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

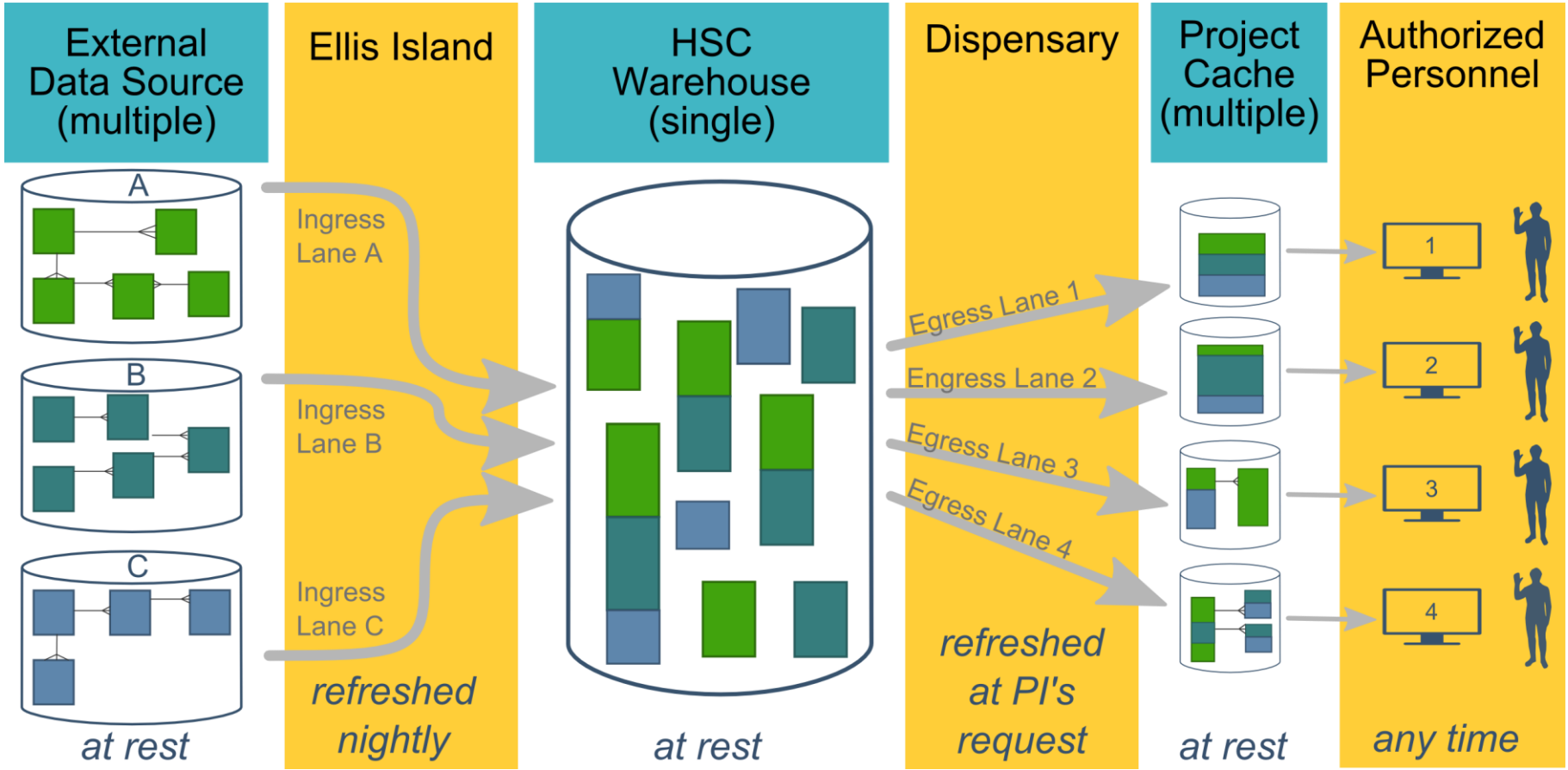
Will Beasley, PhD
Ashley Thumann, MHA
Geneva Marshall, MS
Arnold Kanagwa, MS
David Bard, PhD
University of Oklahoma HSC
Biomedical & Behavioral Methodology Core (BBMC)

