T1D Exchange

Data Governance Committee Meeting

Sept 4, 2024

Data Governance Meeting Agenda

1. Welcome
2. Overview of T1DX-QI's accreditation submission to the Association for the Accreditation of Human Research Protection Programs
3. Updates on Industry Sponsored Projects
4. DGC Project Review Process
5. Next meeting

Association for the Accreditation of Human Research Protection Programs

T1D Exchange

Overview of Regulatory Compliance

September 2024

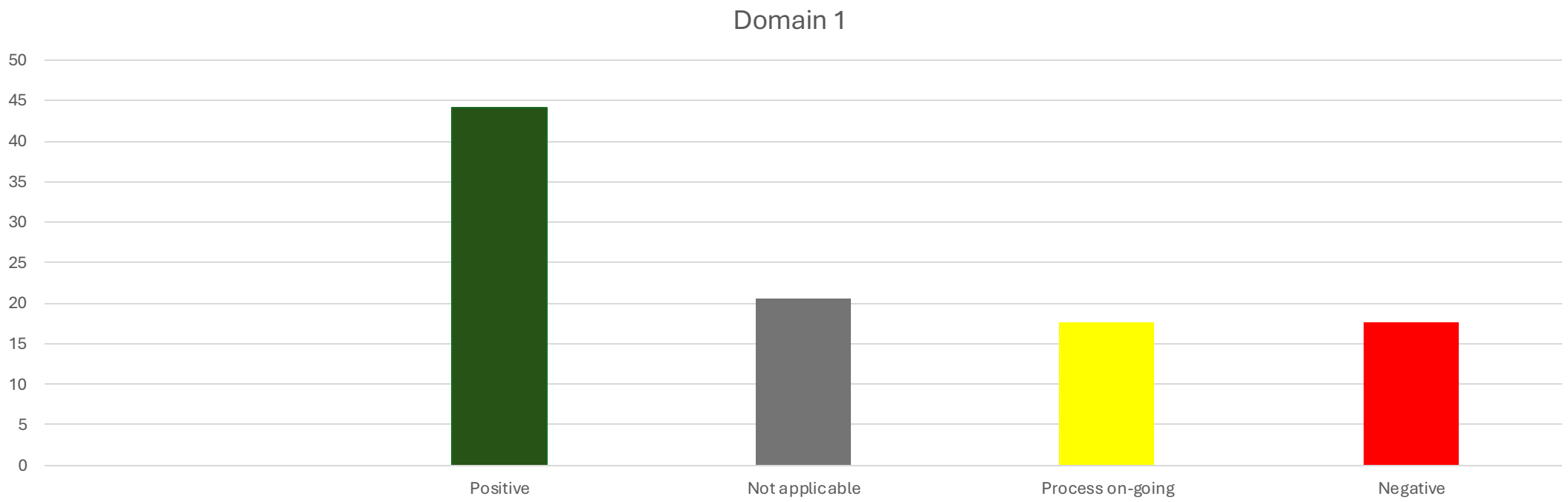
T1D Exchange Regulatory Compliance Self-Assessment

- Using the Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation framework
- Domain 1: Organization.
- Nine Standards and 25 Elements.

STANDARD I-1

STANDARD I-1: The organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program.

Domain 1


Domain 1
50
45
40
35
30
25
20
15
10
5
0
Positive
Not applicable
Process on-going
Negative

Domain 2

- INSTITUTIONAL REVIEW BOARD

- Five standards and 20 Elements.

STANDARD II-1

STANDARD II-1: STANDARD II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.

