



**T1D**  
*Exchange*

# T1D Exchange Overview

November 2023: QI Learning Session

[t1dexchange.org](http://t1dexchange.org)

# T1D Exchange Overview

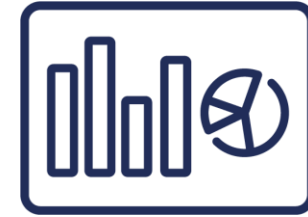
- Nonprofit focused on diabetes RWE, research and outcomes improvement
- HQ in Boston
- 35 people (24 in Boston area)
- Dynamic mix\*
  - 2 w/ MD
  - 7 w/ PhD
  - 8 w/ MPH
  - 7 w/ T1D
- Funding
  - 60% from foundations
  - 40% from industry projects & collaborations/sponsorships



\* Some have combo degrees

# T1D Exchange: Key Programs (other than QI / Pop Health)

- Online Direct to Patient Registry



- Online Community



- Custom Research (e.g., outcomes / market)



- Study Recruiting



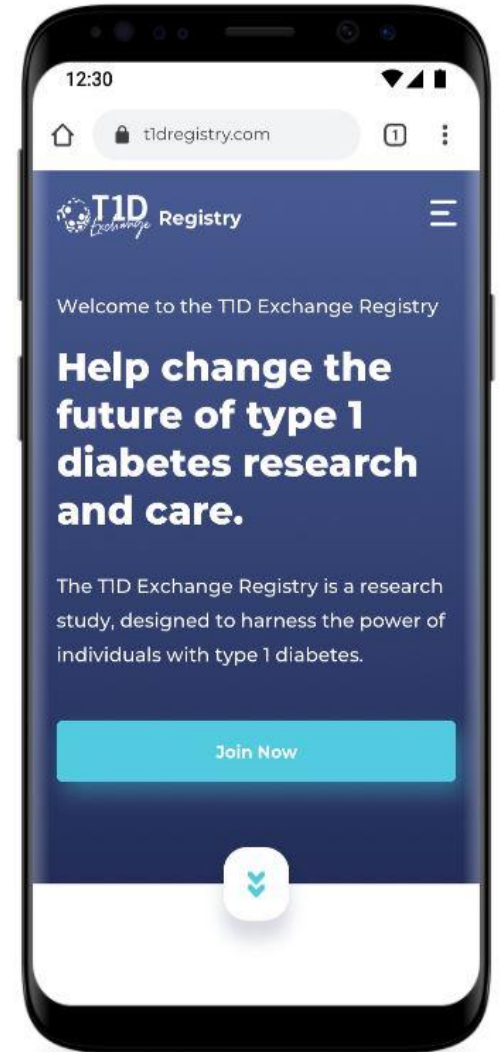
# Direct to Patient Online Registry Overview

Longitudinal study that seeks to create a well-characterized cohort of people living with type 1 diabetes in the US

Participants can sign up for other studies on various topics related to T1D

## Goals:

- Create a well-characterized cohort of T1D patients, including underrepresented populations in research
- Improve awareness of and facilitate enrollment into T1D research studies and clinical trials
- Gather longitudinal data on disease, health status, and self-reported outcomes
- Generate evidence to support policy/insurance coverage changes that help the T1D community





