



IDeA States Pediatric Network



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

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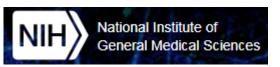
University of Oklahoma HSC

Biomedical & Behavioral Methodology Core (BBMC)

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#### **Terms**

• EMR (or EHR): Electronic Medical/Health Records

A huge database with patient records used by providers

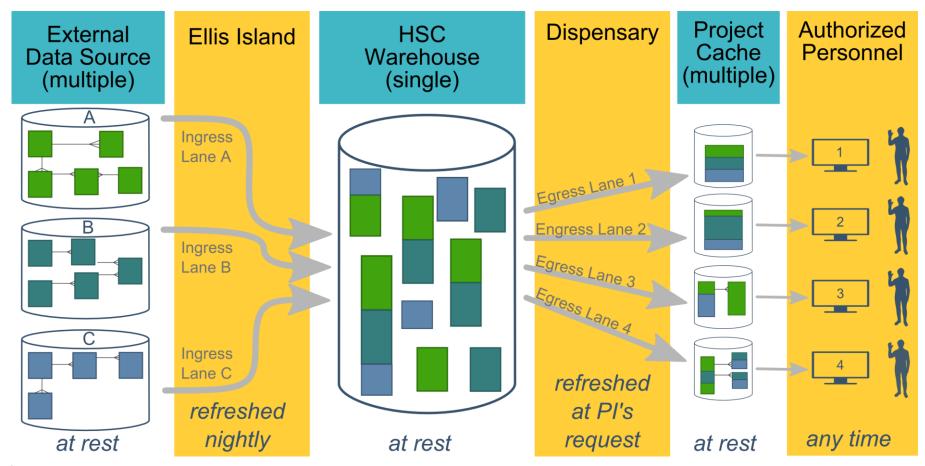
• CDW: Clinical Data Warehouse

A collection of databases (such as EMRs and project-specific datasets) that has been transformed to make research more efficient and complete

