A Tale of Two Standards: iCoDE and the Diabetes Research Hub

Tuesday, June 3, 2025

Session 1: Success Stories of Data Collection, Integration, and Interoperability, Including Data from Wearables Devices

Addressing Gaps, Challenges, and Opportunities Related to Data and Metadata Standards for NIDDK Research Priorities

Juan Espinoza, MD
Chief Research Informatics Officer | Stanley Manne Children's Research Institute
Ann & Robert H Lurie Children's Hospital of Chicago
Associate Director, Center for Biomedical Informatics and Data Science | Northwestern University

Ann & Robert H. Lurie Children's Hospital of Chicago®

Stanley Manne Children's Research Institute™

Northwestern Medicine® Feinberg School of Medicine

Disclosures

- I have received research funding from FDA, The Helmsley Charitable Trust, NIDDK, NIMHD, NICHD, and NCATS.
- I have received consulting and/or speaker fees from Sanofi, Glooko, and Dexcom.
- These entities played no role in the design, execution, analysis, or development of this work. They did not play a role in the decision to prepare this presentation and had no editorial input.

- I am not an endocrinologist (apologies if I say anything wrong) - I am a pediatrician and informaticist, but I love working in the field of diabetes.

Overview

- Brief overview of CGM data ecosystem
- iCoDE: Integration of Continuous Glucose Monitoring Data into the EHR
- DRH: Diabetes Research Hub
- What's Next

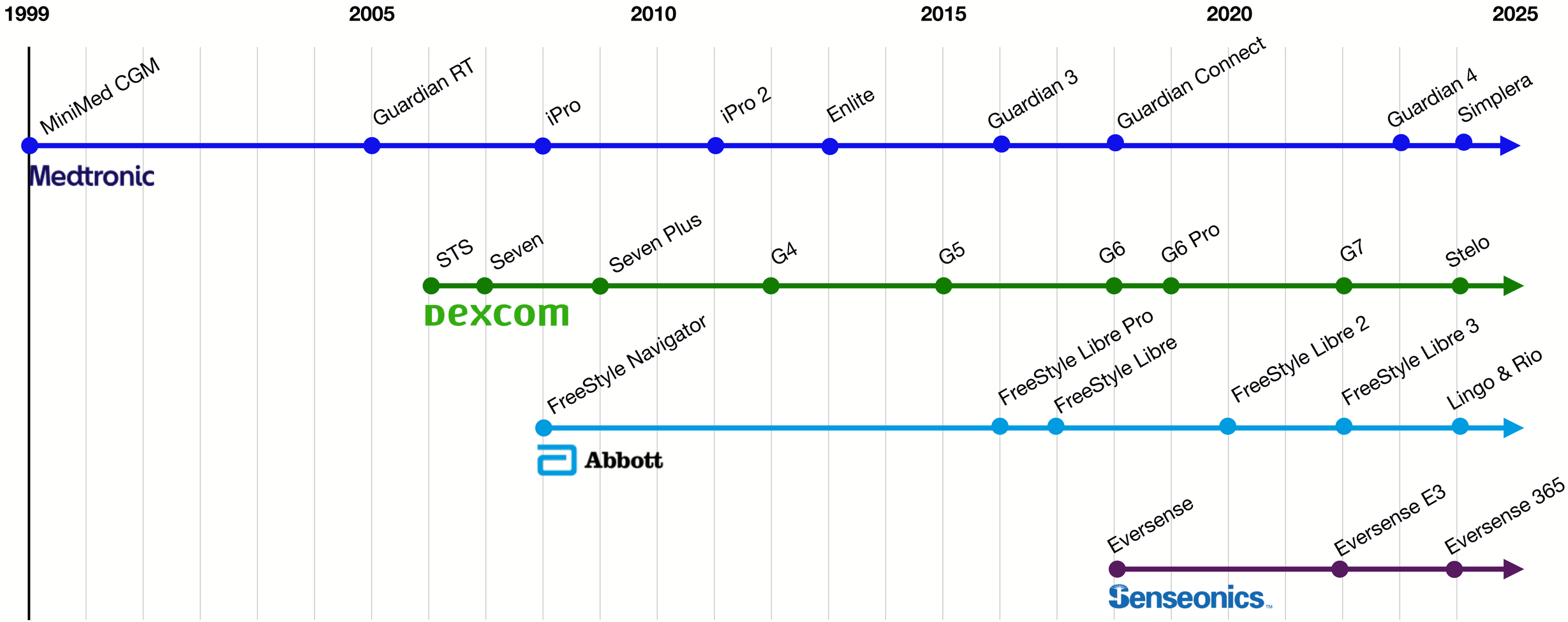
Ann & Robert H. Lurie Children's Hospital of Chicago®

Stanley Manne Children's Research Institute™

Northwestern Medicine® Feinberg School of Medicine

Brief Overview of CGMs

CGMs Over Time (US only)



Benefits of CGMs

- Improved glycemic control
- Reduced risk of hypo- and hyperglycemia
- Improved time in range
- Cost savings
- Increased self-efficacy
- Reduced diabetes-specific emotional distress
- Reductions in fear of hypoglycemia
- Improvements in sleep quality
- Improvement in quality of life
- Increased treatment satisfaction

"… the success of these technologies is predicated upon whether the user finds more benefits than burdens and is therefore willing to not only try the device, but also continue using it."

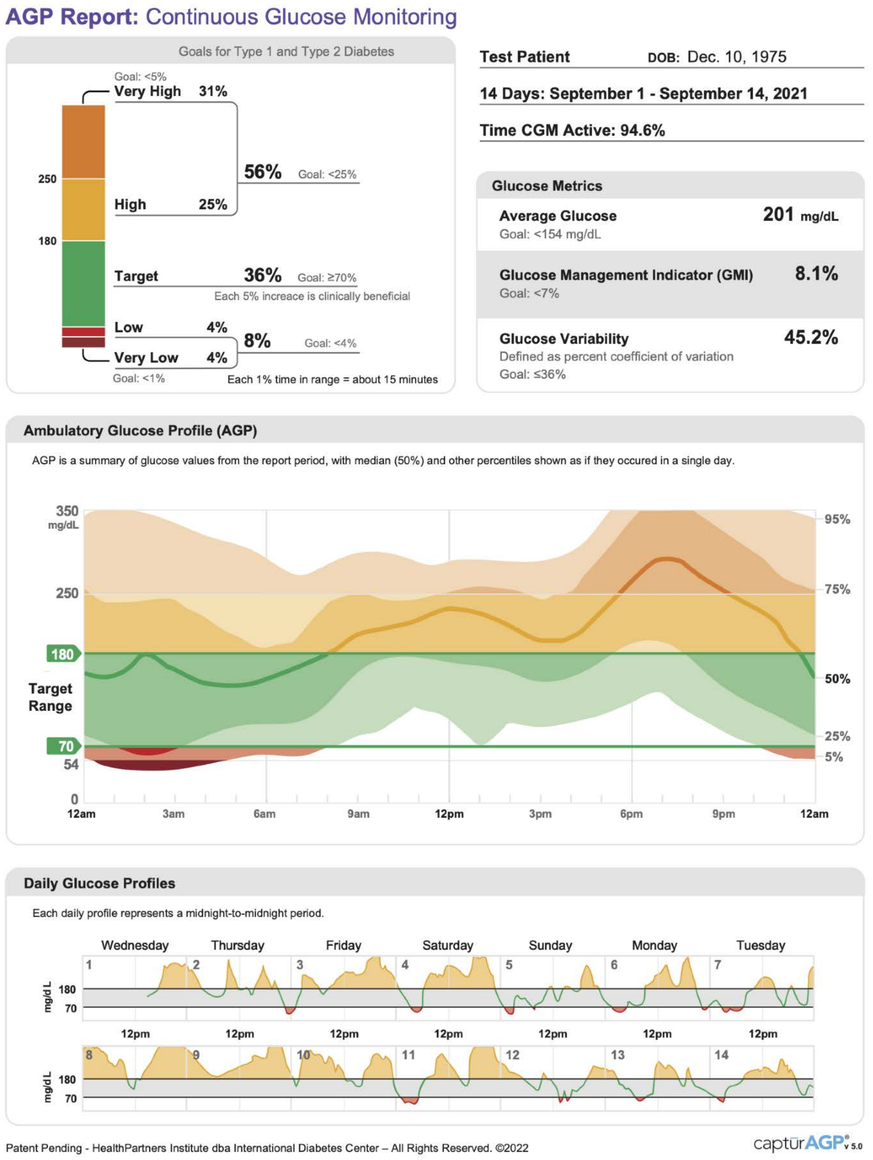
HOWEVER, we know that:

- these benefits are not experienced equally by all
- for some, can increase learned helplessness
- dependent on support from clinicians

• *Barnard-Kelly K, Gonder-Frederick L, Weissberg-Benchell J, Wisk LE. Psychosocial Aspects of Diabetes Technologies: Commentary on the Current Status of the Evidence and Suggestions for Future Directions. J Diabetes Sci Technol. 2025;19(1):27-33. doi:10.1177/19322968241276550*

… But it Took Years to Get There

- Data workflows were burdensome
  - Data portals came much later
- Interpretation guidance evolved slowly:
  - 2006: IDC first applies the AGP to CGM data
  - 2012: AGP Consensus meeting (IDC + Helmsley)
  - 2017: ATTD consensus on CGM Metrics
  - 2021: ADA first includes CGM in practice guidelines
- CMS did not cover CGMs until 2017



CGM Ecosystem Today

Manufacturers

Medtronic
dexcom
Abbott
Senseonics™

Aggregators & Integrators

TIDEPOOL
glooko
dreamed
rimidi
Redox
VALIDIC
Locus
RISING T1DE ALLIANCE

Professional Societies

American Diabetes Association®
ENDOCRINE SOCIETY
ATTD Advanced Technologies & Treatments for Diabetes
DIABETES TECHNOLOGY SOCIETY
ADCES
AACE American Association of Clinical Endocrinology
ISPAD International Society for Pediatric and Adolescent Diabetes

Funding, Support, & Advocacy

Breakthrough T1D™ Formerly JDRF
T1D Exchange
BEYOND TYPE 1
THE DIABETES LINK Where Young Adults Thrive
THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST
NIH NIDDK
TIME IN RANGE COALITION

Digital Health and Health Management Platforms

omada®
welldoc®
virta
Livongo by Teladoc Health®
Lifescan
lark
eddi
verily
mySugr
dario

Major Research Centers

Center for Diabetes Technology UVAHealth
DIABETES RESEARCH CENTERS
JCHR JAEB CENTER FOR HEALTH RESEARCH
SANSUM DIABETES RESEARCH INSTITUTE
Barbara Davis Center for Diabetes BDC
Barbara Davis Center for Diabetes UNIVERSITY OF COLORADO SCHOOL OF MEDICINE
HealthPartners Institute
International Diabetes Center
Stanford Diabetes Research Center
Beth Israel Lahey Health Joslin Diabetes Center

Not an exhaustive list!

