





## Leveraging the OUHSC Clinical Research Data Warehouse to Inform Research & Practice

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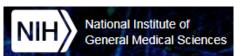
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Biomedical & Behavioral Methodology Core (BBMC)

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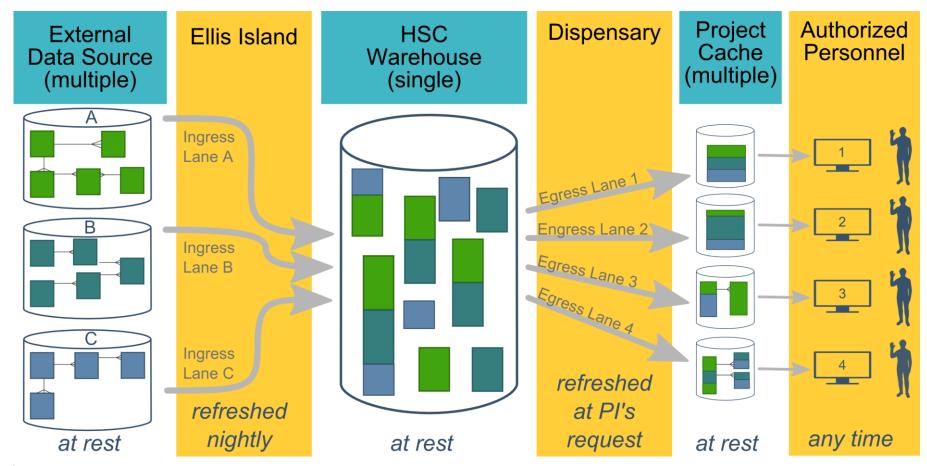
Award Numbers: UG10D024950 U54GM104938



### CRDW (Clinical Research Data Warehouse)

https://github.com/OuhscBbmc/prairie-outpost-public

Ecosystem Architecture



- Data Source (column 1): contains unique info
- Warehouse (column 3): contains copy after manipulation
- Project Cache (column 5): transformed to facilitate analyses of a specific research project

