsi/

Our Vision for Informatics

- Data are accessible - privacy is protected
- Broadest possible array of health data available for research
- Researchers focus on questions more than queries
- Data and tools are standardized so they can be shared
- Advancing health equity is foundational

Our “EcoSystem”



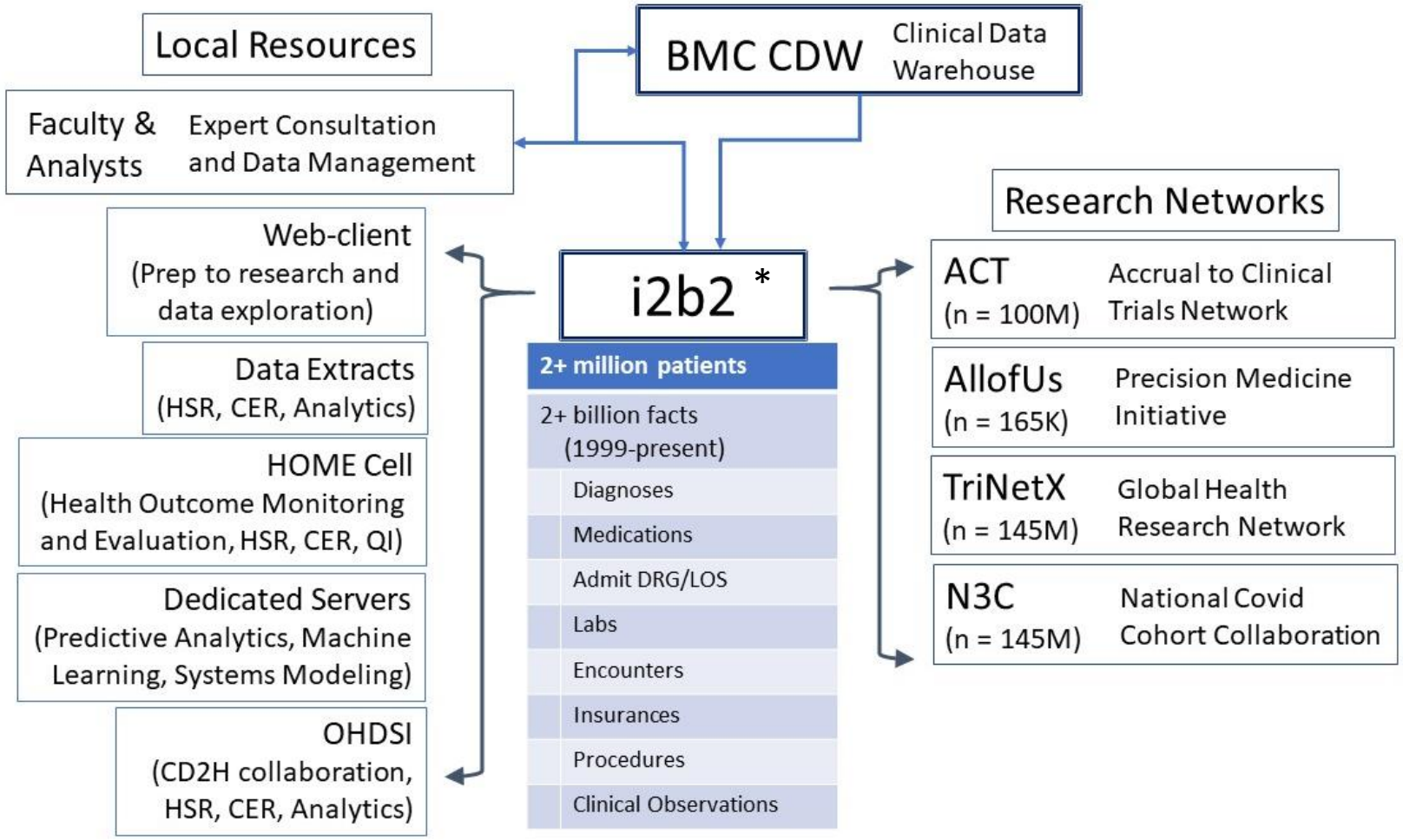
- BMC is largest safety net provider in New England
- Nearly all CHCs are FQHCs
- EHR-based care
  - BMC since 1999
  - CHCs since 2003
- Epic EHR in use at nearly all sites since 2015 (three instances)

Agenda

- Tools and Resources
  - BMC Clinical Data Warehouse (CDW)
  - i2b2, SHRINE, ACT Network
  - TriNetX
  - NC3
  - Consultation Service
- Data for Equity (D4E) Project

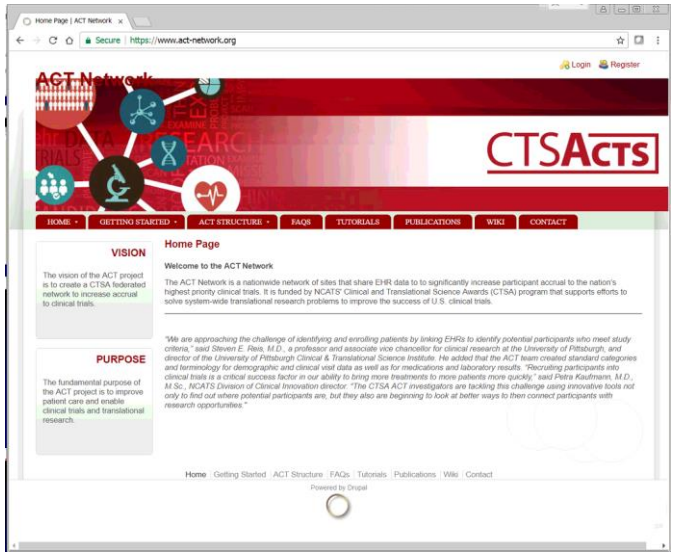
(Please chat in questions – we will address as many as possible at the end)

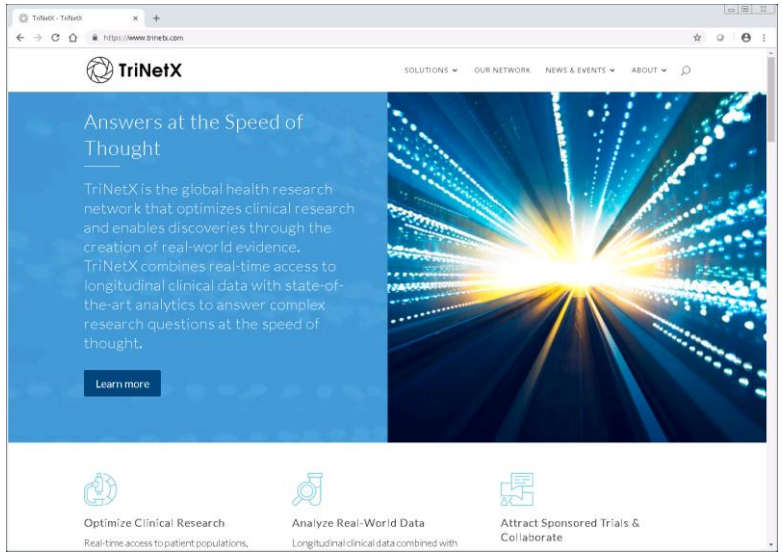
BU-CTSI Clinical Data Resources and Networks

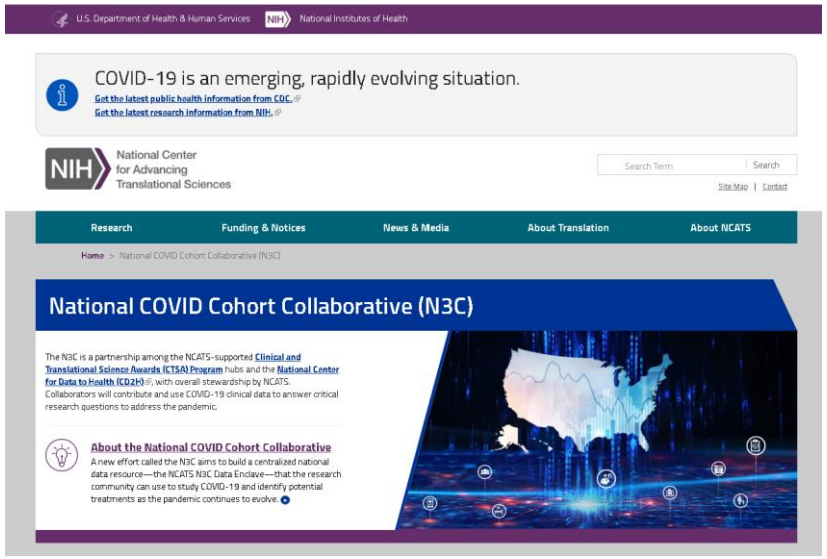


* de-identified limited dataset

Our National Networks

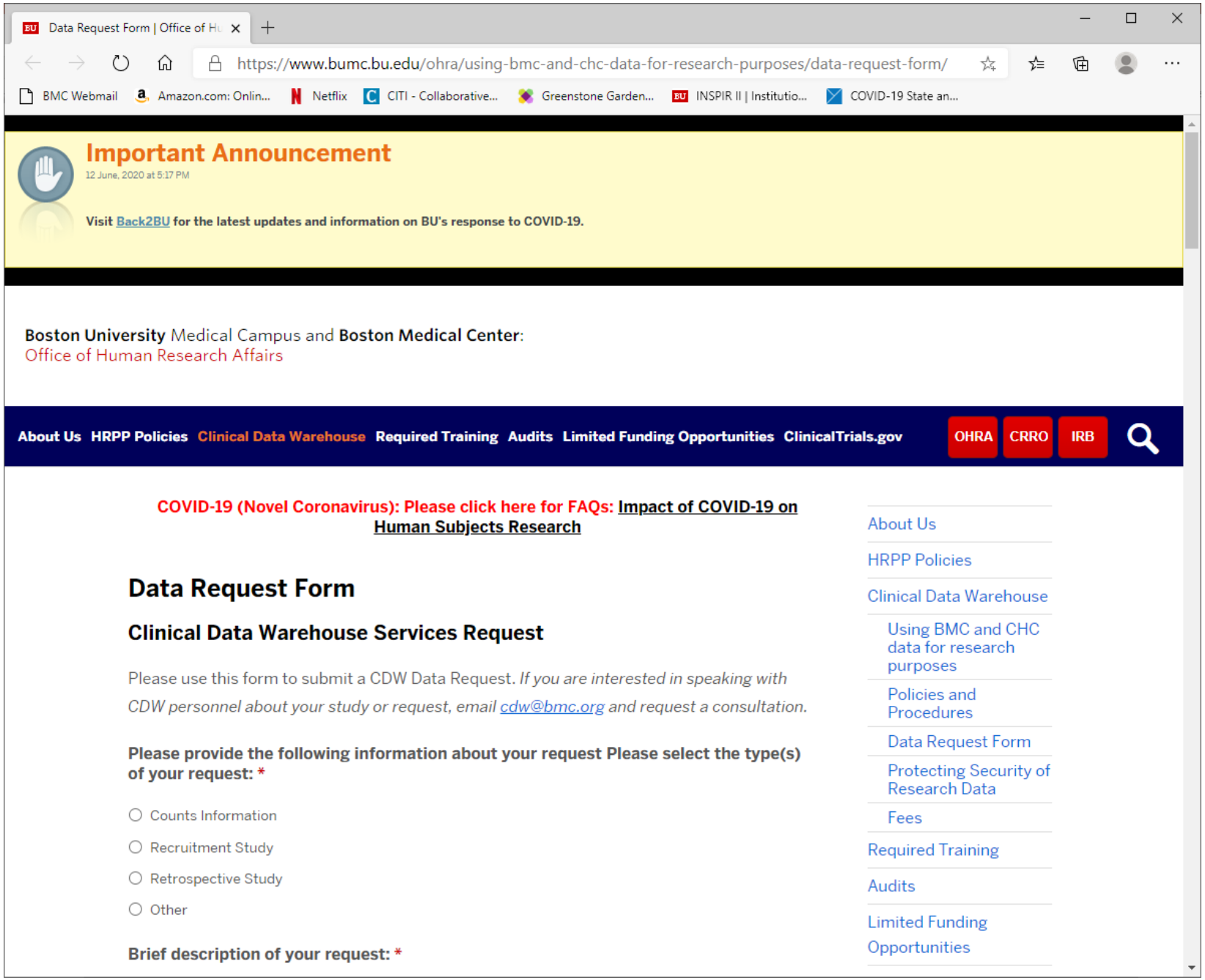






BMC Clinical Data Warehouse (CDW)

- BMC CDW research infrastructure has grown with support from BMC and ACO
- 3 FTE research data analysts
- Specialized focusing on ACO analytics and HSR
- With COVID, group became the primary point of contact for all COVID-related CDW work
- Fee for service model supports ongoing work and scalability
- Requests should be directed to: CDW@bmc.org
- Or…


Data Request Form | Office of Hu
https://www.bumc.bu.edu/ohra/using-bmc-and-chc-data-for-research-purposes/data-request-form/
BMC Webmail
Amazon.com: Onlin...
Netflix
CITI - Collaborative...
Greenstone Garden...
INSPIR II | Institutio...
COVID-19 State an...
Important Announcement
12 June, 2020 at 5:17 PM
Visit Back2BU for the latest updates and information on BU's response to COVID-19.
Boston University Medical Campus and Boston Medical Center:
Office of Human Research Affairs
About Us
HRPP Policies
Clinical Data Warehouse
Required Training
Audits
Limited Funding Opportunities
ClinicalTrials.gov
OHRA
CRRO
IRB
COVID-19 (Novel Coronavirus): Please click here for FAQs: Impact of COVID-19 on Human Subjects Research
Data Request Form
Clinical Data Warehouse Services Request
Please use this form to submit a CDW Data Request. If you are interested in speaking with CDW personnel about your study or request, email cdw@bmc.org and request a consultation.
Please provide the following information about your request Please select the type(s) of your request: *
Counts Information
Recruitment Study
Retrospective Study
Other
Brief description of your request: *
About Us
HRPP Policies
Clinical Data Warehouse
Using BMC and CHC data for research purposes
Policies and Procedures
Data Request Form
Protecting Security of Research Data
Fees
Required Training
Audits
Limited Funding Opportunities

