



T1D
Exchange

Data Governance Committee Meeting

March 6, 2023

Data Governance Meeting Agenda

1. Welcome
2. Updates on Industry Sponsored Projects
3. Expansion of T2D and proposed changes to DGC process/DUA

Purpose of the T1DX-QI/T2DX-QI Data Governance Committee

To expand research focus through academic and industry support for projects:

- To have a better understanding of and improvement in patient care
- Reduction in health disparities
- Improvements in understanding impact of treatments

To expand opportunities for QI team members:

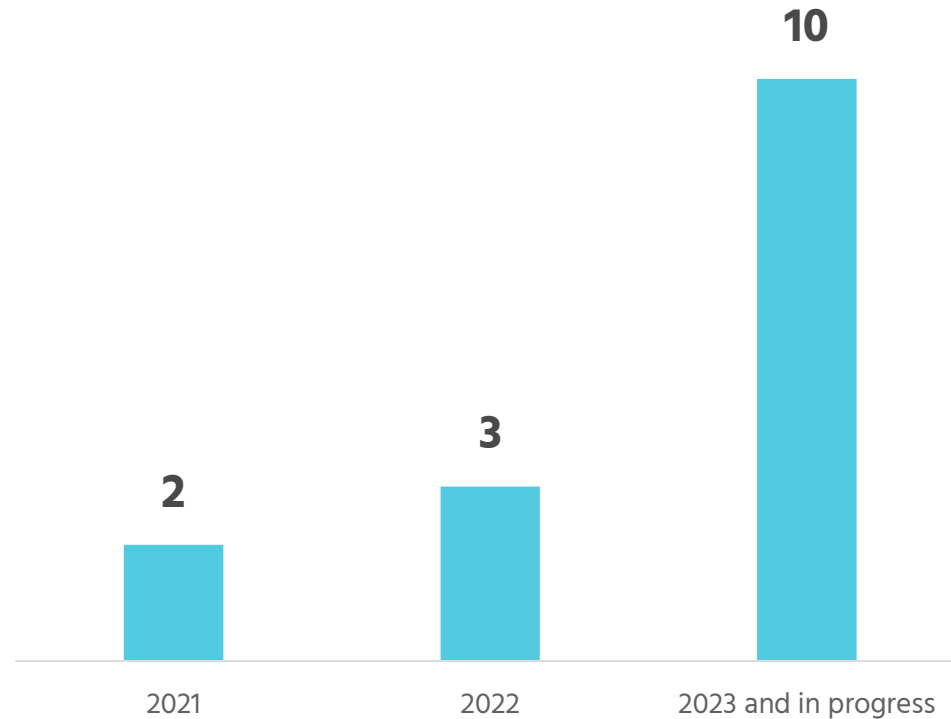
- To serve as PI or Co-Investigators at their sites
- Provide patient opportunities to engage in QI research

T1DX-QI Project Updates

Projects Summary

As of March 2023, T1DX-QI has collaborated with **8** partners on **15** sponsored projects

Projects by year



Completed Projects

Since our last meeting in August 2022, we have completed 4 projects:

MannKind Ultra Rapid Insulin

Objective: Develop a learning resource to increase awareness of the **most current therapeutic modalities and medication regimens related to rapid and inhalable insulins for mealtime and correction boluses** to effectively increase patients' Time-In-Range and decrease post-prandial hyperglycemia and time in hyperglycemia. The outcomes will be measured by an analysis of numerical data obtained through participant evaluation of the stated learning outcomes.

Status: Completed

Medtronic Health Equity in Diabetes Technology pilot

Objectives:

1. Evaluate the **effectiveness of provider unconscious bias training;**
2. Implement the 'T1DX Equity Framework' and PDSA cycles to test changes in participating clinics with an aim to **reduce inequities by at least 10% from baseline in CGM and Pump prescription rate for minoritized patients with T1D as compared with NH Whites in 10 months.**

Status: Completed

Fear of Hypoglycemia

Objectives:

1. To understand the **clinical processes, barriers, and resources needed for clinics and healthcare providers to implement the fear of hypoglycemia (FOH) screener** in their daily practice
2. To **estimate the prevalence of FOH** among adults with T1D in the T1DX-QI
3. To further **evaluate the reliability and validity of the FOH screener** among diverse demographic groups within T1DX-QI

Status: Completed

T1D Antibody Screening Qualitative Assessment

Objective: **Determine provider attitudes toward T1D antibody screening among siblings of patients identified with T1D through focus groups.** Submit at least two abstracts from the results of the survey and focus groups.