# Primary Data Collected in Registry (Patient-Reported)

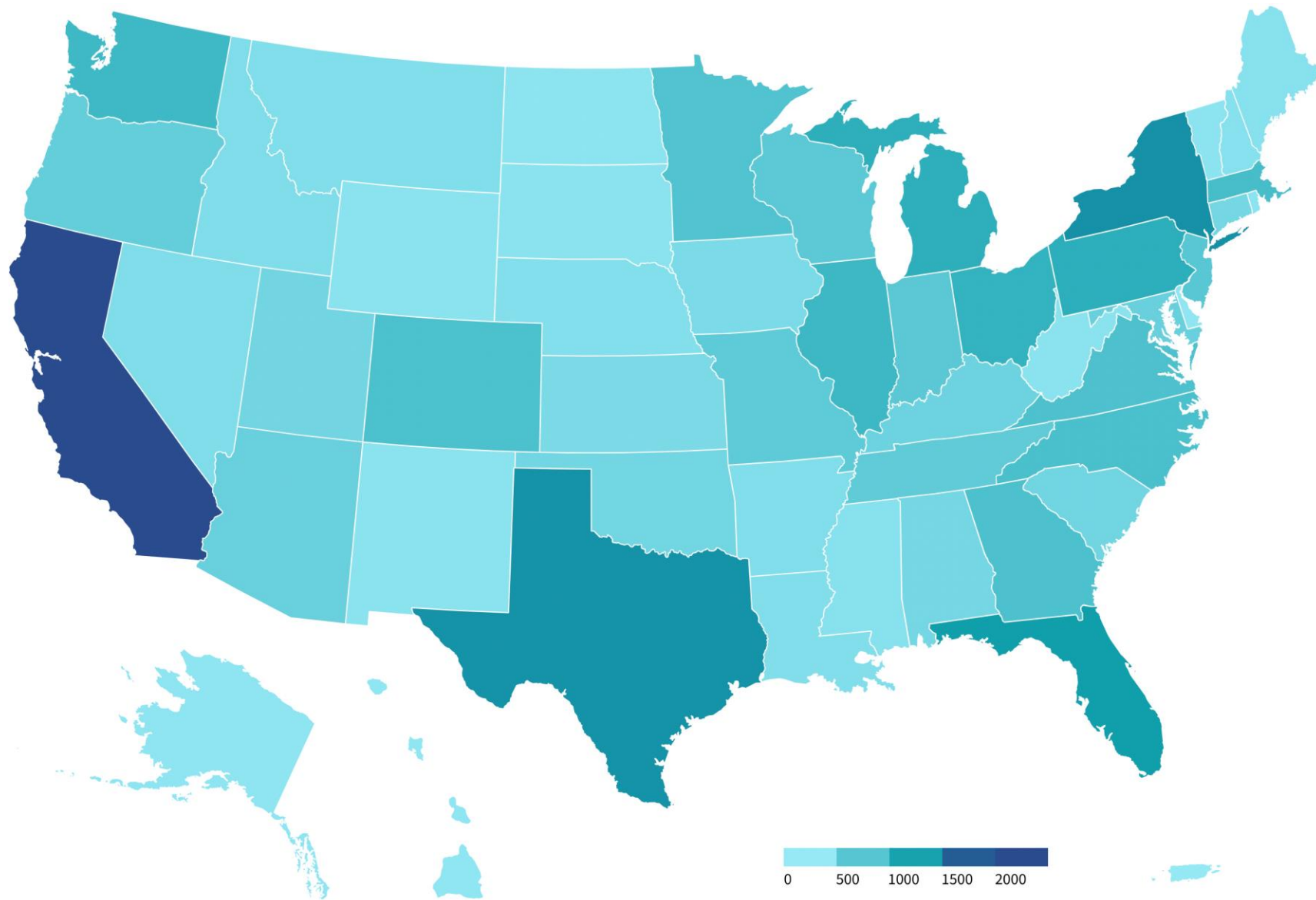
## Baseline Questionnaire\*

- Demographic
- Socioeconomic
- Clinical
  - Age and date diagnosis
  - A1C
  - Care team
  - Family history T1D, T2D
  - Other comorbidities
- Diabetes management
  - Insulin brand
  - Insulin delivery method & brand
  - BGM/CGM use and brand
- Diabetes distress

## Annual Questionnaire\*

- Longitudinal data collection
  - Selected demographic
  - Selected socioeconomic
  - General health information
  - A1Cs
  - Diabetes management
- Self-reported outcomes
  - DKA
  - Hyperglycemic events
  - Hypoglycemic events
- Glucagon prescribing
- Diabetes distress