## Prairie Outpost – CDW (Clinical Data Warehouse)

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

Ecosystem Architecture

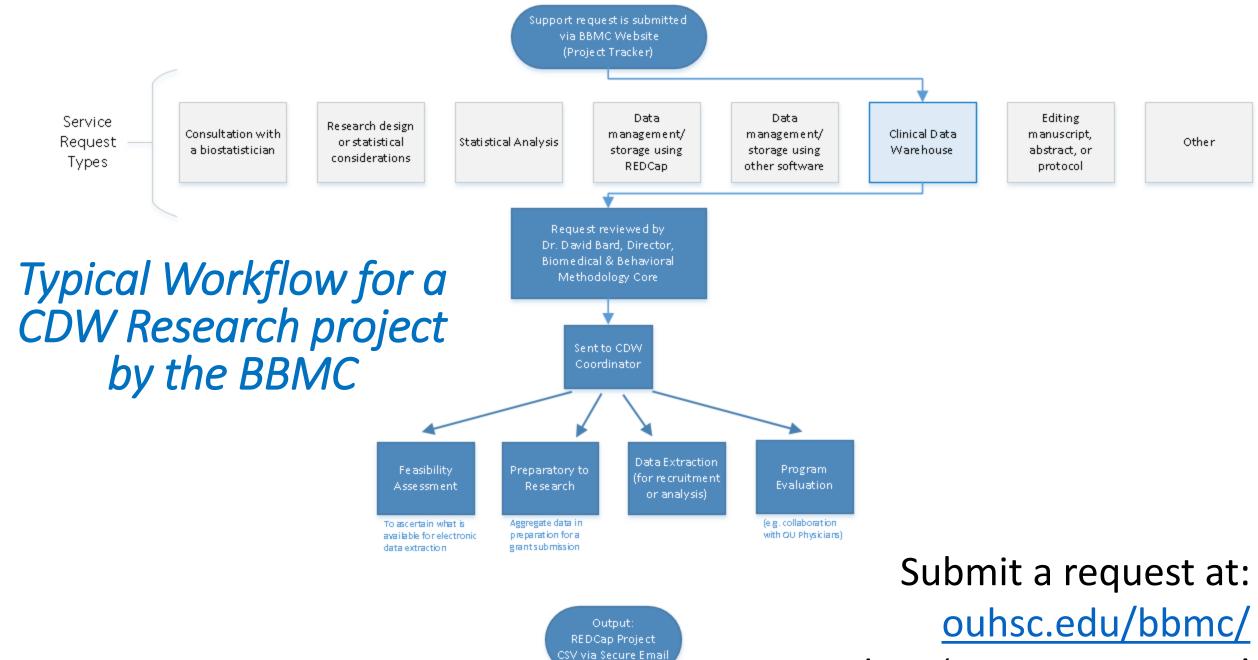


- Data Source (column 1): contains unique info
- Warehouse (column 3): contains copy after manipulation
- Project Cache (column 5): contains copy of copy after a lot of manipulation

#### Patient

#### **HSC Data Sources**

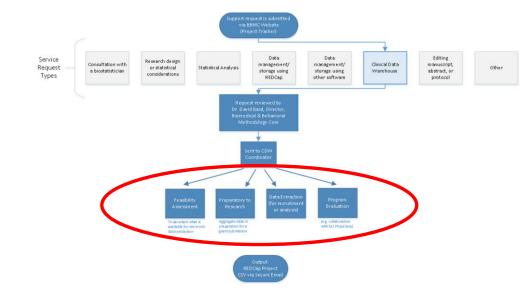
- Outpatient (Centricity)
- Billing and Claims Data
- Inpatient (Meditech)
- Dozens of departmental sources
- Biomedical Research Data
- Epic (in ~1 year)
- Provider
- External Agencies
  - Service Provided (by the Health Dept of Oklahoma)
  - Child Protective Services (Oklahoma Dept of Human Services)
  - SoonerCare (Oklahoma Medicaid)
  - Immunization (Health Dept of Oklahoma)
  - Vital Records (Health Dept of Oklahoma)
  - ...
  - Multi-state collaborations (in the future)
- Administrative Cost
- Employee & Student



then 'Request Support'

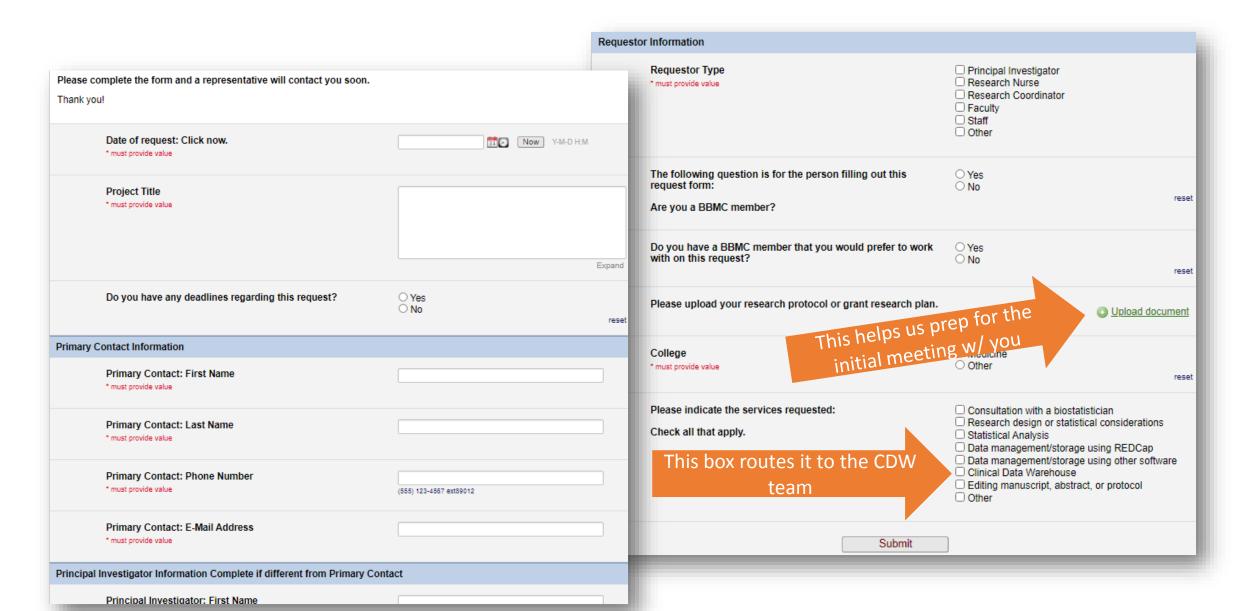
#### Commonly Requested CDW Support Services