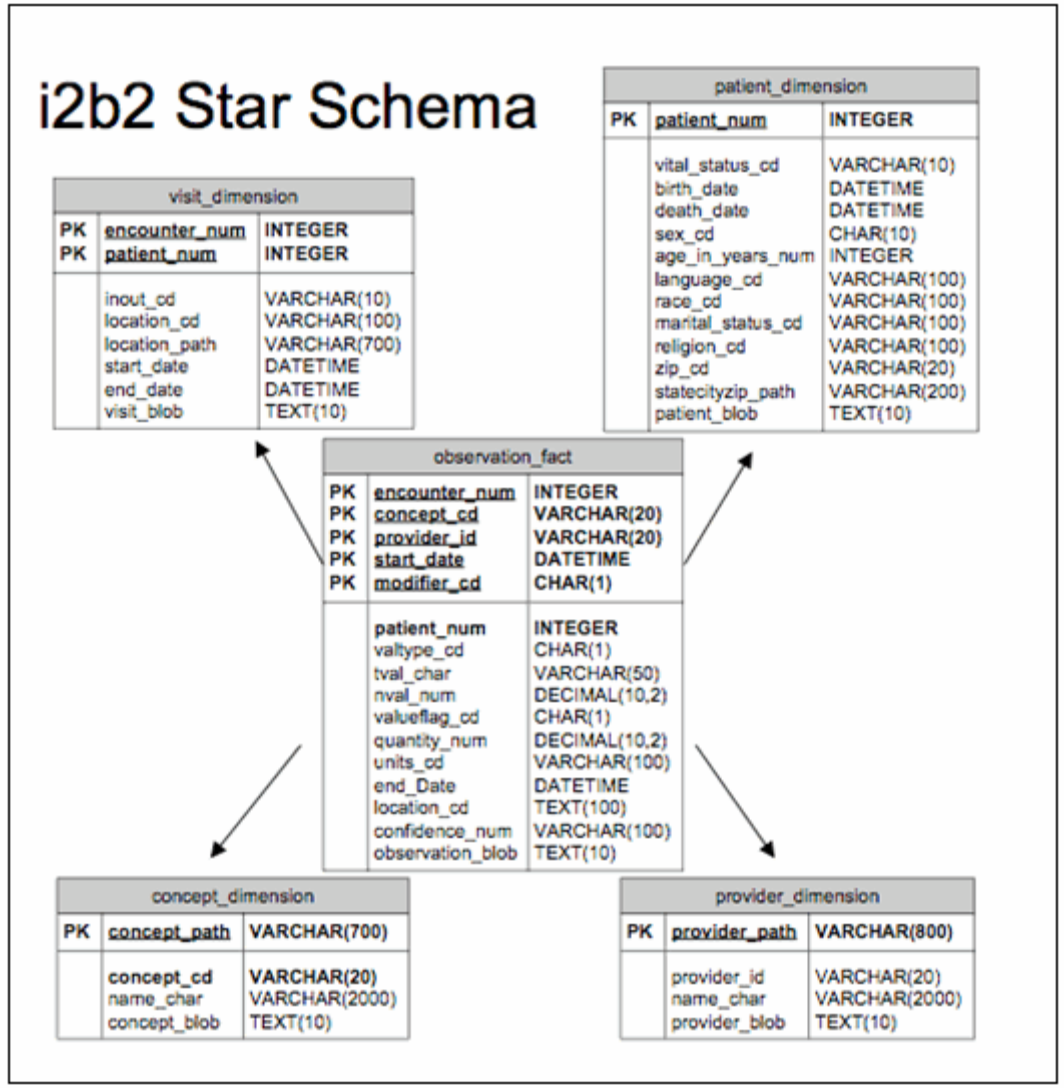
i2b2

- "Informatics for Integrating Biology with the Bedside"
- Open-source software based on the MGH Research Patient Data Repository (RPDR)
- Collection of modules or "cells" constitute the i2b2 "hive"
  - De-identified clinical data repository
  - Data linked to standardized vocabularies
  - Web-based query and analytic tools
- Available at BMC/BUMC since 2009

i2b2 Core Data Elements

- Patients
- Observations (Facts)
- Concept Libraries (Ontologies)

i2b2 Star Schema



Staging Area (PHI containing data)

Billing Data – Site 2

MRN	Visit_date	Location	Dx1	Dx2	CPT1	CPT2	PrimIns
ABCD	2/15/2010	PediPulm	123.4	125.8	90214	90213	Uninsured
ABCD	2/15/2010	MCV	70				

Link Table

ID	MRN	Site
12	1234	Site1
12	ABCD	Site2

i2b2 Repository (de-identified data)

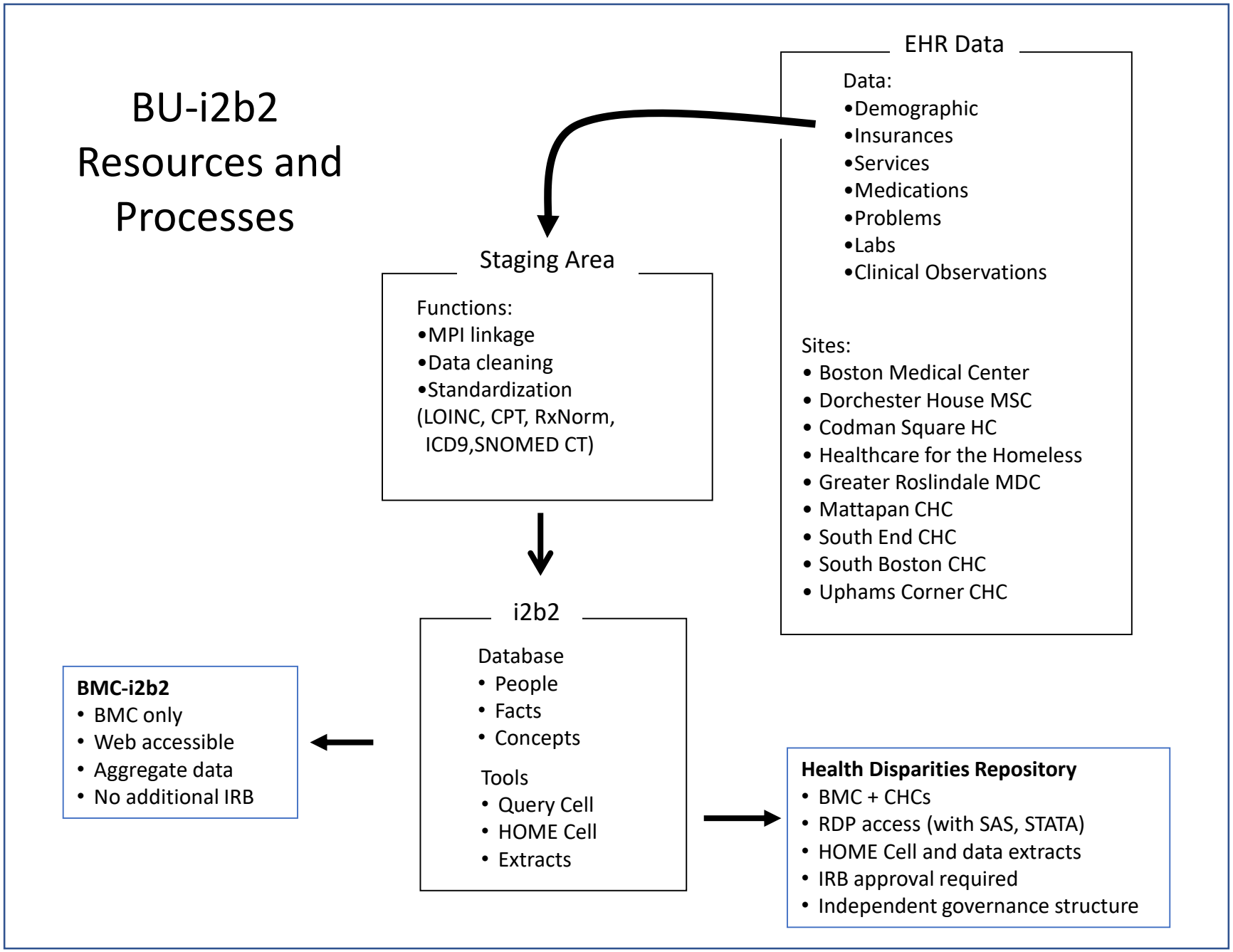
Patients

ID	Birth_Date	Sex_Cd	Race_Cd	…
12	11/07/2000	M	B	

Observation_facts

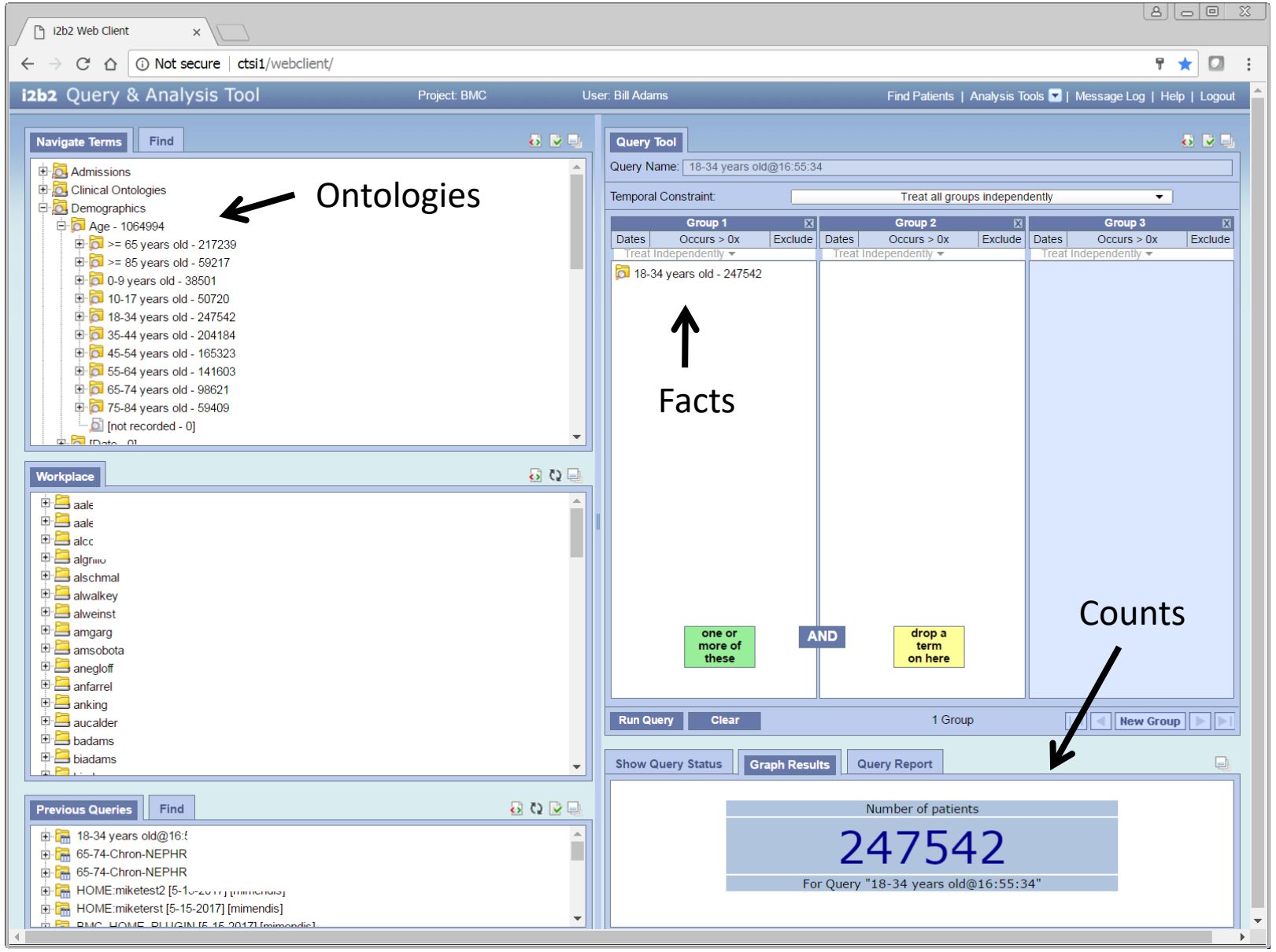
ID	Concept_Cd	Start_Date	Value	Location_Cd	End_Date	…
12	PrimCareVis	1/22/2010	Site1	Site1		
12	Dx	1/22/2010	123.4	Site1		
12	Dx	1/22/2010	125.8	Site1		
12	Proc	1/22/2010	90124	Site1		
12	Proc	1/22/2010	90254	Site1		
12	Ins	1/22/2010	Medicaid	Site1		
12	PediPulm	2/22/2010	Site2-PediPulm	Site2		
12	Dx	2/22/2010	123.4	Site2		
12	Hct	2/22/2010	11.1	Site2		
12	MCV	2/22/2010	70	Site2		