Ann & Robert H. Lurie Children's Hospital of Chicago®

Stanley Manne Children's Research Institute™

Northwestern Medicine® Feinberg School of Medicine

CGM Data Integration: iCoDE

The EHR

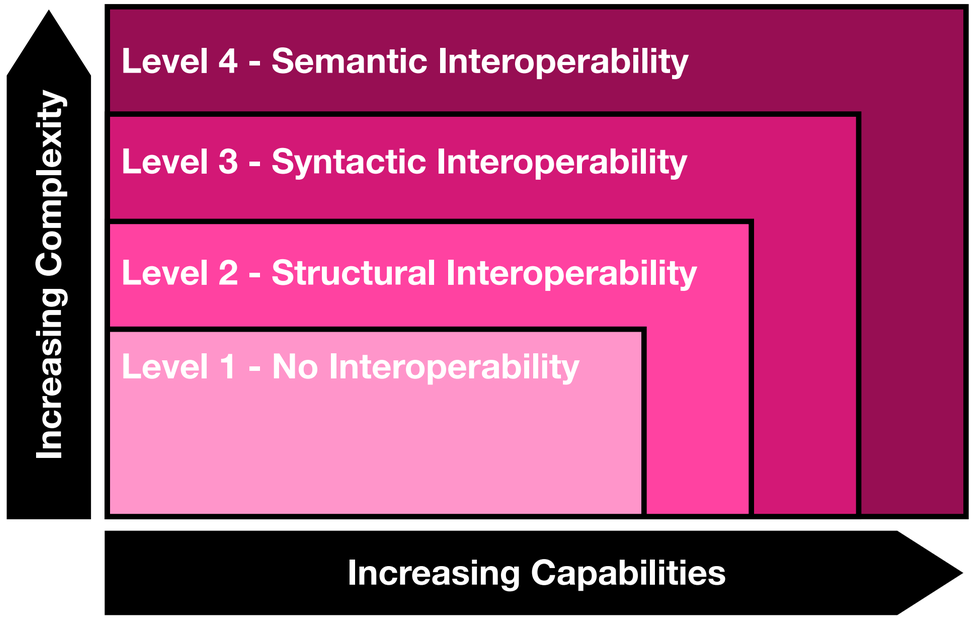
Where We Work

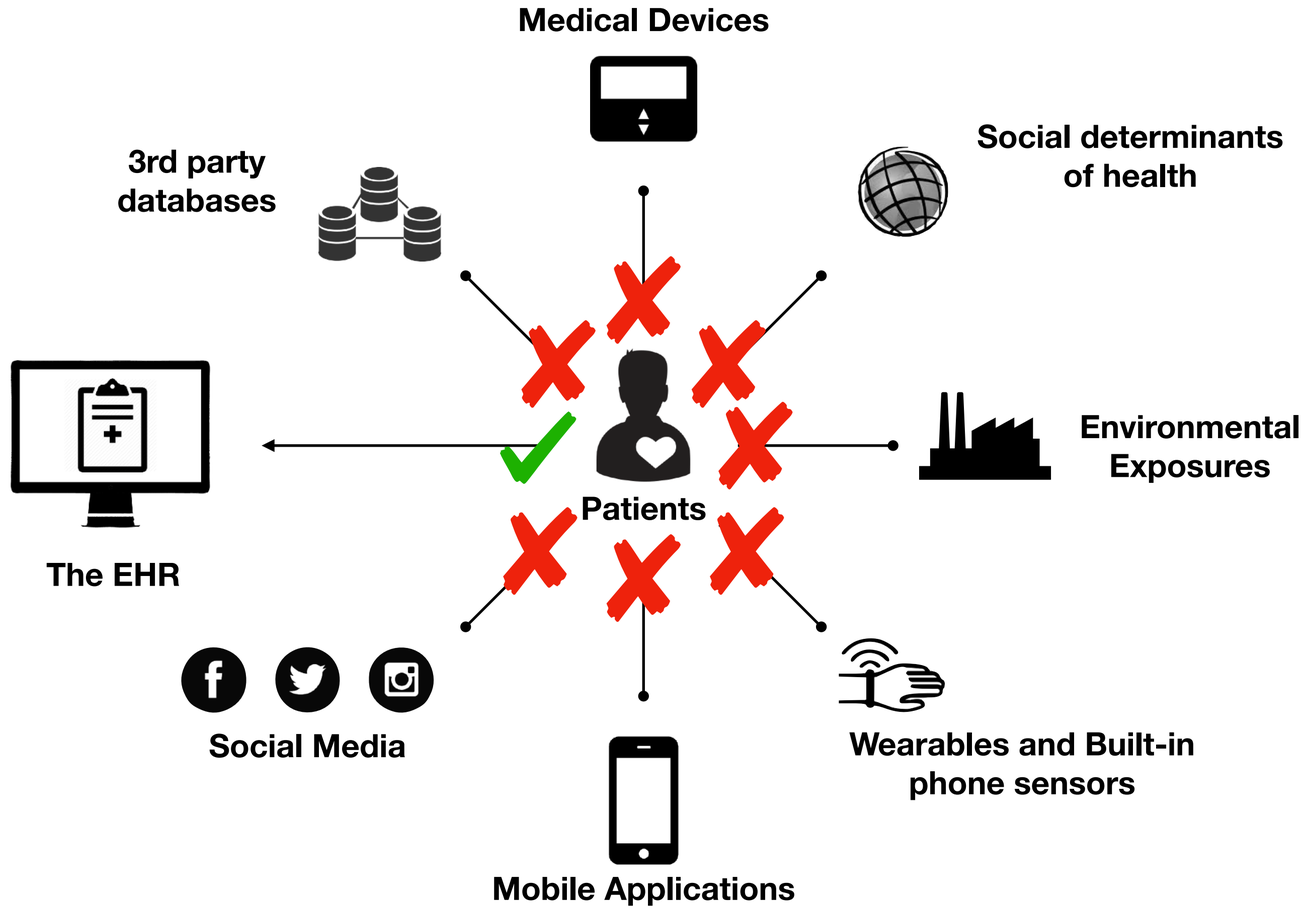
- Documentation
- Billing
- Chart Review
- Order Entry