Status: Completed

CGM Analysis – Status update

Sponsor: Dexcom

Objectives:

1. Examine **patient profiles of rtCGM users vs. SMBG users** (using additional data from newly mapped sites).
2. Examine **patient attributes and clinical outcomes** among CGM initiators compared to a propensity score-matched comparison group.
3. **Describe patient profiles for people currently using Dexcom CGM with Tandem X2 pump and control-IQ software.**

Participating Centers: N/A; analyzing data from mapped centers

Project Status/Results: ✓ Nearly completed; collecting satisfaction surveys

Smart Pen Equity – Status update

Sponsor: Eli Lilly

Objective:

- 1. Increase connected pen dosing data availability by 10%** from baseline in 9 months
- 2. Increase shared decision-making documentation** using the Diabetes Technology Assessment tool for eligible patients on MDI from 0% to 25% in 9 months
- 3. Increase % of patients on a smart/connected pen by 5% from baseline**
- 4. Decrease % of patients on smart/connected pen with HbA1c >9% by 5% from baseline**
- 5. Reduce % racial inequities** between NHW vs NHB & Hispanic patients in the availability of connected pen data reporting for clinical management

Participating Centers: Stanford (A + P), Northwestern (A), Montefiore (A), NYU (A) Mount Sinai (A), Washington University (A), Le Bonheur (P), Children's Healthcare of Los Angeles (P); **8 total**

Project Status/Results: ✓ On Track; regular monthly meetings occurring and centers data-sharing



EMR Analysis – New project update

Sponsor: Vertex

Objective: Complete a **descriptive analysis of total daily dose (TDD) of insulin** across patients with T1D 2-25 years age group

Participating Centers: N/A; analyzing data from mapped centers

Project Status/Results: ✓ On Track; shared two of four data tables with Vertex

Antibody Screening QI Project– **New project update**

Sponsor: JDRF

Objectives:

1. Establish **data elements for antibody screening and patient outcomes** (i.e., stages of T1D diagnosis, DKA events)
2. **Implement the Model for Improvement and PDSA cycles** to identify best practices for antibody screening
3. Host **focus groups** with clinical staff for lessons learned on **establishing a standardized screening process**

Participating Centers: University of Florida (P), Rady Children's (P); **2 total**

Project Status/Results: ✓ On Track; held kick-off meeting with JDRF; completed and distributed SOW; project protocol and planning activities in progress

Type 2 Diabetes expansion – **New project update**

Sponsor: Abbott

Objectives:

1. Establish a **large dataset for T2D patients**;
2. **Evaluate this T2D dataset for benchmarking and metrics** for the purposes of supporting quality improvement activities;
3. **Establish an independent data platform** to share and disseminate patient-level data for the T2D patient population

Participating Centers: BMC, Grady, UPMC; **3 total adult centers**

Project Status/Results: Project initiation begun; request for data initiated

Type 2 Diabetes QI – Contract Pending

Sponsor: ADA

Objectives:

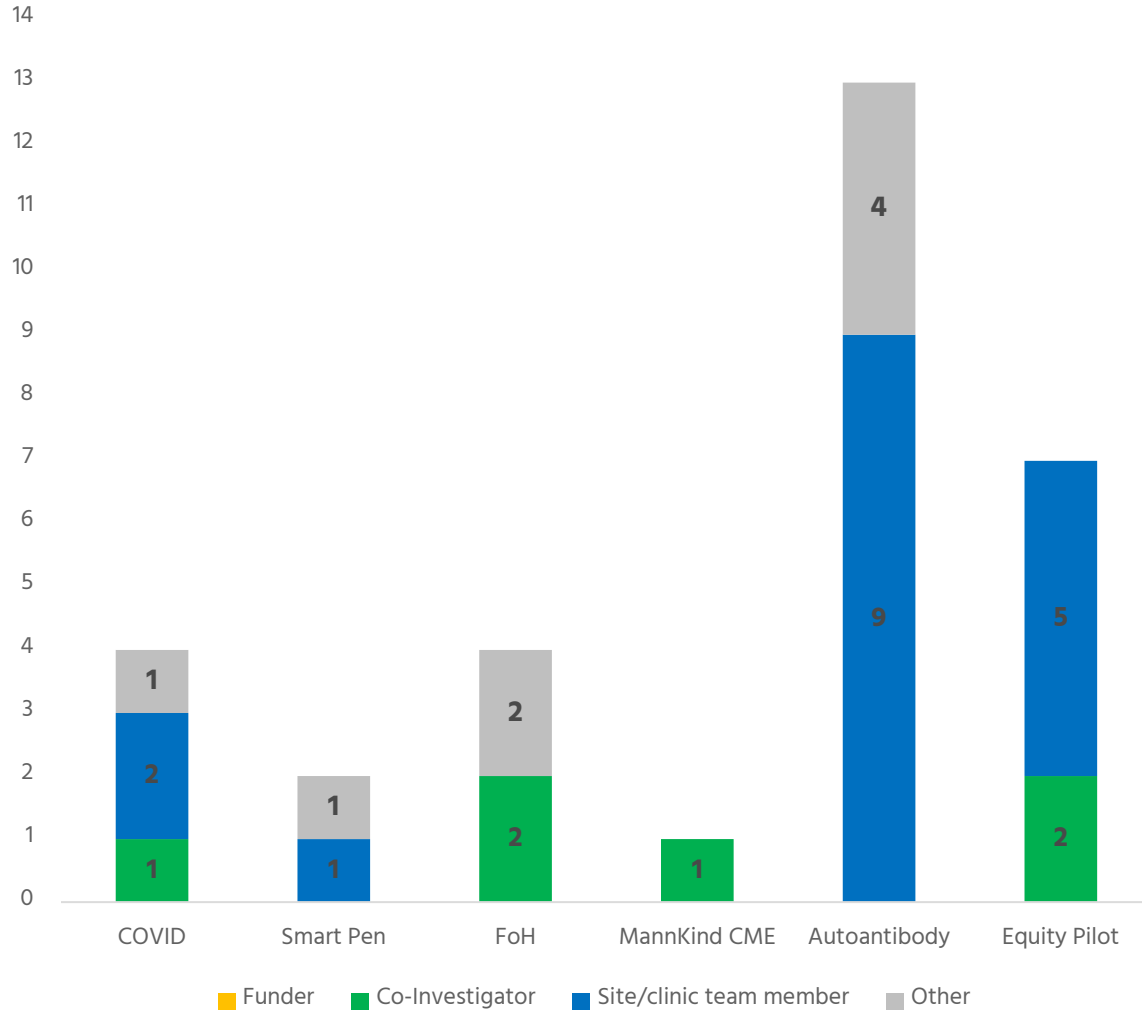
1. Provide **data analysis and quality improvement coaching support** for Know Diabetes by Heart T2D centers

