210: Harmonizing Real-World Data Networks: Bridging Regulatory, Patient and Research Perspectives

Keith Marsolo, PhD
Professor, Department of Population Health Sciences
Member, Duke Clinical Research Institute
Duke University School of Medicine

May 7, 2024

Duke Clinical Research Institute | FROM **THOUGHT LEADERSHIP** TO **CLINICAL PRACTICE**

Disclosures

- Investigator on research contracts to Duke University from Pfizer, Boehringer Ingelheim, Novartis, Bristol Myers Squibb and Eli Lilly

- Co-inventor – Hive Networks, Inc.

- Duke University is part of the Coordinating Center for PCORnet®, which has been developed with funding from the Patient-Centered Outcomes Research Institute® (PCORI®). Duke University's participation in PCORnet has been funded through PCORI Awards (RI-DCRI-01, CC2-Duke-2016). The views presented here are solely the responsibility of the moderator and do not necessarily represent the views of other organizations participating in, collaborating with, or funding PCORnet, or of PCORI.

Design of Real-World Data Networks

	Common protocol	Common Data Model	Distributed analyses	Coordinated data curation	Centralized study data	Interventional studies	Selected examples
Federated	Yes	No	No	No	No	No	COVID-19 Evidence Accelerator
	Yes	Yes	Yes	No	No	No	OHDSI Network Studies
	Yes	Yes	Yes	Yes	No	No	Darwin-EU FDA Sentinel PCORnet®
Centralized	No	Yes	No	No	Yes	No	Komodo Health IQVIA Other commercial data aggregators
	No	Yes	No	Yes	Yes	No	National COVID Cohort Collaborative (N3C) Truveta Epic Cosmos
	No	Yes	No	Yes	Yes	Yes	PCORnet®

Data harmonization – a challenging, but necessary evil
Example – Encounter type (PCORnet®)

REGISTRATION
EMPTY
LAB REQUISITION
INITIAL CONSULT
ANTI-COAG VISIT
PROCEDURE VISIT
OFFICE VISIT
CONSENT FORM
SCREENING FORM
EXTERNAL HOSPITAL ADMISSION
LETTER (OUT)
REFILL
IMMUNIZATION
HISTORY
RESEARCH ENCOUNTER
REFERRAL
ORDERS ONLY
RX REFILL AUTHORIZE
MEDS ONLY (WEB)
MEDS VOID (WEB)
RESOLUTE PROFESSIONAL
BILLING HOSPITAL PROF FEE
EPISODE CHANGES
ANCILLARY ORDERS
PHARMACY VISIT
BPA
ROUTINE PRENATAL
INITIAL PRENATAL
OPHTH OFFICE VISIT
ABSTRACT
WALK-IN
TREATMENT PLAN
ALLIED HEALTH
NURSE ONLY
SOCIAL WORK
NUTRITION
PHYSICAL THERAPY
OCCUPATIONAL THERAPY
SPEECH THERAPY
ROADMAP
TELEPHONE

CASE MANAGEMENT
EDUCATION
SURGICAL H&P
CLINICAL SUPPORT
MEDS ONLY / E - PRESCRIBE
PFT ONLY
TRANSPLANT PRE-EVALUATION
TRANSPLANT EVALUATION
TRANSPLANT FOLLOW-UP
TRANSPLANT RESULTS ENTRY
IMMUNOTHERAPY
ALLERGY TESTING
SPECIMEN COLLECTION
AUTO RELEASE ORDERS
URODYNAMIC TESTING
PRE-NATAL
CONSULT CHECKLIST
BOWEL MANAGEMENT
CARE CONFERENCE
INTAKE/TRIAGE
VNS REPROGRAM/SHUTOFF
CLINICAL NOTE
GENETICS
PASTORAL
THERAPY VISIT
INTAKE - NEW PATIENT
HIM SCANS
PRE-VISIT PLANNING
TRANSCRIBED ORDERS
SCHOOL
TEACHER/INTERVENTION
CHILD LIFE
THERAPY PROGRESS SUMMARY
BRONCHOSCOPY REQUEST
HEMONC SOCIAL WORK
AUD CONSULT
OPH CONSULT
ALG CONSULT
UROLOGY COMPLEX INTAKE
RESPIRATORY THERAPY
HOSPITAL ENCOUNTER