- Feasibility assessment in preparation for research (20% of projects; 10% of CDW staff time)
- Static eligibility (70% of projects; 20% of CDW staff time)
  - Virtually all projects require identification of a patient pool
- Rolling eligibility (30% of projects; 30% of CDW 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 CDW staff time)
- Administrative outcomes for quality improvement (10% of projects; 2% of CDW staff time)
- Program evaluation (20% of projects; 8% of CDW staff time)



### Starting a CDW Project

## Submit a request at <a href="https://ouhsc.edu/bbmc/">https://ouhsc.edu/bbmc/</a>, then click "Request Support"



## Rule of Thumb for Involving CDW Team

- A one-time Meditech extract: contact OU Medicine directly or we're happy to help structure the request Meditech request: <a href="https://ouhealth.service-now.com/sp?id=sc">https://ouhealth.service-now.com/sp?id=sc</a> cat item&sys id=79c250c74f652300ed7229dd0210c7d9
- Recurring Meditech extracts for rolling recruitment: please contact the BBMC about the CDW (<a href="https://ouhsc.edu/bbmc/">https://ouhsc.edu/bbmc/</a>)
- Research involving merged Centricity & Meditech: please contact the BBMC about the CDW (<a href="https://ouhsc.edu/bbmc/">https://ouhsc.edu/bbmc/</a>)
- Research involving (a) data collection outside the EMRs or (b) supplementing chart review: please contact the BBMC about REDCap (<a href="https://ouhsc.edu/bbmc/">https://ouhsc.edu/bbmc/</a>)

#### **Terms**

- Centricity EMR: clinical info for outpatients since ~2010
- Centricity Business: scheduling & billing info for outpatient since ~2010
- Meditech: EMR for ED & inpatients since the bronze age
- Epic: Upcoming EMR that will replace Centricity, Meditech, and many others. May not be useful for your research (at least in time to start your fellowship research project)
- REDCap: campus-recommended software for collecting PHI outside the EMRs (<a href="https://www.project-redcap.org/">https://www.project-redcap.org/</a>)

## POPS Study

Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care

#### POPS Overview

Primary Aim: Evaluate PK of understudied drugs administered to children

 Part of Oklahoma Pediatric Clinical Trial Network (OPCTN), a site for the NIH-funded ECHO IDeA States Pediatric Clinical Trials Network (ISPCTN)

- Enrollment Criteria:
  - Child receiving understudied drug of interest (DOIs) per standard of care
  - meet age range or condition (pre-term, obese, ECMO) open for enrollment.