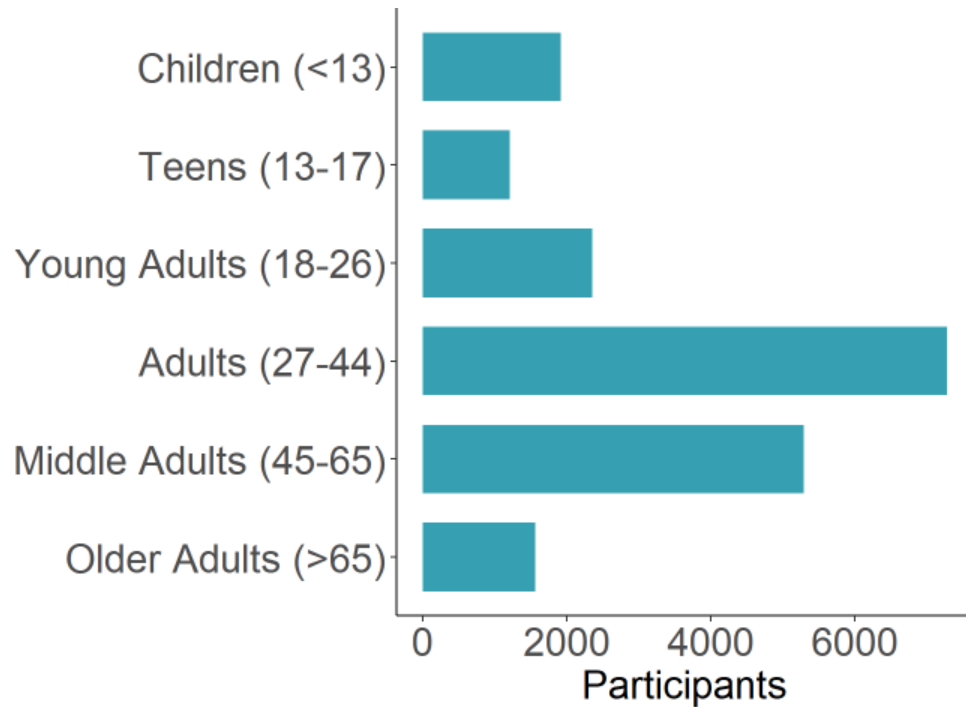
# Nearly 20,000 Registrants Across 50 States and Puerto Rico



**About 3,000 share their CGM data w/ T1DX Registry via Dexcom Clarity API**

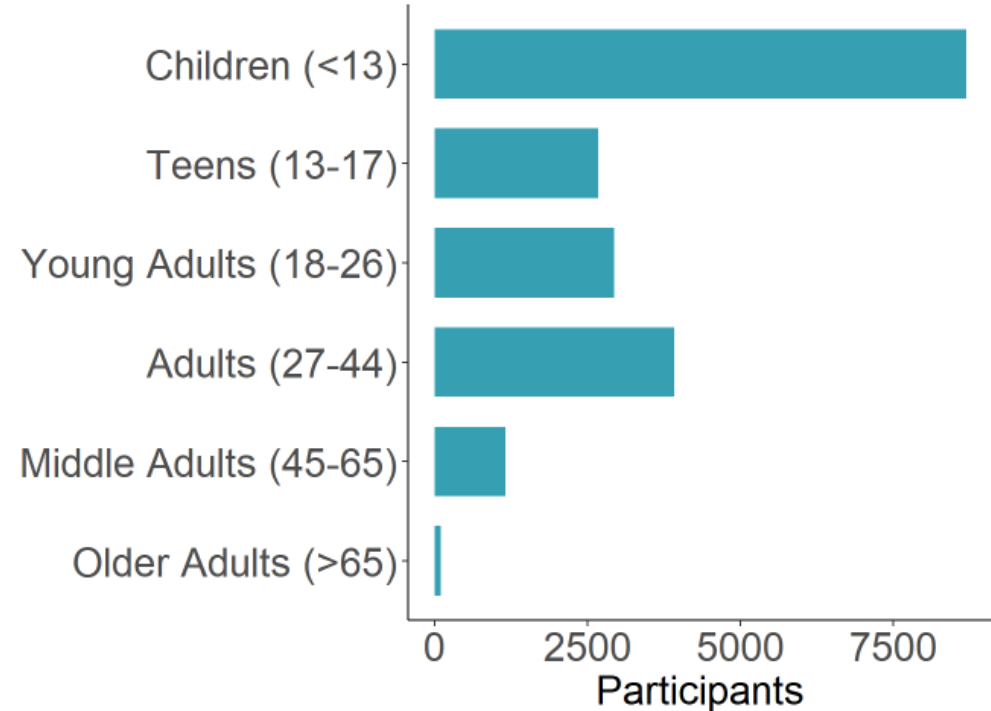
# Age Breakdown of Registry Participants