UPDATE
PCP/CLINIC CHANGE
WAIT LIST
CLERICAL ORDERS
MOTHER BABY LINK
LACTATION ENCOUNTER
CANCELED
APPOINTMENT
SURGERY
ANESTHESIA
ANESTHESIA EVENT
UNMERGE
HEALTH MAINTENANCE LETTER
PATIENT EMAIL
E-VISIT
MOBILE ORDER ONLY
QUESTIONNAIRE SERIES SUBMISSION
PATIENT OUTREACH
CONTACT MOVED
NURSE TRIAGE
E-CONSULT
E-CONSULT COMMUNITY ORDER
TELEMEDICINE
EXTERNAL CONTACT
OPHTH EXAM
HOSPICE ADMISSION
HOME HEALTH ADMISSION
HOME CARE VISIT
HOME CARE UPDATE
PATIENT WEB UPDATE
COMMUNITY ORDERS
COMMITTEE REVIEW
POST MORTEM DOCUMENTATION
BILLING ENCOUNTER
HOSPITAL
CONFIDENTIAL
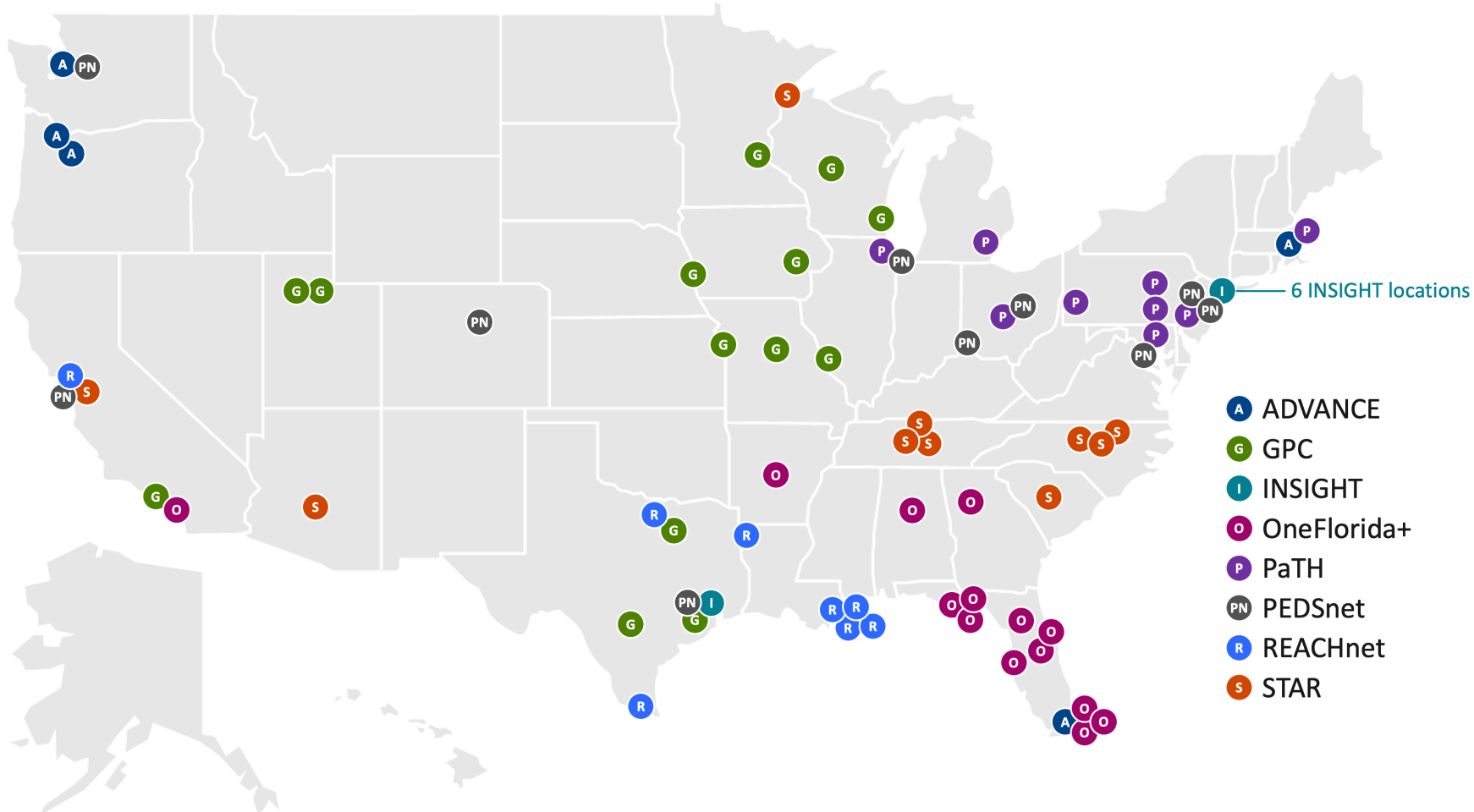OPH TESTING
EDUCATOR
VOICE CLINIC