Harry Campbell
The New York Times

Current State

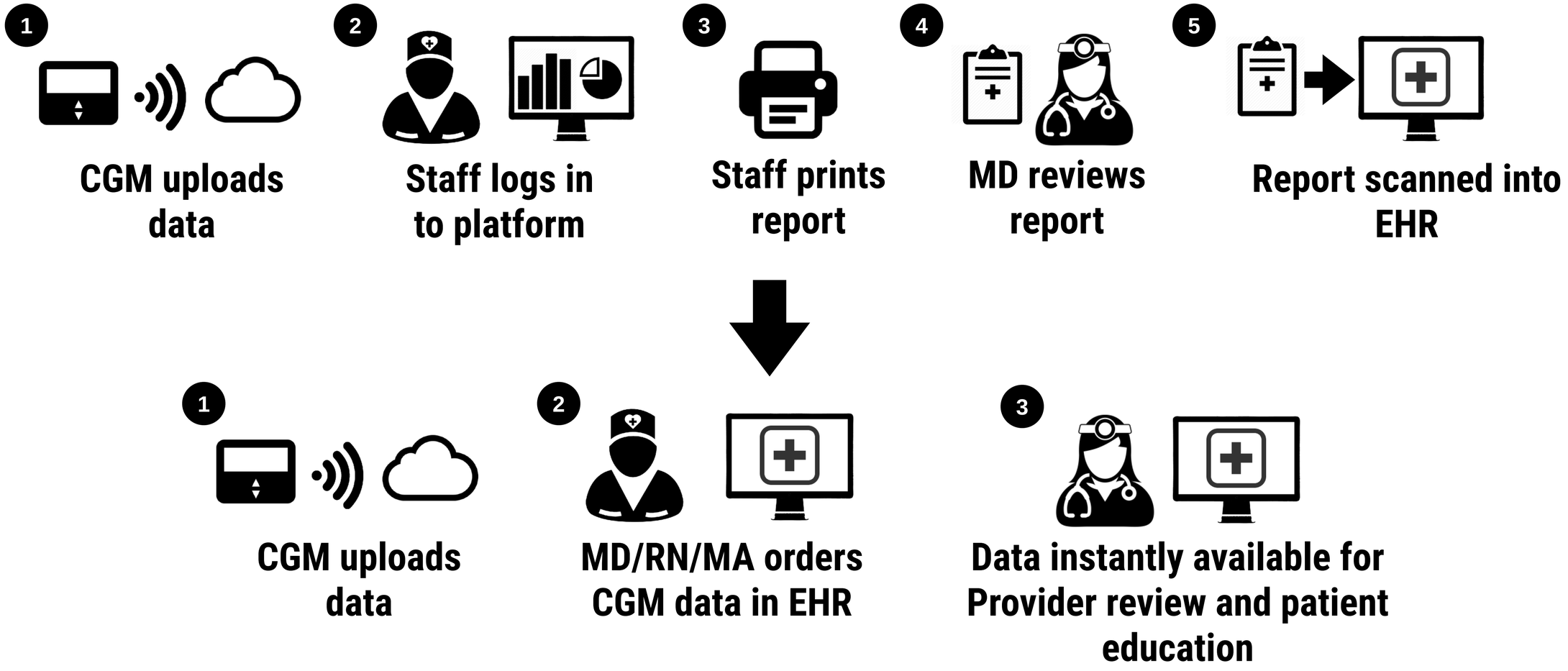
An Interoperability Problem



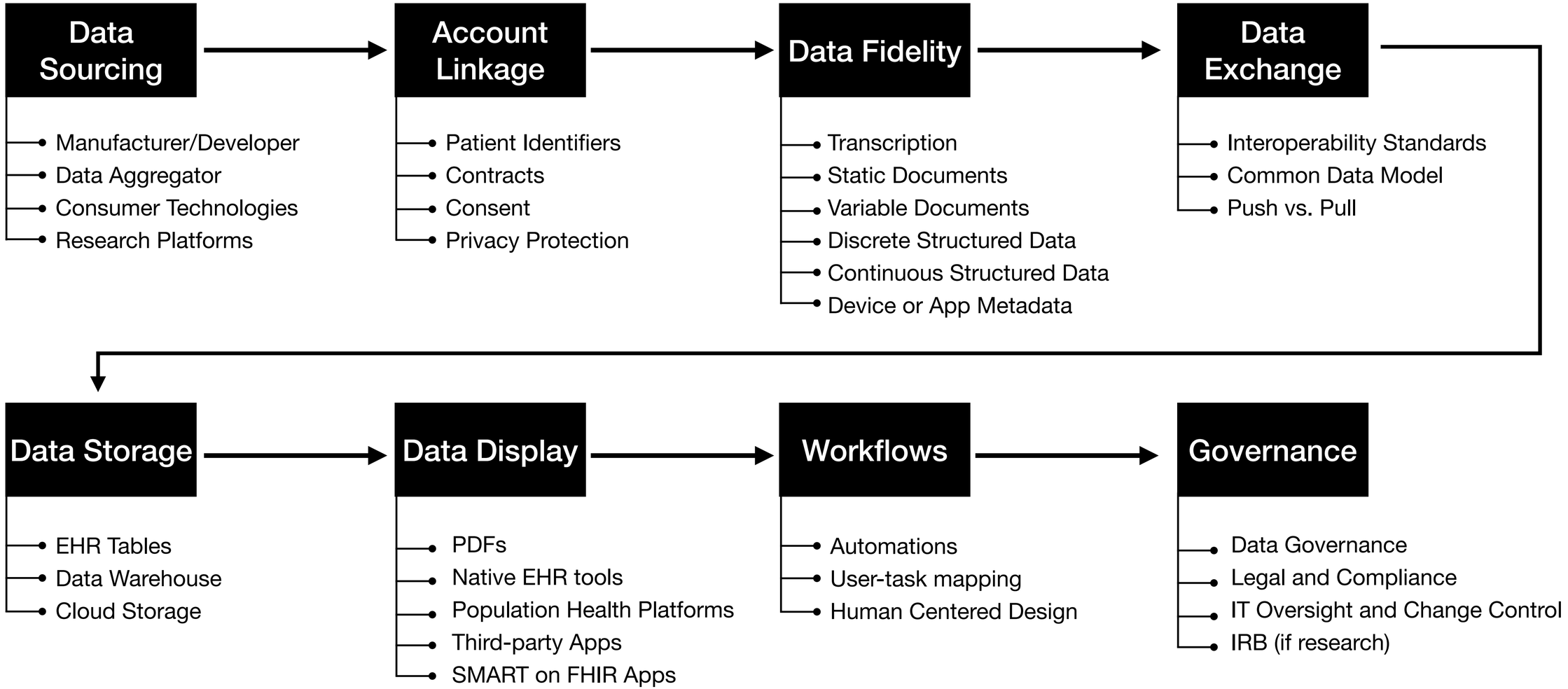


Adapted from: Walker J, Pan E, Johnston D, Adler-Milstein J, Bates DW, Middleton B. The value of health care information exchange and interoperability. Health Aff (Millwood). 2005 Jan-Jun;Suppl Web Exclusives:W5-10-W5-18. doi: 10.1377/hlthaff.w5.10. PMID: 15659453.

Workflows


1
CGM uploads data
2
Staff logs in to platform
3
Staff prints report
4
MD reviews report
5
Report scanned into EHR
1
CGM uploads data
2
MD/RN/MA orders CGM data in EHR
3
Data instantly available for Provider review and patient education

Technology Integration Barriers



Ann & Robert H. Lurie Children's Hospital of Chicago®

Timeline of CGM-EHR Integration

2016 — Dexcom Stanford Project

2017 — Dexcom CHLA Project

2017 - 2020 — Partnerships with Abbott, Medtronic, Glooko, Tidepool

2020
- DTS CGM in the Hospital Consensus
- DTM 2020
- Abbott-IDC integration

2021
- Development of iCoDE concept
- Discussions with industry and DTS

2022
- iCoDE working groups formed
- iCoDE Report published

2023 — Planning for iCoDE 2 (insulin devices)

2024
- Dexom FHIR App
- Argonaut FHIR Write Project

Automated integration of continuous glucose monitor data in the electronic health record using consumer technology Get access

Rajiv B Kumar ✉, Nira D Goren, David E Stark, Dennis P Wall, Christopher A Longhurst

Journal of the American Medical Informatics Association, Volume 23, Issue 3, May 2016, Pages 532–537, https://doi.org/10.1093/jamia/ocv206

Practice Guideline > J Diabetes Sci Technol. 2020 Nov;14(6):1035-1064. doi: 10.1177/1932296820954163. Epub 2020 Sep 28.

Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Consensus Guideline

Rodolfo J Galindo [1], Guillermo E Umpierrez [1], Robert J Rushakoff [2], Ananda Basu [3], Suzanne Lohnes [4], James H Nichols [5], Elias K Spanakis [6 7], Juan Espinoza [8], Nadine E Palermo [9], Dessa Garnett Awadjie [10], Leigh Bak [11], Bruce Buckingham [12], Curtiss B Cook [13], Guido Freckmann [14], Lutz Heinemann [15], Roman Hovorka [16], Nestoras Mathioudakis [17], Tonya Newman [18], David N O'Neal [19], Michaela Rickert [20], David B Sacks [21], Jane Jeffrie Seley [22], Amisha Wallia [23], Trisha Shang [24], Jennifer Y Zhang [24], Julia Han [24], David C Klonoff [25]

The Need for Data Standards and Implementation Policies to Integrate CGM Data into the Electronic Health Record

Juan Espinoza, MD, FAAP, Nicole Y. Xu, BA, Kevin T. Nguyen, BA, more... Show all authors

First Published November 20, 2021 | Article Commentary | Check for updates

https://doi.org/10.1177/19322968211058148

> Diabetes Technol Ther. 2020 Aug;22(8):570-576. doi: 10.1089/dia.2019.0377. Epub 2020 Jul 10.

Integrating Continuous Glucose Monitor Data Directly into the Electronic Health Record: Proof of Concept

Juan Espinoza [1 2], Payal Shah [1], Jennifer Raymond [2 3]

> J Diabetes Sci Technol. 2021 Jul;15(4):916-960. doi: 10.1177/19322968

Diabetes Technology Meeting 2020

Trisha Shang [1], Jennifer Y Zhang [1], B Wayne Bequette [2], Jennifer K Rayn, Jennifer L Sherr [5], Jessica Castle [6], John Pickup [7], Yarmela Pavlovic [8], Laurel H Messer [9], Tim Heise [10], Carlos E Mendez [11], Sarah Kim [12], Barr, Umesh Masharani [12], Rodolfo J Galindo [14], David C Klonoff [15]

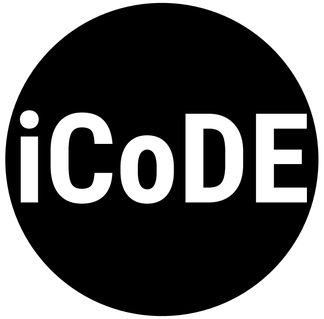
> J Diabetes Sci Technol. 2022 May 9;19322968221093662. doi: 10.1177/19322968221093662. Online ahead of print.

The Launch of the iCoDE Standard Project

Nicole Y Xu [1], Kevin T Nguyen [1], Ashley Y DuBord [2], David C Klonoff [2 3], Julian M Goldman [4], Shahid N Shah [5], Elias K Spanakis [6 7], Charisse Madlock-Brown [8], Siavash Sarlati [2 9], Azhar Rafiq [10], Axel Wirth [11], David Kerr, Raman Khanna [2], Scott Weinstein [12], Juan Espinoza [13]

Stanley Manne Children's Research Institute™

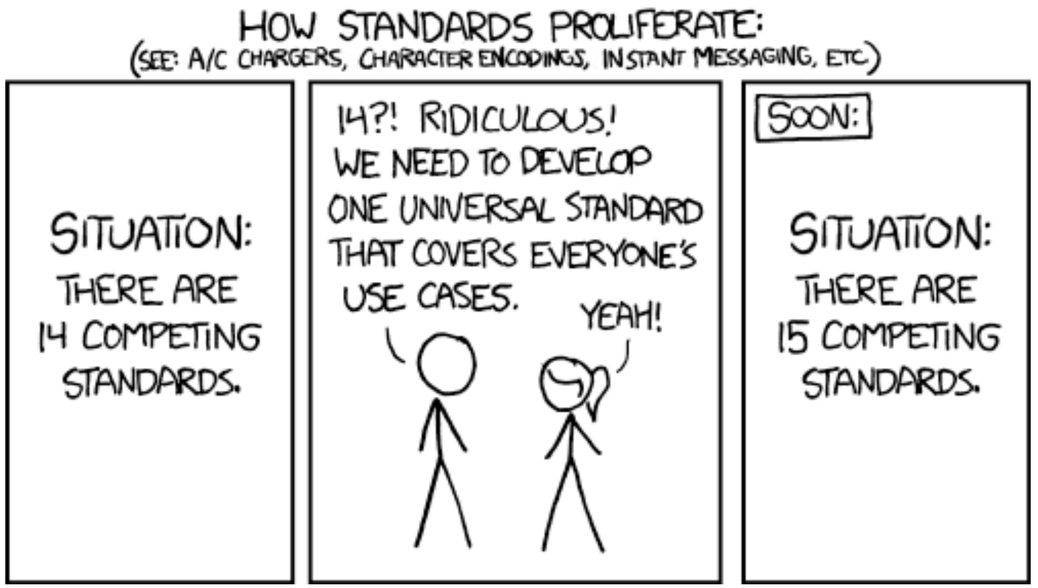
Northwestern Medicine® Feinberg School of Medicine