## Age



**85% are 18 or older**  
**4,500 have had T1D <5 years**

## Age at Diagnosis



**42% diagnosed at 18 or older**

# Novel Data Linking Initiative

- **Title:** Augmentation of T1D Exchange Registry Data with Complementary, External Data: An Anonymized Data-Linkage Secondary Analysis (partially funded by JDRF)
- **Objective**
  - Augment Registry (self-report + CGM tracings) data with external healthcare data (lab and claims) from same individuals to drive novel research
- **Method**
  - Tokenization-and-deidentification techniques allow for HIPAA-compliant patient data-matching across siloed sources to integrate comprehensive patient data
- **Status**
  - Preparing internal data to be securely tokenized; will perform data certification and linkage to lab and claims data, and commence analytics on combined data set





# Example Areas to Probe

- Real-world CGM metrics, A1c values, T1D-related complications diagnoses (e.g., CKD) and related lab values (e.g., eGFR) to assess whether ADA glycemic guidelines are appropriate or should be updated
- Investigate CGM trends and A1c and other lab-value trends prior to and following the prescription/initiation of a glycemia-improving therapy (drug or device)
- Investigate effect of duration of diabetes on the power of CGM metrics and A1c and other lab values in predicting T1D-related clinical outcomes/diagnoses



# Custom Research Areas of Activity

- Interviews
- Focus groups
- Cross-sectional surveys
- Longitudinal surveys
- Mixed method design
- Patient reported outcomes
- CGM trace analysis linked to survey responses
- Quantitative and qualitative data analyses
- EMR data analysis
- Abstract/publication development & presentations

# Key Custom Sponsored Research 2022-2023

- **Unmet needs in CGM** users (T1D and T2D)
- **Psychosocial** experiences with **severe hypoglycemia and nasal glucagon** in young adults and caregivers
- Development of **Fear of Hypoglycemia** (FOH) screener
- Awareness, experience and attitudes of **"Auto Antibody Screening"** market research in T1Ds, family members and HCPs
- Follow-on study of **severe hypoglycemia and impaired hypoglycemia awareness** survey and **CGM analysis**
- Market research on glucagon use in adults
- Assessment of **CGM adhesives** with custom survey & **adhesive site photo** uploads
- EMR analysis of **total daily insulin dose in pediatric** cohort
- **AID use** and characteristics in T1DX **EMR data** and Online Patient Registry (**CGM data** w/ existing and novel survey responses)
- Survey on **severe hypoglycemia** and extensive patient-reported outcomes associated (quantitative and qualitative)

# Select Custom Research Publication Highlights 2023

- Improvements in measuring Fear of Hypoglycemia (FOH)
  - Developed and validated a brief screener for FOH (9-items)<sup>1</sup>
  - Used newly developed screener to characterize FOH in T1D Exchange Registry sample and real-world perceptions of its usefulness in clinic<sup>2</sup>
- Patient perceptions of diabetes technology in glucose monitoring
  - Surveyed a mixed sample (T1D and T2D) to understand patient experiences with CGM, including suggestions for areas of real-world improvements and found – despite advancements – is room for improvement in CGM devices<sup>3</sup>
- Patient experiences with severe hypoglycemic events (SHEs) and glucagon
  - Survey found despite trend of more current glucagon prescriptions, people with T1D continue to experience challenges, including negative emotions with severe hypoglycemia<sup>4</sup>
  - Survey found nasal glucagon may help young adults with T1D and caregivers feel more confident in others' ability to help during an emergency and reduce the distress young adults perceived around severe lows<sup>5</sup>



## Annotated References

<sup>1</sup>Liu et al. (2023). Development and validation of fear of hypoglycemia screener. *Journal of Patient-Reported Outcomes*

<sup>2</sup>Peter et al. (2023). Prevalence of fear of hypoglycemia in adults with type 1 diabetes. *BMJ Open Diabetes Research and Care*

<sup>3</sup>Holt, Nguyen, et al. (2023). Perceptions of CGM Systems in the T1D Exchange Diabetes Registry. *Clinical Diabetes*

