



**T1D**  
*Exchange*

# Data Governance Committee Meeting

February 12, 2024

# Data Governance Committee Meeting Agenda

1. Welcome
2. Updates on Sponsored Projects
3. Process review – ensuring reliable systems
4. Reasons to consider becoming a DGC co-chair in 2024

# 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

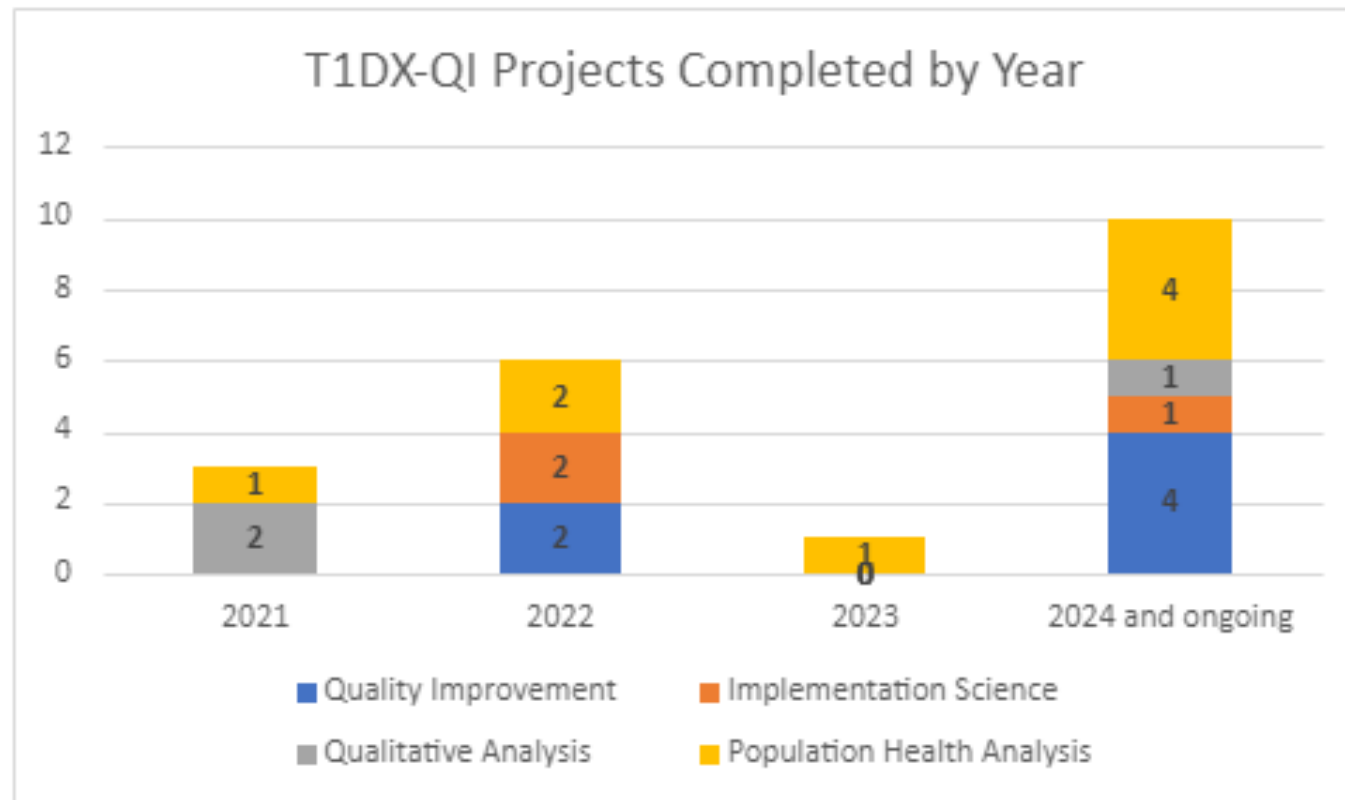
## To expand opportunities for QI team members:

- 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 February 2024, T1DX-QI has collaborated with **9** partners on **20** sponsored projects



# EMR Analysis – Status update

**Sponsor:** Vertex

**Objective:** Evaluate total daily insulin use among individuals with T1D who are between two and twenty-five years of age, stratified by age categories and sex.