BU-i2b2 Resources and Processes

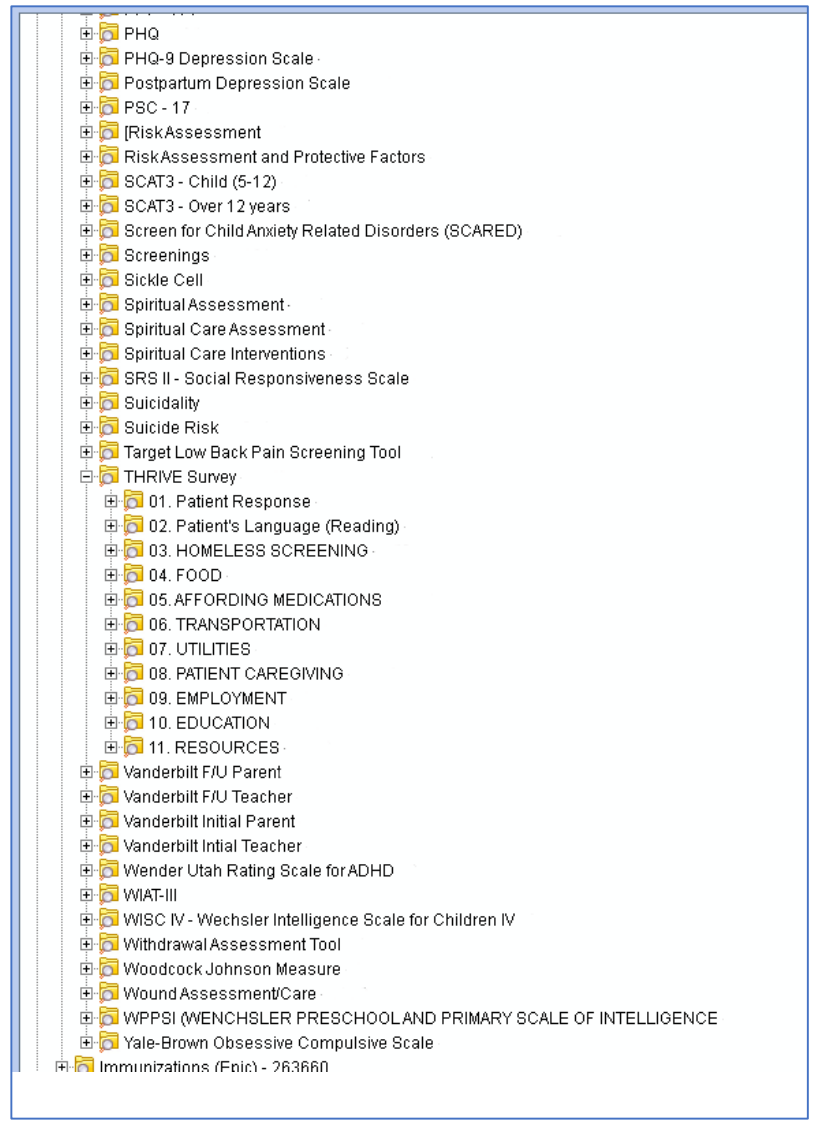


i2b2 Compatible Data

- Demographics
- Problems/Diagnoses
- Medications
- Clinical Observations
- Procedures
- Laboratory Data
- Genomic Data
- Much more…


i2b2 Web Client
Not secure
ctsi1/webclient/
i2b2 Query & Analysis Tool
Project: BMC
User: Bill Adams
Find Patients | Analysis Tools | Message Log | Help | Logout
Navigate Terms
Find
Admissions
Clinical Ontologies
Demographics
Age - 1064994
>= 65 years old - 217239
>= 85 years old - 59217
0-9 years old - 38501
10-17 years old - 50720
18-34 years old - 247542
35-44 years old - 204184
45-54 years old - 165323
55-64 years old - 141603
65-74 years old - 98621
75-84 years old - 59409
[not recorded - 0]
Ontologies
Workplace
aale
aale
alcc
alschmal
alwalkey
alweinst
amgarg
amsobota
anegloff
anfarrel
anking
aucalder
badams
biadams
Previous Queries
Find
18-34 years old@16:
65-74-Chron-NEPHR
65-74-Chron-NEPHR
HOME:miketest2 [5-1
HOME:miketerst [5-15-2017] [mimendis]
Query Tool
Query Name: 18-34 years old@16:55:34
Temporal Constraint:
Treat all groups independently
Group 1
Group 2
Group 3
Dates
Occurs > 0x
Exclude
Treat Independently
18-34 years old - 247542
Facts
one or more of these
AND
drop a term on here
Counts
Run Query
Clear
1 Group
New Group
Show Query Status
Graph Results
Query Report
Number of patients
247542
For Query "18-34 years old@16:55:34"

i2b2 Recent Additions



SHRINE

Journal List > J Am Med Inform Assoc > v.16(5); Sep-Oct 2009 > PMC2744712

Alerts | Author Instructions | Submit | About

JAMIA

Journal of the American Medical Informatics Association

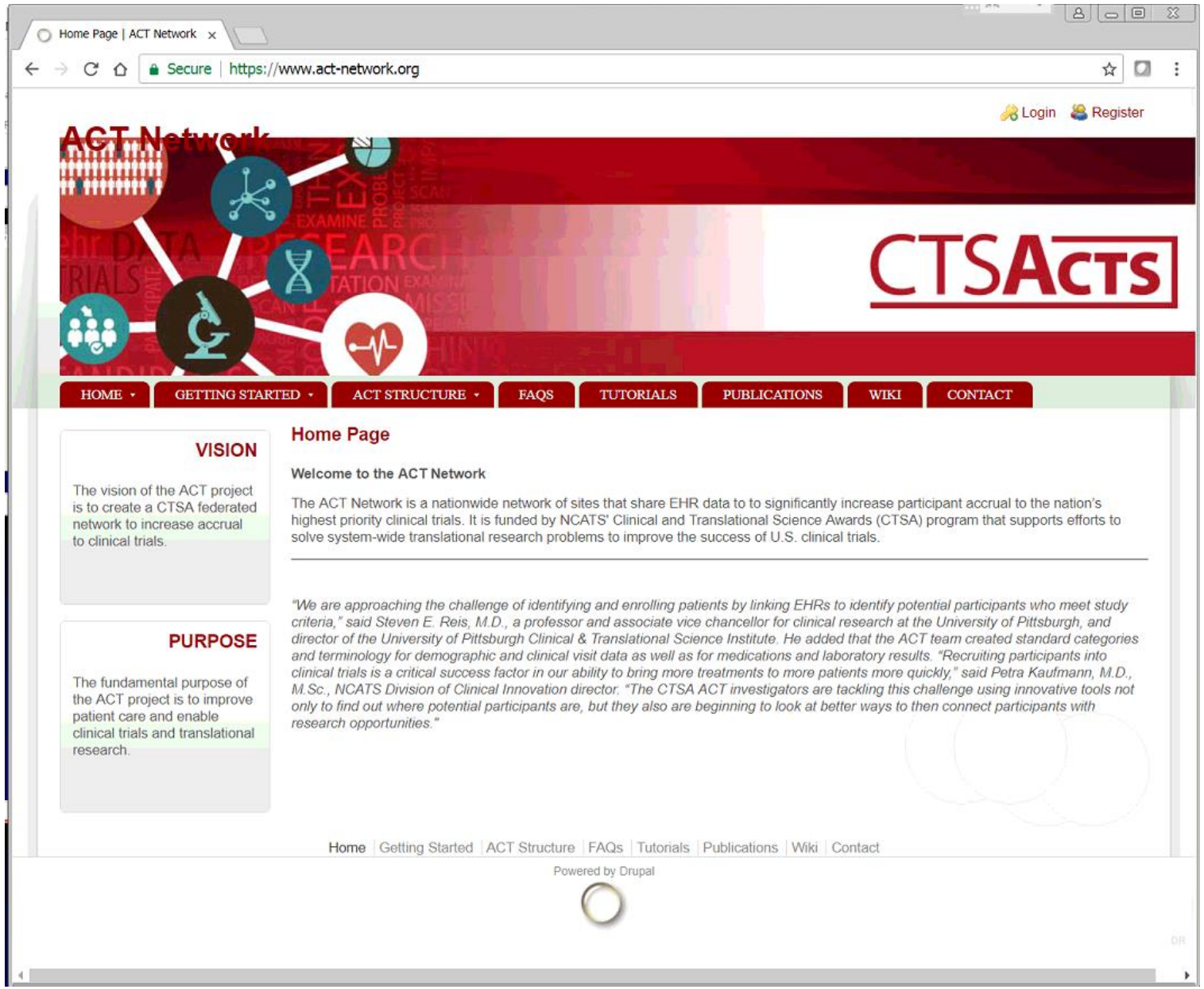
J Am Med Inform Assoc. 2009 Sep-Oct; 16(5): 624–630.
doi: 10.1197/jamia.M3191

PMCID: PMC2744712
PMID: 19567788

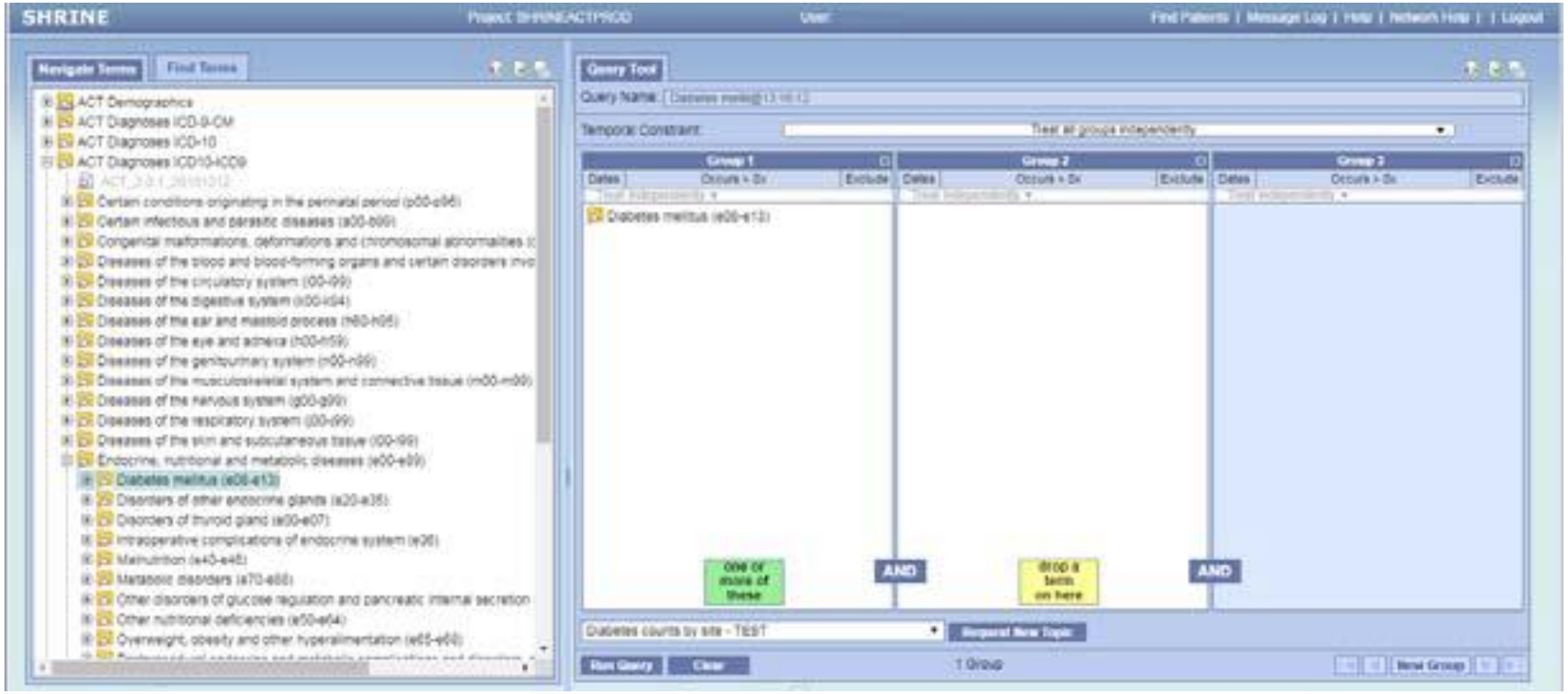
J Am Med Infor

The Shared Health Research Information Network (SHRINE): A Prototype Federated Query Tool for Clinical Data Repositories

Griffin M. Weber, MD, PhD, [a, c, *] Shawn N. Murphy, MD, PhD, [d] Andrew J. McMurry, MS, [b, e] Douglas MacFadden, MS, [e] Daniel J. Nigrin, MD, MS, [b, e] Susanne Churchill, PhD, [c] and Isaac S. Kohane, MD, PhD [b, d, e]

