





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

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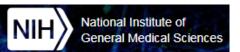
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Biomedical & Behavioral Methodology Core (BBMC)

January 2024





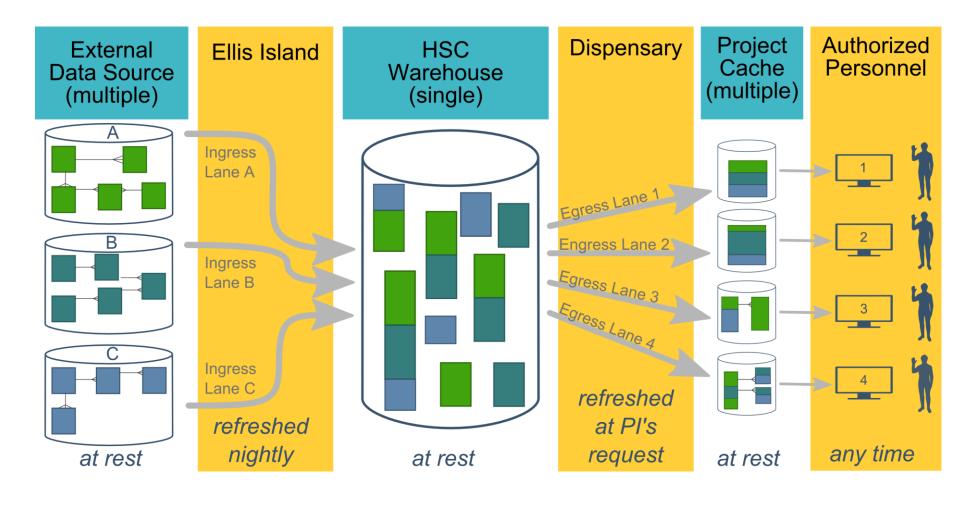


Award Numbers: UG10D024950 U54GM104938



CRDW (Clinical Research Data Warehouse)