Integration of
Continuous Glucose Monitor
Data into the
Electronic Health Record

The Goal of iCoDE

- Develop technical specifications to integrate CGM data into the EHR
- Develop workflows and guidelines to facilitate data integration efforts

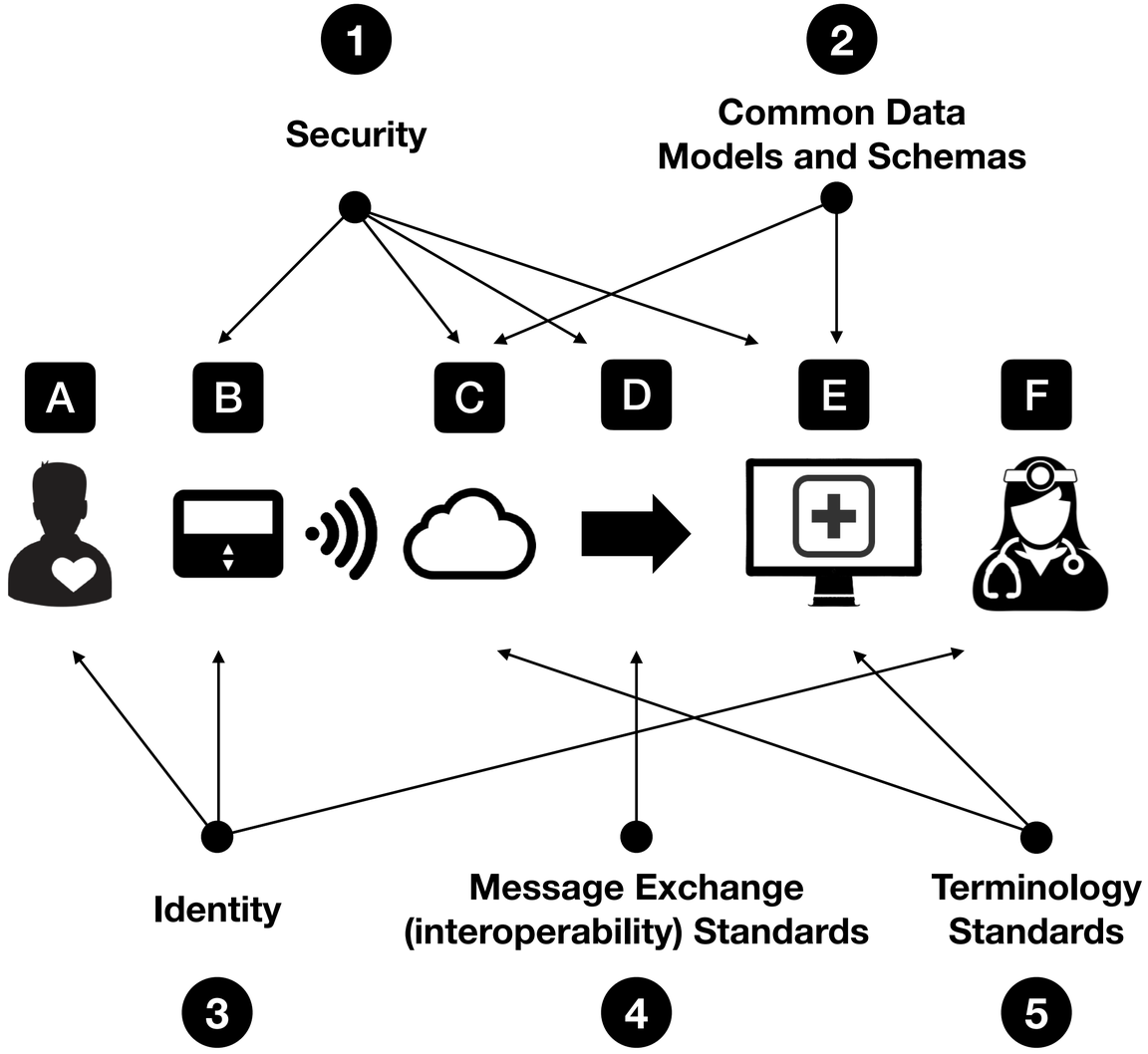


… And not do this!

comic from:

xkcd

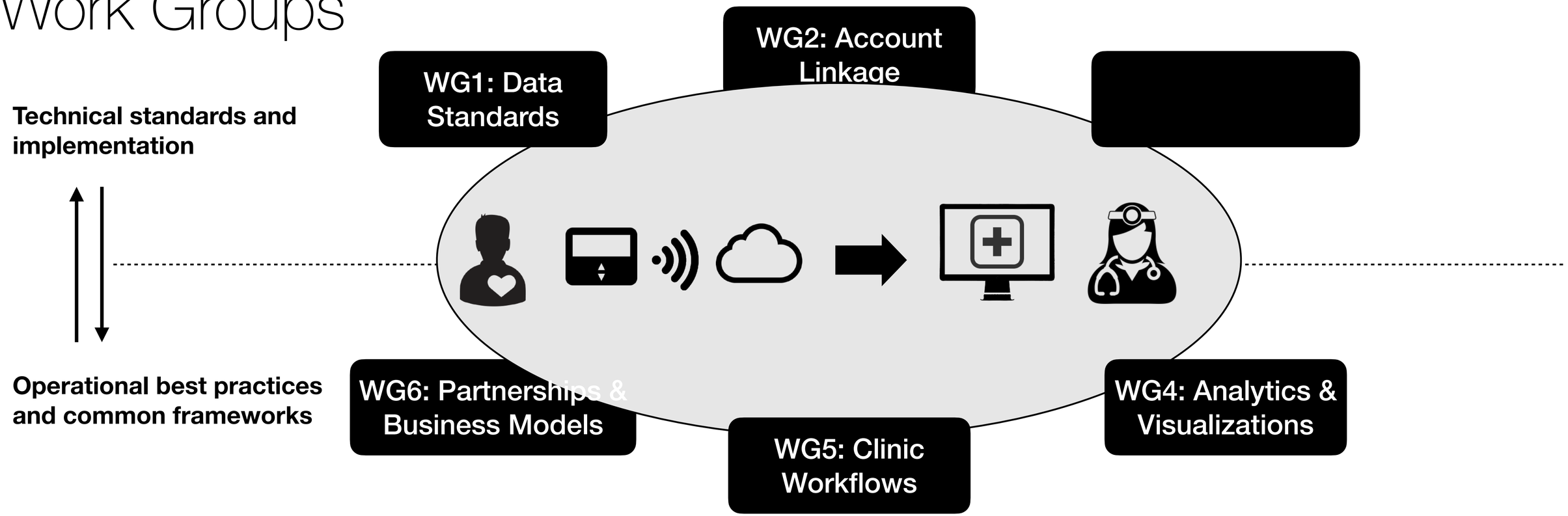
Standards & Best Practices



Components of the CGM data pipeline:	
A	Patient
B	CGM Device
C	Cloud Infrastructure
D	CGM-EHR Interface
E	EHR
F	Clinician

Example relevant standards & frameworks:	
1	HIPAA, HITRUST, SOC2, NIST CSF
2	Open mHealth, IEEE, OMOP
3	OAuth 2.0, NPI, EMPI, UDI
4	CCD, CDA, HL7, FHIR, SMART on FHIR
5	LOINC, RxNORM, SNOMED, CPT, ICD-10

Work Groups

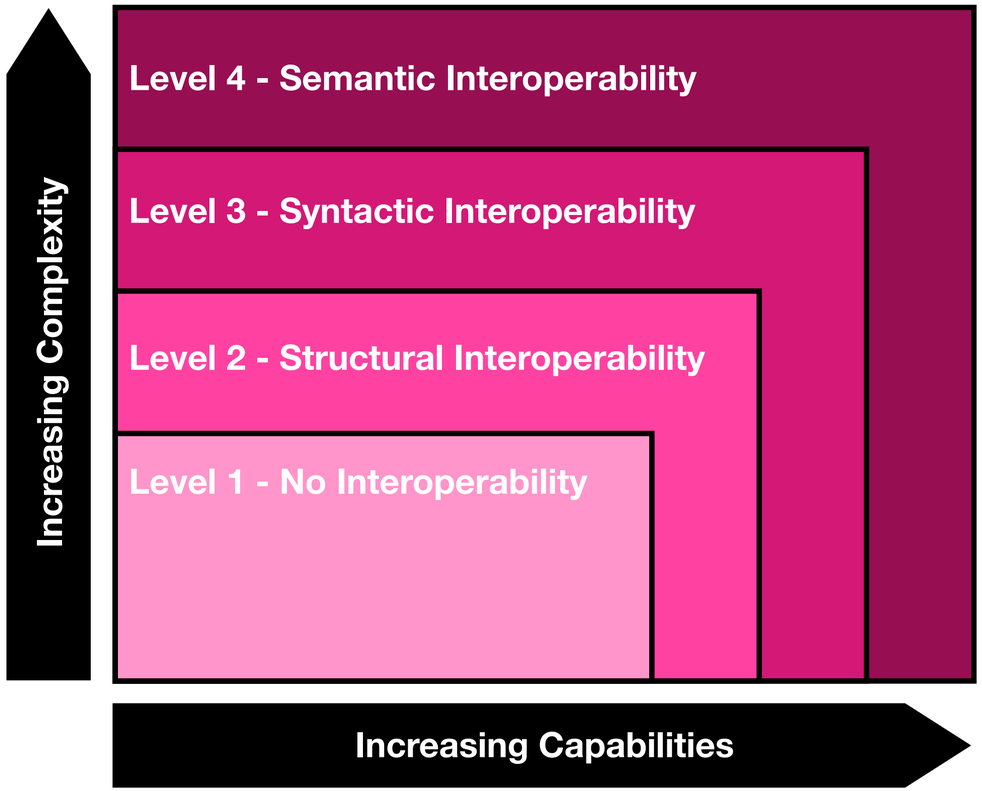


+130 participants from more than 60 organizations

representatives from:
industry, academia, government, healthcare organizations, health IT, providers, and patients

Interoperability

Adapted Interoperability Framework for CGM Data (v2.0)



Adapted from: Walker J, Pan E, Johnston D, Adler-Milstein J, Bates DW, Middleton B. The value of health care information exchange and interoperability. Health Aff (Millwood). 2005 Jan-Jun;Suppl Web Exclusives:W5-10-W5-18. doi: 10.1377/hlthaff.w5.10. PMID: 15659453.