C	D	E	F	G	Н	1	J	K	L	M	N	0
		Target Ages					≤ 20 years <sup>1</sup>					
Drug of Interest (DOI)	Pre-term	<1 mo		1 mo-2 Yrs		2-12 Yrs			13-16 Yrs	17-20 Yrs	Obese	ECMO
			1-5 mos	6-11 mos	1 Yr	2-4 Yrs	5-8 Yrs	9-12 Yrs	13-10 118	17-20 115	Obese	Leme
alfentanil (IV) <sup>16</sup>		х	х	x	x	x	Closed	Closed			х	х
amikacin <sup>5</sup>	х	x	x	x	x	×	×	x	×	x	X	
atropine (IV) <sup>14</sup>		х	х	x	x	x	x	x	x	x	х	х
cefepime <sup>5</sup>	х	х	х	х	х	х	х	х	х	х	х	
ceftazidime											x	х
cidofovir											x	
ciprofloxacin											x	
clozapine <sup>4</sup>		х	х	х	x	x	x	x	x	х	х	х
dexmedetomidine <sup>13</sup>		Closed	Closed	Closed	Closed	Closed	Closed	Closed	Closed	х	х	X
diazepam											x	
etomidate <sup>7, 16</sup>		х	x	х	x	x	X				x	x
fosphenytoin											x	
haloperidol <sup>4</sup>		Х	х	х	х	Х	X	Х	x	х	х	X
heparin (low molecular weight) <sup>8</sup>		x	Closed	Closed	Closed	Closed	Closed	Closed	Closed	Closed	x	x
hydromorphone <sup>15, 16</sup>		Closed	Closed	Closed	Closed	Closed	Closed	Closed	Closed		x	×
lidocaine (IV)		х	х	х	х	х	х	х	х	х	х	х
0 lurasidone <sup>4</sup>		х	х	х	х	х	х	х	х	х	х	х
meropenem (IV) <sup>2, 5</sup>	х	х	х	х	x	x						
methylprednisolone <sup>11</sup> (See special	1. Age ≤30 days on the day of surgery	•										

#### Resource Efficiency: fewer patients, quicker review, less redundancy

#### Old System

#### 2019-01-12 Inpatient Extract

- Finds patients who received a drug of interest
- 109 unique patients
- Record review: ~15 min/pt
- ~1,635 minutes

#### 2019-01-13 Inpatient Extract

• 112 unique patients @15 min/pt (forgets yesterday)

#### New System

#### **2019-01-12 Inpatient Screening Report**

- Finds patients who received a drug of interest and meet an age range or condition currently open for enrollment
- 31 unique patients
- Record review: ~5 min/pt
- ~155 minutes

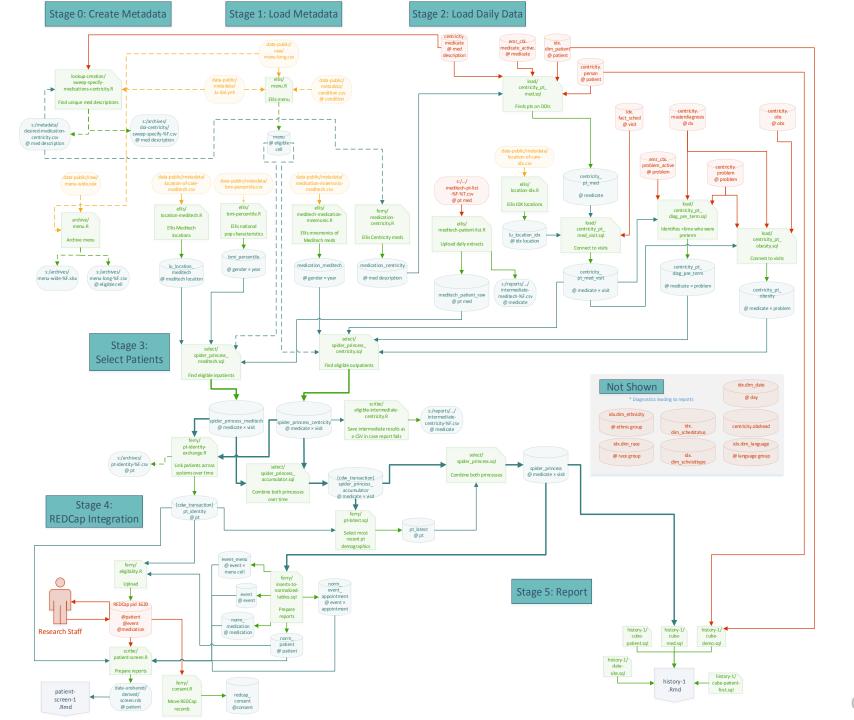
#### **2019-01-13 Inpatient Screening Report**