Participating Centers: TBD; **8 total**

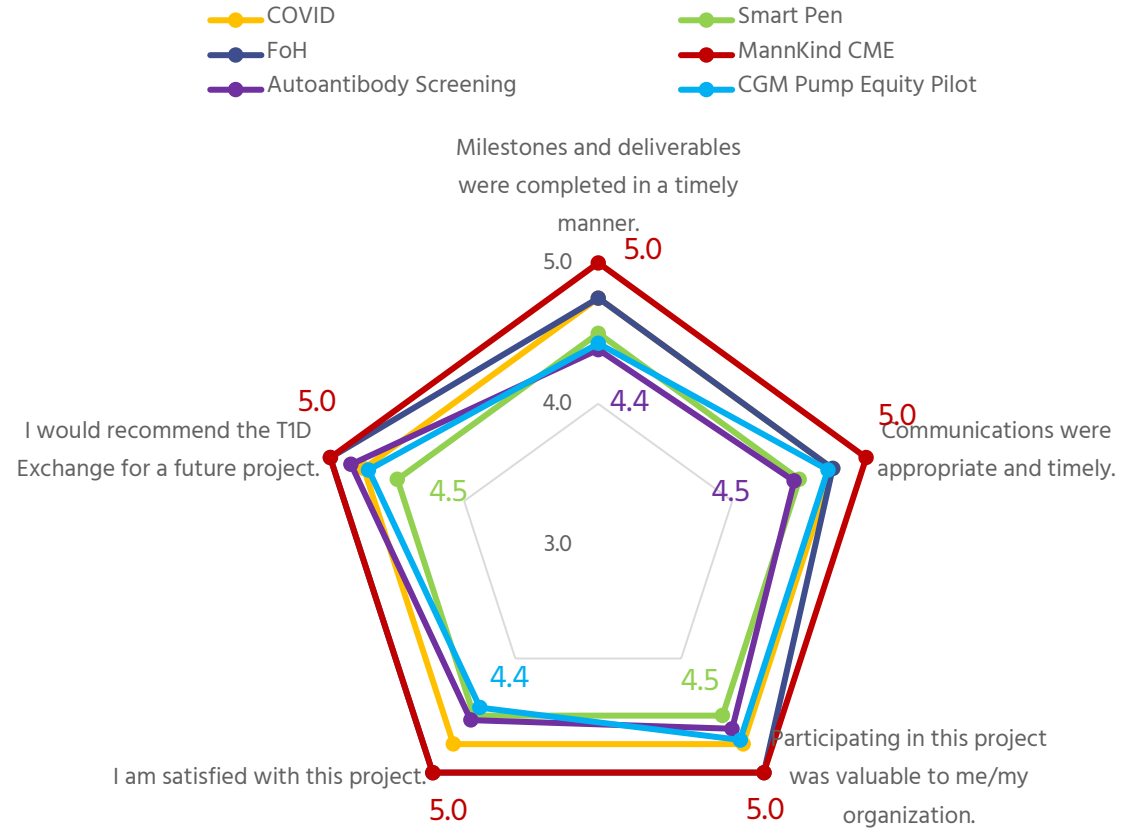
Project Status/Results: Contract pending

Project Satisfaction

Project satisfaction survey results by role



Average responses on a scale of 1-5 agreement with below statements by project



Project Satisfaction Survey Questions

Current questions:

- On a scale from strongly disagree (1) to strongly agree (5), please rank your degree of agreement with the below statements:
 - Milestones and deliverables were completed in a timely manner.
 - Communications were appropriate and timely.
 - Participating in this project was valuable to me/my organization.
 - I am satisfied with this project.
 - I would recommend T1D Exchange for a future project.
- (Optional) What are 1-2 things that worked well on this project?
- (Optional) Are there any recommendations for improvement?

Potential questions:

- Do industry funders/stakeholders feel this project has moved the bar in terms for quality care?
- ???

T2DX-QI Data and Agreements

Two pilot centers, 2021-2022

- SUNY
- PI: Marisa Desimone, MD. Clinical focus: adult endocrinology
- N pts 3,363
- Providers: 7 MDs
- Type: adult endocrine practice



Stanford

- PI: Sandra Tsai, MD. Clinical focus: Preventive Cardiology & Internal Medicine
- N pts 3,049
- Providers: 30 MDs
- Type: adult primary care practice





T2DX-QI Timeline



Results

- Improved team capacity, tracked changes, and make improvements in T2D care in two clinics
- Prescribing rates of Sodium-glucose Cotransporter-2 (SGLT2) and Glucagon-like peptide-1 (GLP-1) receptor agonists increased by 18%
- Depression screening increased by 34%.
- The two clinics began SDOH screening in August 2021 and screened 6,515 patients in the first seven months of the intervention.



[< Previous Article](#) [Next Article >](#)

138-LB: Improving Type 2 Diabetes Medication Prescribing **FREE**

NICOLE RIOLES; MARISA DESIMONE; EMILIE J. HESS; CHINONSO V. IWUMMADU; EMMA L. OSPELT; SAKETH ROMPICHERLA; MARGARET GREENFIELD; SANDRA TSAI



Diabetes 2022;71(Supplement_1):138-LB

<https://doi.org/10.2337/db22-138-LB>

Background: For people with type 2 diabetes, implementing best practice guidelines for diabetes and cardiovascular comorbidities is important to reduce the risks of complications. Two adult medical clinics used population health EMR data reports to increase medication prescribing for statins, ACE & ARB, SGLT2 & GLP-1.