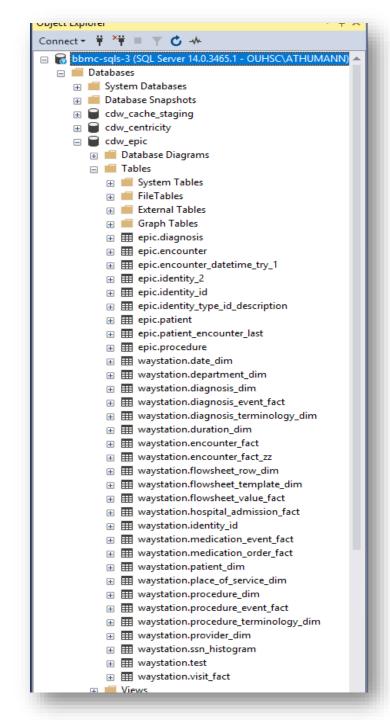
#### Patient

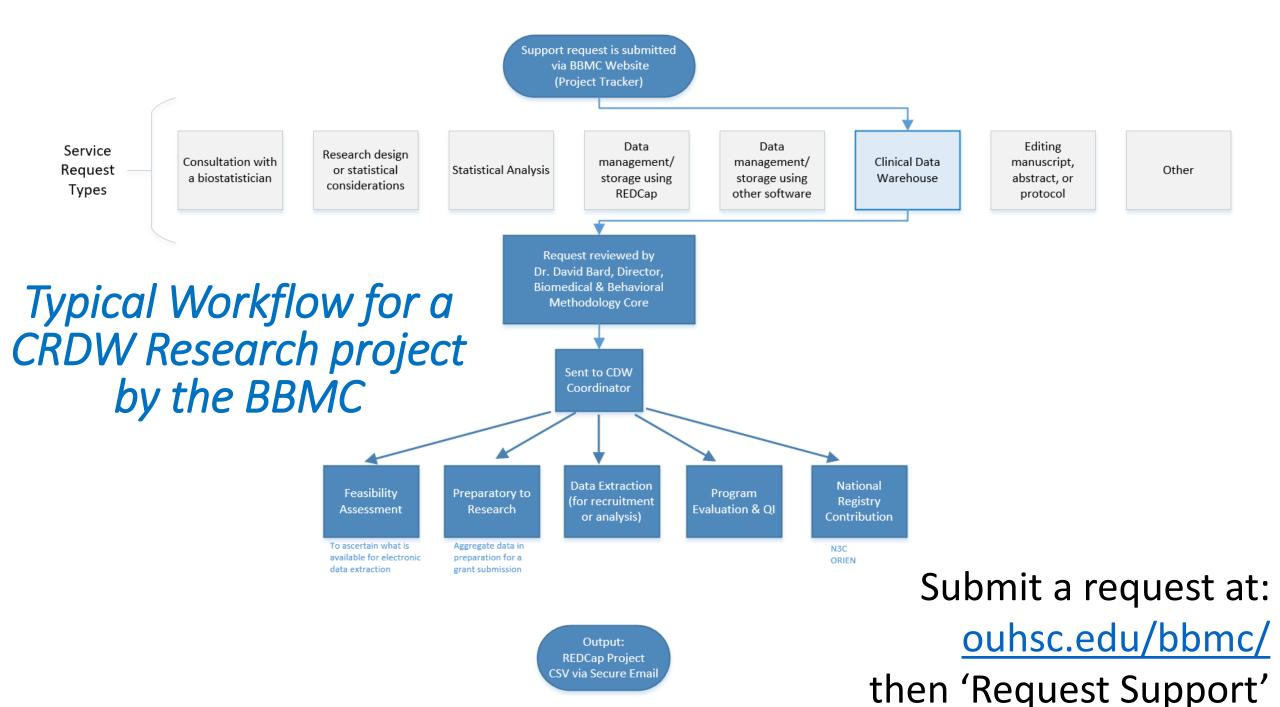
### **HSC Data Sources**

- Epic (we have the basics, and will be adding for a while)
- Legacy Outpatient (Centricity)
- Legacy Billing and Claims Data (GECB)
- Legacy Inpatient (Meditech)
- Dozens of departmental sources
- Biomedical Research Data
- Provider
- External Agencies
  - Service Provided (by the Health Dept of Oklahoma)
  - Child Protective Services (Oklahoma Dept of Human Services)
  - Immunization (Health Dept of Oklahoma)
  - Vital Records (Health Dept of Oklahoma)
  - ...
  - Multi-state collaborations (in the future)
- Administrative Cost
- Employee & Student

### Integration of Epic

- Current Tables automatically updated nightly
  - Patient
  - Diagnosis
  - Encounter
  - Procedure
  - Medication
  - Flowsheet
  - Labs
  - Orders
  - Immunizations
  - Dozens more





### Two Definitions of "QI" -depends on your audience

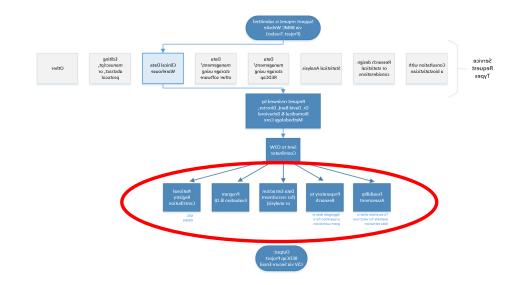
- There are two campus groups who query Epic & the EMRs
  - OUHSC has the BBMC (ie, us)
  - OUH has the DnA group ("Data and Analytics", also known as "Health Informatics")
- "QI with intent to publish or present"
  - Routes to the OUHSC group
    - Go to <a href="https://ouhsc.edu/bbmc/">https://ouhsc.edu/bbmc/</a> and click "Request BBMC Services"
  - Applies to most of your resident research projects
  - Typically has an IRB approval or IRB exemption letter
- "QI to improve an internal process (with no intent to publish)"
  - Routes to the OUH group
    - Go to <a href="https://ouhealth.service-now.com/">https://ouhealth.service-now.com/</a> (with your OUH account)