Domain 2

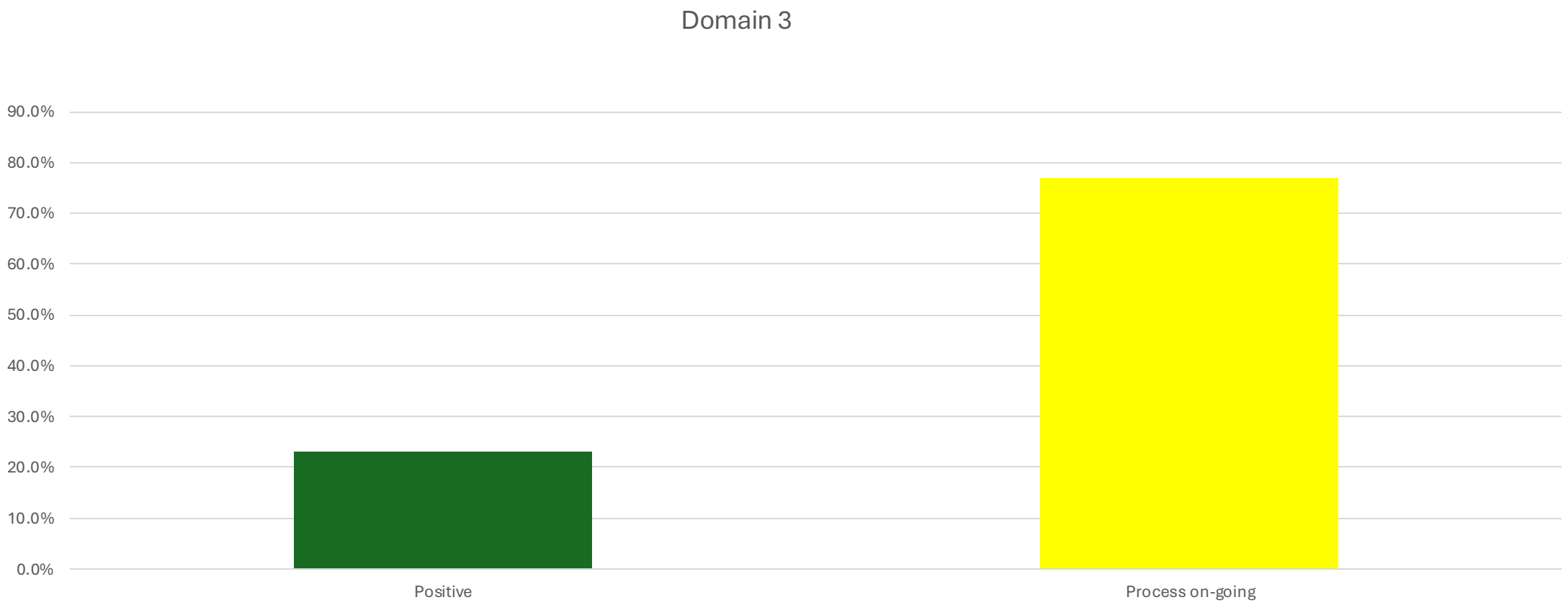
Domain 3

- RESEARCHERS AND RESEARCH STAFF
- Two Standards and 11 Elements.

STANDARD III-1

STANDARD III-1: Standard III-1: In addition to following applicable laws and regulations, researchers and research staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, researchers and research staff have the protection of the rights and welfare of research participants as a primary concern.

Domain 3


Domain 3
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Positive
Process on-going

Implications/Recommendations for T1D Exchange

- Need to strengthen regulatory compliance in Domains 1 and 3

- Review the following documents to include relevant statements according to the AAHRPP language:
  - Publication committee guidelines
  - Data governance, T1dexchange written information program etc

- Develop a Human Research Protection Plan (HRPP)

- HRPP: Director HRPP, Chief Research Compliance Officer, Research Compliance Committee, Quality Assurance team.

Next Steps Towards AAHRPP Accreditation

Part 2 : Build and develop an Application

Part 3: Evaluate written materials

Part 4: Evaluate practice

Part 5 Council Accreditation review

Part 6: Response to council review.

T1DX-QI Project Updates

1. **BPA**
2. **Diabetes Screening**
3. AHRQ, expanding the T1D 10 Step Equity Framework to the T2D space

T1D Exchange

Updates on Industry Sponsored Projects

September 2024

Sanofi Screening Project Overview

AIM Statements

Increase by at least 15% (from baseline) the proportion of people screened for T1D in 18 months. (June 2024- December 2025)

Increase by at least 30% (from baseline) the proportion of eligible people monitored for progression to stage 3 T1D over 18 months. (June 2024-December 2025)