Methods: The clinics tracked measures and used data analytics to identify a cohort population and medication needs for 6241 patients. Table 1 reflects data from a one-year pilot. Patients with a diagnosis of type 2 diabetes, duration of disease for at least one year, ages 18-75, with at least one in-person or telehealth visit were included.

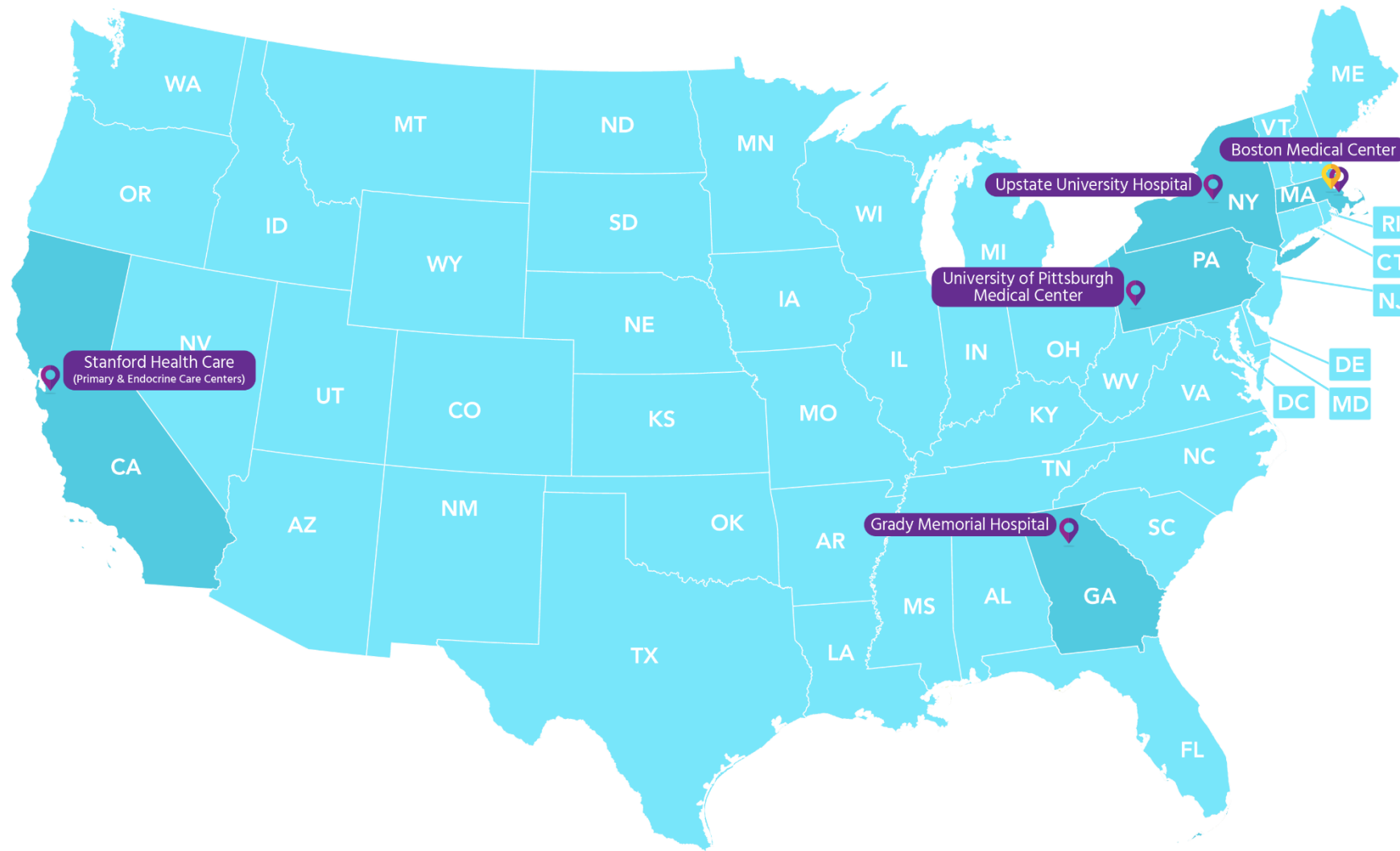
Results: Three medication prescribing baselines were tracked to improve type 2 diabetes and heart disease management. Prescribing rates of SGLT2 and GLP1 increased by 2%, ACE-I and ARB use increased by 1% and statins rates remained at 73%.