• 6 <u>new</u> patients @5 min/pt (remembers yesterday)

darden-pharmaco-2

## Enrollment Rate by Institution

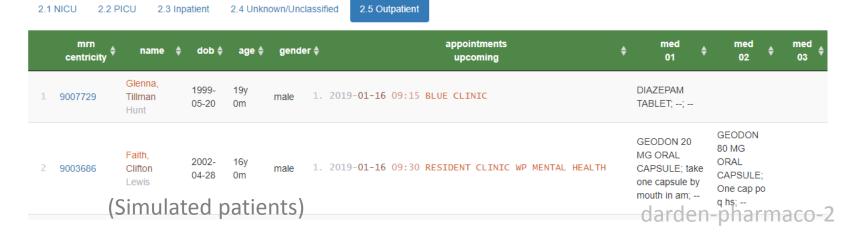
	Total #		
	enrolled	Months	
	since	since	Average enrollment
ISPCTN Sites	activation	activation	per month
Alaska Native Medical Center	2	13	0.15
Children's Mercy Hospitals and Clinics	19	11	1.73
Dartmouth-Hitchcock Medical Center	8	6	1.33
Kapiolani Women's and Children's Medical Center	9	8	1.13
Oklahoma University Medical Center	59	7	8.43
Rhode Island Hospital	46	11	4.18
Tulane University Health Science Center	4	14	0.29
University of Kansas Medical Center	2	2	1.00
University of Mississippi Medical Center	16	9	1.78
University of Montana	12	10	1.20
University of Nebraska Medical Center	14	12	1.17
University of New Mexico, Health Sciences Center	15	15	1.00
University of South Carolina - Palmetto Health	19	14	1.36
University of Vermont Medical Center	2	9	0.22
West Virginia University Hospital	9	13	0.69
Alfred I. duPont Hospital for Children	150	68	2.21
Arkansas Children's Hospital Research Institute	69	91	0.76
Medical University of South Carolina Children's Hospital	90	82	1.10
University of Louisville Norton Children's Hopsital	138	89	1.55



## Screening Reports (for outpatients)

- Shows upcoming appointments of potentially eligible patients
  - Location of care
  - Appt Date & time
  - Qualifying medication (e.g., Diazepam)
  - Qualifying condition (e.g., obese, 24 months old)
  - Similar inpatient process was developed
  - Eligible Patients for POPS