January 2024

Award Numbers:
UG1OD024950
U54GM104938

# CRDW (Clinical Research Data Warehouse)

## Ecosystem Architecture



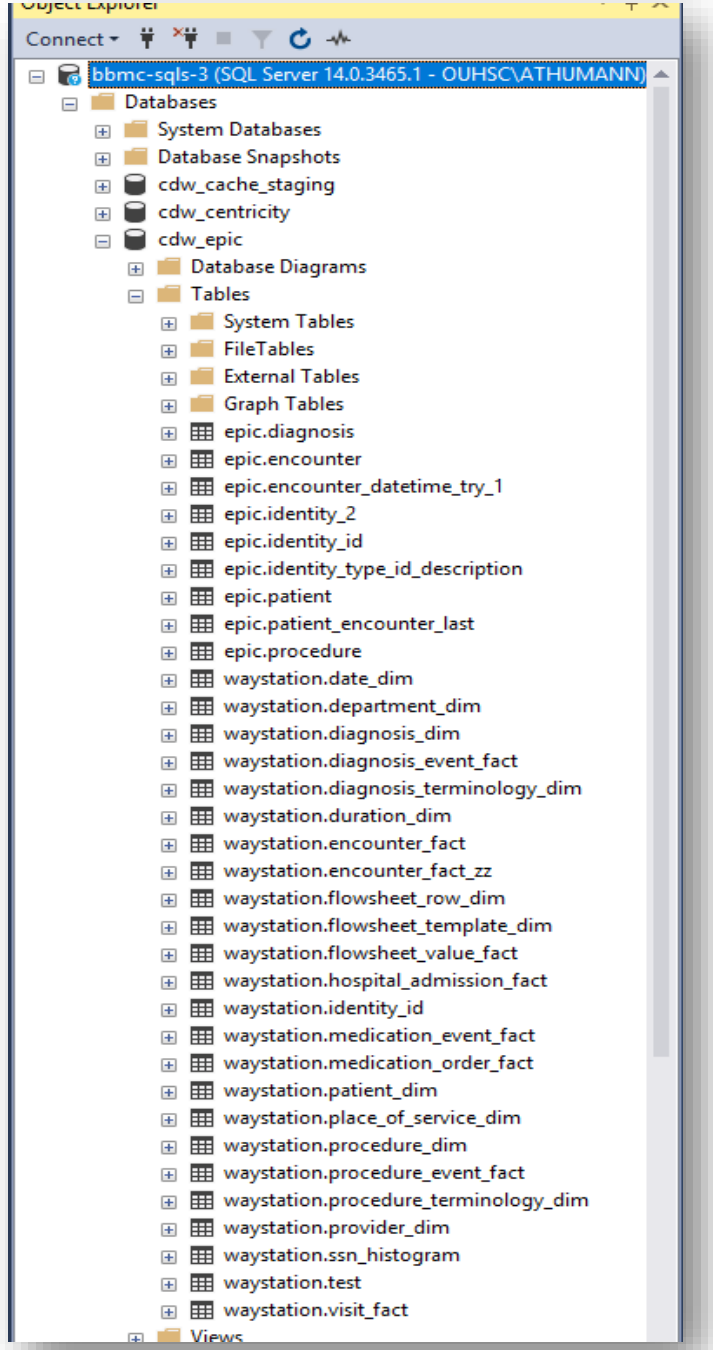

- **Data Source** (column 1): contains unique info
- **Warehouse** (column 3): contains copy after manipulation
- **Project Cache** (column 5): transformed to facilitate analyses of a specific research project

# *HSC Data Sources*

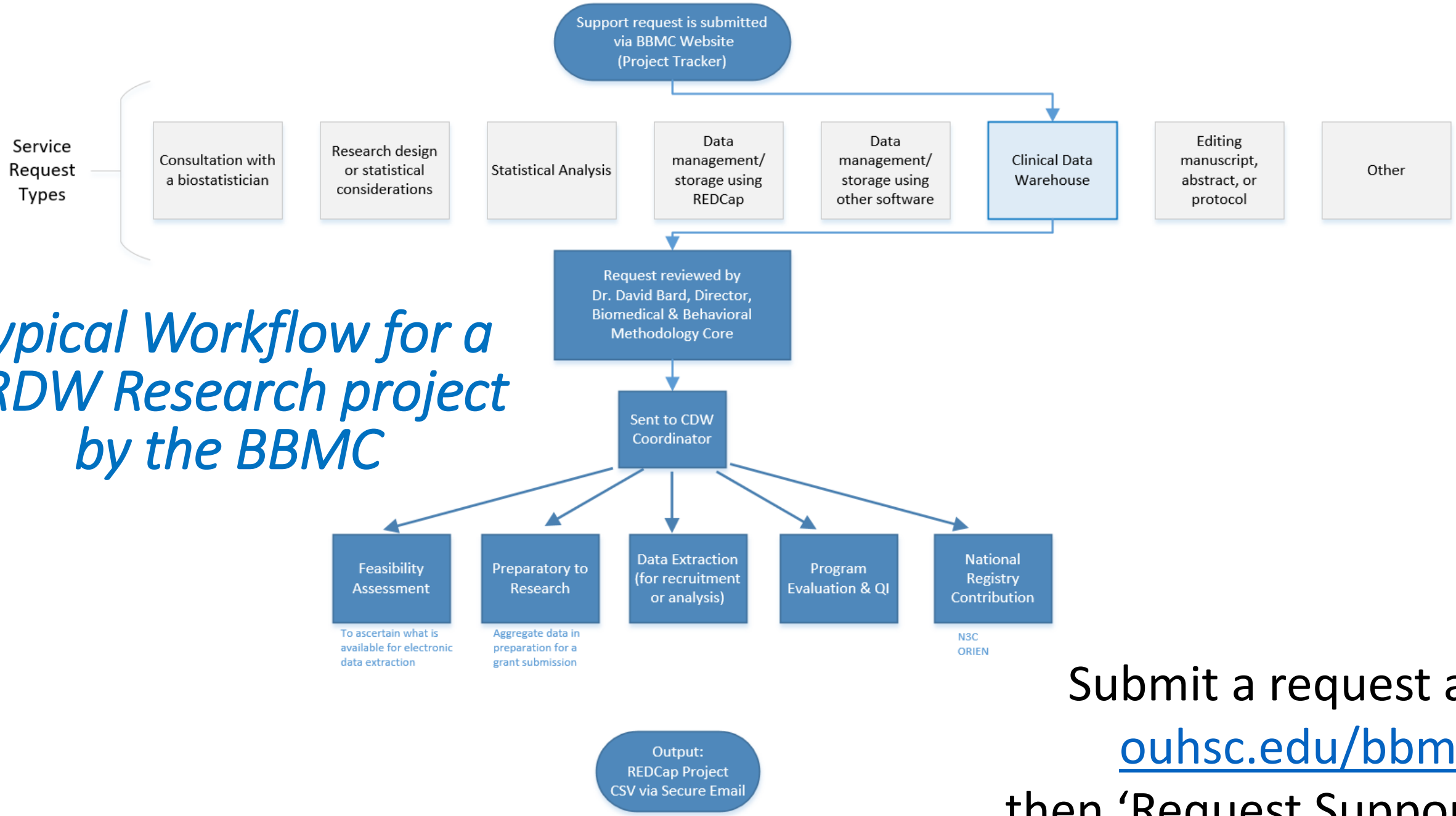
- Patient
  - Epic (we have the basics, and will be adding for a while)
  - Legacy Outpatient (Centricity)
  - Legacy Billing and Claims Data (GECB)
  - Legacy Inpatient (Meditech)
  - Dozens of departmental sources
  - Biomedical Research Data
- Provider
- External Agencies
  - Service Provided (by 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