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

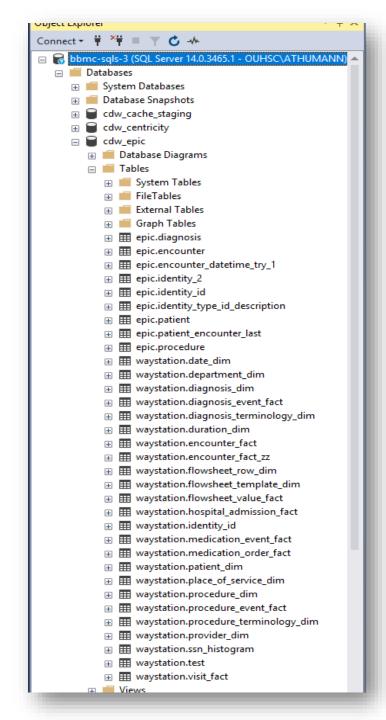
• Patient

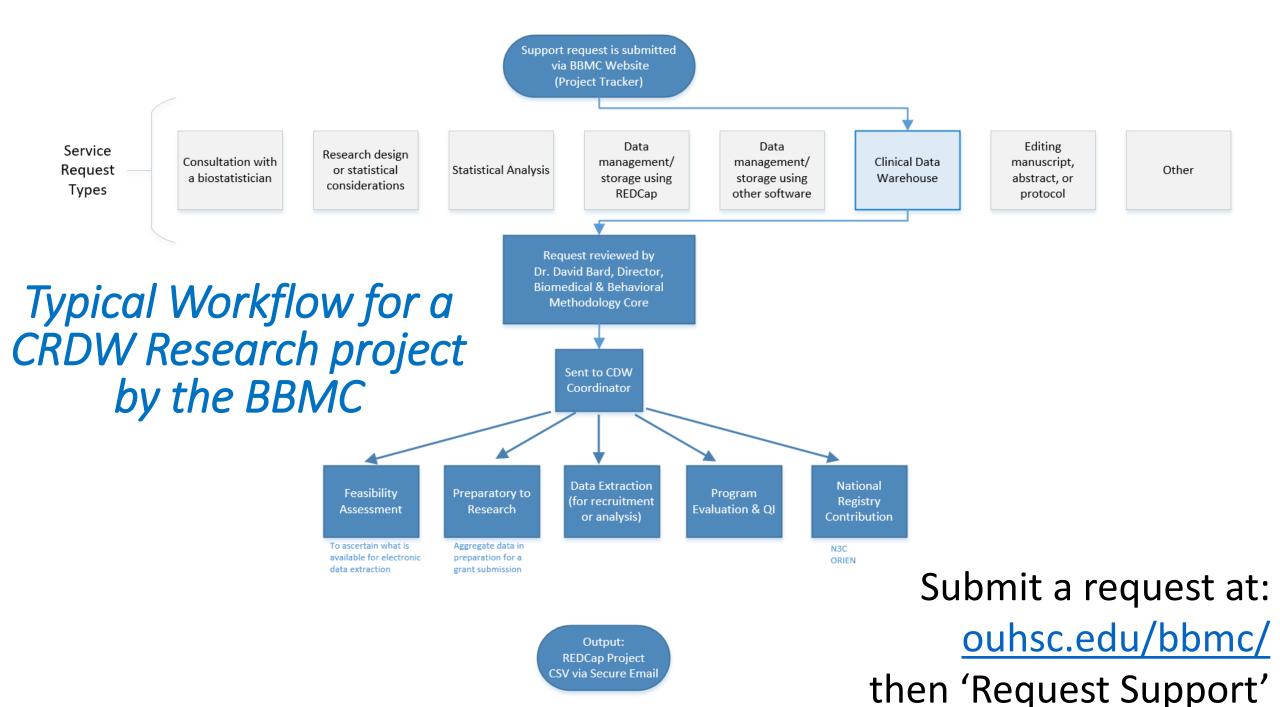
HSC Data Sources

- 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
- In Development
 - Medication
 - Medication OrderFlowsheet
- Future
 - Labs
 - Orders
 - Immunizations



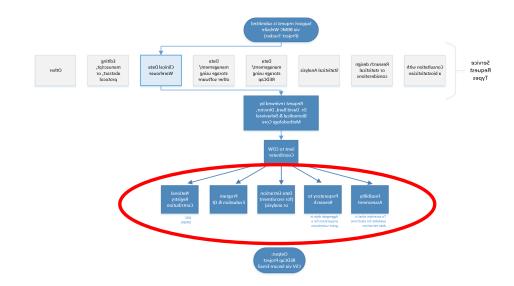


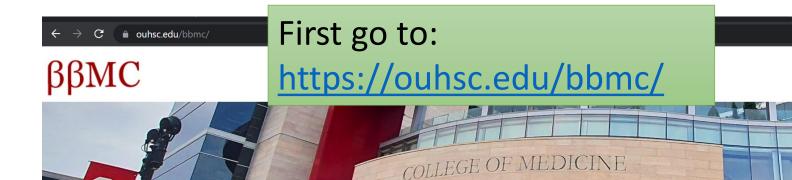
Two Definitions of "QI" —depends on your audience

- 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 https://ouhsc.edu/bbmc/ 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 https://ouhealth.service-now.com/ (with your OUH account)
 - <-- Kacey, what would you like here? -->
 - 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)







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 here for a free one-hour consult with a member of our team.

For general inquiries about BBMC, please reach out to us at bbmc@ouhsc.edu.

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:

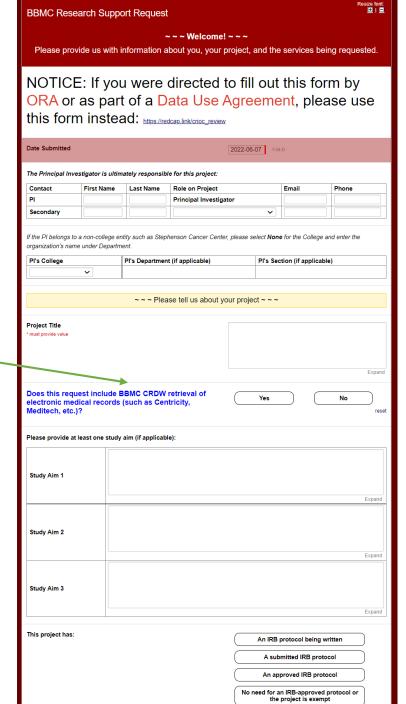
We can help with planning for sample size, analytics, protocol writing, and consulting

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 Marehouse



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 Yes Academic activities Business analytics Yes Health economics Health systems Yes Dissemination/implementation science Yes Outcomes research Yes Feasibility assessment Yes Preparatory to research Data extraction for recruitment or analysis National registry contribution Retrospective chart review

Then "CRDW" Service Reugested

Timeline for 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)

analyst based on skills, workload, & interests Back and forth with Some projects may

Assign project to BBMC

involve multiple

analysts

- Metadata files (such as identifying ICD codes, medications)
- Verifying data formats

investigator

 Identifying locations and sources of data

•SQL, R, & Python

Develop Pipeline

- 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.