#### 2 Eligible Patients



## REDCap Project

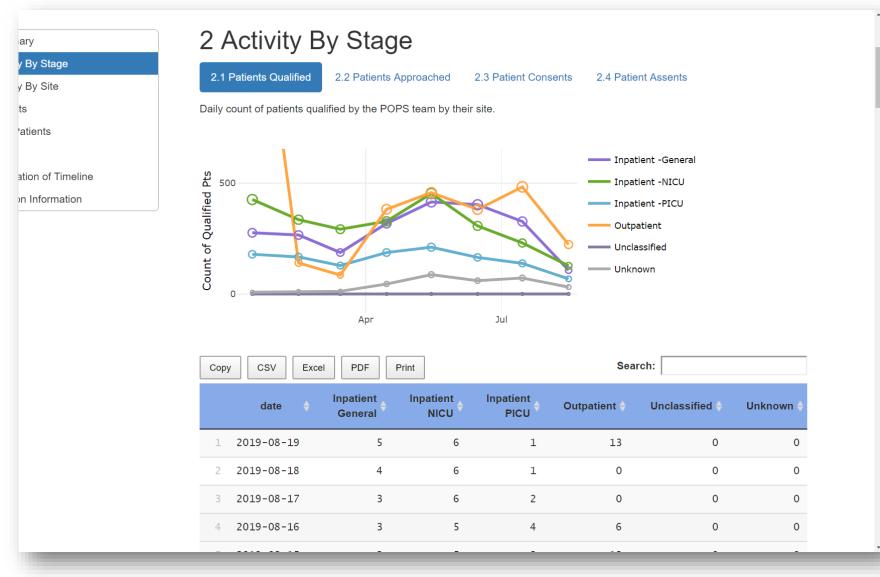
This repeated consent is not necessary. A consent is valid for a period of 90 days.  Has the patient been approached to participate in this study?  Time Constraint Incorrect Location Unable to Collect Required Specimen Ineligible per Manual Chart Review Other  Teset  Other  Teset  Other  Teset  Other  Teset  Accepted Declined Deferred (patient is willling to discuss participation in the future, but has not accepted yet)  The patient of Consent  Date of Consent  Accepted Declined Decli	Days since consent		View equation			
Has the patient been approached to participate in this study?  Time Constraint Incorrect Location Unable to Collect Required Specimen Ineligible per Manual Chart Review Other  Treset  Other  Teset  Today  The Consent result  Accepted Declined Deferred (patient is willing to discuss participation in the future, but has not accepted yet)  The consent result Today  The Consent result Today  The Consent result Today  The Consent result Today  The Consent Reason for Declination of Consent  The Consent Today  The Consent Today	Days since the previous consent		View equation			
Study?  No  Time Constraint Incorrect Location Unable to Collect Required Specimen Ineligible per Manual Chart Review Other  Other  reset  Accepted Declined Deferred (patient is willing to discuss participation in the future, but has not accepted yet)  reset  Warning: Documenting 'declination' of consent will permanently remove this patient from the daily eligibility reports.  Reason for Declined	This repeated consent is not necessary. A consent is valid for	a period of 90 days.	4			
Time Constraint Incorrect Location Unable to Collect Required Specimen Ineligible per Manual Chart Review Other  reset  Consent result  Consent  Con	Has the patient been approached to participate in this study?			rosat		
Other  reset  Accepted Declined Deferred (patient is willing to discuss participation in the future, but has not accepted yet)  Possible of Consent  Date of Consent Age at date of consent  Accepted Declined Deferred (patient is willing to discuss participation in the future, but has not accepted yet)  reset  Today V-M-D View equation  Accepted Declined Unable to Assent  Warning: Documenting 'declination' of assent will permanently remove this patient from the daily eligibility reports.  Reason Assent Not Given	Why has the patient not been approached?	O Incorrect Location				
Consent result  Accepted Declined Deferred (patient is willing to discuss participation in the future, but has not accepted yet)  Preset Warning: Documenting 'declination' of consent will permanently remove this patient from the daily eligibility reports.  Reason for Declination of Consent  Date of Consent Age at date of consent  Wiew equation  Accepted Declined Unable to Assent  Warning: Documenting 'declination' of assent will permanently remove this patient from the daily eligibility reports.  Reason Assent Not Given		<u> </u>				
Consent result  Declined Deferred (patient is willing to discuss participation in the future, but has not accepted yet)  Peset Warning: Documenting 'declination' of consent will permanently remove this patient from the daily eligibility reports.  Reason for Declination of Consent  Date of Consent  Age at date of consent  Warning: Documenting 'declination' of assent will permanently remove this patient from the daily eligibility reports.  Warning: Documenting 'declination' of assent will permanently remove this patient from the daily eligibility reports.  Reason Assent Not Given	If 'other', please explain.					
Reason for Declination of Consent  Date of Consent  Age at date of consent  View equation  Accepted  Declined  Unable to Assent  Warning: Documenting 'declination' of assent will permanently remove this patient from the daily eligibility reports.  Reason Assent Not Given	Consent result	<ul><li>Declined</li><li>Deferred (patient is willing to discuss participation in the</li></ul>				
Date of Consent  Age at date of consent  Accepted  Declined  Unable to Assent  Warning: Documenting 'declination' of assent will permanently remove this patient from the daily eligibility reports.  Reason Assent Not Given		ntly remove this patie	ent from the daily eligibility reports	5.		
Age at date of consent  Assent Result  Declined Unable to Assent  Warning: Documenting 'declination' of assent will permanently remove this patient from the daily eligibility reports.  Reason Assent Not Given	Reason for Declination of Consent					
Assent Result  Obeclined Ounable to Assent  Warning: Documenting 'declination' of assent will permanently remove this patient from the daily eligibility reports.  Reason Assent Not Given	Date of Consent	Tod	lay Y-M-D			
Assent Result  Declined Unable to Assent  Warning: Documenting 'declination' of assent will permanently remove this patient from the daily eligibility reports.  Reason Assent Not Given	Age at date of consent		View equation			
Reason Assent Not Given	Assent Result	O Declined		reset		
Date of Assent Today Y-M-D	Warning: Documenting 'declination' of assent will permanent Reason Assent Not Given	ly remove this patien	t from the daily eligibility reports.			
	Date of Assent	31 Tod	lay Y-M-D			