# *Typical Workflow for a CRDW Research project by the BBMC*




Submit a request at:

ouhsc.edu/bbmc/

then ‘Request Support’

# *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

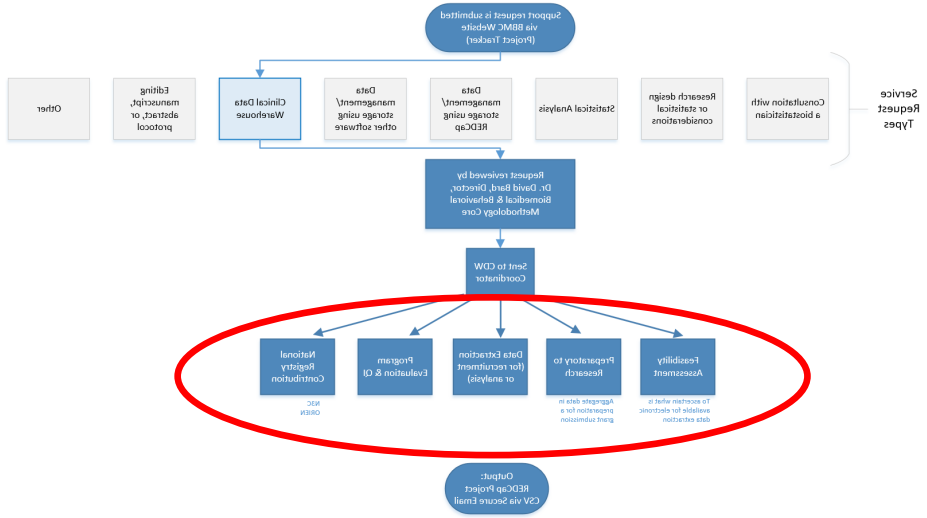
- "QI to improve an internal process (with no intent to publish)"
  - Routes to the OUH group
    - Go to https://ouhealth.service-now.com/ (with your OUH account)
  - <-- Kacey, what would you like here? -->
  - No IRB approval is required for internal QI
    - Human subjects aren't involved; data will 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)

First go to:
https://ouhsc.edu/bbmc/


Then click



# 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 College of Medicine - Department of Pediatrics, Department of Biostatistics and Epidemiology, and College of Public Health. 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 Warehouse

Then “Yes” to CRDW

Then “CRDW” Service Reuqested

BBMC Research Support Request

Resize 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 Investigator is ultimately responsible for this project:***

| Contact | First Name | Last Name | Role on Project | Email | Phone |
|---|---|---|---|---|---|
| PI | | | Principal Investigator | | |
| Secondary | | | | | |

*If the PI belongs to a non-college entity such as Stephenson Cancer Center, please select **None** for the College and enter the organization's name under Department.*

| PI's College | PI's Department (if applicable) | PI's Section (if applicable) |
|---|---|---|
| | | |

~ ~ ~ Please tell us about your project ~ ~ ~

**Project Title**
* must provide value

Expand

**Does this request include BBMC CRDW retrieval of electronic medical records (such as Centricity, Meditech, etc.)?** Yes No reset

**Please provide at least one study aim (if applicable):**

| | |
|---|---|
| **Study Aim 1** | Expand |
| **Study Aim 2** | Expand |
| **Study Aim 3** | Expand |

**This project has:**

- An IRB protocol being written
- A submitted IRB protocol
- An approved IRB protocol
- No need for an IRB-approved protocol or the project is exempt

reset

~ ~ ~ The following table asks which services you are requesting. ~ ~ ~

Please note: 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 | Date Needed | Add Another Service |
|---|---|---|---|
| | | Y-M-D | Yes No |

reset

**Do you have an existing BBMC contact person for this request?** Yes No reset

~ ~ ~ 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.** Yes No reset
* must provide value

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 all categories that fit your project. Underlined phrases have pop-up balloons with definitions.