Levels of data integration ranging from low fidelity to high fidelity

Level 7	**Advanced Analytics**	Use of machine learning and statistical models to develop risk stratification and predictive models, support population management
Level 6	**Device or App Metadata**	In addition to clinical data, diabetes technologies generate metadata about the device, software, and its utilization by the patient. These type of data could be helpful in tracking device serial numbers, understanding patient engagement, and even potentially creating behavioral interventions.
Level 5	**Continuous Structured Data**	Integrations at this level are accessing the dozens or hundreds of data points that diabetes technologies are generating each day. This type of integration creates new questions about data storage, but has the potential to provide more granular insights, as well as generating novel analytics and visualizations
Level 4	**Discrete Structured Data**	Discrete, structured data: at this stage, discrete numerical data can be brought into the EHR and added to existing data tables, where it can be charted, trended, and pulled automatically into notes. Typically these data are summary statistics over time, such as percent time in range for CGMs.
Level 3	**Variable Documents**	At this stage, the systems are still exchanging static documents, but the user has the ability to select the contents of those documents. This may include custom date ranges, data elements, or visualizations.
Level 2	**Static Documents**	Static documents like PDFs containing predetermined data, such as the Ambulatory Glucose Profile (AGP), are relatively simple for two systems to exchange. At this level, there is no customization, but the EHR can retrieve, store, and display the report natively, making them part of the medical record.
Level 1	**Transcription**	There is no data exchange between the data portal and the EHR. Clinicians include data in the patient record by transcribing it in notes, copy and pasting screenshots of the data portal into their notes, or scanning reports into the EHR. This is the current state for many providers.

Final iCoDE Report

- Definition of device data classes
- Creation of iCoDE Core Dataset
- iCoDE Expanded Dataset

Data Class	Data Elements	2019 Consensus	iCoDE Core Dataset	iCoDE Expanded Dataset
Class 1 *Clinical data that is sensed or sensor-derived*	**Calculated metrics**			
	Mean glucose	☑	☑	☑
	Glucose management indicator (GMI)	☑	☑	☑
	Glycemic variability (%CV)	☑	☑	☑
	Time above range (TAR): % of readings and time >250 mg/dL (>13.9 mmol/L)	☑	☑	☑
	Time above range (TAR): % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	☑	☑	☑
	Time in range (TIR): % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	☑	☑	☑
	Time below range (TBR): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	☑	☑	☑
	Time below range (TBR): % of readings and time <54 mg/dL (<3.0 mmol/L)	☑	☑	☑
	Ambulatory Glucose Profile Report	☑	☑	☑
	Individual glucose values		☑	☑
Class 2 *Device- and system-generated data and metadata*	**CGM Utilization**			
	Number of days CGM worn	☑	☑	☑
	Percentage of time CGM is active	☑	☑	☑
	CGM reporting period start date		☑	☑
	CGM reporting period end data		☑	☑
	Device identification, settings			
	CGM manufacturer and model		☑	☑
	Device identifiers (serial numbers, lot numbers, UDI number)			☑
	CGM settings (sensing mode, configuration)			☑
	Software/firmware version			☑
	Sensor/Transmitter status (total use days, time to replacement)			☑
	Calibrations			☑
	Events, human annotations			☑
	Reference ranges			☑
	Alarms			☑
	Performance data (errors, failures, gaps in data)			☑
	"Insights" - recommendations for care			☑
	User identification			☑

Final iCoDE Report

- Data schema recommendations
- Common data models
- Terminologies
- Data quality
- Interoperability

Table 2.2. Useful data schema references and links.

Name	Details	Link
IEEE Standards Association (IEEE SA)	n/a	https://standards.ieee.org/about/
ISO 8601	Data and time formats	https://www.iso.org/iso-8601-date-and-time-format.html
IEEE 11073	Health informatics - Medical / health device communication standards	https://standards.ieee.org/ieee/11073-10207/6032/
P11073-10425	Standard for Health Informatics — Personal Health Device Communication — Part 10425: Device Specialization — Continuous Glucose Monitor (CGM)	https://standards.ieee.org/ieee/11073-10425/7248/
IEEE P1752	Open Mobile Health Data Working Group	https://sagroups.ieee.org/1752/
1752.1-2021	IEEE Standard for Open Mobile Health Data — Representation of Metadata, Sleep, and Physical Activity Measures	https://ieeexplore.ieee.org/document/9540821
IEEE P1752.2 Metabolic subgroup	Standard for Open Mobile Health Data: Representation of Cardiovascular, Respiratory, and Metabolic Measures	https://sagroups.ieee.org/1752/metabolic-subgroup/
IEEE 1752 Repository	n/a	https://opensource.ieee.org/omh/1752
Open mHealth	Precursor to P1752	https://www.openmhealth.org/
Open mHealth Repository of schemas	n/a	https://github.com/openmhealth/schemas

Table 2.5. Recommended CDM location for storing CGM data.

CDM	Table or Domain	Notes
Sentinel	Clinical Data - Lab Result	Can also use Patient Reported Measures Data
PCORnet	OBS_CLIN	
i2b2	OBSERVATION_FACT	-
OMOP	OBSERVATION	can include "interstitial Fluid" as the specimen type in the SPECIMEN Table for additional specificity

Final iCoDE Report

Table 3.1. Roles and responsibilities related to clinical implementation of CGM-EHR integrations.

Domain	Details
Team Composition	MD/DO/NP, RN, CDCES, Medical Assistant, Medical Technician, Front Desk, Pharmacist, Technical Support
Administrative and Programmatic Tasks	**Outpatient champion identified for:** 1) patient education, 2) staff education, 3) technical support (in-person), 4) virtual support, 5) triaging urgent request for data review
	Inpatient champion identified for: 1) patient education, 2) staff education, 3) technical support, 4) data management and monitoring, 5) treatment action, 6) changing sensors
	Staff On-boarding and Training
	Equipment identified: Hardware (multiple devices for use, private room), Software (CGM Manufacturers, Aggregators, Integrators), Wi-Fi
Patient Experience Components	**New User:** - Authorization - New device training - Account setup and linkage - Education for uploading data prior to clinic
	Pre-Clinic: - Log of patients on CGM - Contact patient to upload data
	Clinic: - Real-time download of devices - Request data to EHR (data pull) - Add data sharing instructions to after-visit summary
	Post-Clinic: - Monitoring data in the interim between visits - Notify clinician that new data is available to review

		Task by Role		
Events and Time Points	**Time Estimate**	**Patient**	**Clinical Staff**	**Clinician**
Pre-Clinic	5 min	-Reviews checklist -Uploads data -Arrives 30 minutes before scheduled visit -Access support staff assists with uploads	-Reminder is sent to patient to upload data up to 48 hours prior to visit -A number is provided to call tech-support for questions or barriers to uploading data	
Check-In	5 min	-Arrives for appointment -Checks in at front desk	-Checks in patient -Registers in EHR -Verifies if data has been uploaded -Directs to tech support staff or personal device kiosk if data isn't uploaded	
Data Upload	5 min	-Uploads data prior to visit - no further action -Uploads data during check in -Meets with tech support	-Patient devices synced -Assigned to the patient's account.	
Data Request	10 min	-Patient is processed for visit	-Place data pull request in EHR	
Clinical Encounter	45 min	-Visit with clinician		-Access summary report from EHR and review
Check Out	5 min	-Schedules follow up	-Review upload instruction -Print after-visit summary	
Equipment and Space		*-Clinic room* *-Kiosk* *-Mobile van* *-Personal device* *-Clinic device*	*-Two devices to access web-based upload site and EHR* *-Private clinic space for data/device support to not delay check in for other individuals* *-Need two people assigned to each role per day (point person and back up)*	*-Two screens (one with EHR and one with link to trend data)*

		Task by Role		
Events and Time Points	**Time Estimate**	**Patient**	**Clinical Staff**	**Clinician**
Pre-Clinic	5 min	Uploads data prior to visit Open hours with tech-support person are available each day	Scheduled Telehealth Visit: Reminder sent to patient to upload data - number provided to call for questions or barriers to uploading data Urgent request by patient for data review: - contacts patient, triages request, if appropriate, then schedules TH visit and procedures with workflow. If not appropriate for TH visits, then instructs to call on-call clinicians or go to ER Asynchronous data review: - no action, done by clinician	
Check-In	5 min	Day of visit receives notification to upload data Logs onto virtual visit once invitation received	Scheduled Telehealth Visit: Sends person with diabetes virtual invitation for TH visit Verifies data has been uploaded	
Data Upload	5 min	1. Uploads data prior to visit - no further action needed 2. Uploads data during check in with clinical staff	Devices synced and assigned to the individual's account. -Requires two devices to access web-based upload site and EHR -need point person assigned to TH visit (in addition to point person and back up for in person clinic). Virtual care point person can also triage urgent request (need to consider level of training to triage appropriately for urgent situations).	
Data Request	10 min		Place data pull request in EHR	
Clinical Encounter	45 min	Visit with clinician		-Access summary report from EHR and review
Check Out	5 min	Schedule follow up	Review upload instruction, email after visit summary	
Equipment and Space		*Personal device*	*-Two devices to access web-based upload site and EHR* *- Point person*	*-three screens (one with EHR, one with patient visit, and one with link to trend data)*