The UNIVERSITY of OKLAHOMA

| Health Sciences Center

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
- HSC 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	[I50.31]	Acute diastolic (congestive) heart failure	TRUE	cardiac	

N3C: National COVID Cohort Collaborative

- 60+ US institutions from 20+ statues 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
- We're recruiting OU collaborators
 - particularly statisticians, data scientists, and clinicians
 - tell us if anyone has a research question, or want to join an existing project





IDeA States Pediatric Network



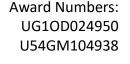
Thank you

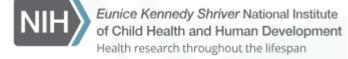
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NIH National Institute of General Medical Sciences



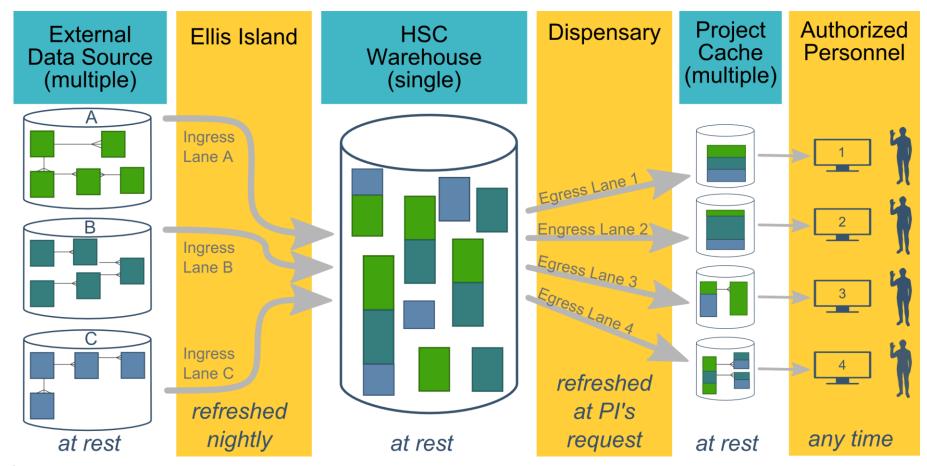




Prairie Outpost – CRDW (Clinical Research Data Warehouse)

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

Ecosystem Architecture



- Data Source (column 1): contains unique info
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Extra Slides

Contributing to External Registries

Regarding decisions around data that leave OU ...should there be policies involving

- Only for a clearly defined research purpose (combined QI + research registry participation e.g. NSQIP, TQIP, etc. should be handled by OUH)
- Deidentification or limited data set
- Not-for-profit requirement of the business associate (Beasley doesn't like this restriction)

Anything outside the stated review purview can still come to committee for recommendation before be passed to the OUH Leadership and data governance bodies

Sample Rolling Eligibility Report

1 Summary

2 Eligible Patients

3 Diagnostics

4 Session Information

POPS Patient Screening Report

Date: 2019-06-10

Enumerates the potenitally eligible patients for the three OUHSC inpatient sites (i.e., NICU, PICU, & General Inpatient) and various outpatient sites (e.g., Sooner Peds) participating in the POPS project (Paul Darden & Christine Allen, PI).

1 Summary

1.1 Note

1.2 GUI Questions

- 1. The current report covers 16 unique patients potentially eligible on June 10, 2019.
- 2. Jump to the in-patient dashboard in REDCap.
- If the MRN starts with an 'F' or '9', the id, name, dob, and age are simulated. The appointment and medication is real though. Check for hidden PHI before releasing

2 Eligible Patients

2.1 NICU 2.2 PICU 2.3 Inpatient 2.4 Unknown/Unclassified 2.5 Outpatient

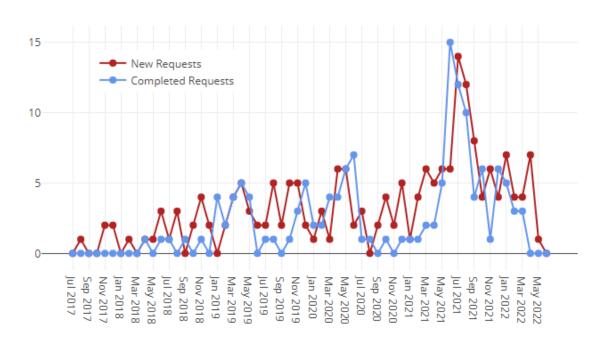
Search:

	mrn centricity [‡]	days since \$ consent	name 🛊	dob age ♦ gender		appointments upcoming	÷	status insight	med 01	†	med 02	‡	med 03		med 04 [‡]
1	9007647	-	Etha, Mason Ione	2000_02_24 22y 11m male	1. 2019-06-10 10:15 2. 2019-08-06 06:45 3. 2019-08-17 10:15	(15 min) OUCP West Gunnarside Cl (90 min) OUCP West Texasside Cli (5 min) OUCP East Aime Clinic	inic nic	Doctor screens this clinic May21_2019	OXYCODONI HCL 10 MG ORAL TABLET; Take 1 tablet by mouth every hours as needed for severe pain;	e 4					
2	9009014	-	Milo, Jossie Tina	2006_04_19 13y 7m female	1. 2019-06-10 11:30 2. 2019-07-25 18:15	(45 min) OUCP Stefanimouth Clini (30 min) OUCP Dietrichchester Cl	c inic	Doctor screens this clinic May22_2019	OXYCODONI HCL 10 MG ORAL TABLET; 10 mg every 4 hours as needed for pain;	E					

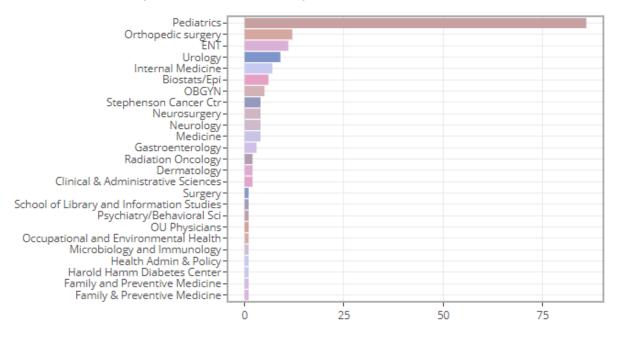
OXYCODONE

Since 2017, the CRDW has provided support for more than 194 projects.

We currently 44 active projects.



Most requests are submitted by the below departments or specialties.



Short Name	PI	Department/Specialty
Asthma Outcomes	M. Naifeh	Pediatrics
Pediatric Diabetic Ketoacidosis	M. Marin	Pediatrics
Anxiety & Depression Education	A. Bax	Pediatrics
Obesity in Foster Care	N. Torres-Garcia	Pediatrics
Posterior Cruciate Ligament Avulsions	S. Algan	Orthopedics
Avulsion Fractures (Tibia & Fibula)	S. Algan	Orthopedics
Avulsion Fractures (Femur)	S. Algan	Orthopedics
STI Screening	R. Leasure	Infectious Disease
Interstitial Cystits Pain	L. Quiroz	Women's Health
Pharmacist-Led Care	T. Truong	Pharmacy
POPS	C. Allen	Pediatrics
NAMCS	S. Gillaspy	Pediatrics
Preschool Behavior	A. Bax	Pediatrics
Psychology Consults	S. Gillaspy	Pediatrics
Chronic Hypertension in Pregnancy	R. Edwards	Women's Health
High Blood Pressure in Children	N. Connolley	Pediatrics
Sickle Cell Disease Transition Program	A. Sinha	Pediatrics
Molecular Alterations in Brain Tumors	J. Battiste	Cancer Center
Pelvic Floor Disorders	L. Quiroz	Women's Health
Cancer Patient Navigation Program	J. Vidrine	Cancer Center
Medical Homes for Youth in Foster Care	S. Gillaspy	Pediatrics

Short Name	PI	Department/Specialty
Subtalar Arthrodesis	A. Haleem	Orthopedics
Pulmonary Hypertension	H. Bhardwaj	Cardiovasular
Pelvis & Acetabulum Fractures	D. Teague	Orthopedics
Spica Casting	W. Puffinbarger	Orthopedics
Fragile X Syndrome	L. Ethridge	Pediatrics
Splinting with Side Struts	T. Lewis	Orthopedics
Humeral Fractures	D. Chong	Orthopedics
Child Trauma Services	E. Risch	Pediatrics
Humeral Fractures	D. Teague	Orthopedics
Asthma Population Management	D. Hahn	Pediatrics
Tobacco Exposure in Pediatrics	S. Gillaspy	Pediatrics
Utility of Chest X-Rays for Asthma in the ED	A. Bogie	Pediatrics
OxyContin Study	D. Hahn	Pediatrics
Transition of Care Clinic	T. Truong	Pharmacy
Lipid Screening	S. Gillaspy	Pediatrics
Sickle Cell Port Placement	A. Sinha	Pediatrics
Tranexamic Acid in Ankle Replacement	A. Haleem	Orthopedics
Newborn Metabolic Screenings	J. Lees	Pediatrics
Scapula Fractures	C. Pasque	Orthopedics
Adrenal Insufficiency	J. Lim	Endocrinology
Brain Metastases with Ovarian Cancer	J. Gillen	Cancer Center
Sever's Disease	S. Algan	Pediatrics