**This project involves ...**

| | | | |
|---|---|---|---|
| Quality improvement | Yes | **No** | reset |
| Scientific research | Yes | **No** | reset |
| Other scholarly activity for future publication | Yes | **No** | reset |
| Program evaluation | Yes | **No** | reset |
| Academic activities | Yes | **No** | reset |
| Business analytics | Yes | **No** | reset |
| Health economics | Yes | **No** | reset |
| Health systems | Yes | **No** | reset |
| Dissemination/implementation science | Yes | **No** | reset |
| Outcomes research | Yes | **No** | reset |
| Feasibility assessment | Yes | **No** | reset |
| Preparatory to research | Yes | **No** | reset |
| Data extraction for recruitment or analysis | Yes | **No** | reset |
| National registry contribution | Yes | **No** | reset |
| Retrospective chart review | Yes | **No** | reset |

Please explain how you would categorize your project that may be

# *Timeline for Requests*

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

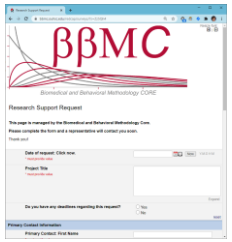
1. We can help with the IRB language and avoid some of the common reasons the IRB rejects your initial application

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

**Intake via BBMC request form**




**BBMC Triage to services:**

- Feasibility
- Preparatory to Research
- Program Evaluation
- QI
- Recruitment
- Retrospective Analysis
- Registry
- Facilitate Abstraction

**Meet with investigator to determine data needs, feasibility**

- Structured vs. unstructured?
- How well meet project needs with what's available?
- IRB considerations

**Back and forth with investigator**

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

**Assign project to BBMC analyst based on skills, workload, & interests**

- Some projects may involve multiple analysts

**Develop Pipeline**

- SQL, R, & Python
- Automated daily data pulls
- 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

- 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)

- 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:

demo-for-presentation.md

```
1   Patient: TEST A PATIENT
2   ID: HCA_MIC E123456789
3   Note: All result statuses are Final unless otherwise noted.
4
5   Tests: (1) SARS-CoV-2 PCR (NASAL)
6     SARS-CoV-2 PCR ..... See Below ..... *1
7       SARS-CoV-2 PCR(F) ..... Coll Date/Time: 08/30/2021 10:05
8                                 Ver Date/Time: 08/31/2021 04:55
9       SOURCE: NASAL
10      SPEC DESC: (NOT SPECIFIED)
11
12      VIROLOGY PCR
13      Not Detected
14
15  Tests: (2) METHOD PCR: (NASAL)
16  ! METHOD PCR: ..... See Below ..... *2
17
```

Saved to the flowsheet

Has to be parsed out with regexes and programming (and funding)