Conclusion: The clinics used data to identify the cohort and prescribe necessary medications. Partnering with clinical pharmacists helped to support patients, educate providers, and standardize medication prescribing workflows. Planning care so that the teams consistently identified appropriate medications for diabetes and cardiovascular disease management were clinical priorities. While the goal rate of medication prescribing has not been achieved yet, new reporting workflows are now incorporated, setting up the clinics for continued improvement.



Abbott Funded 2022-2025 Program

Expanded to Five Centers for 2023-2025



 Adult  T1D Exchange HQ

Participating Centers



Sonya Haw, MD



Jason Ng, MD



Margaret Zupa, MD



Kathryn Fantasia, MD



Timeline	Milestones
November-December 2022 (Complete)	<ul style="list-style-type: none"> • Soliciting interest • Contracting, Statements of Work • Data Agreements for T2D • IRB protocol
January-February 2023 (In progress)	<ul style="list-style-type: none"> • Measure definitions • Data mapping initiated • Official kick-off with centers • Recruiting benchmarking centers • Preliminary aggregate data
March-May 2023	<ul style="list-style-type: none"> • Each site will identify champions for the QI project, including at least one patient/parent who identifies as Black or Hispanic • Introduce the Equity 10 step Framework program to clinics. • Develop measures set related to race/ethnicity and device use. • Use PDSA Cycles to test interventions starting with one provider and scaling across the clinic. Weekly/bi-weekly Plan-Do-Study-Act Cycles. Each team will have the opportunity to complete at least 20 PDSA cycles. • Teams map out current process and annotate pain points in the process. • Teams will share process map at meeting in April

Timeline	Expectations
June 2023 –June 2025	<ul style="list-style-type: none"> • Teams map out current process and annotate pain points in the process. • Teams will share process map at meeting in April • Team will perform a fishbone activity/ create KDD • Submit abstracts for ADA Scientific Sessions (2024) • Submit T2D Establishment manuscript (2023) • Submit T2D Benchmarking manuscript (2024) • Submit abstracts for ADA Scientific Sessions (2025)
July 2025- December 2025	<ul style="list-style-type: none"> • Each center will present projects at conference calls and learning sessions. • Develop a Type 2 Diabetes Pilot Change Package that supports new QI strategies and interventions to improve equitable care in diabetes practices. • Submit T2D Health Equity abstract to the ADA Scientific Sessions. • Submit ATT abstract • Draft T2D Health Equity manuscript intended for 2025 publication. • Submit T2D outcome manuscript

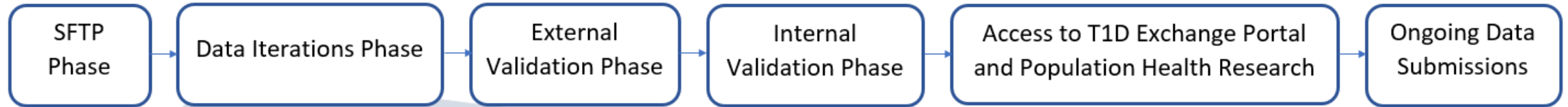
Real World Data Aggregate Insights on 33,000+ Adult T2D Patients