Stanley Manne Children's Research Institute™

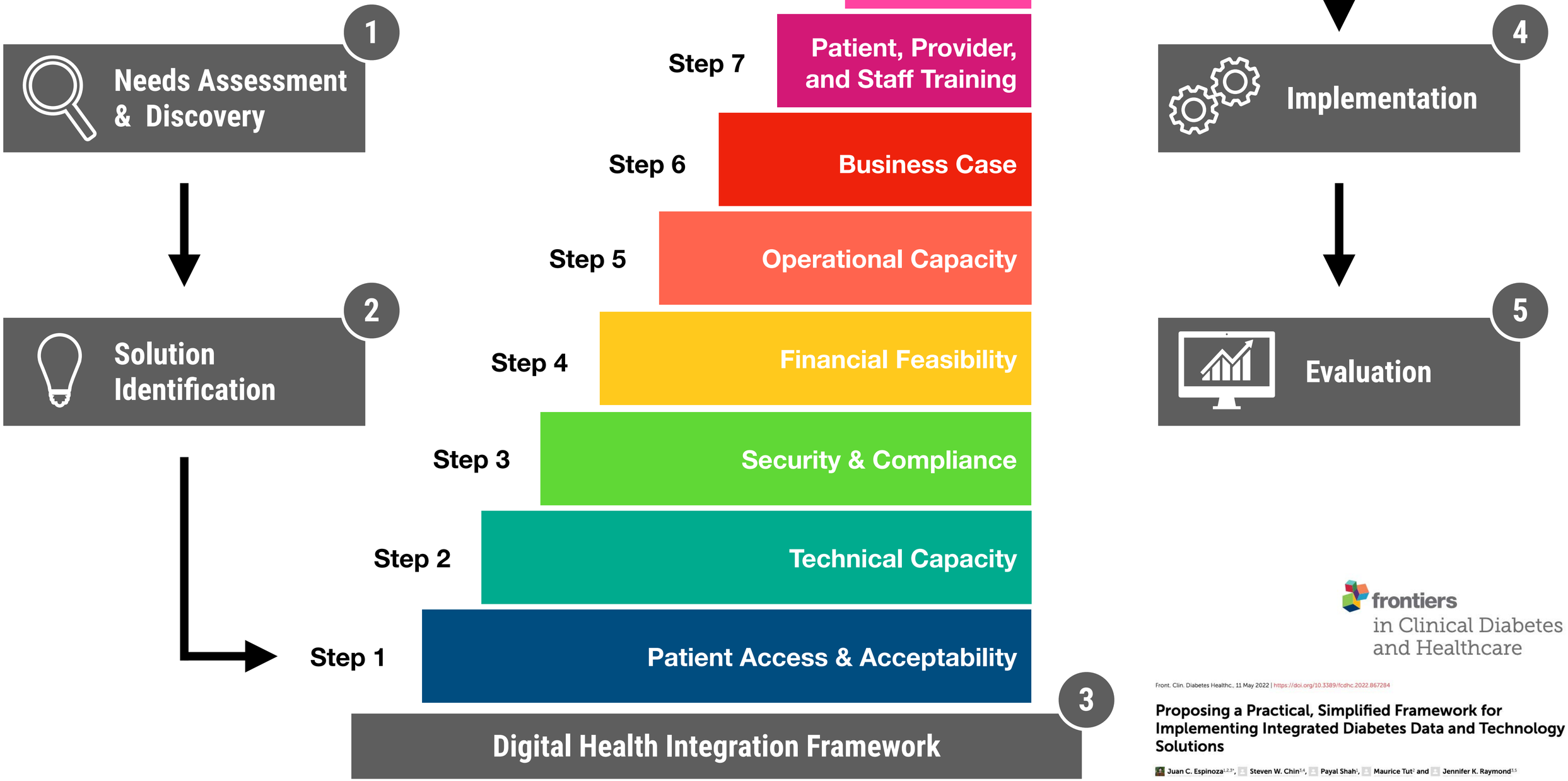
Northwestern Medicine® Feinberg School of Medicine

Final iCoDE Report

Modality	Codes	Reimbursement	Frequency	Technical Requirements
In-person visit	9920X 9921X 9924X	Variable compensation	Per Insurance	Baseline
Telehealth visit	same as above + modifier	Same as above*	Per Insurance*	Telehealth Platform
Virtual Check-in	G2012 G2010	~$15	2-4 times per month	Phone, Email, Patient Portal
Remote Patient Monitoring	99091 99453 99454 99457	~$60	once a month	Devices, Data Platform
Chronic Care Management	99490 99487 99489 G0506	~$45	once a month	None

				Gross billing revenue based on percent of encounters captured			
Code	**Medi-cal rate**	**# of patients**	**Times billed/year**	**100%**	**10%**	**25%**	**50%**
99453	$17.77	750	1	$13,327.50	$1,332.75	$3,331.88	$6,663.75
99454	$58.92	750	1	$44,190.00	$4,419.00	$11,047.50	$22,095.00
99091	$46.15	750	12	$415,350.00	$41,535.00	$103,837.50	$207,675.00
			TOTAL	*$472,867.50*	*$47,286.75*	*$118,216.88*	*$236,433.75*

Code	Code Name	Code Description	Medi-Cal Rate	Patient Contact Required?	Billable Frequency	Requires Physician?
99453	REM MNTR PHYSIOL PARAM SETUP	CPT code 99453 covers the time spent for the initial setup. That includes the onboarding of a patient for RPM services by clinical staff — in other words, the initial explanation of how the device works, and setting up a treatment schedule.	$17.77	YES	Every 30 days	NO
99454	REM MNTR PHYSIOL PARAM DEV	CPT code 99454 covers monthly remote monitoring of the patient. This includes the supply and use of the medical devices used to remotely monitor and collect patient-generated health data (PGHD). This specifically means data transmission, and does not include time spent educating and setting up the use of the device. 99454 must be billed in conjunction with 99453, and requires the transmission of data from a remote device for a minimum of 16 days within a 30-day period. Requires review of at least 16 days of data.	$58.92	NO	Every 30 days	NO
99457	REM PHYSIOL MNTR 1ST 20 MIN	Care Management by Clinical Staff: After analyzing and interpreting remotely collected physiologic data, the data is used to develop a treatment plan and then manage the plan until the targeted goals of the treatment plan are attained. CPT codes 99457 & 99458 are designated as care management services and as such can be provided by clinical staff under the general supervision of the physician or NPP. Interactive Communication: Services are typically provided remotely using communications technologies that allow interactive communication. Interactive communication, involves, a realtime synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission; as well as, time engaged in non-face-to-face care management services during calendar year. The first 20 minutes of interactive communication is reporting using CPT 99457 and each additional 20 minutes is reported using CPT 99458.	$44.84	YES	Every 30 days	NO
99458	REM PHYSIOL MNTR EA ADDL 20	Same as above	$44.32	YES	Every 30 days	NO
99091	COLLECT/REVIEW DATA FROM PT	After the data collection period for CPT codes 99453 and 99454, the physiologic data that are collected and transmitted may be analyzed by a "physician or other qualified health care professional, qualified by education, training, licensure/regulation." This code includes only professional work and does not contain any direct practice expense (PE). The valuation for CPT code 99091 includes a total time of 40 minutes of physician or NPP work, broken down as follows: 5 minutes of preservice work (for example, chart review); 30 minutes of intra-service work (for example, data analysis and interpretation, report based upon the physiologic data, as well as a possible phone call to the patient); and 5 minutes of post-service work (that is, chart documentation).	$46.15	NO	Every 30 days	NO
95250	CGM setup and training	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording.	no Medi-Cal, some private payers	YES	Once when device first deployed	NO
95251	CGM itnerpretation	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report.	no Medi-Cal, some private payers	NO	Every 30 days	NO



frontiers in Clinical Diabetes and Healthcare

Front. Clin. Diabetes Healthc., 11 May 2022 | https://doi.org/10.3389/fcdhc.2022.867284

Proposing a Practical, Simplified Framework for Implementing Integrated Diabetes Data and Technology Solutions

Juan C. Espinoza[1,2,3*], Steven W. Chin[3,4], Payal Shah[1], Maurice Tut[2] and Jennifer K. Raymond[3,5]

Final iCoDE Report

- **What's in it?**
  - 3 Sections:
    - Introduction
    - Technical Standards and Considerations
    - Clinical Implementation
  - Project Implementation Guide
  - 54 Recommendations
  - Appendix of references and resources
- **Endorsed by:**
  - American Association for Clinical Chemistry (AACC)
  - Canadian Society of Clinical Chemists (CSCC)
- **Reach:**
  - Downloaded >500 times since November 2022
  - 300+ different organizations