Approached?

Consented?

Assented?

## **Progress Reports**



See the forest.

3-way breakdowns of:

- time
- site
- drug
- age
- gender
- stage
  - 1. qualified
  - 2. approached
  - 3. consented
  - 4. assented

## **Progress Reports**

#### 3 Activity By Site

Summary of screening and recruitment acitivities by site.

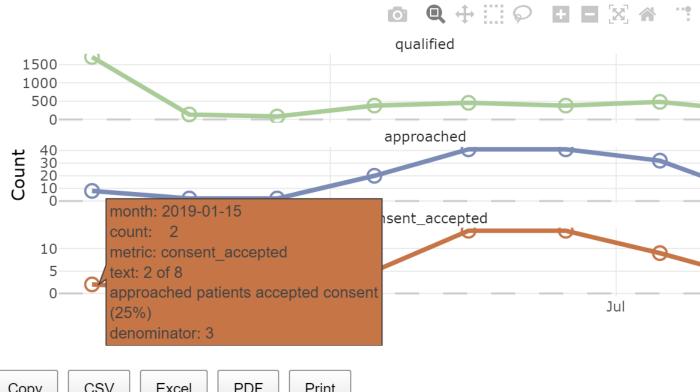
3.1 General

3.2 NICU

3.3 PICU

3.4 Outpatient

Daily count of patients qualified by the POPS team by their site.



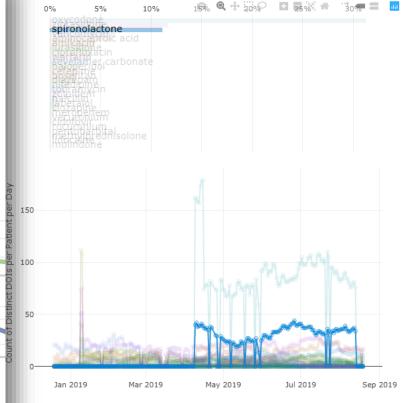


#### 6.1 Overall

The DOI per day is calculated by (a) counting the orders of a DOI and then (b) dividing by the daily count of unique patients. Since a patient may receive more than one DOI order on a single day, the DOI percentages will exceed 100%.

The histogram represents 'Sum of Daily Medication Counts': (out of 34,867 total medication-days across 237 days)'. Sum of Daily Medication Counts'. The uniqueness of the DOI is considered; a patient eligible for three variations of the same DOI will lengthen the bar by only 1.

e spaghetti represents the count of each DOI during a given day.