Short Name	PI	Department/Specialty
Brain Tumor Database	S. Sung	Cancer Center
Immunization Data Restructure	D. Bratzler	OUP
Off-Label Drug Use in Children	C. Allen	Pediatrics
Continuity of Care	P. Darden	Pediatrics
Prescribing Practices for Psychotropic Medications	S. Gillaspy	Pediatrics
Lactation Services for Diabetic Mothers	B. Mannel	Women's Health
Supplementation of LPI	J. Dilley	Women's Health
PCOS in Psoriasis	P. Allen	Dermatology
Assessment of Medication Problems	T. Truong	Pharmacy
Cancer Genetic Syndrome	J. Walker	Cancer Center
Maternal Depression Screening	M. Dunlap	Pediatrics
PROSpect Study	E. Henry	Pediatrics
Behavioral Health in the ED	R. Johnson	Pediatrics
Stem Cell Transplant Study	R. Shah	Pediatrics
Outcomes of Adalilumab in Colitis	J. Tung	Pediatrics
Mohs Surgery for High Risk cSCC	L. Collins	Dermatology
Electronic Cigarettes in Youth with Asthma	T. Wagener	Pediatrics
Vasoplegic Syndrome	C. Allen	Pediatrics
Patterns of Care Among Children with Cancer	A. Janitz	Epidemiology
Preoperative Airway Evaluation	D. Mann	ORL
Osteoporosis Prevention in Cancer Patients	J. Walker	Cancer Center

Short Name	PI	Department/Specialty
Radial Neck Fractures	TR Lewis	Orthopedics
High Grade VAIN	K. Smith	Women's Health
E-Cigarette and Tobacco Use During Pregnancy	A. Cohn	Cancer Center
Analysis of C. Diff Toxins	P. Lang	Immunology
Inpatient Transition of Care Pharmacist	T. Truong	Pharmacy
Children with Medical Complexity	M. Akande	Pediatrics
Outcomes of Patients with Merkel Cell Carcinoma	C. Henson	Cancer Center
Glucocorticoid Receptor Antagonism in the Treatment of Cushing Syndrome	J. Lim	Endocrinology
Influenza A and Sialadenitis	R. Johnson	Pediatrics
Surgical Complications in Patients with Spinal Muscular Atrophy	Chong	Orthopedics
Tissue Eosinophil Count in IBD Patients	J. Tung	Pediatrics
Bone Health Study	S. Krishnan	Pediatrics
Association between Urinary Parameters and Urological Issues	A. Pal	Pediatrics
Synthetic Cartilage Implant vs Osteochondral Autologous Transfer for Advanced Hallux Rigidus	A.Haleem	Orthopedics
Outcomes of External Fixation with the Ilizarov Frame in Complex Ankle and Hindfoot Fusions	A. Haleem	Orthopedics
Effect of Surgical Treatment of Vesicoureteral Reflux on Stone Passage Rates	A. Rensing	Urology
Tobacco and Marijuana Exposure Among Youth	M. Naifeh	Pediatrics

Short Name	PI	Department/Specialty
Hereditary thrombotic thrombocytopenic purpura (HTTP)	J. Journeycake	Pediatrics
Neonatal Venous Thromboembolism	J. Journeycake	Pediatrics
Evaluation of Hematologic Parameters in Patients on PARPi Therapy	K. Moore	Gyn Onc
Hip Fracture Repair	D. Teague	Orthopedics
Anterior Cruciate Ligament Reconstruction	S. Algan	Orthopedics
Bone-Grafting for Glenoid Deficiency	C. White	Orthopedics
Hospital Admission Rates for Children Living with Asthma	M. Akande	Pediatrics
Hearing Screens	J. Butcher	Pediatrics
Cesarean Scar Ectopic Pregnancy	H. Burks	Reproductive Medicine
Urologic Trauma Study	J. Furr	Urology
Oral Cavity Cancer	C. Henson	Cancer Center
Moberg Advancement Flap for Soft-Tissue Loss of the Thumb	T. Lehman	Orthopedics
Reduce Postoperative Hemorrhage	J. Sanclement	ORL
Anti-Incontinence Procedures	J. Furr	Urology
Acute Anosmia in Patients with COVID-19	G. Krempl	ORL
Cervical Spondylotic Myelopathy (CSM)	Z. Smith	Neurosurgery
Sellar and Parasellar Tumors	I. Dunn	Neurosurgery