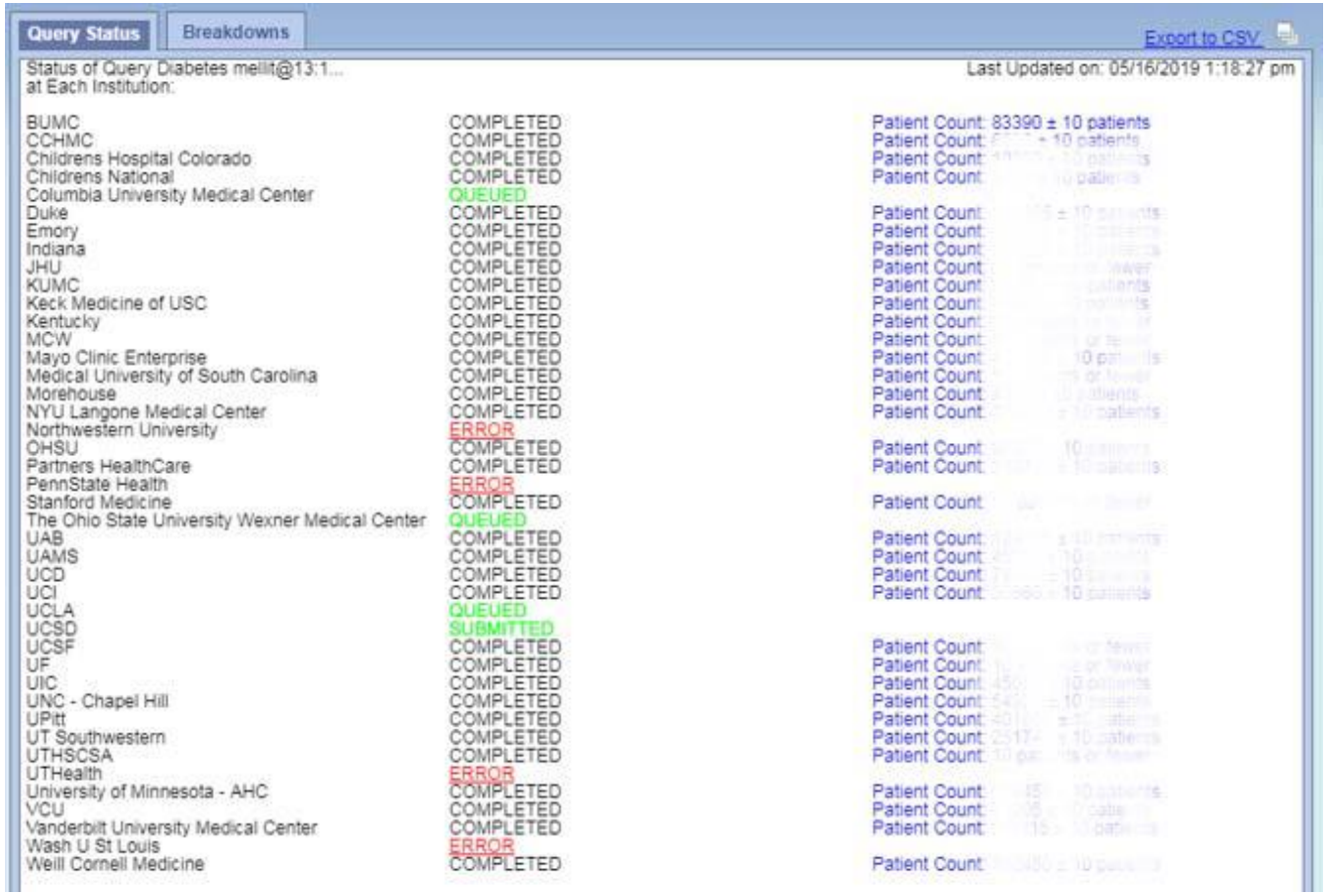

Home Page | ACT Network
Secure | https://www.act-network.org
Login
Register
ACT Network
CTSACTS
HOME
GETTING STARTED
ACT STRUCTURE
FAQS
TUTORIALS
PUBLICATIONS
WIKI
CONTACT
VISION
The vision of the ACT project is to create a CTSA federated network to increase accrual to clinical trials.
PURPOSE
The fundamental purpose of the ACT project is to improve patient care and enable clinical trials and translational research.
Home Page
Welcome to the ACT Network
The ACT Network is a nationwide network of sites that share EHR data to to significantly increase participant accrual to the nation's highest priority clinical trials. It is funded by NCATS' Clinical and Translational Science Awards (CTSA) program that supports efforts to solve system-wide translational research problems to improve the success of U.S. clinical trials.
"We are approaching the challenge of identifying and enrolling patients by linking EHRs to identify potential participants who meet study criteria," said Steven E. Reis, M.D., a professor and associate vice chancellor for clinical research at the University of Pittsburgh, and director of the University of Pittsburgh Clinical & Translational Science Institute. He added that the ACT team created standard categories and terminology for demographic and clinical visit data as well as for medications and laboratory results. "Recruiting participants into clinical trials is a critical success factor in our ability to bring more treatments to more patients more quickly," said Petra Kaufmann, M.D., M.Sc., NCATS Division of Clinical Innovation director. "The CTSA ACT investigators are tackling this challenge using innovative tools not only to find out where potential participants are, but they also are beginning to look at better ways to then connect participants with research opportunities."
Home | Getting Started | ACT Structure | FAQs | Tutorials | Publications | Wiki | Contact
Powered by Drupal

Sample ACT SHRINE Query*



*self-service use of i2b2 query tool for local queries available but network wide queries are done with CTSI support

Sample ACT SHRINE Query



Additional projects/activities

BMC Projects

- BMC Cancer Registry Integration
- BP Normalization and Care
- VVV in BP, lipid, and Hgb1C
- Sickle Cell QI (children and adults)
- Sickle Cell BH
- Community-based smoking cessation
- Pneumonia rates in PCV vaccine era
- HPV vaccination and morbidity
- Algorithms for Personalized Decision Making
- Vital Village – geographic health effects
- Household Health Study
- Comparative Effectiveness of Bariatric Surgical Procedures

I2b2 Networking

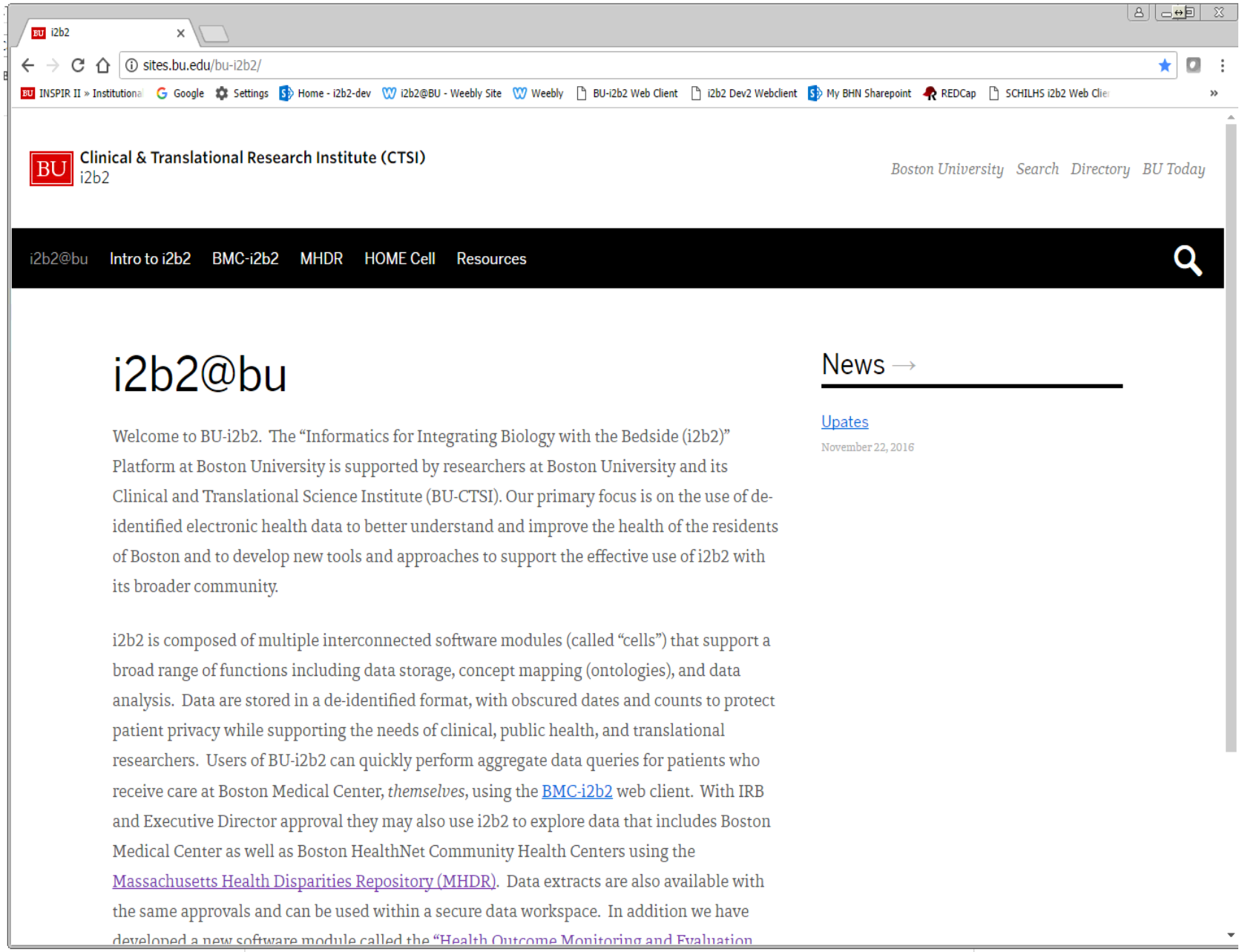
ePROS – psychotropic medication use in kids

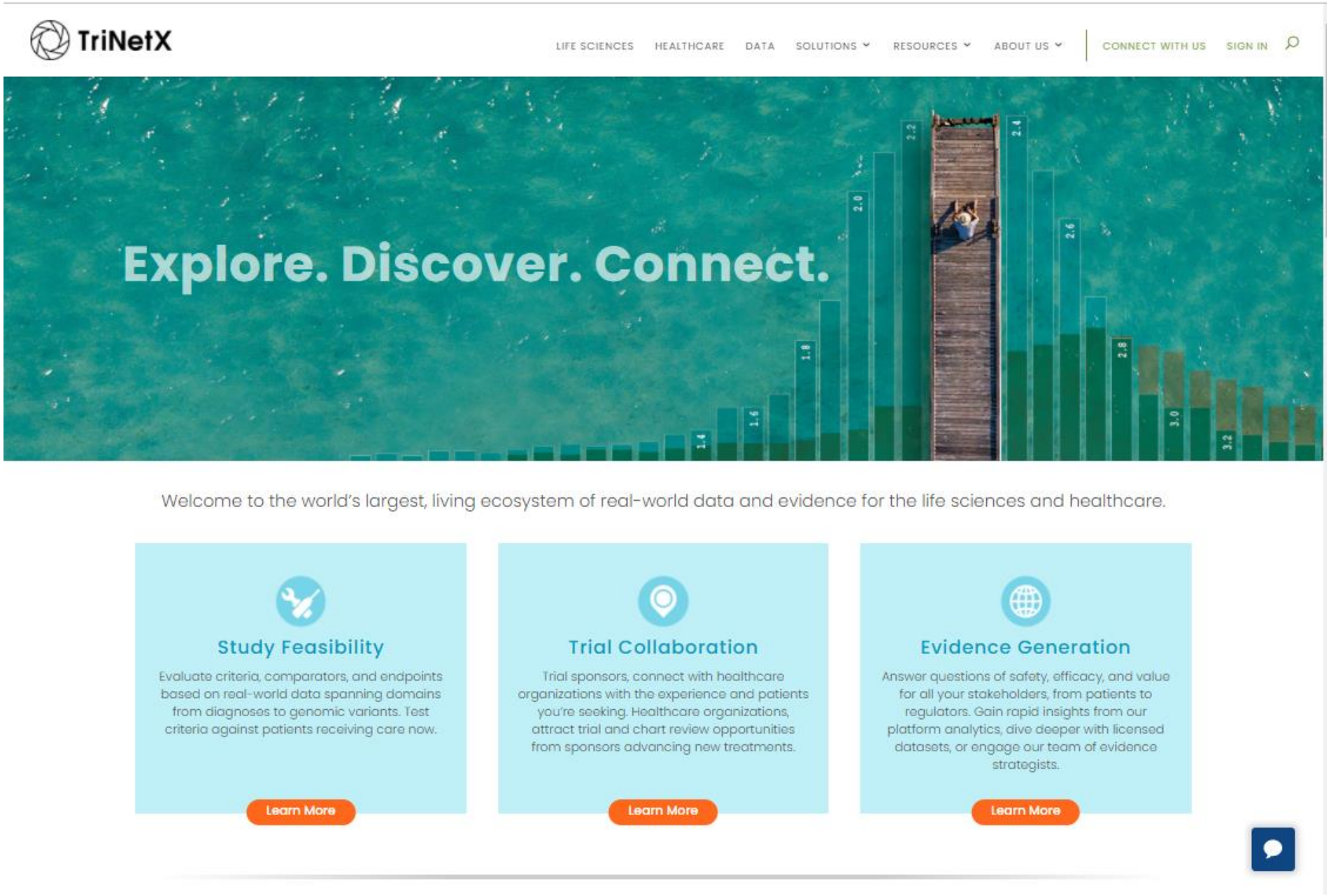
ePROS – on- off-label safety

Insurance switching

Pediatric uveitis

Precision Medicine Initiative/All of Us


i2b2
sites.bu.edu/bu-i2b2/
INSPIR II » Institutiona
Google
Settings
Home - i2b2-dev
i2b2@BU - Weebly Site
Weebly
BU-i2b2 Web Client
i2b2 Dev2 Webclient
My BHN Sharepoint
REDCap
SCHILHS i2b2 Web Clie
Clinical & Translational Research Institute (CTSI)
i2b2
Boston University Search Directory BU Today
i2b2@bu Intro to i2b2 BMC-i2b2 MHDR HOME Cell Resources
i2b2@bu
Welcome to BU-i2b2. The "Informatics for Integrating Biology with the Bedside (i2b2)" Platform at Boston University is supported by researchers at Boston University and its Clinical and Translational Science Institute (BU-CTSI). Our primary focus is on the use of de-identified electronic health data to better understand and improve the health of the residents of Boston and to develop new tools and approaches to support the effective use of i2b2 with its broader community.
i2b2 is composed of multiple interconnected software modules (called "cells") that support a broad range of functions including data storage, concept mapping (ontologies), and data analysis. Data are stored in a de-identified format, with obscured dates and counts to protect patient privacy while supporting the needs of clinical, public health, and translational researchers. Users of BU-i2b2 can quickly perform aggregate data queries for patients who receive care at Boston Medical Center, themselves, using the BMC-i2b2 web client. With IRB and Executive Director approval they may also use i2b2 to explore data that includes Boston Medical Center as well as Boston HealthNet Community Health Centers using the Massachusetts Health Disparities Repository (MHDR). Data extracts are also available with the same approvals and can be used within a secure data workspace. In addition we have
News →
Upates
November 22, 2016