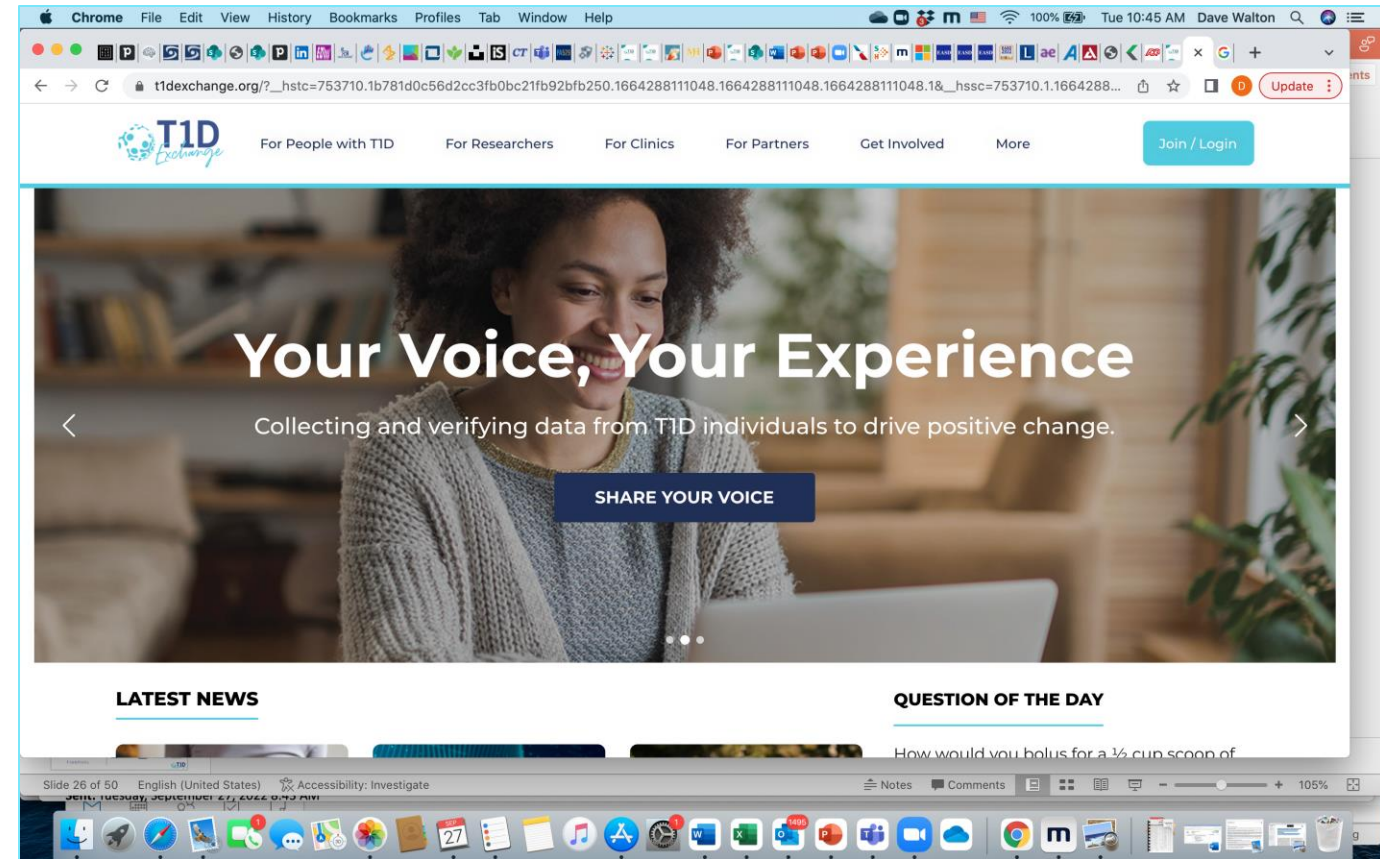
<sup>4</sup>Hughes, Chapman, et al. (2023). Severe hypoglycemia and the use of glucagon rescue agents. *Clinical Diabetes*

<sup>5</sup>Kelly, et al. (2023). Emerging adult and caregiver psychosocial experiences with SHEs and the perceived Impact of nasal glucagon. *Diabetes Therapy*