Short Name	PI	Department/Speci	ialty
Detection and Management of Bladder Cancer	S. Patel	Urology	
Survey of Patients Regarding Care Utilization During COVID-19	D. Hahn	Pediatrics	
Circumcision Complications Requiring Surgical Revision	D. Frimberger	Urology	
Genetic Counseling Services for Children with Neurodevelopmental Disorders	A. Wadley	Genetics	
ECO-RESET	R. Harty	Gastroenterology	
Vasopressor Use in Microvascular Free-Flap Reconstruction of the Head and Neck	N. Vasan	ORL	
Genetic Testing for the BRCA gene	I. Shim	Genetics	
Bronchiolitis	A. Sparkman	Pediatrics	
Mirikizumab in Patients with Moderately to Severely Active Crohn's Disease	H. Bitar	Gastroenterology	
Renal Cell Carcinoma	J. Heinlen	Urology	Regisi
Stress Hydrocortisone in Pediatric Septic Shock (SHIPSS)	C. Allen	Pediatrics	
Severe Neurologic Injury Outcomes during COVID 19 Crisis (NCC COVID 19 OUTCOMES)	D. Masoom	Neurology	
Implementation of pain protocol and outcome of sickle cell patients	L. Rooms	Pediatrics	
ORIEN Project; Total Cancer Care Protocol	A. Tripathi	Cancer Center	Regist

Short Name	PI	Department/Specialty	Short Name	PI	Department/Specialty
National COVID Cohort Collaborative (N3C): A National Resource for Shared Analytics	D. Bard	OUHSC	,	S. Brown	Pediatrics
•			Incidence & Risk Factors of NSAID Use in Post-Operative	5	
Predictors of Sever Sepsis in Patients with Intestinal Failure	C. Knoles	Pediatrics		H. Bitar	Gastroenterology
Relationship Between Pretreatment Anxiety/Depression & Patient Decision-Making in Prostate Cancer Treatment	J. Heinlen	Urology	Tube Complications in Pediatric Patients with Congenital Heart Disease	C. Hunter	Pediatrics
Quality of Life of Ethnically Diverse Black Prostate Cancer		0.0.087	Medical marijuana legalization in Oklahoma: effects on	0	
Survivors: Development of a Conceptual Model Using			•	A. Makkar	Pediatrics
Grounded Theory	M. Ogunsanya	Pharmacy	PROSpect: Prone and Oscillation Pediatric Clinical Trial		
Clinical Presentations, Laboratory Findings, Treatment, and			COVID-19 Supplement	E. Henry	Pediatrics
Outcomes of Pediatric COVID-19 Patients	A. Bogie	Pediatrics	Addressing Epidemiologic Gaps in Immune		
PEMCRC Anaphylaxis Study	A. Bogie	Pediatrics	Thrombocytopenia: Pregnant and African American Patients	D. Terrell	Public Health
Analysis of Pediatric Migraine Treatment	A. Bogie	Pediatrics	TBD		Neurology
Impact of COVID-19 on Distress Levels in Cancer Patients	R. Funk-Lawler	Psychiatry	TBD		Pulmonary, Critical Care, and Sleep Medicine
Pituitary Adenoma Patient Outcomes	I. Dunn	Neurosurgery	Promoting Human Papillomavirus Vaccine Uptake in High-		Family and Preventive
Oncologic Outcomes in Renal Cell Carcinoma	B. Cross	Urology	,		Medicine
		Harold Hamm	External Validation of an AI-Based ECG Tool to Identify Cardiomyopathy in Women of Reproductive Age	M. Williams	Obstetrics and
Using ML to Quantify Molecular Phenotypes	K. Jones	Diabetes Center			
Improving Detection & Management of Bladder Cancer	D. Parker	Urology			Pediatrics
Neuromodulation of Inflammation to Treat Heart Failure		0,	Fluid Management in Acute Respiratory Distress Syndrome due to COVID 19		Pulmonary, Critical Care, and Sleep Medicine
with Preserved Ejection Fraction (TIN HF)	S. Stavrakis	Cardiology	due to COVID 19		Pulmonary, Critical Care,
Management of Asthma	M. Naifeh	Pediatrics	TBD		and Sleep Medicine
VTE Automated Surveillance	A. Wendelboe	Public Health			
Oklahoma COVID19 Registry and Repository	N. Agudelo	Infectious Disease Registr	У		