[TriNetX website]

TriNetX at BMC/BUMC

- TriNetX is global health research network
- Primary source of support is from pharma industry
- Goals are to connect the world of drug discovery and development from:
  - Pharmaceutical company to study site
  - Investigator to patient
  - Via sharing real-world data to make clinical and observational research easier and more efficient
- Two pathways for research
  - Query tool – user-friendly self-service tool for aggregate data exploration (active at BMC)
  - Research network participation

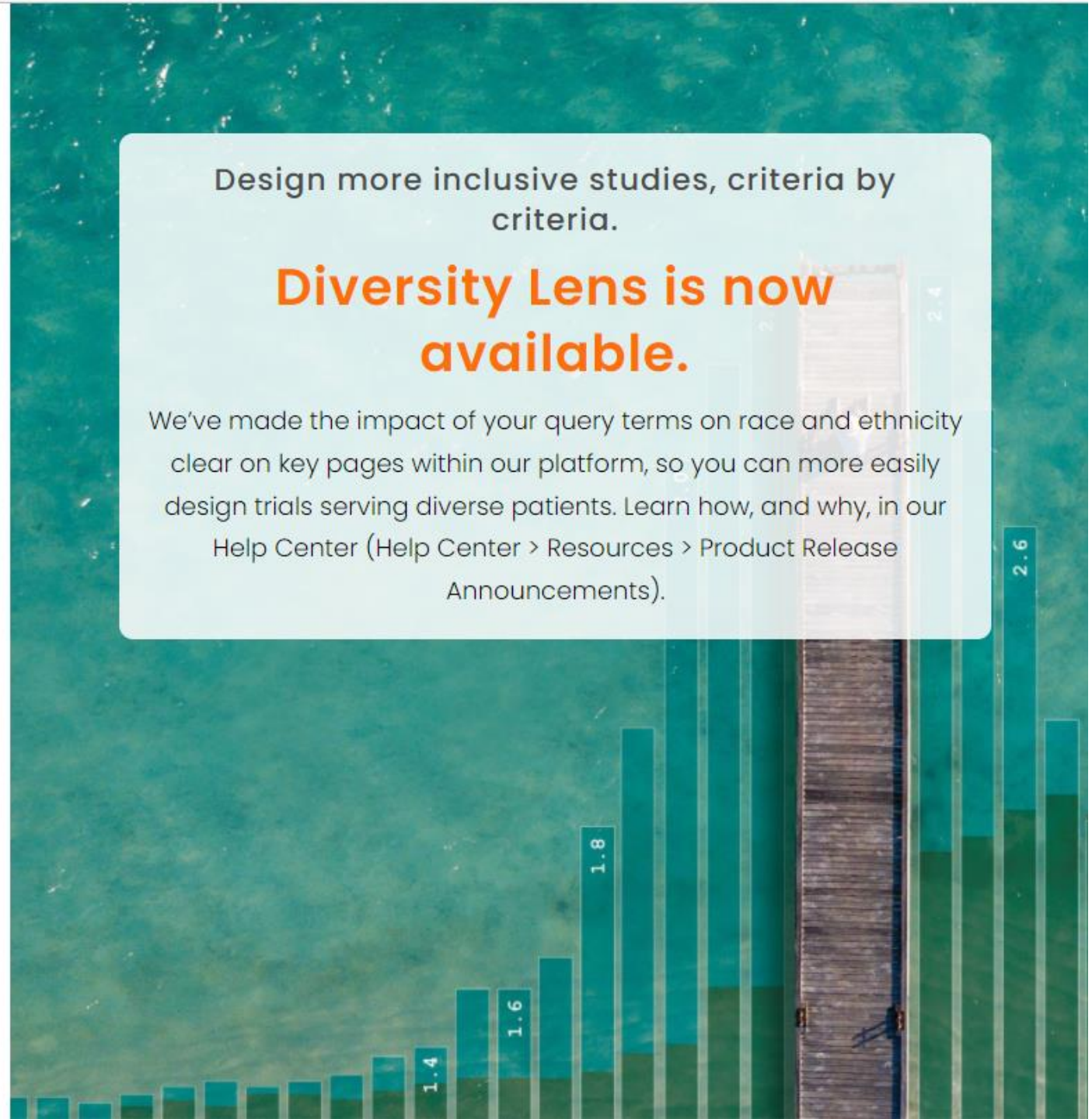
TriNetX

Your organization email address

Need to reset your password?

Login >

The TriNetX platform has regularly scheduled maintenance every Wednesday from 8pm to 10pm ET.



Create New Study

Created by on Dec 15, 2021

*Study Name (required) Enter a descriptive name for the study

Study Name

Diabetes and A1C

*Research Purpose (required) Select one or more from the list below

Clinical Trial Research

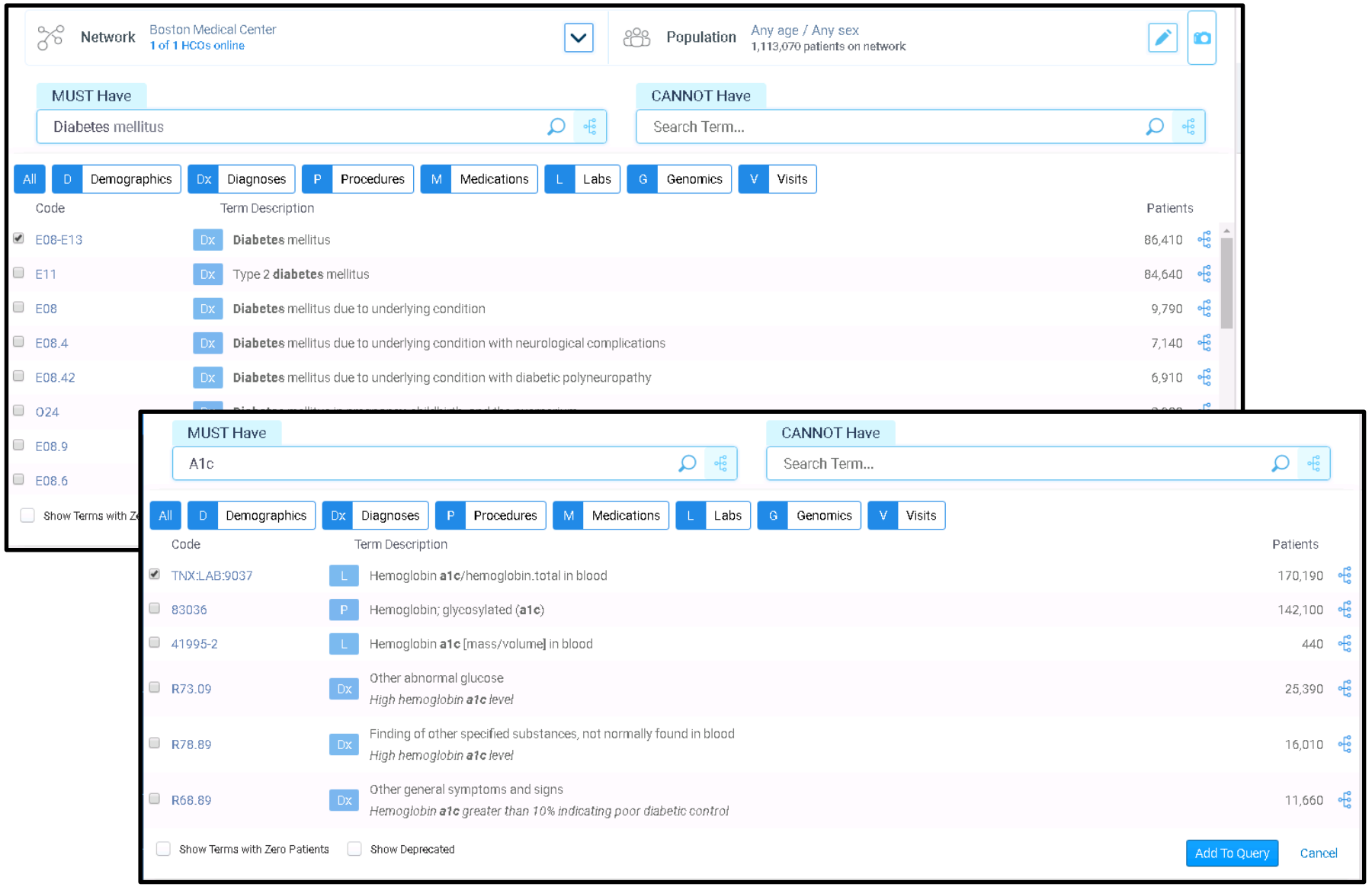
- [ ] Design clinical trial
- [x] Assess feasibility of clinical trial
- [ ] Identify clinical trial sites
- [ ] Recruit trial subjects

Other Scientific Research

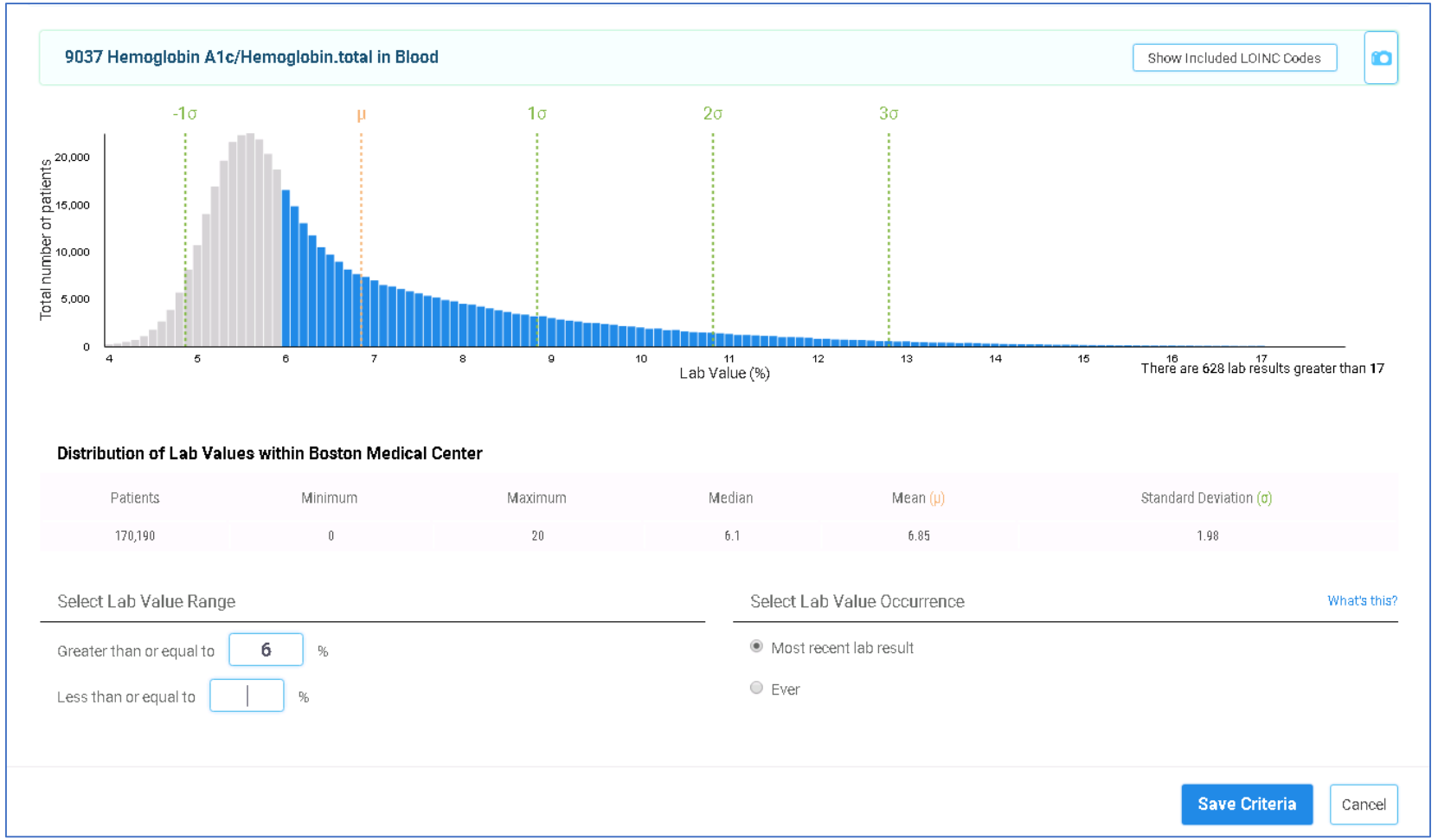
- [ ] Conduct health economics and outcomes research (HEOR)
- [ ] Explore patient populations
- [ ] Conduct other secondary research

Study Identifying Information (optional)