Project Metrics

Screening
A) Number of individuals seen in reporting month who have been screened for T1D antibodies
Autoantibody Screening
1) Number of individuals in [A] that have been screened and confirmed positive for antibodies (GAD65, Anti-IA2, Tyrosine Phosphatases IA2 and IA-2β, ZnT8)
1a) Number of individuals in [A] that have been confirmed positive for a single autoantibody
1b) Number of individuals in [A] that have been confirmed positive for multiple autoantibodies

Stage 1 Diagnosis
2) Number of individuals in [A] who have multiple islet autoantibodies, normal blood glucose
Stage 2 Diagnosis
3) Number of individuals in [A] who have multiple islet autoantibodies, abnormal glucose tolerance OR HbA1c 5.7-6.4%
Stage 3 Diagnosis/New Onset Patients
4) Number of individuals in [A] who have blood glucose levels above ADA diagnostic thresholds OR HbA1c >= 6.5%

Project Metrics

Monitoring
5) Number of individuals in [2] + [3] with a scheduled endocrinology (per monitoring guidelines)*
DKA Events
6) Number of individuals monitored for T1D diagnosis in last 12 months who have a DKA in reporting month
Intervention
7) Number of individuals in [4] offered Teplizumab prescription

Participating Centers

Pilot Centers:

Rady Children's Hospital-San Diego

UC San Diego School of Medicine

UF Diabetes Institute University of Florida

Participating Centers:

Indiana University School of Medicine

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

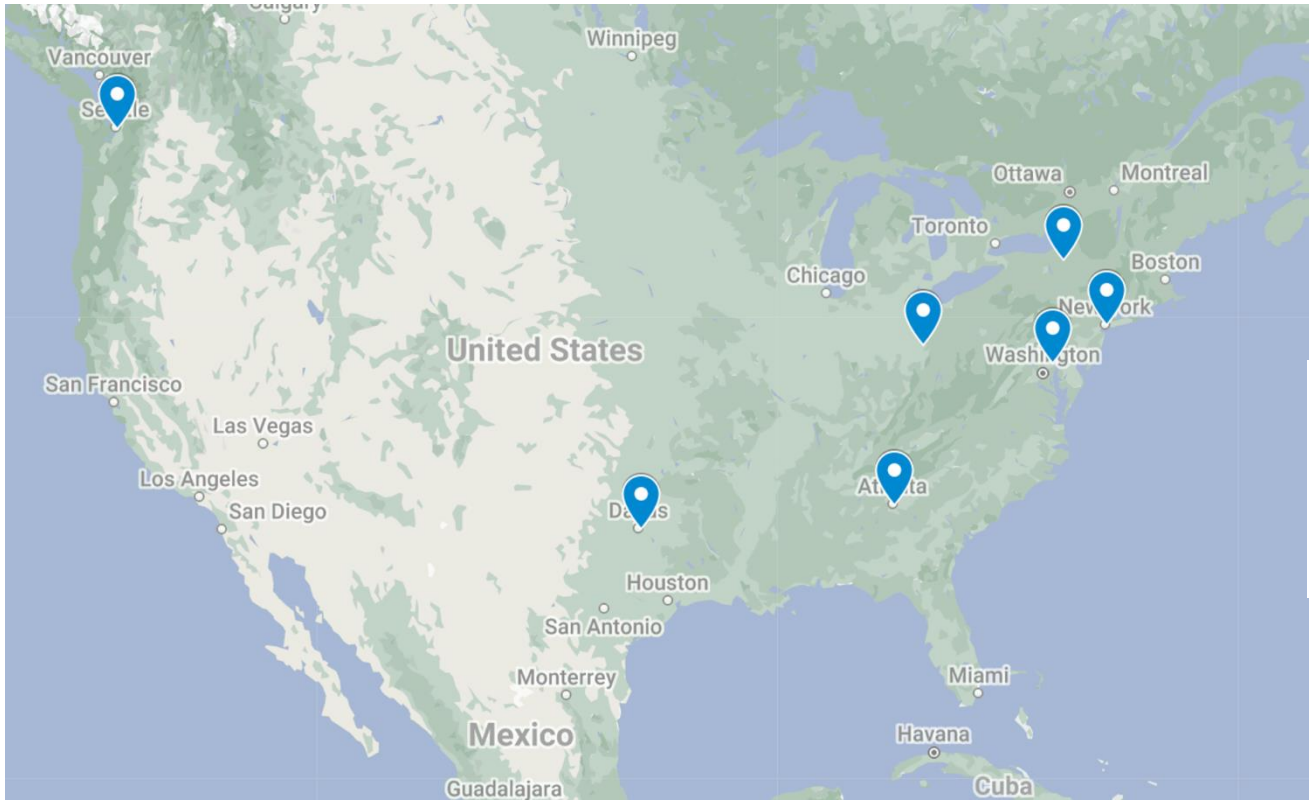
Texas Children's Hospital

Children's National

T1D Exchange

Best Practice Advisories for Tech Equity (BPA-TECH)

Participating Centers



Grady

Seattle Children's
HOSPITAL · RESEARCH · FOUNDATION

HASSENFELD CHILDREN'S HOSPITAL AT NYU LANGONE

UT Southwestern Medical Center

Joslin Diabetes
Affiliate at SUNY Upstate Medical University

Nationwide Children's
When your child needs a hospital, everything matters.

Johns Hopkins Medicine

T1D Exchange

Study Objectives

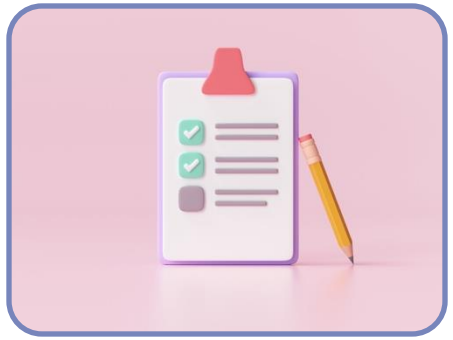
Aim 1	Aim 2	Aim 3
• To develop and implement an EMR-based BPA using stakeholder feedback to standardize the approach for prescribing and documentation of ADT use among children and adults with T1D	• To determine the effectiveness of an EMR-based BPA in reducing racial inequities in ADT use	• To explore the reasons identified for providers' decision to not prescribe ADT and whether they were patient or provider led, and the association between reason provided and patient's race/ethnicity

T1D Exchange

Aim 1: Qualitative Research

Focus groups/ structured interviews:

- Pediatric and adult endocrine providers who are part of T1DX-QI
- PWD/caregivers with T1D



Electronic surveys

- T1D Exchange Registry

Aim 2: Effectiveness

Non-randomized matched-pair intervention design

Compare ADT use following BPA intervention among non-Hispanic Black and Hispanic PwT1D receiving care at 6 T1DX-QI centers with matched control non-Hispanic Black and Hispanic PwT1D receiving care at a non-intervention center over a 12-month period

Primary Outcome

Progression in ADT use in intervention PwT1D compared with matched-pair control PwT1D during the 12-month study period:

- No CGM → Any CGM
- MDI → Insulin pump
- No AID → AID

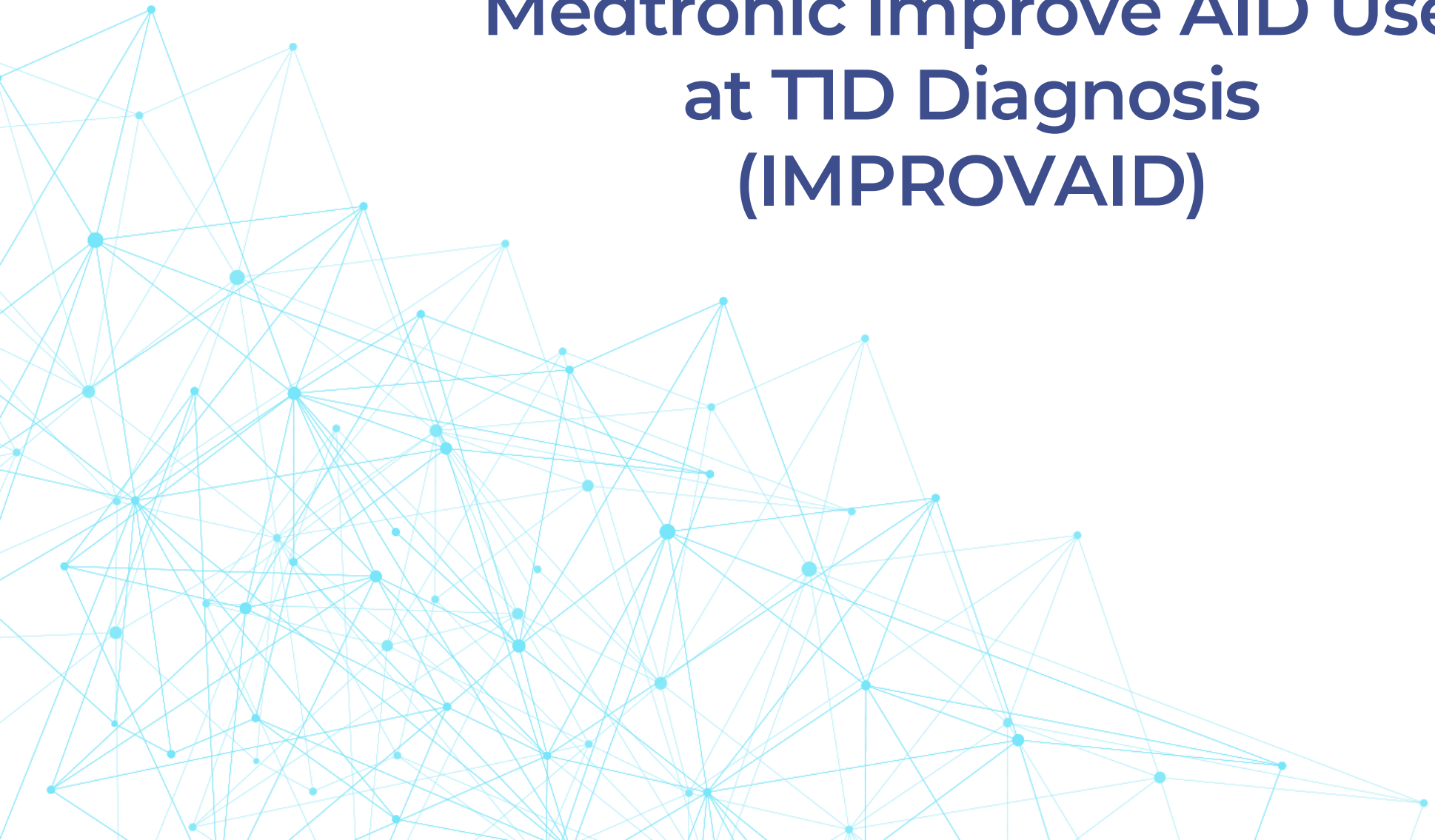
Aim 3

Explore reasons for not prescribing ADT

Determine if reasons are PwT1D- or provider-led

Analyze relationships between reasons and PwT1D race/ethnicity

Medtronic Improve AID Use at T1D Diagnosis (IMPROVAID)