IRB and Privacy Review Guidance

- Requests that are preparatory to research must be submitted to the IRB/University Privacy Board for review and approval.
- Program Evaluation, CQI, & Feasibility Assessments:
 - If PHI is **NOT** included, it is generally not considered human subjects research.
 - A determination of human subjects research (DHSR) may be submitted to the IRB.
 - Aggregate data may be provided without an IRB submission.
- The following activities are <u>NOT</u> human subjects research:
 - Classroom evaluation activities when assessment involves regular classroom activities and the results of the evaluation process are intended to be used for the sole purpose of enhancing teaching practices of the instructor
 - Quality improvement activities designed to enhance functionality of a department or campus program provided that results are not intended to be shared outside of the University
 - Program evaluations
 - Public health practice surveillance activities

CRDW Faculty & Staff

David Bard, PhD, Chief Research Information Officer

Will Beasley, PhD, BBMC Director of Informatics

Geneva Marshall, MS, MHR joined the CRDW team in August 2020 after spending 8 years supporting academic research led by Drs. Bard and Beasley. Her experience includes the expansion and upkeep of a data pipeline using R and SQL to combine datasets for programs evaluation, as well as creating and streamlining a common set of procedures in R for data analysis. Geneva anticipates graduating OSU in May with a MS in Business Analytics specializing in Data Science.

Nellie Oliver, MBA, MPH is a biostatistician by training with over 15 years of experience leading projects and analyzing data across various settings, including academic hospital settings, medical credentialing, health insurance, and others. Prior to joining OUHSC in June 2021, Nellie served as a Senior Data Analyst and a Project Manager at the Care Management department of Blue Cross and Blue Shield of North Carolina.

Ashley Thumann, MHA has 15 years of healthcare administration experience. Prior to joining the CRDW team in October 2017, she served as a Clinics Administrator and Quality Manager for OU Physicians. Ashley has end-user experience with many of the data systems on campus and is the CRDW's primary liaison with investigators.

OUM BI Team

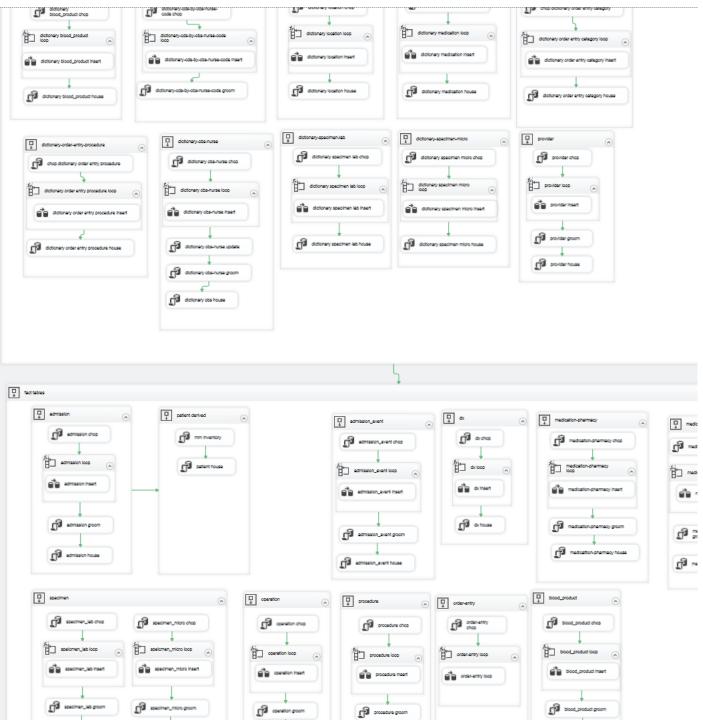
Jimmie Hackworth

- Sr. Meditech Reporting Analyst in the Business Intelligence area of the Information Technology Department.
- Meditech expert hired a few months ago to support Meditech while campus's focus is pulled toward Epic.
- Works with Ashley, Will, & Geneva to design daily extracts that populated the Meditech portion of the CRDW warehouse.
- Since October, meets with us weekly to review our progress and discuss the upcoming week's enhancements (eg, adding columns or tables)
- For every 1 problem that he solves, there are probably another 10 that he anticipates that the CRDW team is never aware of.
- His approach has become our model for how we want to ingest future data sources.



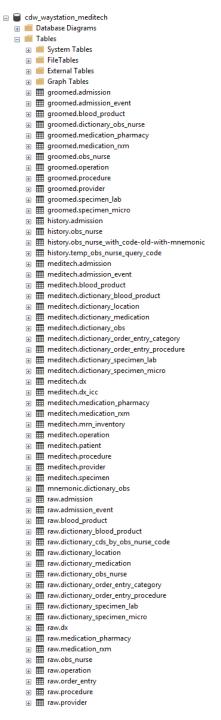
Meditech Warehouse ETL





Meditech in the CRDW

- Pipeline
 - Text files are saved to OUM's ftp server around 1am.
 - CRDW downloads, grooms, & ingests them into the warehouse.
 - Data available by 5:30am every morning.
- Tables/views available: patient, visit, visit event, diagnosis, lab, operation, procedure, blood product, obs, order entry, & medication.
- Tables to develop: images, room history
- Occasional requests still require the OUH BI Team (for elements that aren't frequently used in research)
- Role in the future Data Lake



Meditech in the CRDW

The CRDW now receives daily Meditech feeds (starting spring 2021).