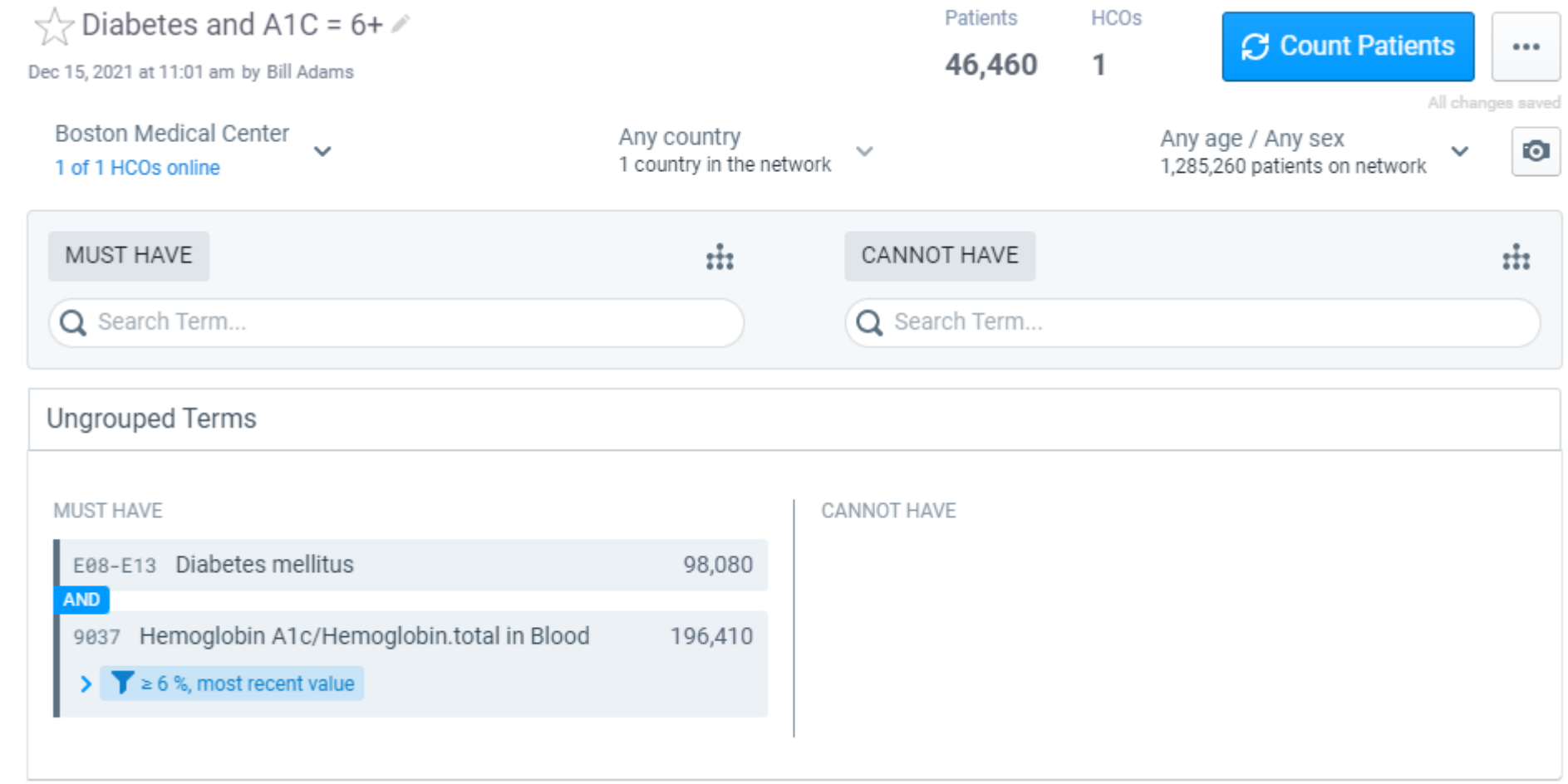
Sample Query: Diabetes and A1C Cohort



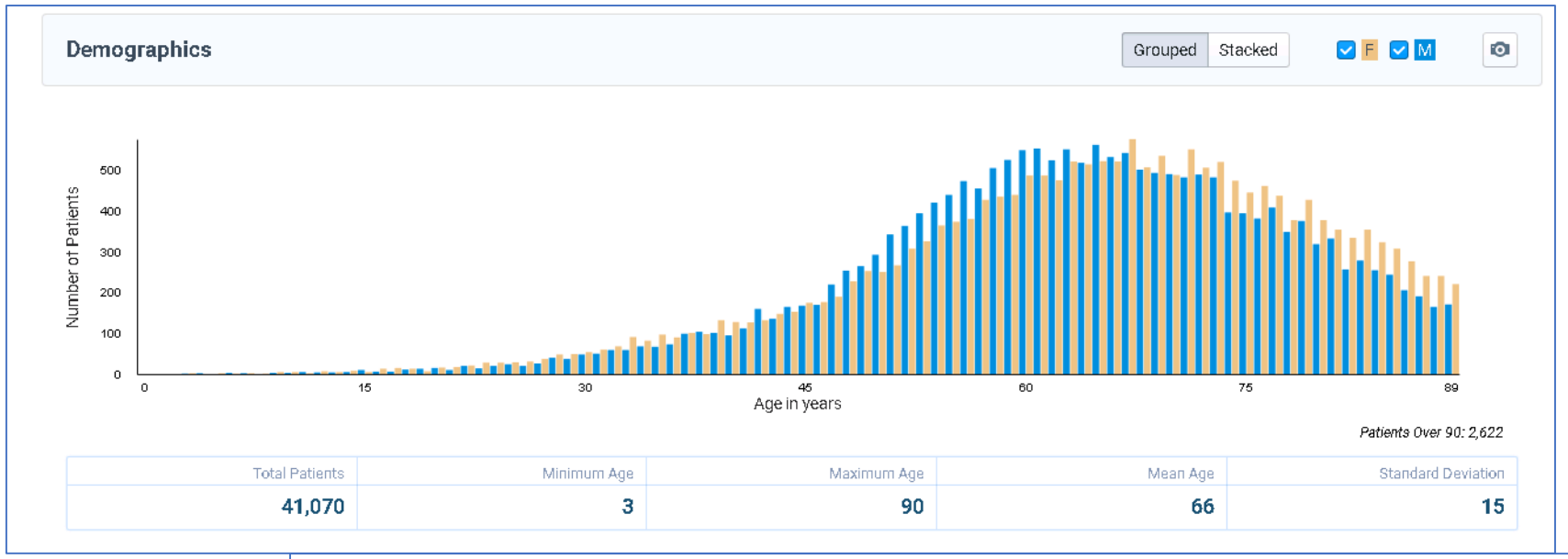
Sample Query: Narrowing Results Range

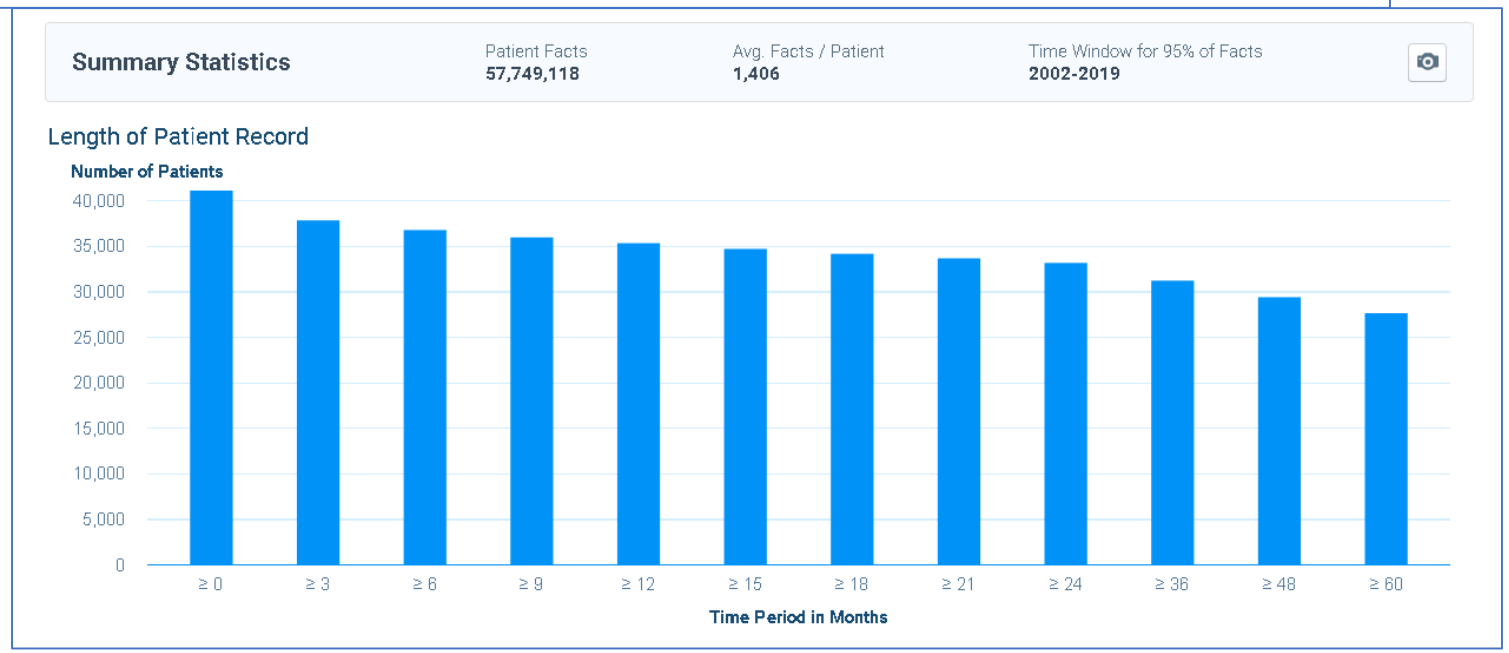


Sample Query: Counting Patients

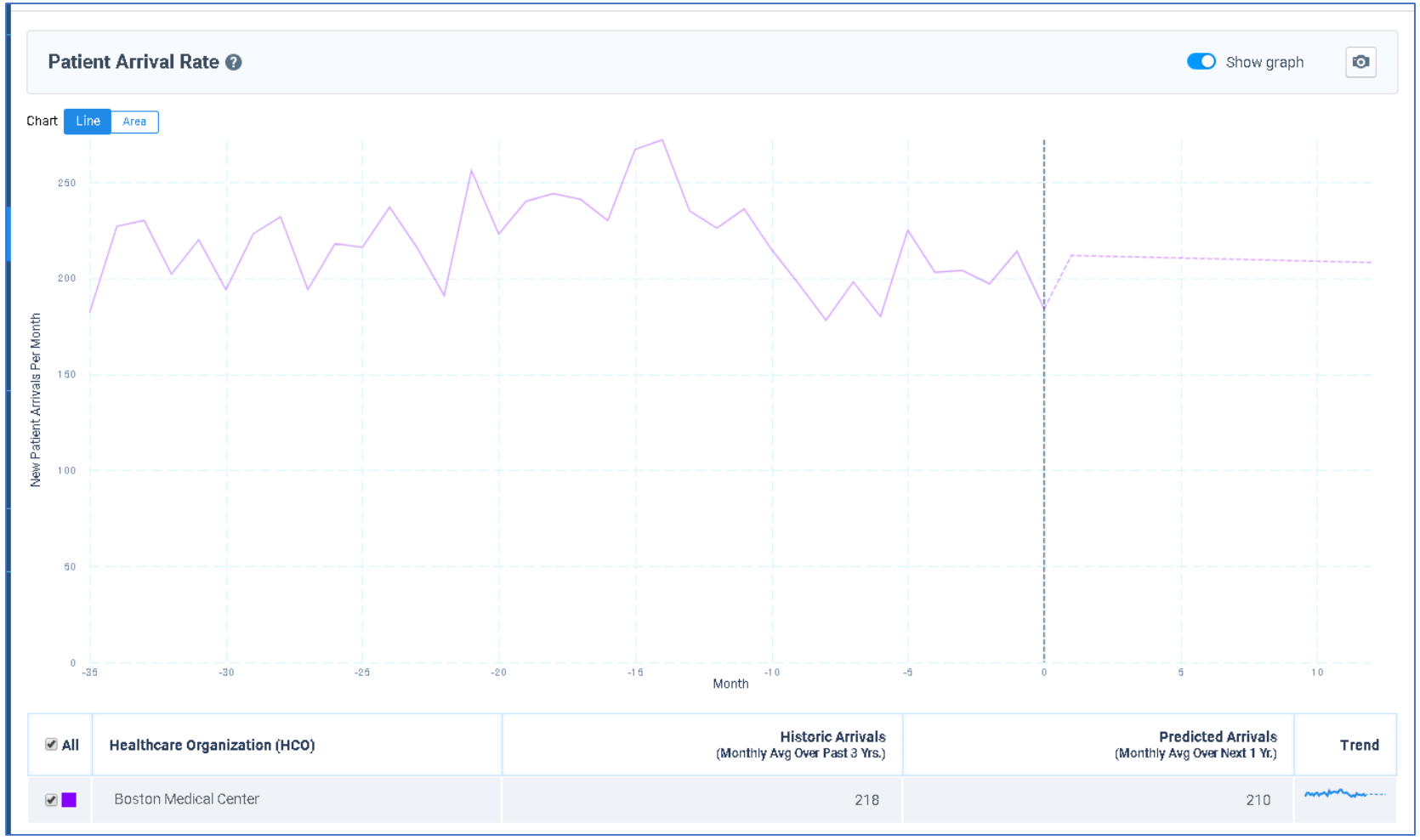


Sample Query: Exploring the Cohort

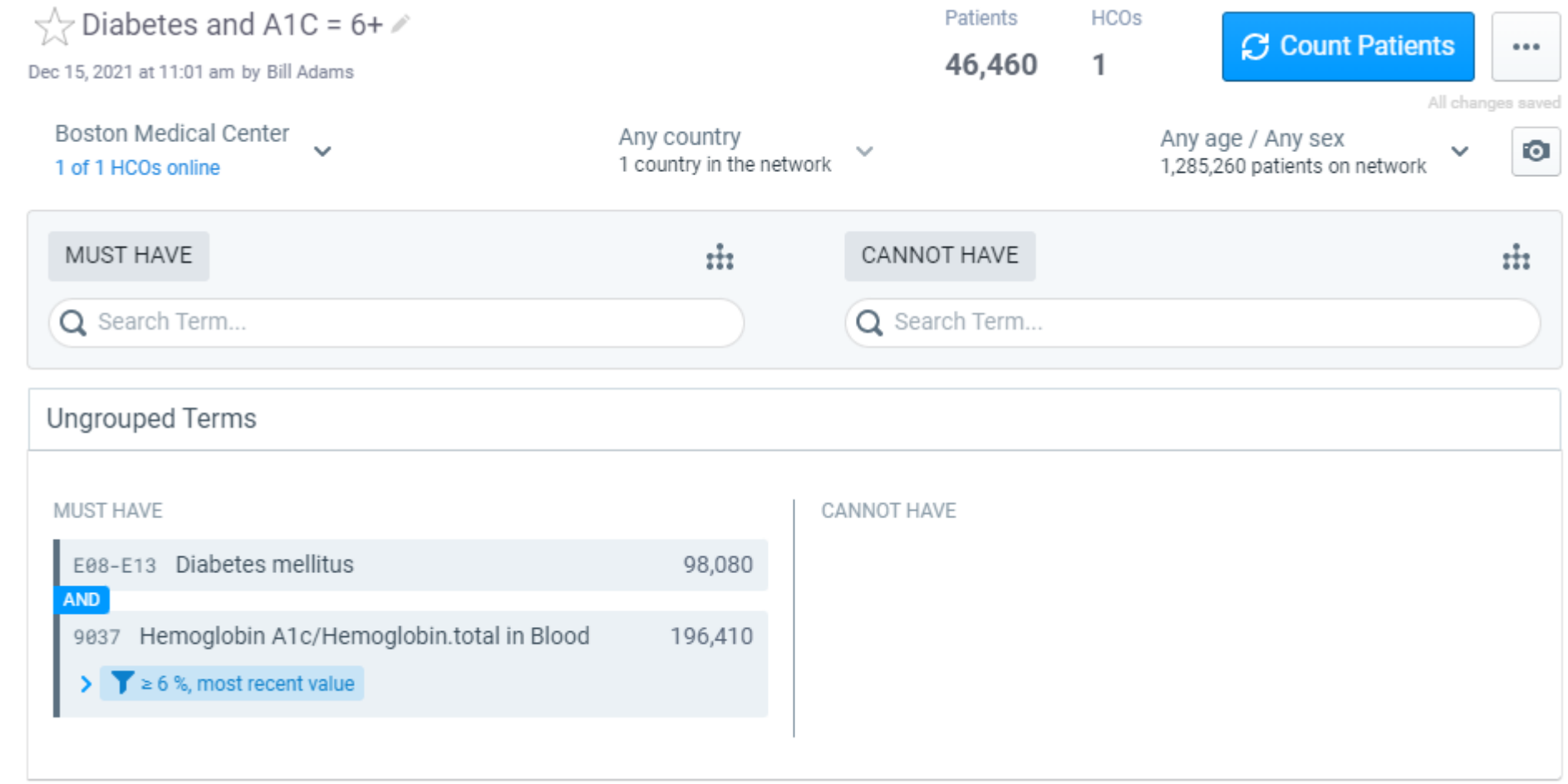




Sample Query: Predicting Arrivals



Sample Query: Counting Patients



Diabetes and A1C = 6+

Dec 15, 2021 at 11:01 am by Bill Adams

Patients 46,460

HCOs 1

Count Patients

All changes saved

Research
56 of 57 HCOs online

Any country
6 countries in the network

Any age / Any sex
81,221,267 patients on network

Select a network from the list below

Boston Medical Center | 1,285,260 Patients
- **1 of 1 Online** | Last Update: 12 days ago

Trial Connect | Analytics | Data sets

COVID-19 Research Network | 89,206,888 Patients
- **65 of 66 Online** | Last Update: 4 hours ago

Trial Connect | Analytics | Data sets

Diamond Network | 212,777,108 Patients
- **92 of 92 Online**

Trial Connect | Analytics | Data sets

EMEA Collaborative Network | 11,201,788 Patients
- **18 of 18 Online** | Last Update: 24 minutes ago

Trial Connect | Analytics | Data sets

Global Collaborative Network | 89,069,623 Patients
- **73 of 75 Online** | Last Update: 24 minutes ago

Trial Connect | Analytics | Data sets

LATAM Collaborative Network | 2,380,597 Patients
- **5 of 5 Online** | Last Update: 2 days ago

Trial Connect | Analytics | Data sets

Research | 81,221,267 Patients
- **56 of 57 Online** | Last Update: 4 hours ago

Trial Connect | Analytics | Data sets

Diabetes with A1C 6+ Research Network

Dec 15, 2021 at 11:06 am by Bill Adams

Patients 2,187,359

HCOs 52

Count Patients

All changes saved

Research
56 of 57 HCOs online

Any country
6 countries in the network

Any age / Any sex
81,221,267 patients on network

MUST HAVE

Search Term...

CANNOT HAVE

Search Term...

Ungrouped Terms

MUST HAVE

E08-E13 Diabetes mellitus 5,576,220

AND

9037 Hemoglobin A1c/Hemoglobin.total in Blood 9,034,516

≥ 6 %, most recent value

CANNOT HAVE

New Query

Hide

Filter By: Filter

Sort By: Most Recent

Request Dataset

Diabetes with A1C 6+ Research Network

by Bill Adams Dec 15, 2021 11:06 AM

Patients 2,187,359

HCOs 52

Network Research

Diabetes and A1C = 6+

Patients 46,460

HCOs 1

Diabetes and A1C

Patients 65,030

HCOs 1

Research-Ready Real-World Data

Eliminates the cost, complexity, and lengthy timelines associated with licensing, mapping, normalizing, and hosting multiple third-party data sets.

On-Demand Real-World Evidence Generation

Quickly gain real-world insights into how patients are treated and their health outcomes or conduct full protocol-driven observational research studies in a fraction of the usual time.