**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 "========== new hpppd note ==========").**

```
OU MEDICAL CENTER (COCPN)
History Physical
REPORT#
DATE          Time:

PATIENT:              UNIT No
ACCOUNT#:               ROOM:
REPORT AUTHOR:
**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

- SFT 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 | [I50.1] | Left ventricular failure, unspecified | TRUE | cardiac | |
| 3 | [1569179] | ICD10CM | [I50.2] | Systolic (congestive) heart failure | TRUE | cardiac | |
| 4 | [45586587] | ICD10CM | [I50.20] | Unspecified systolic (congestive) heart failure | TRUE | cardiac | |
| 5 | [45543182] | ICD10CM | [I50.21] | Acute systolic (congestive) heart failure | TRUE | cardiac | |
| 6 | [45576878] | ICD10CM | [I50.22] | Chronic systolic (congestive) heart failure | TRUE | cardiac | |
| 7 | [45567180] | ICD10CM | [I50.23] | Acute on chronic systolic (congestive) heart failure | TRUE | cardiac | |
| 8 | [1569180] | ICD10CM | [I50.3] | Diastolic (congestive) heart failure | TRUE | cardiac | |
| 9 | [45601038] | ICD10CM | [I50.30] | 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

# Thank you

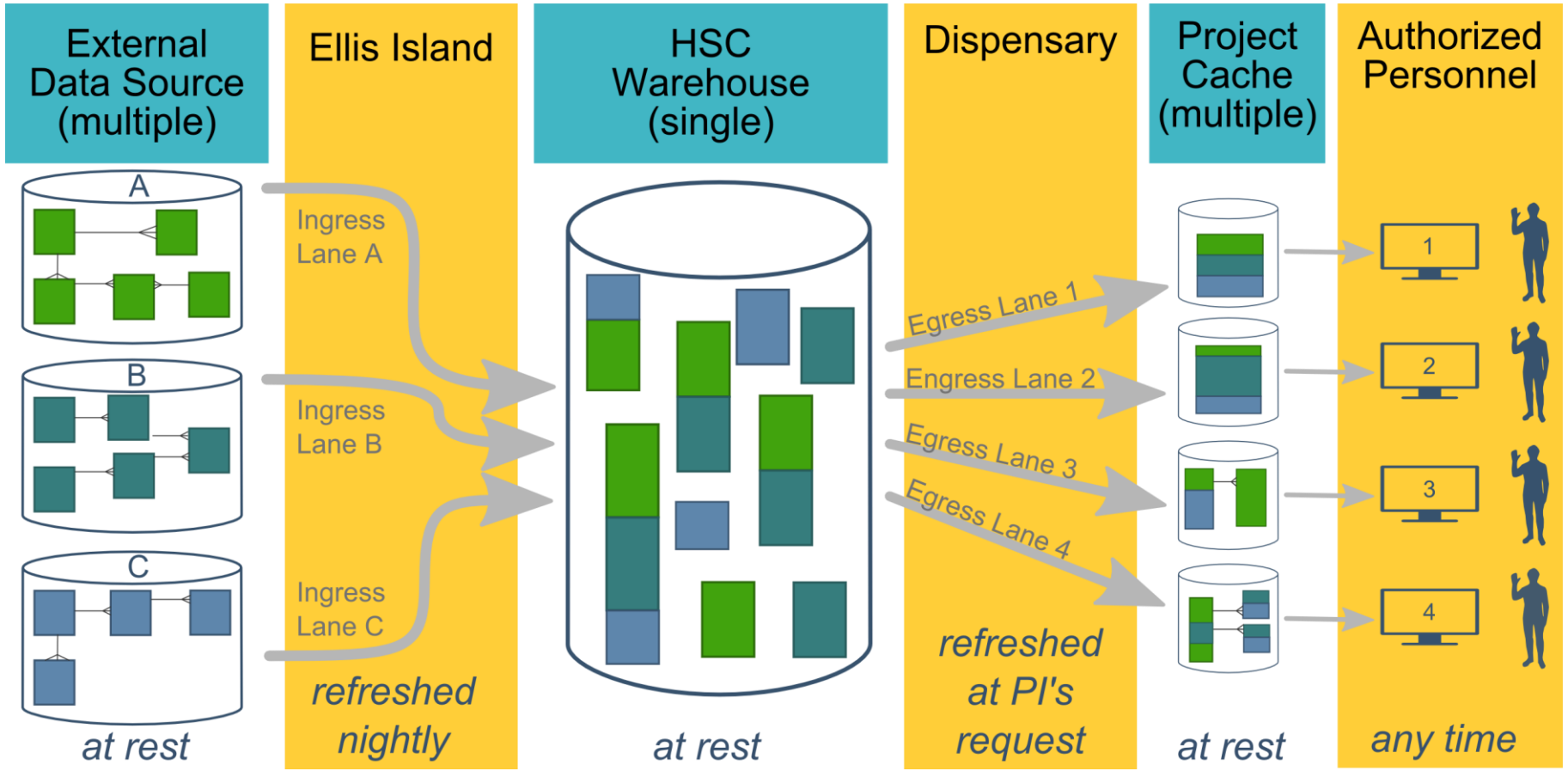
Will Beasley, PhD
Ashley Thumann, MHA
Geneva Marshall, MS
Arnold Kanagwa, MS
David Bard, PhD
University of Oklahoma HSC
Biomedical & Behavioral Methodology Core (BBMC)

Award Numbers:
UG1OD024950
U54GM104938

# Prairie Outpost – 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

# 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*



## 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 Notes | 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.
3. 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

