Making the Most of Real-World Data

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Disclosures

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Outline

• Drug Repurposing
• Real-World Data
• The Edge Tool
  – Use Case: COVID-19
• Real-World Evidence
• Future Directions
Drug Repurposing

• Significant portion of conditions have no FDA approved treatments
• Traditional drug development and labeling is slow and expensive.
• Repurposing may be needed in diseases which are:
  – rapidly emerging
  – extremely rare
  – impacting vulnerable groups
  – treated by standardized guidelines
Real-World Data

- Explore clinical practice
- Develop and refine hypotheses
- Provide external controls
- Observational research

Real-World Data: Challenges

• Unstructured data
• Defining outcomes
• Privacy concerns
• Loss to follow up
• Data harmonization
Imagine we instructed everyone in this meeting to collect the eye color, hair color, height, and coffee preferences of people at the grocery store.

How would you store the data?

What variable names would you use?

How would you classify responses?

Would you code responses? Free text?

<table>
<thead>
<tr>
<th>Eye_Color</th>
<th>Hair_Color</th>
<th>Height</th>
<th>Coff_Pref</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown</td>
<td>Blonde</td>
<td>5ft6in</td>
<td>Black</td>
</tr>
<tr>
<td>Blue</td>
<td>Brown</td>
<td>5ft8in</td>
<td>Cream</td>
</tr>
<tr>
<td>Brown</td>
<td>Grey</td>
<td>4ft11in</td>
<td>Just sugar</td>
</tr>
<tr>
<td>Hazel</td>
<td>Brunette</td>
<td>6ft1in</td>
<td>Oat milk</td>
</tr>
<tr>
<td>Brown</td>
<td>Red</td>
<td>5ft11</td>
<td>Iced</td>
</tr>
<tr>
<td>Green</td>
<td>Dirty Blonde</td>
<td>5ft9in</td>
<td>Tea only</td>
</tr>
</tbody>
</table>
Real-World Data: Data Harmonization

EXTRACT
TRANSFORM
LOAD

ETL
Real-World Data: Data Harmonization

• Centralized harmonization

• Sites use common data model at baseline

• Only for US data

• Limited to COVID-19

National COVID Cohort Collaborative (N3C)

The N3C is a partnership among the NCATS-supported Clinical and Translational Science Awards (CTSA) Program hubs, the National Center for Data to Health (CD2H)®, and NIGMS-supported Institutional Development Award Networks for Clinical and Translational Research (IDeA-CTR), with overall stewardship by NCATS. Collaborators will contribute and use COVID-19 clinical data to answer critical research questions to address the pandemic.

Scientists Use N3C Data to Identify Common Features of Long COVID

NIH-supported researchers used electronic health record data from the National COVID Cohort Collaborative (N3C) Data Enclave to identify people with long COVID and those likely to have it.

ncats.nih.gov/n3c
Observational Medical Outcomes Partnership (OMOP)

153 Controlled Vocabularies
9 Million concepts

ICD-10

NIH
National Library of Medicine

SNOMED
International
Leading healthcare terminology, worldwide

LOINC®
from Regenstrief
The Edge Tool

Proprietary Data Model

OMOP CDM V5.3.1
The Edge Tool

• Web-based decision support for concept mapping
• Base configuration settings for major EMR Vendors.
• Configuration management documentation tool
• Inspection Report of DevOps on ETL processes
• Data Quality Dashboard framework of 3,000+ data quality tests
• Collaborative cohort subset definition
• Perform de-identification and submission
• All open-source resources
The Edge Tool on Azure

ETL
- Perseus
- EMR base config
- Usagi
- White Rabbit
- Rabbit in the Hat

DevOps
- Data Quality Dashboard
- Documentation Engine
- Submission extraction
- Change control

Analysis
- Atlas
- WebAPI
- Hades
- R-Studio
- Methods Library

Azure SQL Server
OMOP Data Model
Vocabulary Management
Authentication and Authorization
The Edge Tool Use Case: COVID-19

- Drug Repurposing
- Broad Impact
- Identifiable Cases
- Discreet Data
- Acute Disease
- Definitive Outcomes
Real-World Evidence: COVID-19

- Emulate findings of clinical trials
- Evaluate key agents: dexamethasone, baricitinib, tocilizumab
- Demonstrate utility of Edge Tool

• What motivates institutions to build infrastructure to extract and share RWD?

https://episframework.com/
RWD: Beyond COVID

- Sepsis
  - Isolating organisms
  - Case definition
  - Sites highly motivated

- Meningitis
  - Isolating organisms
  - Rarer cases of more interest

- Osteomyelitis
  - Isolating organisms
  - Linking encounters
  - Lost to follow up
Thank You
References