https://www.diabetestechnology.org/icode/

Ann & Robert H. Lurie Children's Hospital of Chicago®

Stanley Manne Children's Research Institute™

Northwestern Medicine® Feinberg School of Medicine

Diabetes Research Hub

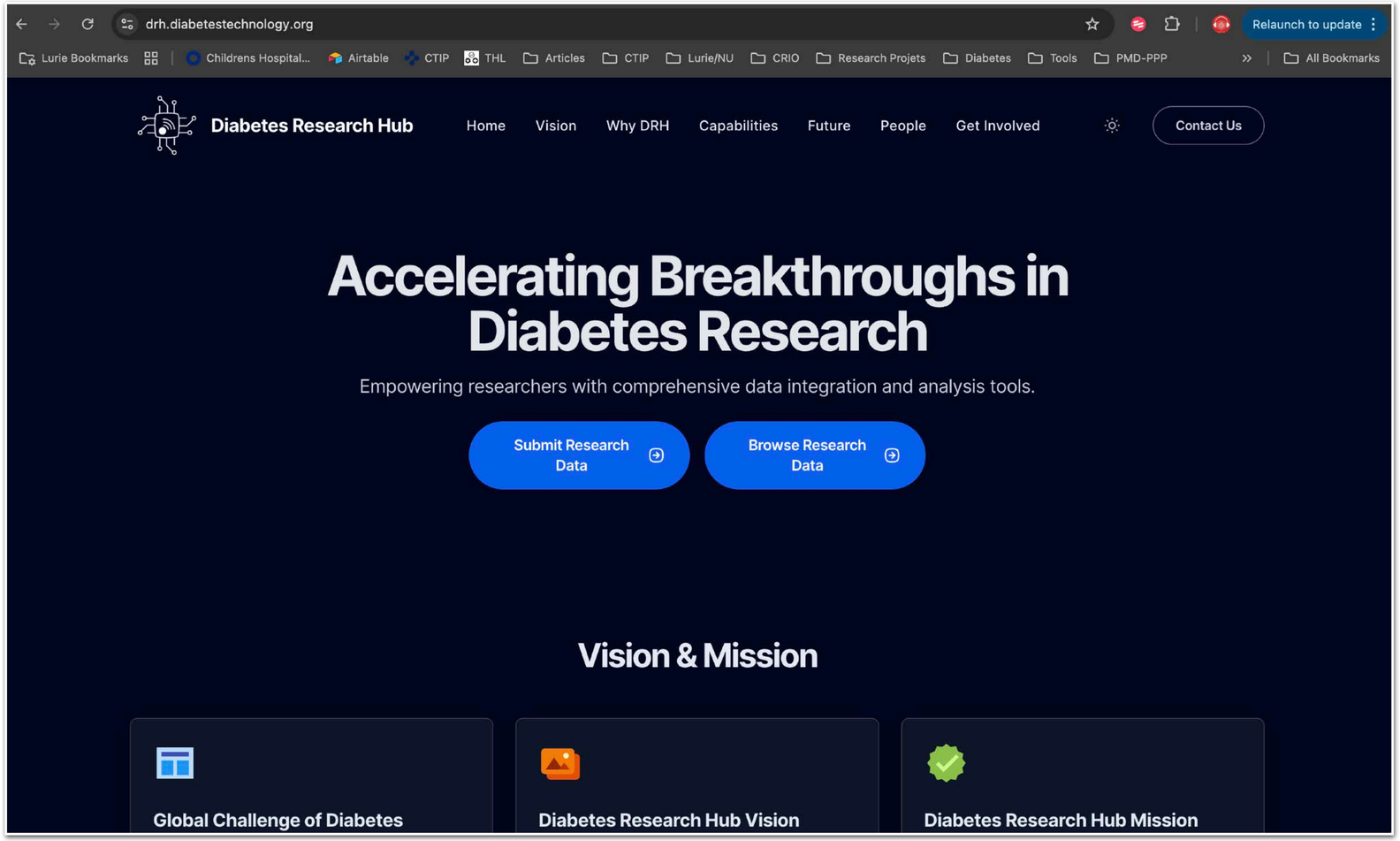
Barriers to Progress in CGM Research

Technology Barriers	Knowledge Barriers	Community Barriers
Proprietary data platforms	Lack of methodological consensus	No central hub for CGM research
Complex data workflows	Lack of education and guidance	Ineffective data sharing and re-use
Lack of CGM data-specific tools	Inconsistent reporting of methods	Siloed research groups across fields

Current Resources:

Category	# Repositories	Types of Data	CGM Support	Time-Series Analysis	Glycemic Variability Metrics
NIDDK Funded	6	metabolomics, genomics, metaradata, omics	❌	❌	❌
NIH Supported (NIDDK)	8	Omics, clinical trials, sequencing	❌	❌	❌
Specilaized Community Repositories	9	clinical trials, microscipy imaging, proteint strucutre, physioloigcal data, microaray, NGS, proteomics, genotype and phenotype	❌	PhysioNet has time series tools	❌
Generalist Repositories	9	multiple data types	❌	❌	❌
NIDDK Funded Community Projects	14	Clinical data, omics, microscopy	❌	❌	❌
Other	2	DBDP: code repository, no data	✅	❌	✅
		Awesome-CGM: CGM data collection, R code	✅	✅	❌