# Online Community & Resources

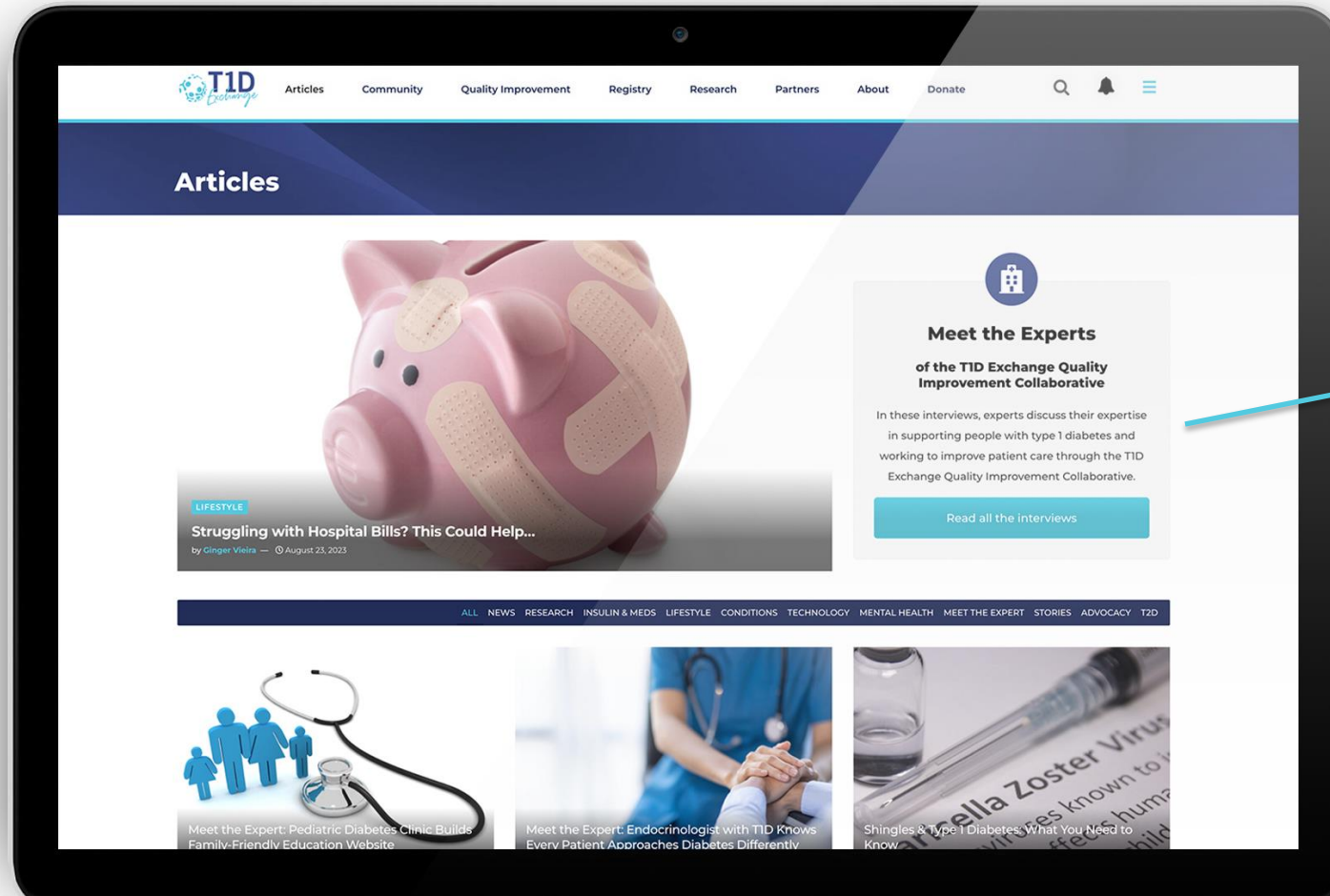


- 30,000+ email addresses (75%+ are T1Ds)
- More than 40,000 social media followers
- We engage with community in different way
  - Question of the Day
  - Featured articles of interest (e.g., new product approvals)
  - Resources on website (e.g., Automated Insulin Delivery review)
  - Opportunities to participate in certain research studies





# T1D Exchange Online Community – Featured Articles



**“Meet the Expert” series highlights members of the T1D Exchange Quality Improvement Collaborative and the important work you are doing**