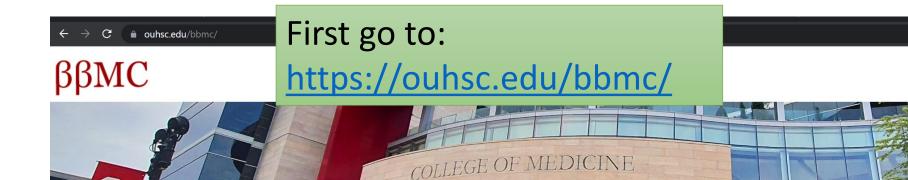
No IRB approval is required for internal QI

• Human subjects aren't involved; data will not be shared outside OU

### Commonly Requested CRDW Support Services

- Feasibility assessment in preparation for research (20% of projects; 10% of CRDW staff time)
- Static eligibility (70% of projects; 20% of CRDW staff time)
  - Virtually all projects require identification of a patient pool
- Rolling eligibility (30% of projects; 30% of CRDW staff time)
  - Remember study team's assessment of eligibility as well as the participant's response
  - Daily automation requires stability & good logging; e.g., a 3 hour delay might mean zero subjects are enrolled
- Clinical outcomes for retrospective investigations (50% of projects; 30% of CRDW staff time)
- Administrative outcomes for quality improvement (10% of projects; 2% of CRDW staff time)
- Program evaluation (20% of projects; 8% of CRDW staff time)





# Then click

#### **HOMEPAGE**

REQUEST BBMC SERVICES

REDCAP

BBMC TEAM MEMBERS

CLINICAL RESEARCH DATA WAREHOUSE

FIND US ON GITHUB

STATISTICAL COMPUTING USER GROUP (SCUG)

#### Biomedical & Behavioral Methodology Core

The BBMC mission is to support and enhance study design, data capture, and analytics for academic research.

Established in 2013, BBMC is a collaboration with <u>College of Medicine</u> - <u>Department of Pediatrics</u>, <u>Department of Biostatistics and Epidemiology</u>, and <u>College of Public Health</u>. Our team is comprised of biostatisticians and experienced researchers. The Core offers a variety of support services for projects at any stage of development.

In addition to the consultation services our team provides, many members of the team continue to lead their own research studies within their own departments. BBMC is home to the EmBRACER Center and has close affiliations with the Child Study Center and the Center on Child Abuse and Neglect (both within OU Pediatrics).

BBMC also provides general and advanced research training opportunities for researchers at all levels of experience. If you would like to receive methodology support, including statistics consultation, project design help, or database support, please submit a request <a href="here">here</a> for a free one-hour consult with a member of our team.

For general inquiries about BBMC, please reach out to us at <a href="mailto:bbmc@ouhsc.edu">bbmc@ouhsc.edu</a>.

#### Expertise



Biostatistician Support: Our team has several faculty and staff biostatisticians with specialized

expertise in Pediatric research, quantitative methods, Bayesian statistics, genetics, and much more.



#### Research Support:

We can help with planning for sample size, analytics, protocol writing, and consulting

on project aims. We can also help with manuscripts, reviewing publications, as well as mentoring and graduate committee memberships.