Project Aims

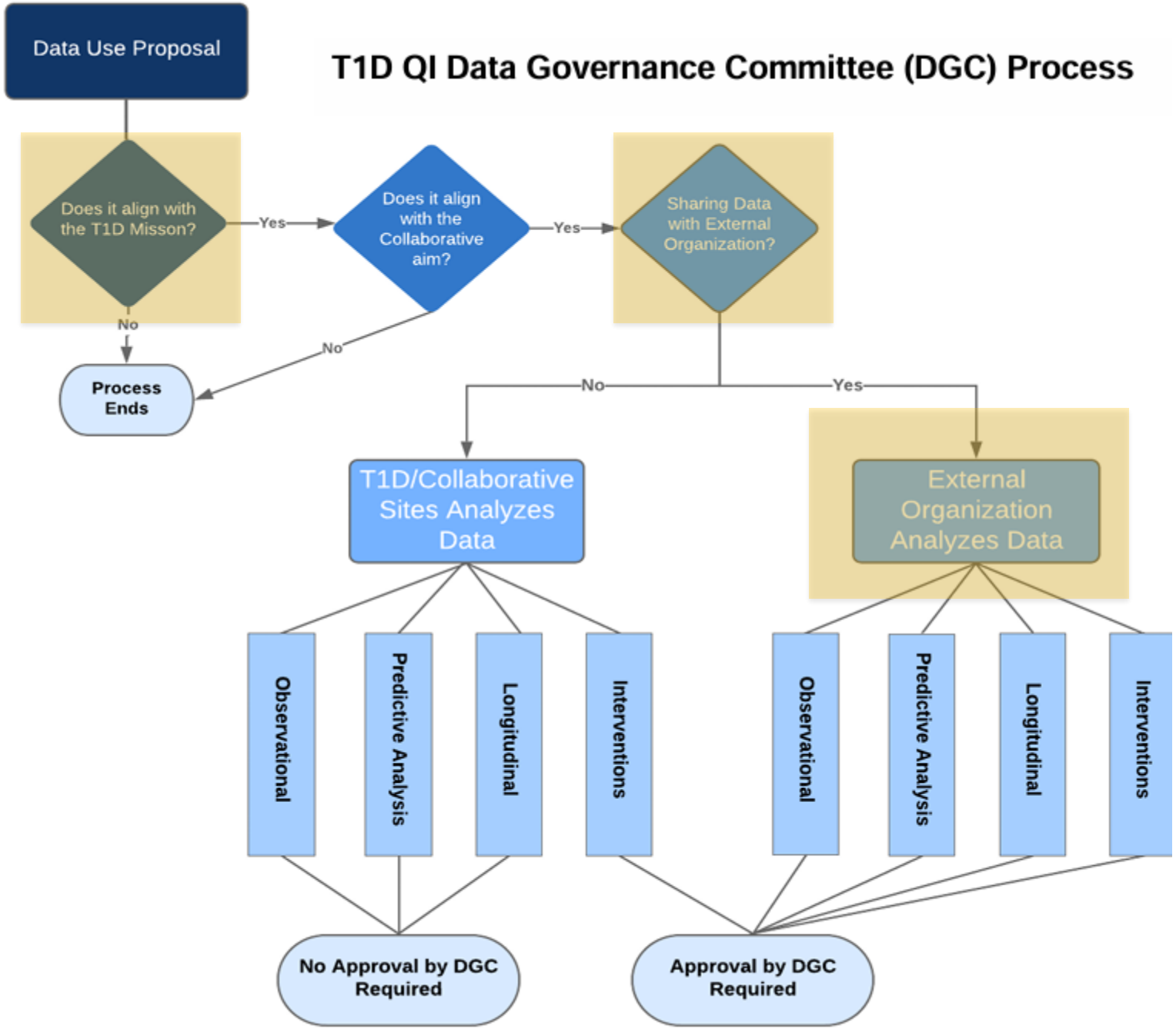
- Aim 1: Accelerate AID data collection and conduct AID real world analysis.
- Aim 2: Analysis to understand factors that influence diabetes providers recommendations of AID systems.
- Aim 3: Reduce therapeutic inertia and enhance AID Prescription for newly diagnosed people with T1D.

AHRQ Grant Application: Sept 29, 2024

- Draft Title: Reducing Inequities in type 2 diabetes continuous glucose monitoring use
- T1DX-QI aims to leverage our existing efforts in addressing inequities in T1D and establish a similar framework for T2D.
- Publication committee guidelines
  - Aim 1. Identify real-world barriers and facilitators to improving CGM equity in T2D.
  - Aim 2. Refine and adapt the T1DX-QI T1D Equity Framework for T2D.
  - Aim 3. Disseminate and implement the refined T2D Equity Framework
- At the end of the project, T1DX-QI will have successfully identified factors affecting T2D CGM equity, adapted our previously launched and successful T1D Equity Framework for T2D, and implemented and disseminated our new T2D Equity Framework across 18 adult T2D centers.
    - 9 Adult and 6 pediatric centers will be selected for participation