	Current Expansion Centers			Benchmarking Non-Intervention Centers			
Clinic Name	BMC	UPMC	Grady	SUNY	Stanford	Wash U	U Miami
Denominator	4350	9641	4893	3193	3000	4437	3500
Public Insurance	3045 (70%)	5396 (56%)	3180 (65%)	2427 (76%)	1000 (33%)	2584 (58%)	1950 (58%)
White pop	2080 (48%)	7915 (82%)	139 (2.9%)	2267 (70%)	1200 (40%)	3378 (76%)	2450 (70%)*
Hispanic pop	780 (18%)	96 (<1%)	295 (6%)	148 (<1%)	600 (20%)	84 (<1%)	2100 (60%)
CGM use	n/a	3085 (32%)	<5%	1013 (32%)	1000 (33%)	861 (19%)	n/a
A1c	3900 (90%)	8574 (90%)	n/a	2207 (69%)	2600 (87%)	2428 (58%)	3500 (100%)
Mean A1c	8.7%	7.8%	n/a	7.9%	8.0%	8.7%	7.5%
A1c below 8%	n/a	6127 (71%)	n/a	1351 (61%)	1200 (46%)	944 (38%)	2275 (65%)

Real World Aggregate Data Insights on 2,500+ Pediatric T2D Patients

Clinic Name	CCHMC	Seattle	Rady	Indiana	Lurie	Johns Hopkins	UCSF	CHLA
Denominator	260	315	352	272	350	215	300	750
Public Insurance	169 (65%)	259 (81%)	314 (89%)	184 (76%)	280 (80%)	170 (79%)	270 (90%)	693 (92%)
White pop	105 (40%)	67 (21%)	144 (41%)	99 (43%)	53 (15%)	35 (16%)	30 (10%)	58 (7%)
Hispanic pop	20 (8%)	154 (49%)	148 (42%)	39 (17%)	210 (60%)	25 (12%)	180 (60%)	548 (73%)
CGM use	20 (8%)	51 (16%)	3 (<1%)	N/A	32 (9%)	49 (23%)	10 (3%)	47 (6%)
A1c	250 (96%)	252 (80%)	340 (97%)	216 (79%)	320 (91%)	212 (99%)	250 (83%)	649 (87%)
Mean A1c	8.0	8.1	8.3	8.3	7.6	7.9	8.5	7.9
A1c below 8%	75 (29%)	169 (67%)	208 (61%)	125 (58%)	211 (66%)	132 (62%)	150 (60%)	397 (61%)

Patient Level De-Identified Data Mapping Process



T1D Exchange data files to map:



*Indicates phases where provider input is requested.

T2DX-QI Data Mapping Timeline

Grady Memorial

- March-May 2023

UPMC and BMC

- December 2023

Stanford

- May-July 2023

Amendment #2 to the Data Use Agreement

This Amendment is dated as of **MONTH, DAY, YEAR** (the "Effective Date"), by and between T1D Exchange Inc., located at 11 Avenue De Lafayette, Boston, Massachusetts 02111, and the **HOSPITAL/CONTRACTOR NAME** with a location at **HOSPITAL/CONTRACTOR'S ADDRESS** ("Contractor").

WHEREAS the Parties entered into Data Use Agreement on **MONTH, DAY, YEAR**.

WHEREAS the Parties executed an Amendment to the Agreement on **MONTH, DAY, YEAR** to include a type 2 diabetes project.

WHEREAS the Parties hereby agree to extend the term of the Agreement in accordance with them terms of the Agreement as well as the terms provided herein.

In consideration of the mutual covenants contained herein, each of T1D Exchange, Inc., and the contractor mutually covenant and agree as follows:

The Agreement, which is attached, continues from the effective date and automatically renews for additional one (1) year periods.

The parties agreed to the existing terms of the executed Data Use Agreement and all other terms and conditions of the Agreement remain unchanged.

The **MONTH, DAY, YEAR** Amendment added the following project work:

1. The Parties agree that a newly designated Principal Investigator, leading all work associated with type 2 diabetes, be assigned to the project.
2. The Parties agree that all existing terms of the DUA, related to Practice and Business Associate responsibilities, Data and Copyright Ownership, Privacy Laws, Security and the Parties acknowledge that beginning at the date of Amendment signature, the program's dataset will expand to include both type 1 and type 2 diabetes.