Database management: We are the campus maintainers of REDCap. Our Clinical

Research Data Warehouse

BBMC Research			Re	esize font:							
~~~ Welcome! ~~~  Please provide us with information about you, your project, and the services being requested.											
NOTICE: If you were directed to fill out this form by ORA or as part of a Data Use Agreement, please use this form instead: https://redcap.link/crioc_review											
Date Submitted 2022-06-07 Y-M-D											
The Principal Investigate	or is ultim	ately responsib	le for this project:								
Contact First	t Name	Last Name	Role on Project		Email	Phone					
PI			Principal Investigate	or							
Secondary				~							
If the PI belongs to a non-college entity such as Stephenson Cancer Center, please select <b>None</b> for the College and enter the organization's name under Department.											
Pi's College		PI's Departmen	t (if applicable)	Pi's Sec	ction (if applic	able)					
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		~ ~ ~ Plea	ise tell us about you	ır project ~ ~ ~							
Project Title											
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Does this request in electronic medical r				Yes		No					
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Study Aim 1											
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This project has:				An IDD	protocol bein	a written	)				
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				A sub	mitted IRB pr	otocol	)				

An approved IRB protocol

No need for an IRB-approved protocol or the project is exempt

Then "Yes"

to CRDW

#### ~ ~ ~ The following table asks which services you are requesting. ~ ~ ~ <u>Please note</u>: Requests for data from the Clinical Research Data Warehouse (electronic health records) typically take 4-6 weeks to complete and are prioritized by date submitted, funding source, IRB status, etc. Service Requested Short Description Do you have an existing BBMC contact person for this request? No ~ ~ ~ Please answer the following questions. ~ ~ ~ Your answers will help the BBMC team and governance board to (1) prioritize your project, (2) justify the funding to provide these services, and (3) describe our impact on campus research. This project is currently funded. The BBMC must report to our funding sources on the kinds of projects we have supported. The availability of our services depends on your answers. Please choose <u>all</u> categories that fit your project. Underlined phrases have pop-up balloons with definitions. This project involves ... Quality improvement Scientific research Other scholarly activity for future publication Yes Program evaluation Academic activities Business analytics Yes Health economics Health systems Yes Dissemination/implementation science Yes Outcomes research Feasibility assessment Yes Preparatory to research Yes Data extraction for recruitment or analysis National registry contribution Retrospective chart review

# Then "CRDW" Service Reugested

### Timeline for Basic Requests

We strongly recommend that you submit your request to CRDW before the IRB.

1. We can help with the IRB language and avoid some of the common reasons the IRB rejects your initial application

2. We need 6+ weeks for basic requests. It doesn't take us 6 weeks, but we have a lot of people asking for data. Please don't initially approach us a week before your research month begins.

There are a few cycles of communication between you and us (such as metadata files that specify the inclusion criteria meds and dxs).

### **CRDW Typical Workflow**

#### Meet with investigator to determine data needs, feasibility BBMC Triage to •Structured vs. services: unstructured? Intake via BBMC Feasibility How well meet request form Preparatory to project needs with Research what's available? Program Evaluation •IRB considerations •QI Recruitment Retrospective Analysis Registry • Facilitate Abstraction •Investigators are asked to add CRDW team to IRB application as KSP •CRDW team reviews & evaluates protocol to ensure data requested are authorized •Some have required modifications prior to release of data This occasionally causes delays •Ideally, the IRB would implement a procedure to allow

investigators to indicate utilization of CDRW upon initial approval without adding team as KSP (e.g., a check-box on the

application indicating use of CDRW to extract data)

### Back and forth with investigator

- Metadata files (such as identifying ICD codes, medications)
- Verifying data formats
- Identifying locations and sources of data

#### Develop Pipeline

Assign project to BBMC

analyst based on skills,

workload, & interests

Some projects may

involve multiple

analysts

- •SQL, R, & Python
- •Automated daily data
- •Varies vastly in complexity by project, data sources, etc.

Review with investigator and distribute via approved method

- CSV tables via SFT
- Push to REDCap
- Dashboards
- Follows HIPAA & least privileges principles

•Some may be very complex and/or rely on complicated code (e.g., Regular Expressions to extract structured data from unstructured notes, etc.). These requests can make completion take longer than usual.



#### **Data Formats**

#### **Structured** (easier)

- Patient demographics
- Problem list or billed diagnoses (ICD-10)
- Visits/encounters
- Medications (GPI, RxNorm, NDC)
- Most lab results (LOINC), but some are like this:

#### **Unstructured** (harder)

- Diagnoses entered in the past medical history
- Symptoms in HPI
- Histories
- Full notes
- Some lab results
- Radiology & pathology reports