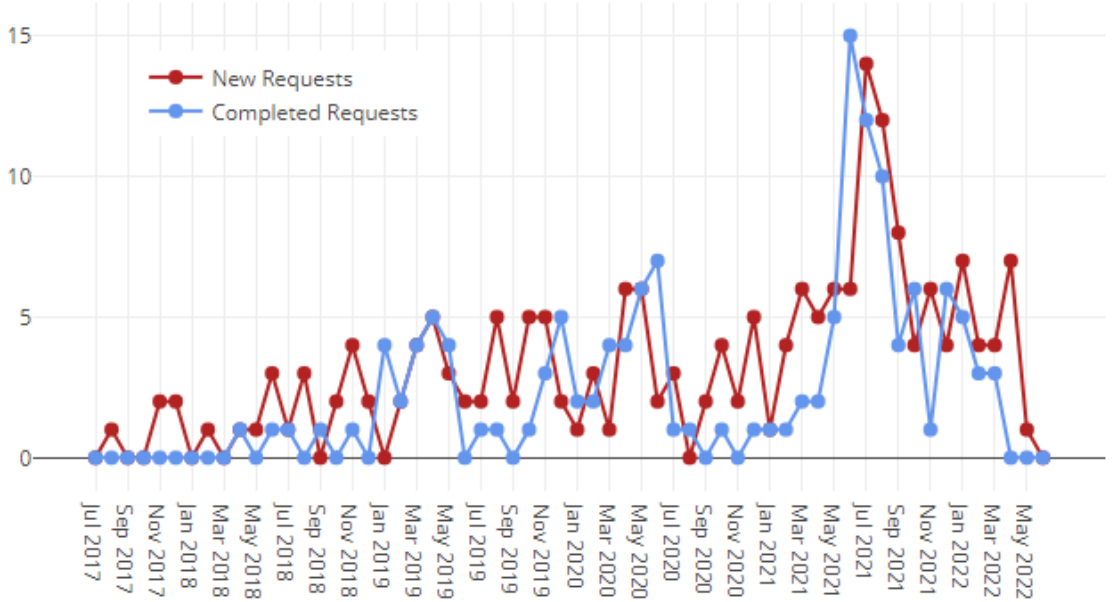
2.1 NICU | 2.2 PICU | 2.3 Inpatient | 2.4 Unknown/Unclassified | 2.5 Outpatient

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 ( 15 min) OUCP West Gunnarside Clinic<br>2. 2019-08-06 06:45 ( 90 min) OUCP West Texasside Clinic<br>3. 2019-08-17 10:15 ( 5 min) OUCP East Aime Clinic | Doctor screens this clinic May21_2019 | OXYCODONE HCL 10 MG ORAL TABLET; Take 1 tablet by mouth every 4 hours as needed for severe pain; -- | | | |
| 2 | 9009014 | - | Milo, Jossie Tina | 2006_04_19 13y 7m female | 1. 2019-06-10 11:30 ( 45 min) OUCP Stefanimouth Clinic<br>2. 2019-07-25 18:15 ( 30 min) OUCP Dietrichchester Clinic | Doctor screens this clinic May22_2019 | OXYCODONE HCL 10 MG ORAL TABLET; 10 mg every 4 hours as needed for pain; -- | | | |
| | | | | | | | | | | 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.

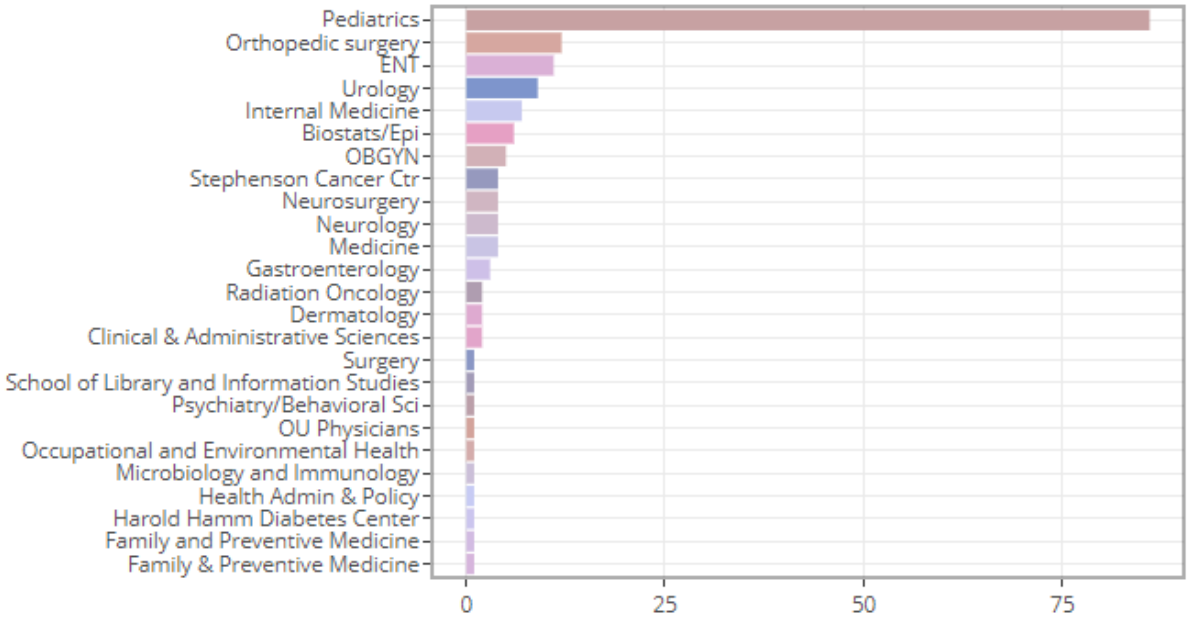



*Chart & table last updated Feb 2021*

# *Clinical Trials & Other Research Studies Supported by the CRDW*

since 2017; page 1

| 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 |

# *Clinical Trials & Other Research Studies Supported by the CRDW*

since 2017; page 2

| 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 |

# *Clinical Trials & Other Research Studies Supported by the CRDW*

since 2017; page 3

| 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/Specialty |
|---|---|---|
| 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 Registry |
| 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 Registry |

# *Clinical Trials & Other Research Studies Supported by the CRDW*

since 2017; page 4

| Short Name | PI | Department/Specialty |
|---|---|---|