EEG
EXERCISE
CARDIOLOGY TESTING
PUMP/CGM INITIATION ORDERS
MED TAPER SCHEDULE
GENETIC COUNSELOR
NEONATOLOGY TESTING
CARE CONFERENCE - PATIENT/FAMILY PRESENT
HOME VISIT - PALLIATIVE CARE
ABUSE REPORTING
CARE COORDINATOR
SPECIAL NEEDS SUMMARY
EARLY INTERVENTION
HI NEURODEVELOPMENTAL CLINIC TRACKING
INFUSION ORDERS
ENT CLINIC VISITS
FEES/VOICE
HEPATOBLASTOMA LIVER TRANSPLANT FOLLOW UP
PRE-ADOPTION ENCOUNTER
EB PLANNING
FEES CLINIC
VPI - ENT/SPEECH
INTAKE
HVMC PLANNING
PRE-OP PHYSICAL
PLAN OF CARE
ENT INPATIENT VISIT
HOSPITAL TO HOSPITAL TRANSFER
DEVELOPMENTAL TESTING
BIOETHICS CONSULT
ENDO STIM TESTING
HIM INTERFACE CREATED
SURGICAL SITE INFECTION
DERM PATCH TESTING
INTAKE CONSULT
ADEC INTAKE
CPST-PSY ENCOUNTER
ECONSULT TELEMEDICINE

AV=Ambulatory Visit
ED=Emergency Department
EI=Emergency Department Admit to Inpatient Hospital Stay (permissible substitution)
IP=Inpatient Hospital Stay
IS=Non-Acute Institutional Stay
OS=Observation Stay
IC=Institutional Professional Consult (permissible substitution)
OA=Other Ambulatory Visit
NI=No information
UN=Unknown
OT=Other

Encounter type.

Details of categorical definitions:
Ambulatory Visit: Includes visits at outpatient clinics, physician offices, same day/ambulatory surgery centers, urgent care facilities, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Emergency Department (ED): Includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care facility visits. ED claims should be pulled before hospitalization claims to ensure that ED with subsequent admission won't be rolled up in the hospital event. Does not include observation stays, where known.

Emergency Department Admit to Inpatient Hospital Stay: Permissible substitution for preferred state of separate ED and IP records. Only for use with data sources where the individual records for ED and IP cannot be distinguished.

Inpatient Hospital Stay: Includes all inpatient stays, including: same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date. Does not include observation stays, where known.

Observation Stay: "Hospital outpatient services given to help the doctor decide if the patient needs to be admitted as an inpatient or can be discharged. Observation services may be given in the emergency department or another area of the hospital." Definition from Medicare, CMS Product No. 11435, https://www.medicare.gov/Pubs/pdf/11435.pdf.

Institutional Professional Consult: Permissible substitution when services provided by a medical professional cannot be combined with the given encounter record, such as a specialist consult in an inpatient setting; this situation can be common with claims data sources. This includes physician consults for patients during inpatient encounters that are not directly related to the cause of the admission (e.g. a ophthalmologist consult for a patient with diabetic ketoacidosis) (guidance updated in v4.0).

Non-Acute Institutional Stay: Includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis, and other non-hospital stays.

Other Ambulatory Visit: Includes other non-overnight AV encounters such as hospice visits, home health visits, skilled nursing visits, other non-hospital visits, as well as telemedicine, telephone and email consultations. May also include "lab only" visits (when a lab is ordered outside of a patient visit), "pharmacy only" (e.g., when a patient has a refill ordered without a face-to-face visit), "imaging only", etc.

PCORnet® Clinical Research Network locations

PCORnet infrastructure offers access to real-world data through partnerships with Clinical Research Networks (CRNs)

6 INSIGHT locations

Legend:
- **A** ADVANCE
- **G** GPC
- **I** INSIGHT
- **O** OneFlorida+
- **P** PaTH
- **PN** PEDSnet
- **R** REACHnet
- **S** STAR

What are Clinical Research Networks?

CRNs are groups of diverse healthcare institutions across the U.S., from large academic health centers to local community clinics, united by a commitment to speed patient-centered research via PCORnet.

pcornet

The National Patient-Centered Clinical Research Network

Example strategies for mitigating quality issues in PCORnet®

- "RAW" fields in the Common Data Model (CDM) for storing original, unharmonized values – can potentially be used by study teams to verify mappings

- CDM Implementation Guidance – additional instructions that accompany the CDM specification to reduce variability when loading data

- Coordinated data curation – all Network Partners run a data curation package to identify quality issues & develop mitigation plans

- Targeted Improvement Sessions – Network-level investigations of common issues to reduce variability

- Record linkage – Use of tokenization to mitigate potential gaps with additional data sources

- Engagement with Clinicians / Datamart Administrators – Clinicians can advise on workflow(s) used within local health system to capture data; Datamart personnel can investigate issues locally and potentially modify code used to load the CDM

Panelist perspectives

- James Wiggins – Amazon Web Services

- Daniel Morales – European Medicines Agency

- Donna Rivera – US Food and Drug Administration