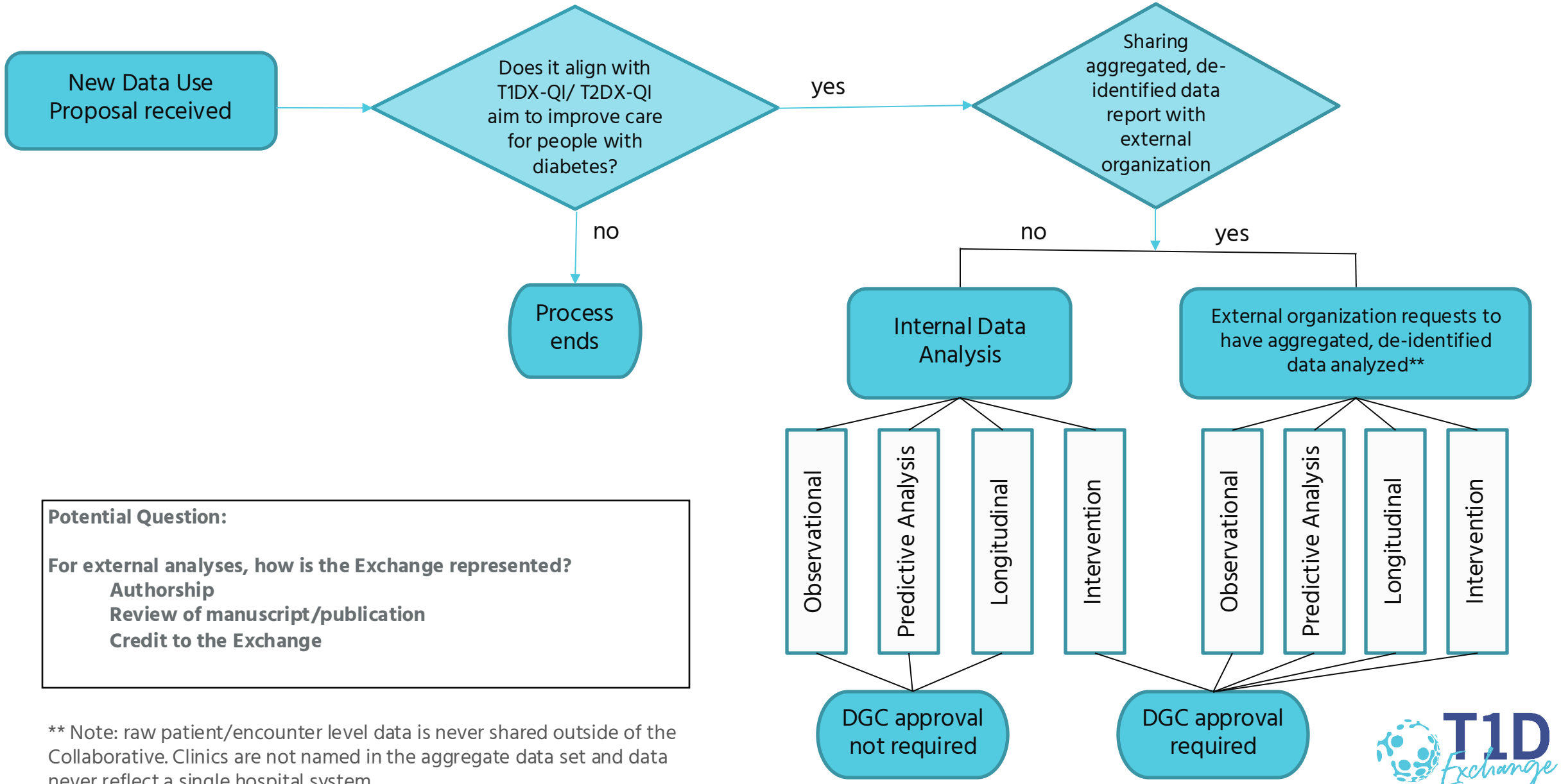
DGC Project Review Process

T1D QI Data Governance Committee (DGC) Process



Proposed changes to DGC process

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



Potential Question:

For external analyses, how is the Exchange represented?

- **Authorship**
- **Review of manuscript/publication**
- **Credit to the Exchange**

** Note: raw patient/encounter level data is never shared outside of the Collaborative. Clinics are not named in the aggregate data set and data never reflect a single hospital system.

Questions