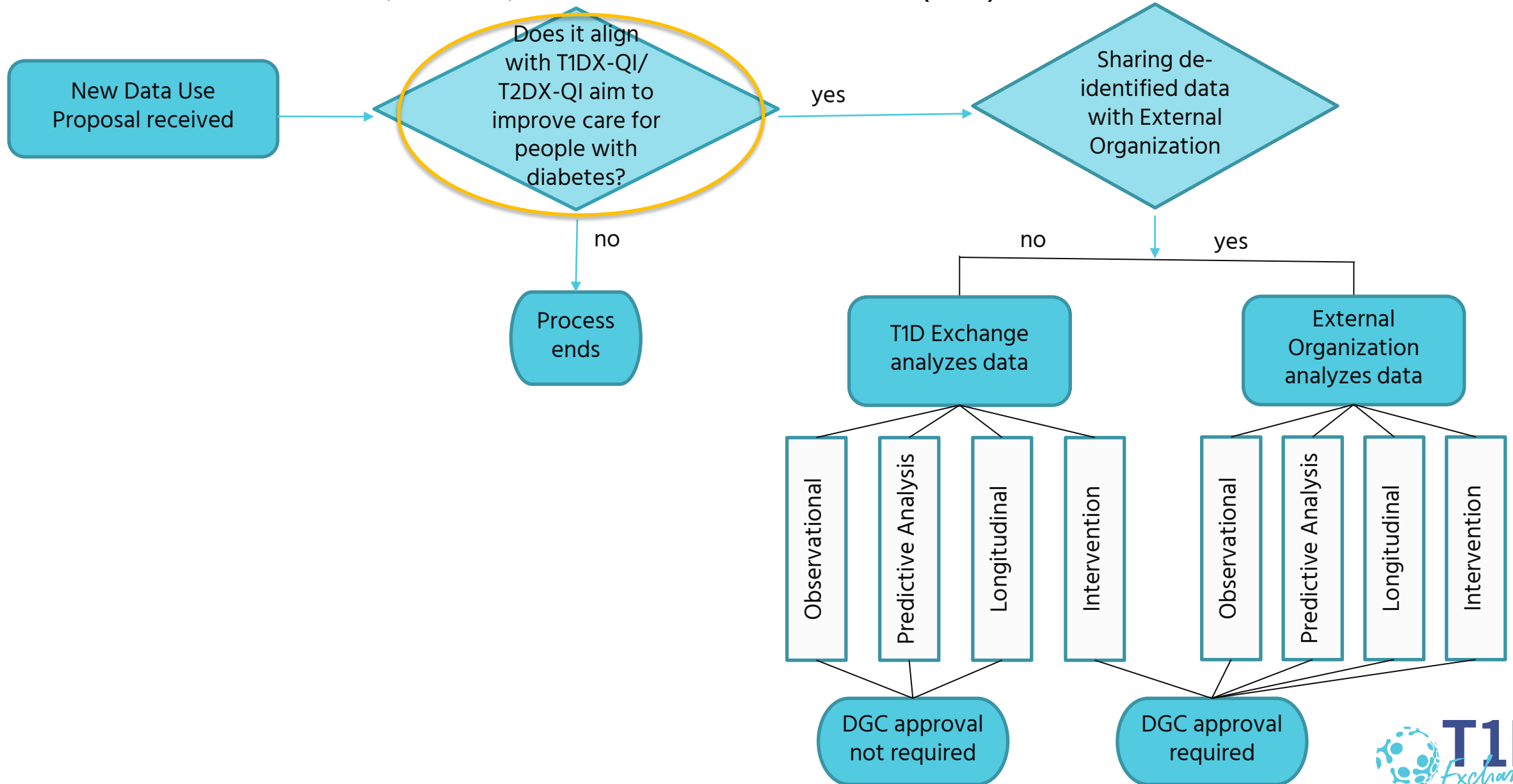
This Amendment shall be signed on behalf of T1D Exchange Inc., by **NAME**, its **ROLE**, and on behalf of the **CONTRACTOR NAME**.

Proposed Amendment to T1DX-QI/T2DX-QI DUAs



Proposed changes to DGC process

T1DX-QI/T2DX-QI Data Governance Committee (DGC) Process



Questions

- General concerns with the language of the DUA Amendment?
- Potential industry partnerships for T2D?