The OHDSI Collaboration: Mission, Accomplishments, and the Road Ahead

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Alternative title (and motivation for OHDSI):
Scientific Cacophony,
Harmony achieved through **collaboration**, not randomization
The journey to real-world evidence

Patient-level data in source system/schema

Reliable evidence
The journey to real-world evidence

Different types of observational data:
- **Populations**
  - Pediatric vs. elderly
  - Socioeconomic disparities
- **Care setting**
  - Inpatient vs. outpatient
  - Primary vs. secondary care
- **Data capture process**
  - Administrative claims
  - Electronic health records
  - Clinical registries
- **Health system**
  - Insured vs. uninsured
  - Country policies
The journey to real-world evidence

Types of evidence desired:
• Clinical characterization
  • Clinical trial feasibility
  • Treatment utilization
  • Disease natural history
  • Quality improvement
• Population-level effect estimation
  • Safety surveillance
  • Comparative effectiveness
• Patient-level prediction
  • Precision medicine
  • Disease interception

Patient-level data in source system/schema

Reliable evidence
## Desired attributes for reliable evidence

<table>
<thead>
<tr>
<th>Desired attribute</th>
<th>Question</th>
<th>Researcher</th>
<th>Data</th>
<th>Analysis</th>
<th>Result</th>
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<tbody>
<tr>
<td>Repeatable</td>
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<tr>
<td>Reproducible</td>
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<td>Different</td>
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<td>Replicable</td>
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<td>Similar</td>
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<td>Similar</td>
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<td>Generalizable</td>
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<td>Similar</td>
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<td>Robust</td>
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<td>Calibrated</td>
<td>Similar (controls)</td>
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<td>Identical</td>
<td>Identical</td>
<td>Statistically consistent</td>
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OHDSI is
an open science community
OHDSI’s mission

To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care
OHDSI’s vision

A world in which observational research produces a comprehensive understanding of health and disease
OHDSI community

We’re all in this journey together...

Different stakeholders: academia, medical product industry, regulators, government, payers, technology providers, health systems, clinicians, patients

Different disciplines: computer science, epidemiology, statistics, biomedical informatics, health policy, clinical sciences
OHDSI’s community engagement

• Active community online discussion: forums.ohdsi.org
  – >3,800 distinct users have made >24,400 posts on >4,200 topics
  – Implementers, Developers, Researchers, CDM Builders, Vocabulary users, OHDSI in Korea, OHDSI in China, OHDSI in Europe
• Weekly community web conferences for all collaborators to share their research ideas and progress
• >25 workgroups for solving shared problems of interest
  – ex: Common Data Model, Population-level Estimation, Patient-level Prediction, Phenotype, NLP, GIS, Oncology, Women of OHDSI
• Quarterly tutorials in OHDSI tools and best practices, taught by OHDSI collaborators for OHDSI collaborators
• OHDSI Symposia held annually in North America, Europe and Asia to provide the community opportunities to showcase research collaborations (2020 Symposium virtual Oct 18-22)
• Follow us on Twitter @OHDSI and LinkedIn
OHDSI is an international data network
Data across the OHDSI community

- 152 entries on [2019 OHDSI data network inventory](#)
- 133 different databases with patient-level data from various perspectives:
  - Electronic health records, administrative claims, hospital systems, clinical registries, health surveys, biobanks
- Data in 18 different countries, with >369 million patient records from outside US

All using one open community data standard: [OMOP Common Data Model](#)
Common data model to enable standardized analytics

Transformation to OMOP common data model

Source 1 raw data
- Electronic health records
Source 2 raw data
- Administrative claims
Source 3 raw data
- Clinical data

Source 1 CDM
Source 2 CDM
Source 3 CDM

Open-source analysis code
Open evidence

Electronic health records
Clinical data
Administrative claims
OHDSI is collaborating to generate reliable evidence
What is OHDSI’s strategy to deliver reliable evidence?

• **Methodological research**
  – Develop new approaches to observational data analysis
  – Evaluate the performance of new and existing methods
  – Establish empirically-based scientific best practices

• **Open-source analytics development**
  – Design tools for data transformation and standardization
  – Implement statistical methods for large-scale analytics
  – Build interactive visualization for evidence exploration

• **Clinical evidence generation**
  – Identify clinically-relevant questions that require real-world evidence
  – Execute research studies by applying scientific best practices through open-source tools across the OHDSI international data network
  – Promote open-science strategies for transparent study design and evidence dissemination
Complementary evidence to inform the patient journey

Clinical characterization: What happened to them?

Patient-level prediction: What will happen to me?

Population-level effect estimation: What are the causal effects?

observation

inference

causal inference
Harmony through collaboration:
Case study in COVID-19 pandemic

- Real-world data for COVID-19 standardized to OMOP CDM in OHDSI network (16 databases in US, Europe, Asia)
  - 4.5 million patients tested for SAR-COV-2
  - 1.2 million patients diagnosed or tested positive
  - 380k patients with a confirmed positive laboratory test
  - 249k patients hospitalized with a COVID diagnosis or positive test
- Real-world evidence generated by OHDSI community
  - COVID disease natural history: Patients hospitalized with COVID are systematically different from those hospitalized with flu ([link to paper](#))
  - Comparative safety of hydroxychloroquine: In history use in RA population, HCQ alone is generally safe but combination of HCQ+azithromycin shows doubling of risk of 30-day cardiovascular mortality ([link to paper](#))
  - Psychiatric safety of hydroxychloroquine: EMA was concerned about risk of neuropsychiatric events associated with HCQ based on spontaneous reports, but we showed no difference between HCQ and sulfasalazine ([link to paper](#))
  - ACE inhibitors and susceptibility to COVID: There is no difference in risk of developing COVID between prevalent users of ACE inhibitors, ARBs, or other antihypertensive medications. ([link to paper](#))
  - COVID risk prediction: developed and externally validated a model that can predict hospitalization, intensive service use, and death amongst symptomatic patients ([link to paper](#))
- Regulatory impact:
  - 3 invited presentations to FDA/Reagan-Udall Evidence Accelerator sessions to guide RWE best practices in COVID research
  - EMA risk communication on HCQ cites OHDSI study ([link](#))
  - EMA requests OHDSI to study neuropsychiatric events on HCQ after spontaneous reports emerge; results delivered to EMA in weeks
  - EMA/ENCEPP guidelines on pharmacoepidemiology cite OHDSI studies as illustrative best practices ([link to guidance](#))