Elegant UI with Research Workflow

Intuitive interface for those without advanced data training and robust statistical analysis capabilities for experienced epidemiology and outcomes research professionals.

Global and Diverse Healthcare Databases

Conduct region-specific studies compliant with local privacy regulations; studies using academic medical center or cardiology specialty EMRs, HemOnc registries, or our Diamond Network.

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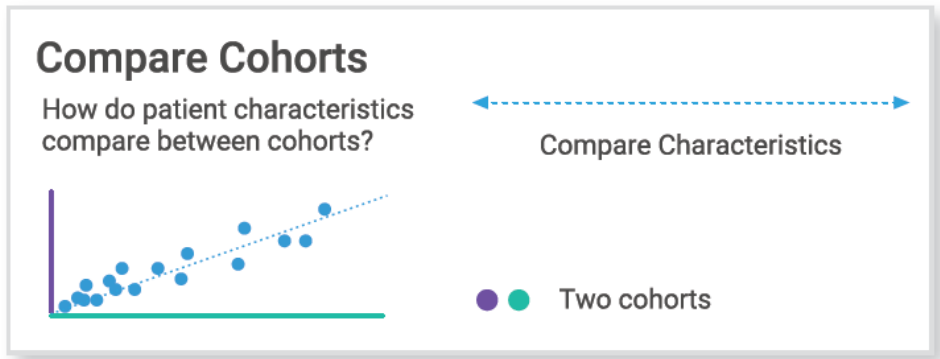
TriNetX

Highly Intuitive Analytics

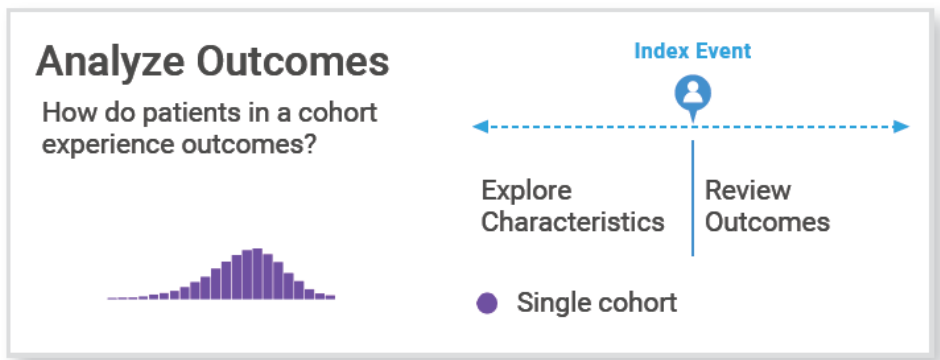
TriNetX combines longitudinal clinical data with powerful, self-service analytics, making it the fastest and easiest method for creating real-world evidence.



Compare Cohorts

Investigate characteristics of patients on different treatments, in different geographies, or in different demographic groups.

- Compare the prevalence of comorbidities, laboratory results, treatments, and medications across cohorts
- Discover meaningful differences between the characteristics of two cohorts



Analyze Outcomes

Identify risk of outcomes in a cohort and use retrospective data as a control arm.

- Understand baseline characteristics and natural disease progression
- Define your cohort according to eligibility criteria of a clinical trial and use real-world data as your control arm

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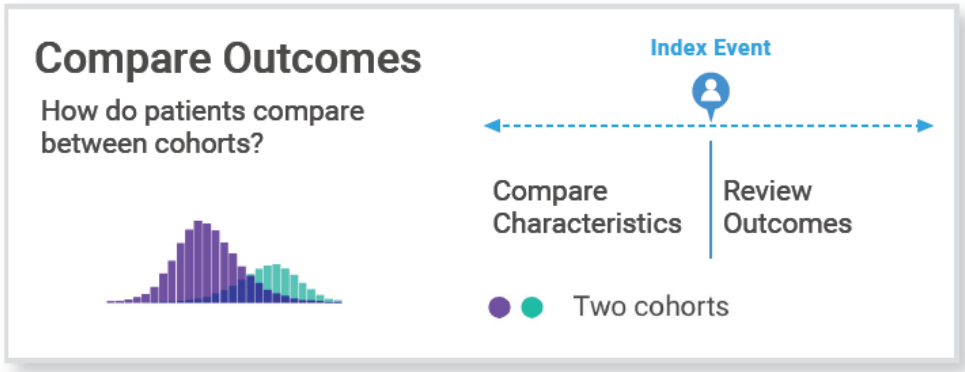
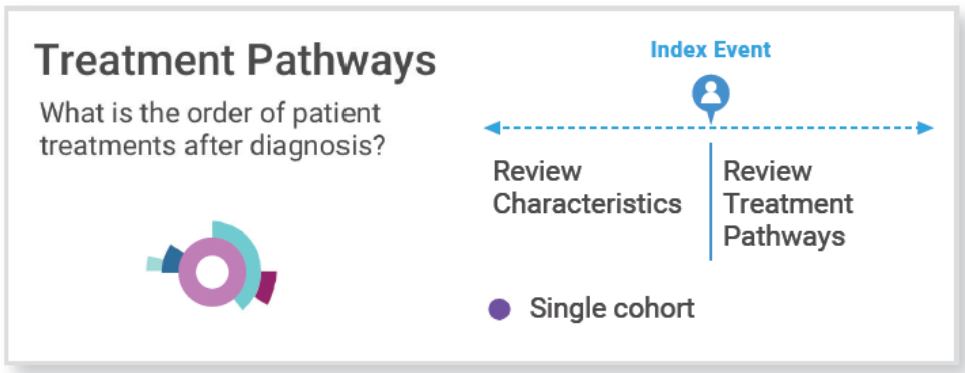


Compare Outcomes

Conduct comparative effectiveness research with propensity score matching, stratification, and Kaplan-Meier analyses.

- Conduct retrospective observational analysis
- Compare cohorts' baseline characteristics
- Compare risk of outcomes across cohorts
- Perform time-to-event analysis



Treatment Pathways

Analyze how patients are treated and when they switch treatments. Compare lines of treatment for any disease.

- Understand typical care pathways
- Analyze characteristics of patients who switch treatments
- Compare outcomes across different lines of treatment

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TriNetX

Additional TriNetX Opportunities

- TriNetX Research
  - Collaboration between 50+ HCOs
  - Aggregate queries available through query tool
  - Limited datasets (LDS) can also be requested
  - Downloads of potentially very large LDS require IRB protocol, approval, and funding
  - Next year hope to add death data claims
- Trial Connect
  - Industry partners reachout (blinded) to potential sites using aggregate counts
  - Interested sites respond to invitation for further discussion

National COVID Cohort Collaborative (N3C)