| National COVID Cohort Collaborative (N3C): A National Resource for Shared Analytics | D. Bard | OUHSC Registry |
| Predictors of Sever Sepsis in Patients with Intestinal Failure | C. Knoles | Pediatrics |
| Relationship Between Pretreatment Anxiety/Depression & Patient Decision-Making in Prostate Cancer Treatment | J. Heinlen | Urology |
| Quality of Life of Ethnically Diverse Black Prostate Cancer Survivors: Development of a Conceptual Model Using Grounded Theory | M. Ogunsanya | Pharmacy |
| Clinical Presentations, Laboratory Findings, Treatment, and Outcomes of Pediatric COVID-19 Patients | A. Bogie | Pediatrics |
| PEMCRC Anaphylaxis Study | A. Bogie | Pediatrics |
| Analysis of Pediatric Migraine Treatment | A. Bogie | Pediatrics |
| Impact of COVID-19 on Distress Levels in Cancer Patients | R. Funk-Lawler | Psychiatry |
| Pituitary Adenoma Patient Outcomes | I. Dunn | Neurosurgery |
| Oncologic Outcomes in Renal Cell Carcinoma | B. Cross | Urology |
| Using ML to Quantify Molecular Phenotypes | K. Jones | Harold Hamm Diabetes Center |
| Improving Detection & Management of Bladder Cancer | D. Parker | Urology |
| Neuromodulation of Inflammation to Treat Heart Failure with Preserved Ejection Fraction (TIN HF) | S. Stavrakis | Cardiology |
| Management of Asthma | M. Naifeh | Pediatrics |
| VTE Automated Surveillance | A. Wendelboe | Public Health |
| Oklahoma COVID19 Registry and Repository | N. Agudelo | Infectious Disease Registry |

| Short Name | PI | Department/Specialty |
|---|---|---|
| Patterns of Clinical Deterioration in Critically Ill Children | S. Brown | Pediatrics |
| Incidence & Risk Factors of NSAID Use in Post-Operative Patients | H. Bitar | Gastroenterology |
| Tube Complications in Pediatric Patients with Congenital Heart Disease | C. Hunter | Pediatrics |