Diabetes Research Hub



10
Studies

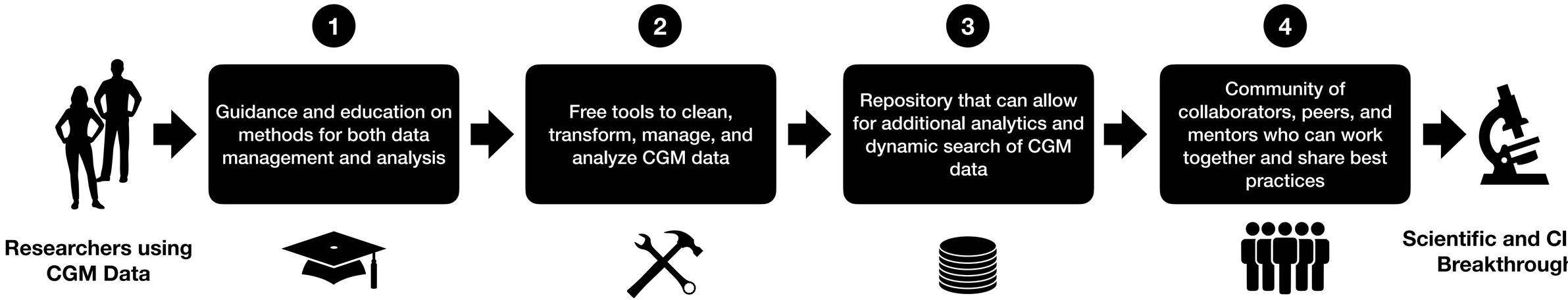
1271
Participants

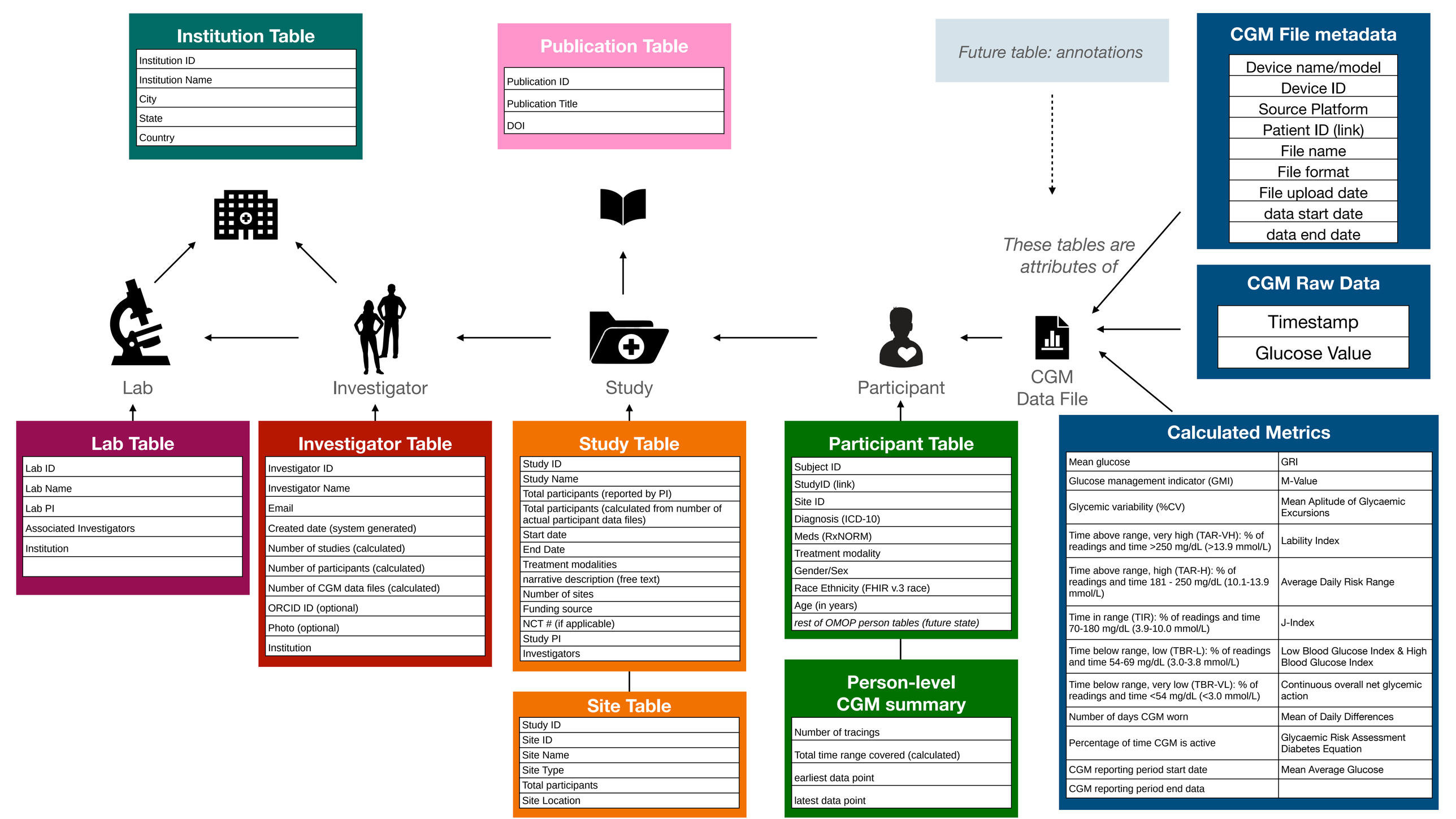
52%
Female

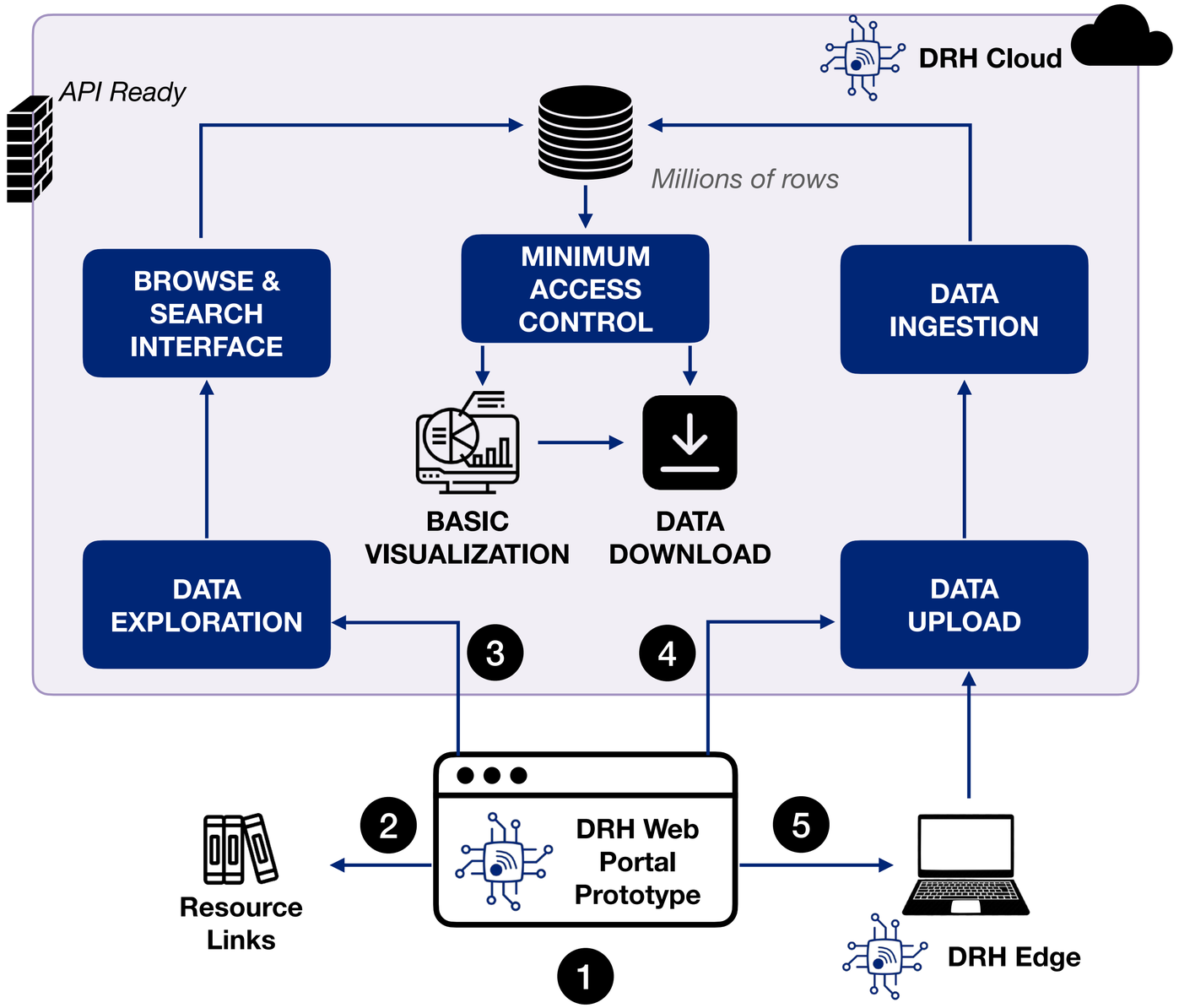
43.57M
Data Points

Diabetes Research Hub

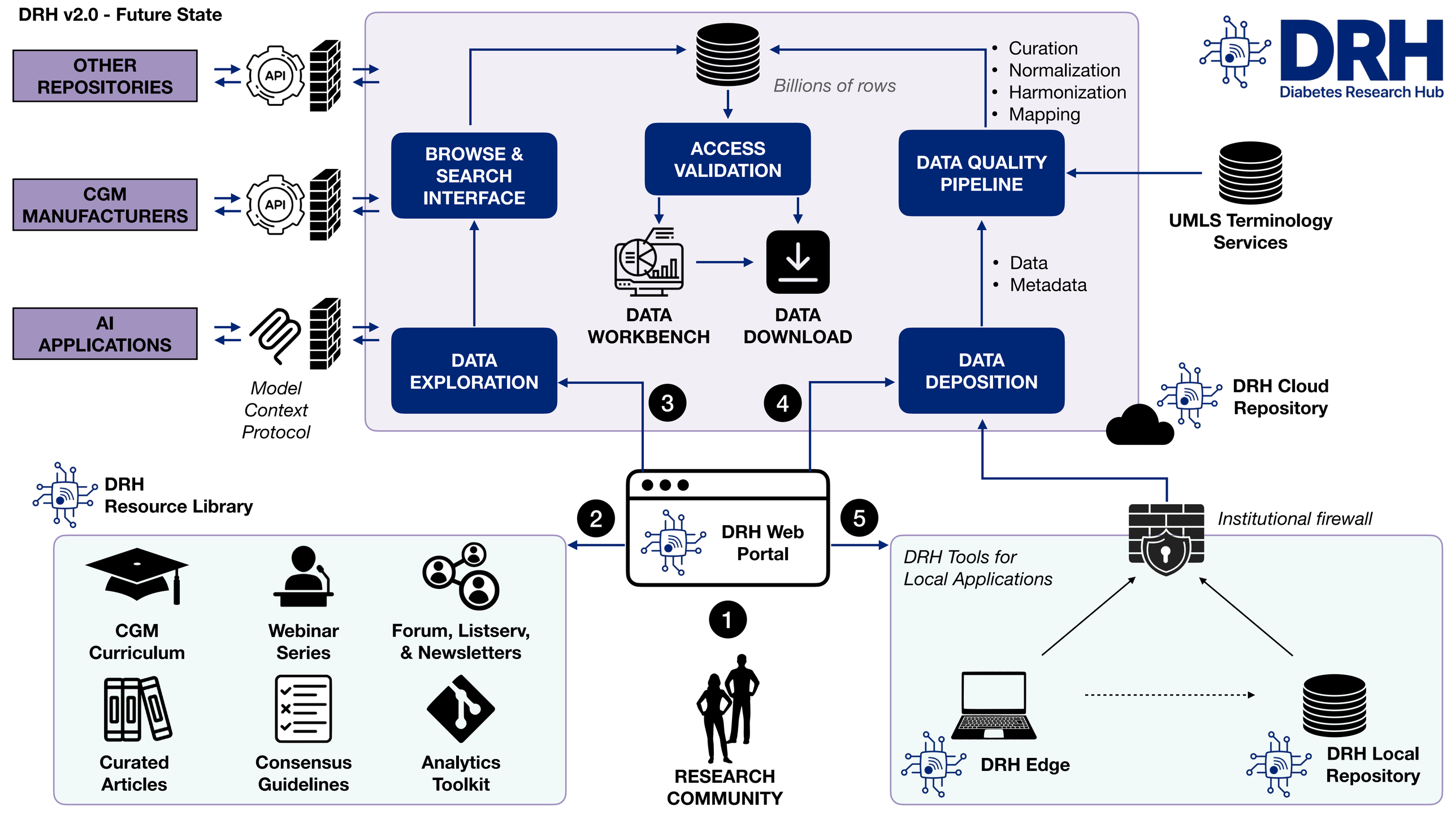
How the DRH Accelerates Diabetes and CGM Research




Institution Table
Institution ID
Institution Name
City
State
Country
Publication Table
Publication ID
Publication Title
DOI
Future table: annotations
CGM File metadata
Device name/model
Device ID
Source Platform
Patient ID (link)
File name
File format
File upload date
data start date
data end date
These tables are attributes of
CGM Raw Data
Timestamp
Glucose Value
Lab
Investigator
Study
Participant
CGM Data File
Lab Table
Lab ID
Lab Name
Lab PI
Associated Investigators
Institution
Investigator Table
Investigator ID
Investigator Name
Email
Created date (system generated)
Number of studies (calculated)
Number of participants (calculated)
Number of CGM data files (calculated)
ORCID ID (optional)
Photo (optional)
Institution
Study Table
Study ID
Study Name
Total participants (reported by PI)
Total participants (calculated from number of actual participant data files)
Start date
End Date
Treatment modalities
narrative description (free text)
Number of sites
Funding source
NCT # (if applicable)
Study PI
Investigators
Site Table
Study ID
Site ID
Site Name
Site Type
Total participants
Site Location
Participant Table
Subject ID
StudyID (link)
Site ID
Diagnosis (ICD-10)
Meds (RxNORM)
Treatment modality
Gender/Sex
Race Ethnicity (FHIR v.3 race)
Age (in years)
rest of OMOP person tables (future state)
Person-level CGM summary
Number of tracings
Total time range covered (calculated)
earliest data point
latest data point
Calculated Metrics
Mean glucose
GRI
Glucose management indicator (GMI)
M-Value
Glycemic variability (%CV)
Mean Aplitude of Glycaemic Excursions
Time above range, very high (TAR-VH): % of readings and time >250 mg/dL (>13.9 mmol/L)
Lability Index
Time above range, high (TAR-H): % of readings and time 181 - 250 mg/dL (10.1-13.9 mmol/L)
Average Daily Risk Range
Time in range (TIR): % of readings and time 70-180 mg/dL (3.9-10.0 mmol/L)
J-Index
Time below range, low (TBR-L): % of readings and time 54-69 mg/dL (3.0-3.8 mmol/L)
Low Blood Glucose Index & High Blood Glucose Index
Time below range, very low (TBR-VL): % of readings and time <54 mg/dL (<3.0 mmol/L)
Continuous overall net glycemic action
Number of days CGM worn
Mean of Daily Differences
Percentage of time CGM is active
Glycaemic Risk Assessment Diabetes Equation
CGM reporting period start date
Mean Average Glucose
CGM reporting period end data


DRH Cloud
API Ready
Millions of rows
BROWSE & SEARCH INTERFACE
MINIMUM ACCESS CONTROL
DATA INGESTION
BASIC VISUALIZATION
DATA DOWNLOAD
DATA EXPLORATION
DATA UPLOAD
3
4
2
DRH Web Portal Prototype
5
Resource Links
DRH Edge
1

DRH v2.0 - Future State



Open Data, Open Stack

1 DATA DEPOSITION

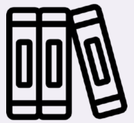
Submit datasets via:
- DRH Edge Application
- DRH Web Portal

2 DATA CURATION

Review datasets for:
- Compliance
- Completeness
- Documentation

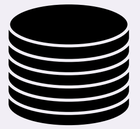
3 DATA PUBLICATION

Publish datasets with:
- Metadata
- DOI
- Usage Metrics



4 DATA PRESERVATION

Preserve datasets with:
- Indefinite Storage
- Fixity Checks
- Succession Plan



DRH Tech Stack *(Future State)*	
Storage: PostgreSQL in Amazon S3	**Author disambiguation:** ORCiD
Application front end: Java + Spring Boot	**Metadata schema:** DataCite, schema.org
Data catolog platform: InvenioRDM	**Audit Logs:** ELK Stack
User Access Control: InCommon	**Code Repository:** GitHub
Minting DOIs: DataCite	**Data use metrics, impact:** Make Data Count

What's Next

Takeaways and Work still to do

- **What has worked well:**
  - Core philosophy: Adopt, Adapt, Create (in that order)
  - Hyper-collaborative and open
  - Patience - it takes a while
- **What's been hard:**
  - Standards work is rarely attractive to funders, so we often bootstrap
  - Standards are compromises by definition - they need to work for everyone
- **What still needs doing:**
  - Policy changes to device data accessibility (RIN 0938-AV68 - Comments due June 16th)
  - Diabetes Technology CDEs for research
  - Tabular data models -> Time series data models
  - Device metadata standards, including reporting structure

Thank You.

Juan Espinoza, MD

jespinozasalomon@luriechildrens.org

@juanespinozamd

Please, give me feedback on today's talk:

https://tinyurl.com/JuanEval

https://airtable.com/shrgBH0ltwKdyyjDW

Ann & Robert H. Lurie Children's Hospital of Chicago®

Stanley Manne Children's Research Institute™

Northwestern Medicine® Feinberg School of Medicine