Сору	CSV	FUI	Fillit							
Ш	date +	patient +	amikacin +	aminocaproic acid +	bosentan +	cefepime +	cidofovir +			
) 1	2019-08-19	77	0	16	7	0	0			
2	2019-08-18	14	0	1	0	0	0			
2	2019_08_17	7/	0	16	7	0	0			

Search:

# National Registry Example: COVID-19 CDW Registry Based on OMOP

## National Registry

• Institutions from 20+ states combine covid data from their EMRs

 There's a national movement for investigations to be informed by multiple sites/institutions. Every research study and institution collects their data differently.

• A CDM (common data model) is a standardized convention to store & describe data. Institutions extract and transform their EMR data

See <a href="https://ncats.nih.gov/">https://ncats.nih.gov/n3c</a>









## Thank you

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**Award Numbers:** 



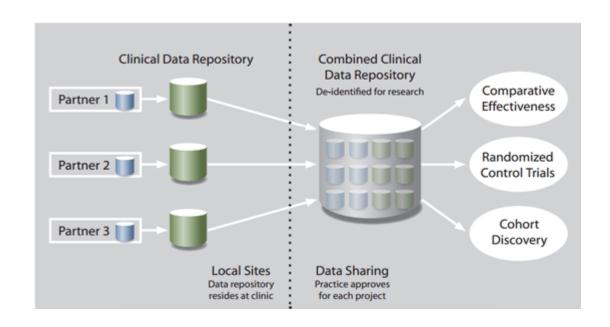




## Extra Slides

#### Where Other Universities are Headed

- University of Washington:
  - Data Quest (<a href="https://dataquest.iths.org/">https://dataquest.iths.org/</a>)
  - Leaf- Integrates of Regulatory Oversight with Data Accession
    - De-identified prep to research
    - PHI access
- TriNetX
  - Attract Industry-Sponsored Trials
  - Peer-institution Collaborations
- University of Michigan
  - EMERSE (Electronic Medical Records Search Engine; <a href="http://project-emerse.org/">http://project-emerse.org/</a>)
    - Google for your free text EMR documents and notes
    - Similar to natural language processing (NLP)







#### **About LEAF**

- Self-service web application for querying and extracting clinical data
- Flexible biomedical concept system to define hierarchical items and ontologies
- Drag & drop user interface
- Designed to seamlessly integrate with existing enterprise user authentication systems and clinical databases
- Produces results which are identifiable (with IRB approval) or de-identified

#### **Potential Uses**

- Cohort discovery: determine if enough patients meet a given set of conditions which match recruitment criteria
- Statistics: quickly pull numbers, "How many patients were seen last month?"
- Chart Abstraction: Generate a dataset for research or quality improvement purposes

## Brief Summary of CDW Value

## Brief Summary of CDW Value

- POPS: dynamic recruitment
- OxyContin: electronic sorting and merging/patient matching
- ADHD studies: Apply standard clinical vocabulary to support interoperability to help information exchange; isolated retrieval of text documents for mining
- Diabetes Management/Transition of Care: Sharing of data across various sources improves quality of care and efficiency; maximizes utility of data
- Immunization: Harmonization of records for quality reporting and improved accuracy of record history

## Tung-ibd-1

Tissue Eosinophil Count in IBD patients

## Steps to Leverage EMR "documents"

#### CDW-level tasks

- (Notes are stored as multiple rows --2k characters per "document")
- Concatenate the 2-4,000 rows per document
- Strip the RTF. (RTF is a markup language that specifies cosmetics like font size and color.)
- Include a search index (similar to a book index) that makes searches & parsing more efficient

#### **Project-specific tasks**

- Identify keywords that might indicate the document contains a relevant lab.
- Extract the stem and result
  - eg, "normal fecal flora (moderate growth)"
  - eg, "negative for salmonella, shigella, and campylobacter"