| Medical marijuana legalization in Oklahoma: effects on neonatal exposure to opiates | A. Makkar | Pediatrics |
| PROSpect: Prone and Oscillation Pediatric Clinical Trial COVID-19 Supplement | E. Henry | Pediatrics |
| Addressing Epidemiologic Gaps in Immune Thrombocytopenia: Pregnant and African American Patients | D. Terrell | Public Health |
| TBD | A. Paul | Neurology |
| TBD | H. Wu | Pulmonary, Critical Care, and Sleep Medicine |
| Promoting Human Papillomavirus Vaccine Uptake in High-Risk Adults (Uptake 2) | T. Bui | Family and Preventive Medicine |
| External Validation of an AI-Based ECG Tool to Identify Cardiomyopathy in Women of Reproductive Age | M. Williams | Obstetrics and Gynecology |
| Aggregate Counts of COVID-19/MIS-C Patients | P. Darden | Pediatrics |
| Fluid Management in Acute Respiratory Distress Syndrome due to COVID 19 | S. Dauok | Pulmonary, Critical Care, and Sleep Medicine |
| TBD | C. Cross | Pulmonary, Critical Care, and Sleep Medicine |

# *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 **NOT** 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.

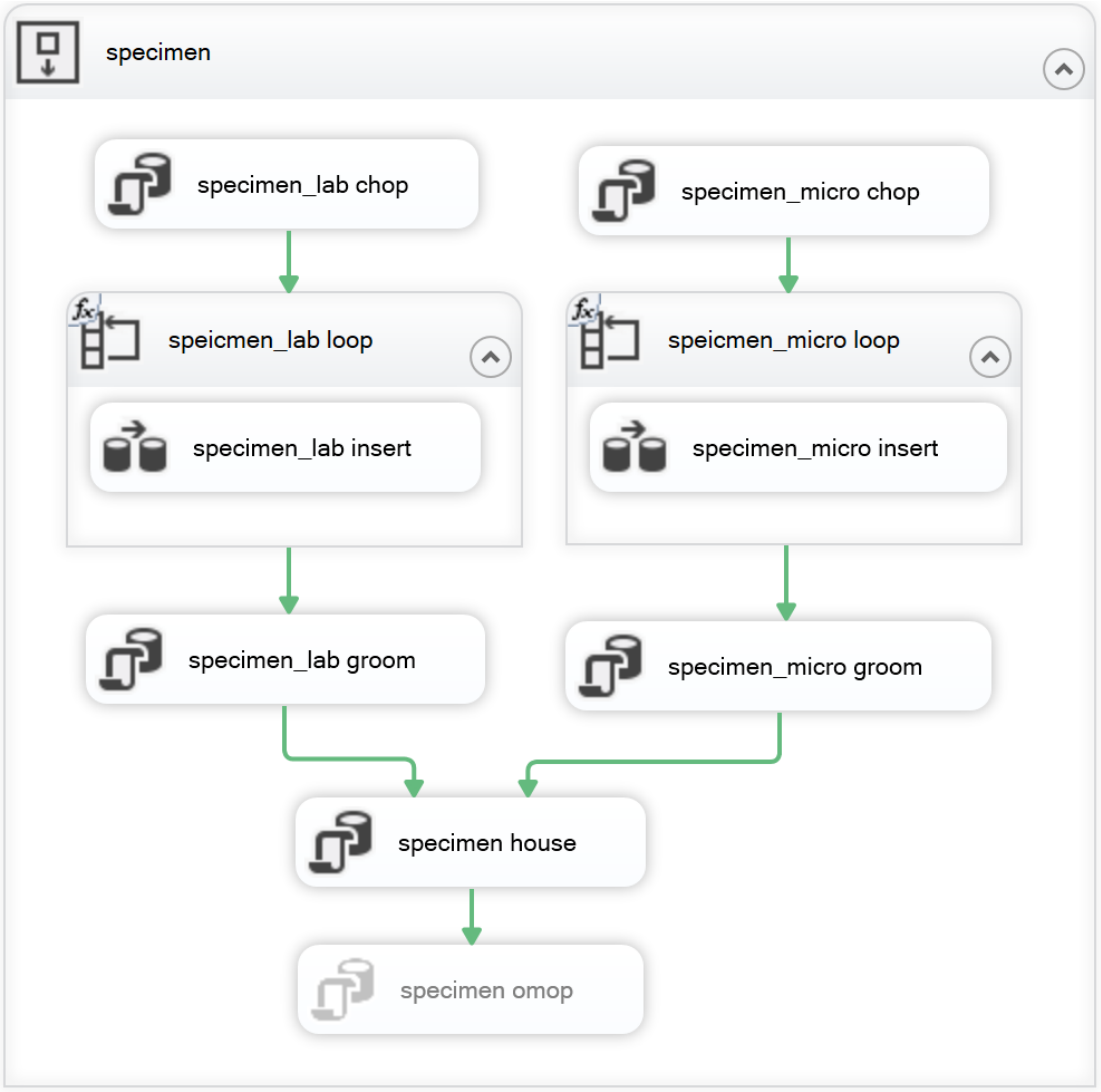
# *OUM BI Team*

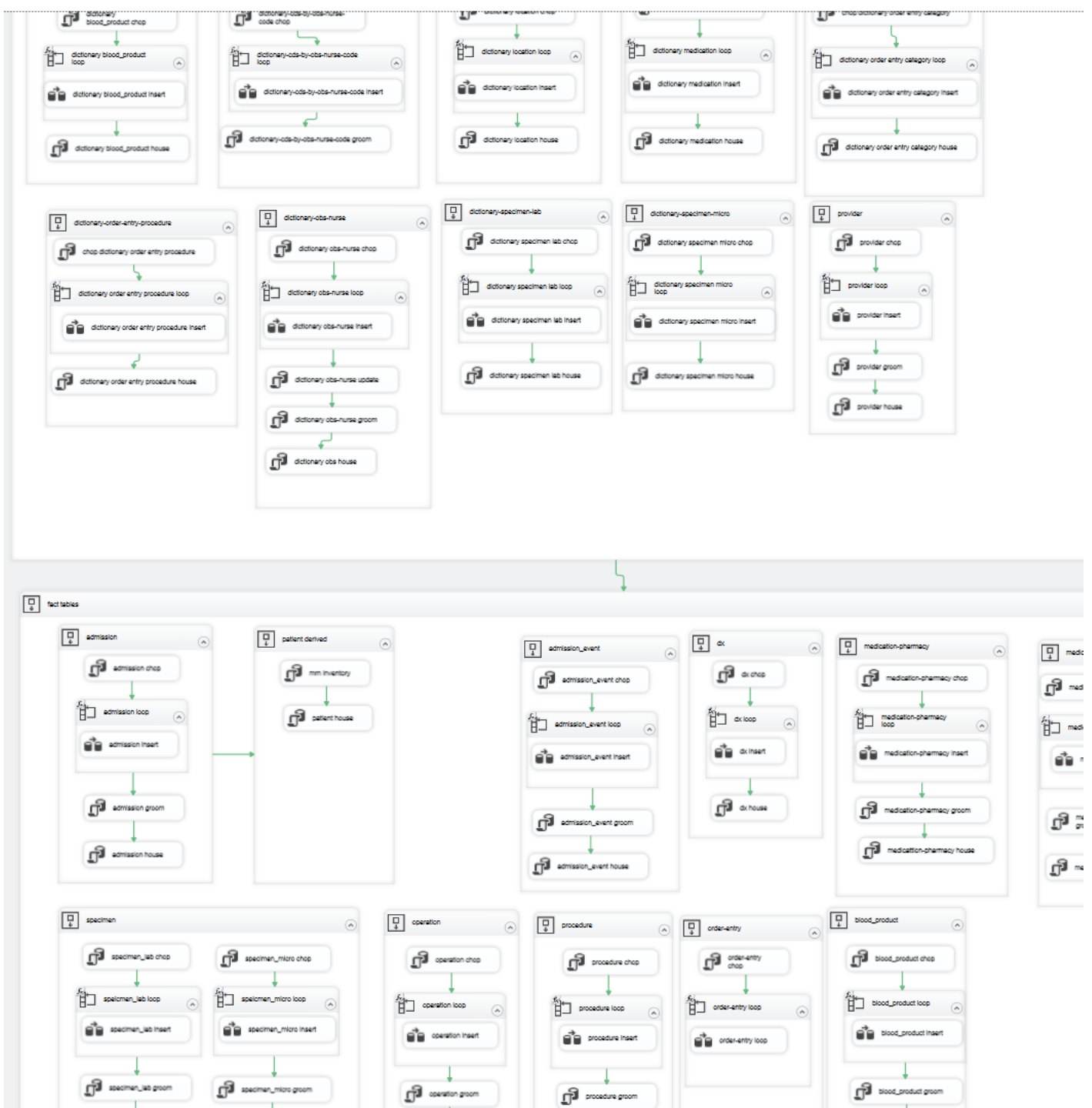
Jimmie Hackworth

- 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.

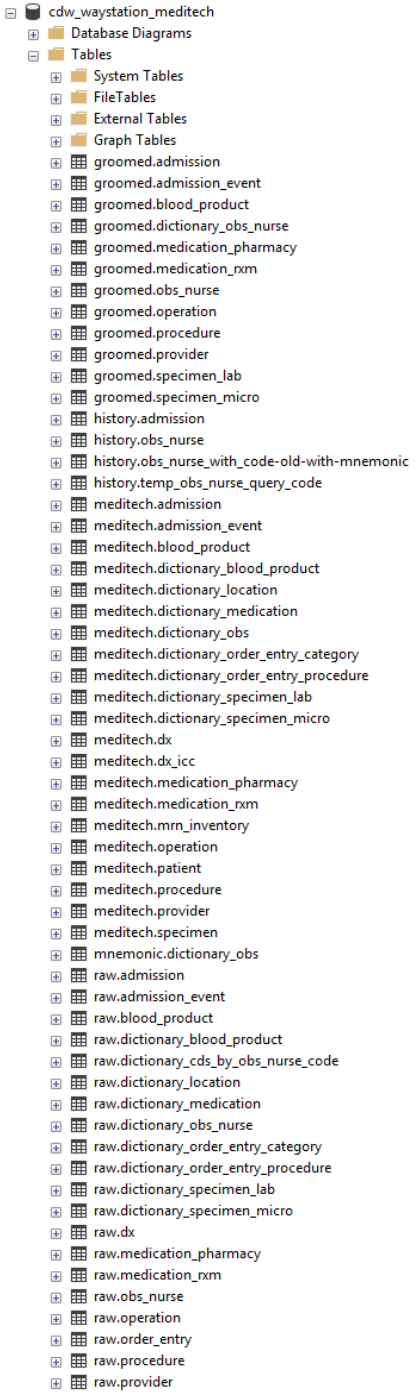
# Meditech Warehouse ETL



# *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. *mrn_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 | Length of stay in DAYS in all OUM locations for the entire | |

https://github.com/OuhscBbmc/cdw-doc-1

# *Requested Resources to Further Develop the CRDW*

1. 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