- Research-related requested for Meditech have changed hands
 - Until spring 2021, requests were routed to the "OU Health BI Team" using OUH's ticketing system.
 - Now it's routed to us (an OUHSC team), and we query our own warehouse.

Establish Thresholds for Tier 2 Governance Review

All CRDW requests must be submitted to the IRB, but some may warrant additional review by this board. Our proposed thresholds are:

- 1. Count of included patients exceeds 10,000, or
- 2. PI requests a new method for delivery of PHI (e.g., automated exports to a new OSDH FTP server), or
- 3. Recipients of PHI are external to OUHSC, or
- 4. CRDW team has concerns about broad language in the protocol or study application (e.g., "relevant medical history", "clinical documentation", "outcomes"), or
- 5. Extracted CRDW dataset contributes to a registry (internal or multi-site).
- 6. Does this board want to review sensitive & confidential fields beyond IRB's?

If so, how can organize these additional reviews to avoid delays post-IRB approval?

For example, a checkbox in iRIS for each threshold triggers the review submission

Development of CRDW Policies & Procedures

- Tier 0 (no approval required)
 - Feasibility assessment: these are typically last minute requests on the tail end of a grant proposal. Common masking guidelines are followed, such as all cell sizes are 20+.
- Tier 1 (IRB approved conventional research)
- Tier 2 (IRB and Governance Board approved)
- Tier 3 (TBD)
 - The CRDW is infrequently contracted to provide operational support, such as transforming immunization records in preparation for Epic implementation.

CRDW Documentation

GE Centricity EMR

3.4 Clinical Data Tables

Data descriptions below created using CRDW Warehouse tables. Many definitions within this document (for data which remain unchanged from source to warehouse) are obtained from Data Dictionary for Centricity® Physician Office – EMR 2005 December 2005 2027167-007 Rev A where relevant.

3.4.1 business

One row per business (e.g., vendors, pharmacies, etc.).

variable	definition	notes
busid	PK for businesses	Primary key
searchname	Human-friendly name for business.	
name	Properly formatted name for business.	
primphone	Business primary phone number	
secphone	Business secondary phone number	
faxphone	Business fax number	
email	Business primary email	
contact	Specific instructions for contact	may be a name, an addrress, instructions, etc.
contactby		

Meditech

Chapter 5 Meditech

The Meditech EMR covers primarily the OUM operations (as opposed to Centricity EMR and GECB, which covers primarily OUP operations).

5.1 Clinical Data Tables

5.1.1 visit

One row per visit (including events like an ED visit) per patient.

variable	definition	notes
account_number	Primary Key: Account number for a single visit	(E/L/W & 11 digits)
mrn_meditech	Medical record number - Primary key for records sourced from Meditech.	Starting letter corresponds to location of record creation. mm_meditech may combine and change upon records updates (E/L/W + 9 digits)
extract_date	date of extract	
mrn_meditech_internal	TODO: Describe this.	(E/L/W + 9 digits)
facility	Facility	(eg, "OUMC", "COCPN")
campus	Campus of visit	(eg, "Surgery Center", "Presby", "Children's Hospital")
	Length of stay in DAYS in all	
length_of_stay	OUM locations for the entire	

Requested Resources to Further Develop the CRDW

- Ideally, IRB would implement a procedure to allow for CDRW upon initial approval without adding staff to KSP (e.g., a check-box on the application indicating use of CDRW to obtain data).
- 2. Routine meetings with an OUM Clinical Information Specialist / Application Analyst (someone like Megan Posada).
- 3. We would like read-only access to the other Meditech warehouse (being developed by CereCore). This would help validate our version of the warehouse, and occasionally fill-in holes for requests not covered by our research-focused warehouse.
- 4. Ticketing system to manage incoming CRDW requests
- 5. OMOP's Atlas Reporting Tool (https://www.ohdsi.org/atlas-a-unified-interface-for-the-ohdsi-tools/)
- 6. TriNetX (https://trinetx.com/)
- 7. Spark (https://spark.apache.org/)
- Completed:
 - Meditech Compiled HTML Help