A national resource for shared analytics

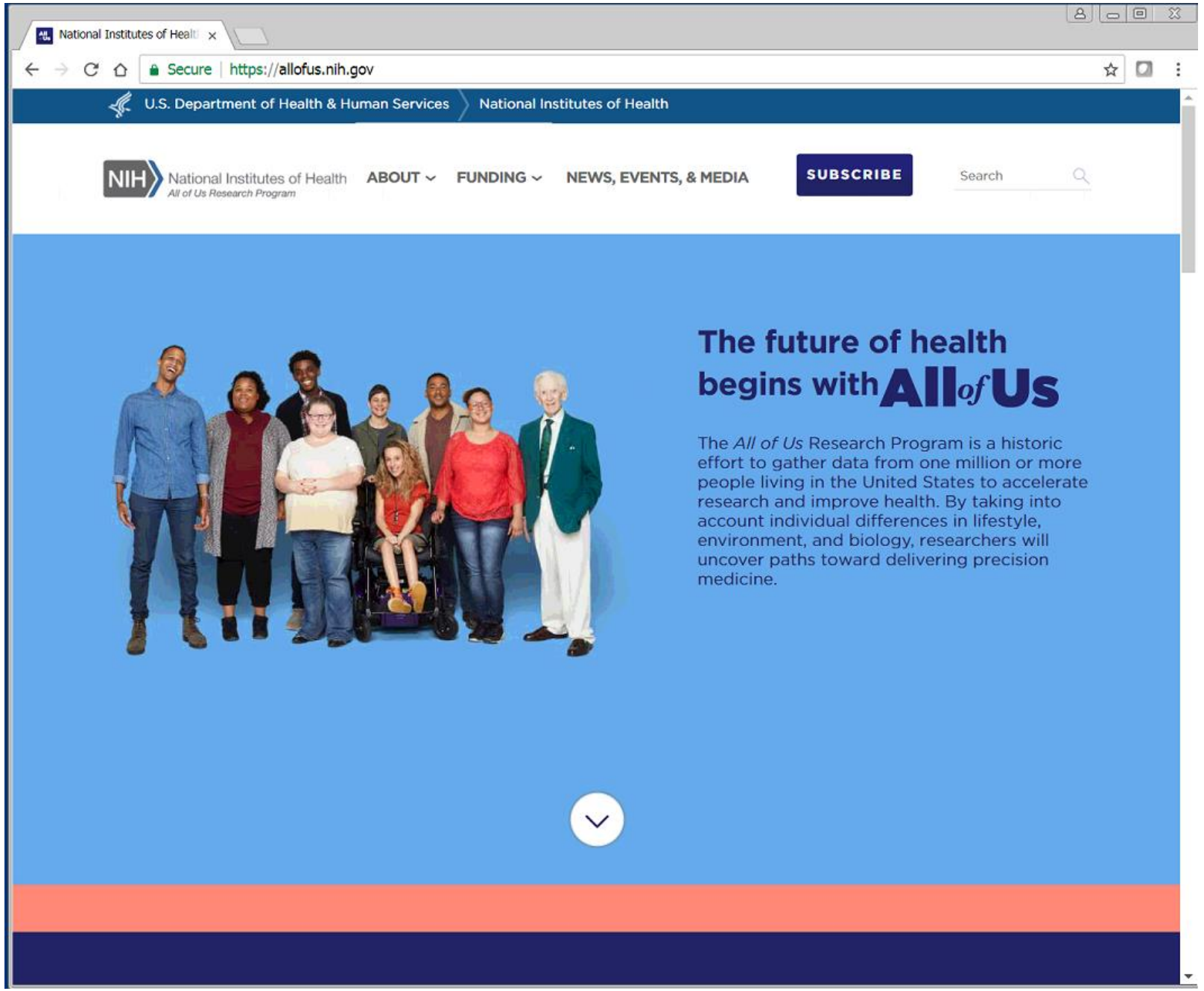
22 April 2020

National
COVID
Cohort
Collaborative

NC3 Goals

- Establish a central registry of patients who have been tested for COVID or have a clinical diagnosis of COVID.
- Harmonize COVID clinical data extracted from federated clinical repositories associated with one of several Common Data Models (CDM) (ACT/i2b2, PCORNet, OHDSI, TriNetX)
- Provide secure analytic platform for analytics using minimum required identifiers (HIPAA limited data set, de-identified, synthetic)

Additional information at: https://ncats.nih.gov/n3c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The future of health begins with All of Us
The All of Us Research Program is a historic effort to gather data from one million or more people living in the United States to accelerate research and improve health. By taking into account individual differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine.

BU-CTSI Biomedical Informatics Core Key Personnel

Investigator	Expertise	Roles
William Adams	CRI, Epi, i2b2	Director, clinical and population health informatics lead, manages and promotes i2b2 and OMOP networks
Eric Kolaczyk	CDS,ML-PA,EDS	Computational and data science lead
Marc Lenburg	BI	Bioinformatics lead, CRC bioinformatics liaison
Rebecca Mishuris	CRI, EHR, PH	EHR innovation research, ITS-liaison, Epic SME
Christopher Shanahan	CRI,RD	CRITC lead, app and registry SME, addiction informatics SME
Ioannis Paschalidis	CDS,ML-PA	Machine learning, prediction, School of Engineering liaison
Belinda Borelli	MH, TBC	Mobile/Digital Health lead technology-based behavior change SME
Heather Hsu	HSR, PH, ACO	Population Health and ACO Analytics lead, data governance
Martha Werler	PHI, Epi, PH	Public Health Informatics, promotes Optum and other data
Adam Gower	BI	Bioinformatics analytic support, OpenSesame and GeneHive

Expertise Legend: ACO-Accountable Care Organization, BI-Bioinformatics, CDS-Computational and Data Sciences, CRI–Clinical Research Informatics, EHR-Electronic Health Record, Encryption and Data Security (EDS), HSR-Health Services Research, i2b2-Informatics for Integrating Biology and the Bedside, ML-PA-Machine Learning/Predictive Analytics, MH-Mobile Health, OMOP-Observational Medical Outcomes Project, PH-Population Health, RD-Registry Development, SME-subject matter expert, TBC-Technology-based Behavior Change

Important Announcement

Visit Back2BU for the latest updates and information on BU's response to COVID-19.

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Accelerating Discoveries Toward Better Health

The BU-CTSI is a center of expertise providing tools, services and resources to clinical investigators, maximizing the impact of discoveries & speeding the translation of research into improved patient care

SUCCESS STORY

BU CTSI Funds 21 COVID-19 Related Research Projects in 2020

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BU CTSI Receives 38.3 Million Renewal from NIH

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CTSI Services

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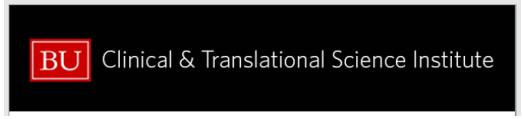
Data for Equity (D4E)



Contributions to Health Outcome Composite Score*:

- 47% socio-economic factors
- 34% health behaviors
- ***16% clinical care***
- 3% physical environment

***Hood et al / Am J Prev Med 2016;50(2):129–135**

Social Determinants of Health | Healthy People 2020

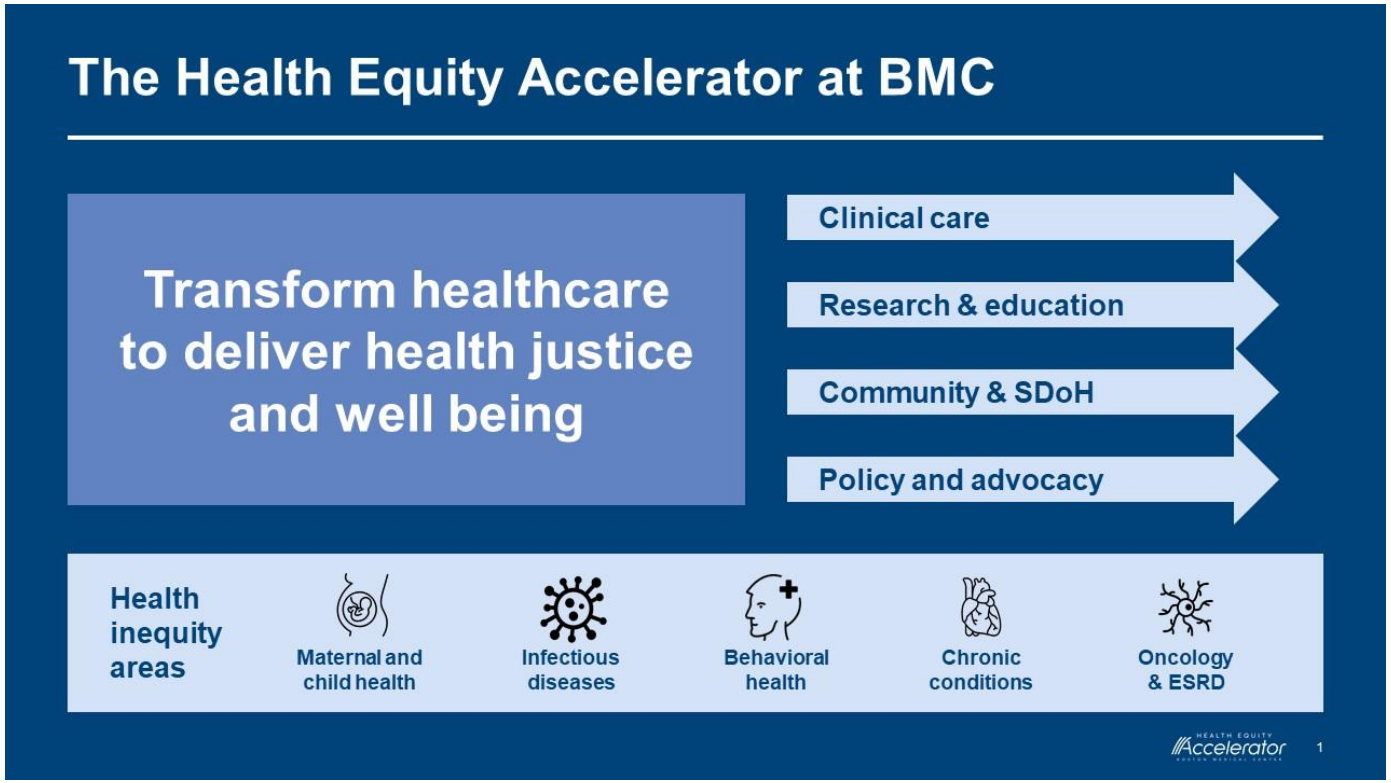
Boston Medical Center launches new plan to address racial disparities in health care

By Priyanka Dayal McCluskey Globe Staff, Updated November 16, 2021, 10:27 a.m.

Dr. Thea James, left, and Elena Mendez-Escobar are the codirectors of Boston Medical Center's new Health Equity Accelerator. SUZANNE KREITER/GLOBE STAFF

Boston Medical Center, the safety-net hospital where the majority of patients identify as people of color, is launching a broad new effort to pinpoint racial inequities in health care and work to eliminate those disparities for Black and brown people.

The initiative announced Tuesday, called the Health Equity Accelerator, will bring together researchers and clinicians and include feedback from patients to address longstanding discrepancies in health care and outcomes.



www.bmc.org/health-equity-accelerator

OHDSI/OMOP Common Data Model*

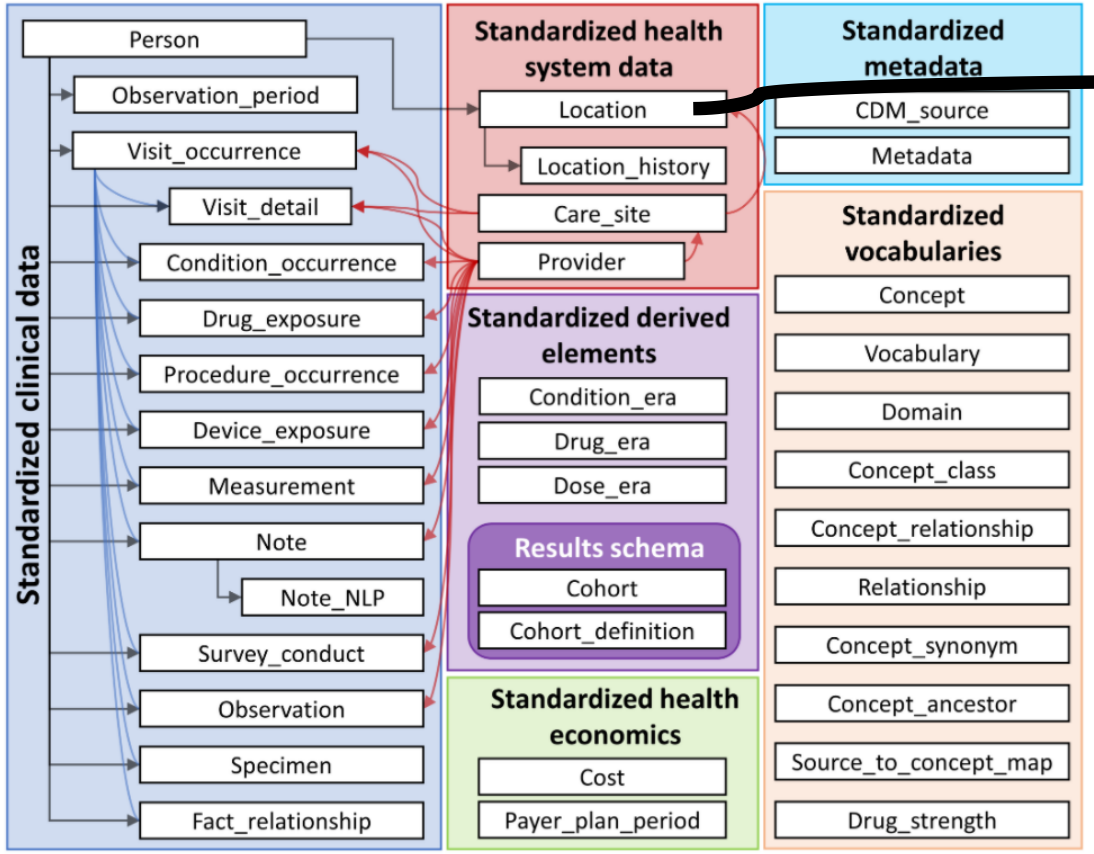


Figure 4.1: Overview of all tables in the CDM version 6.0. Note that not all relationships between tables are shown.

+

Figure 1

Social Determinants of Health

Economic Stability	Neighborhood and Physical Environment	Education	Food	Community and Social Context	Health Care System
Employment	Housing	Literacy	Hunger	Social integration	Health coverage
Income	Transportation	Language	Access to healthy options	Support systems	Provider availability
Expenses	Safety	Early childhood education		Community engagement	Provider linguistic and cultural competency
Debt	Parks	Vocational training		Discrimination	Quality of care
Medical bills	Playgrounds	Higher education		Stress	
Support	Walkability				
	Zip code / geography				

Health Outcomes
Mortality, Morbidity, Life Expectancy, Health Care Expenditures, Health Status, Functional Limitations

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*Used by N3C, AllofUs, many other academic institutions

www.ohdsi.org

Data for Equity (D4E) Platform - 2022

- 20-year integrated clinical dataset
  - CHCs and BMC
- Rich location-based data
- Common data governance
- Common data model (OMOP CDM)
- Shared software and analytic code
- Open-source learning community (OHDSI)
- De-identified population level research
    - HSR, CER, ML, AI, QI

BU Clinical & Translational Science Institute

Thank you for joining us today!

For additional questions please contact:

Nicholas Trombley (nst5775@bu.edu)
Bill Adams (badams@bu.edu)

(or visit the BU-CTSI website and put in a request)

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