```
Meditech's History & Physical Note
(concatenated if a visit has multiple hpppd notes by "------").
OU MEDICAL CENTER (COCPN)
History Physical
REPORT#
DATE
            Time:
PATIENT:
                    UNIT No
ACCOUNT#:
                     ROOM:
**See Addendum**
Ped Standard H&P
History And Physical
Primary Care Physician
Primary Team: Red
History and Physical
Chief Complaint: increased work of breathing
History Of Present Illness:
```

### **Encouraging Secure Data Practices**

Our goal is to deliver the data extracts to researchers in a way that makes it easy for them to follow best practices.

### Delivery of PHI, depending on the dataset and researcher

- <u>SFT</u> for one-time transfers
- OU file servers for recurring transfers
- REDCap for recruiting projects (users manually enter data as we refresh info daily)
- Never email

### Common mitigations include

- Withholding PHI fields
- Obfuscating PHI fields (e.g., birth year instead of birth date)
- Pre-calculating fields to avoid PHI (e.g., we calculate the age at visit, instead of sending visit & birth dates)

# Using Metadata to Transfer your Clinical Knowledge into the Workflow

The CRDW team requests specific codes (eg, ICDs). The typical steps are

- 1. You send us some keywords (eg, "ventricular" and "heart")
- 2. We *sweep* the code list and send you ~100 possibilities.
- 3. You *specify* the ~30 exact codes that reflect the inclusion criteria
- 4. Some projects also use a "category" variable (eg, "acute" vs "chronic" failure)

1	concept_id	vocabulary_id	icd_code	icd_description	desired	category	comments
2	[35207792]	ICD10CM	[150.1]	Left ventricular failure, unspecified	TRUE	cardiac	
3	[1569179]	ICD10CM	[150.2]	Systolic (congestive) heart failure	TRUE	cardiac	
4	[45586587]	ICD10CM	[150.20]	Unspecified systolic (congestive) heart failure	TRUE	cardiac	
5	[45543182]	ICD10CM	[150.21]	Acute systolic (congestive) heart failure	TRUE	cardiac	
6	[45576878]	ICD10CM	[150.22]	Chronic systolic (congestive) heart failure	TRUE	cardiac	
7	[45567180]	ICD10CM	[150.23]	Acute on chronic systolic (congestive) heart failure	TRUE	cardiac	
8	[1569180]	ICD10CM	[150.3]	Diastolic (congestive) heart failure	TRUE	cardiac	
9	[45601038]	ICD10CM	[150.30]	Unspecified diastolic (congestive) heart failure	TRUE	cardiac	
10	[45548022]	ICD10CM	[150.31]	Acute diastolic (congestive) heart failure	TRUE	cardiac	

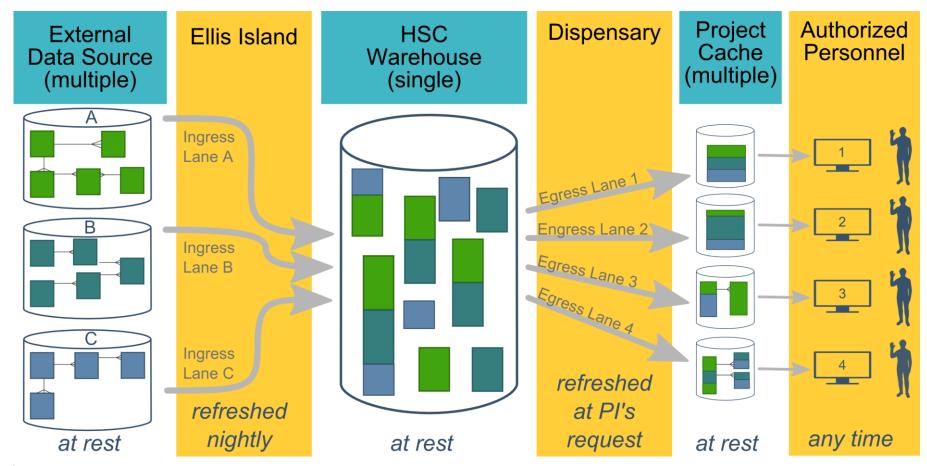
### N3C: National COVID Cohort Collaborative

- One of several examples of OU contributing EHR to a national investigation
- 80+ US institutions from 20+ states contribute EHR data in an OMOP model
- Datasets are accessible only through a browser to NIH's cluster
  - Spark, Python, R
  - Lots of governance steps, but not as many as you'd think
- We believe this type of collaboration will be important in the future
- Daily contributions during the pandemic
- Patients connected across sites safely
  - Each site tokenized PII via <a href="PPRL">PPRL</a> (privacy preserving record linkage)

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IDeA States Pediatric Network



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