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

**Project Status/Results:** ✓ On Track; shared all data tables with Vertex and engaged in conversations about expanding the analyses (phase II).

# Severe Hypo Events EMR Analysis – Status update

**Sponsor:** Vertex

**Objective:** Analyze the distribution of patient attributes by number of SHE events experienced

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

**Project Status/Results:** ✓ On Track; preparing final tables for submission to Vertex

# Know Diabetes by Heart QI – Status update

**Sponsor:** ADA

**Objectives:** Use QI Science to improve the quality of care for people living with **T2D** by reducing cardiovascular death, heart disease, heart failure, and stroke.

**Participating Centers:** 3 adult centers (outside of T1DX/T2DX-QI)

**Project Status/Results:** ✓ On Track; all centers engaged in data sharing and PDSA activities



# Type 2 Diabetes QI expansion – Status 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:** ✓ On Track; all centers engaged in PDSA activities and initial T2D analyses initiated

# Tandem Diabetes Technology Analysis – Status update

**Sponsor:** Tandem

**Objectives:** **Analyze diabetes technology use** (insulin pump, CGM, and automated insulin delivery) prescriptions and usage by device brand and model to assess market dynamics

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

**Project Status/Results:** ✓ On Track; shared all data tables with Tandem and will prepare for next quarterly update in April

# Antibody Screening QI – Expansion update

**Sponsor:** JDRF/Sanofi

## 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 PLUS 5 additional pediatric centers, to be identified**

**Project Status/Results:** ✓ On Track; QI project ongoing with two original centers; expanding to five additional centers in Q2 2024

# Tempo Smart Pen Qualitative Assessment– **New project update**

**Sponsor:** Eli Lilly

**Objectives:** **Conduct qualitative research via interviews with healthcare providers and care teams** with familiarity and experience with various smart pen offerings, with a particular focus on Tempo TM Personalized Diabetes Management Platform.

**Participating Centers:** 21 provider and care team members

**Project Status/Results:** ✓ On Track; focus groups completed and initial qualitative analysis initiated

# DKA and Kidney Disease Analysis – Contract Pending

**Sponsor:** Lexicon

## **Objectives:**

1. Understand the association between diabetic ketoacidosis and kidney disease by age group, T1D duration, HbA1c, cardiovascular disease, race/ethnicity, gender, and other factors of interest

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

**Project Status/Results:** Contract pending

# Data Governance Process Review

**2019**



Building  
Infrastructure

**2020**



Capturing  
Opportunities/Tailwinds

**2021**



Takeoff

**2022**



Growth and  
Expansion

**2023**



Cruising - Satisfaction  
and Experience

**2024**



Strengthening  
Robust Systems and  
Reliability

## 2024 PRIORITIES

- Systems and processes to prevent failures and mistakes
- Improve outcomes and efficiency

# Ensuring reliability in data governance processes

## A. Analysis Results

- Current DGC policy states that T1DX owns the raw data, not the sponsor/requestor
- What about analysis results?
  - Same rule, or different (i.e., require DGC vote)

## B. FDA Submission

- If a sponsor/requestor wants to submit results to the FDA, if/when does DGC get involved?

## C. Requests from national organizations

- If the CDC/NIH/HHS reach out for T1DX data, does their request supersede DGC policies?



# Data Governance Co- Chair Nomination Timeline

# Data Governance Co-Chair Nomination Timeline

Reasons to co-chair the DGC

- Seat at the table; contribute as a subject matter expert
- Leadership on a national committee
- Co-lead with peers across populations (pediatric and adult)

Co-chair nomination call for next term **June 2024 – May 2026**

- **Nominate a peer to serve as co-chair**
  - **Nominations due March 15<sup>th</sup>**

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