# Recent “Meet the Expert”: Dr. Laura Jacobsen

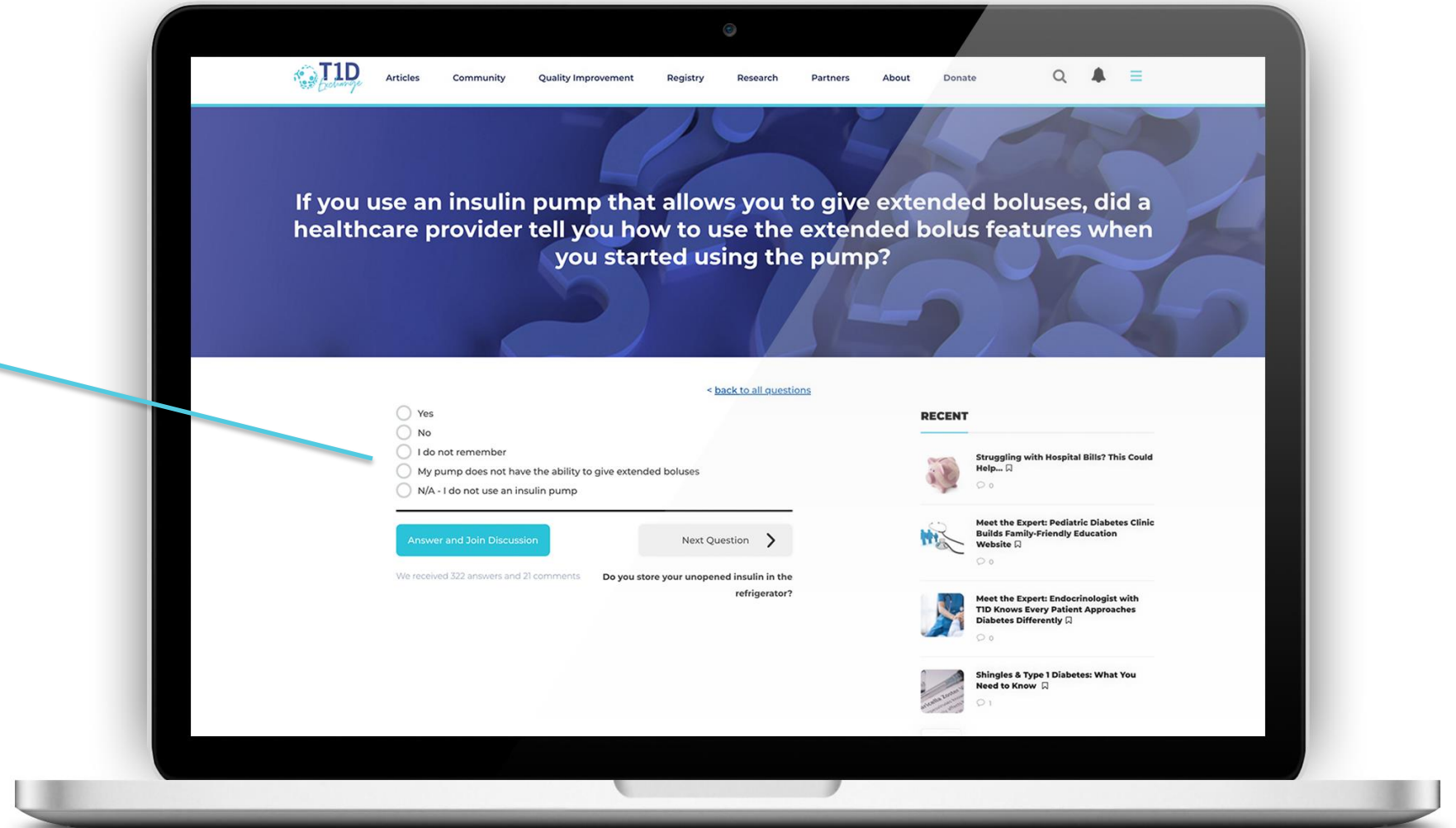
The screenshot shows a Google Chrome browser window with the URL `t1dexchange.org/meet-the-expert-laura-jacobsen/`. The page features the T1D Exchange logo and navigation menu (Articles, Community, Quality Improvement, Registry, Research, Partners, More). The main content is titled "Interview with Laura Jacobsen, MD" and includes a portrait of Dr. Jacobsen. The text describes her role as an endocrinologist and researcher with the T1D Exchange Quality Improvement Collaborative (T1DX-QI). A consent form on the right allows users to receive communications from T1D Exchange, with a "Submit" button below. The browser's taskbar at the bottom shows various application icons.

“Developing the T1D Exchange Screening Project”



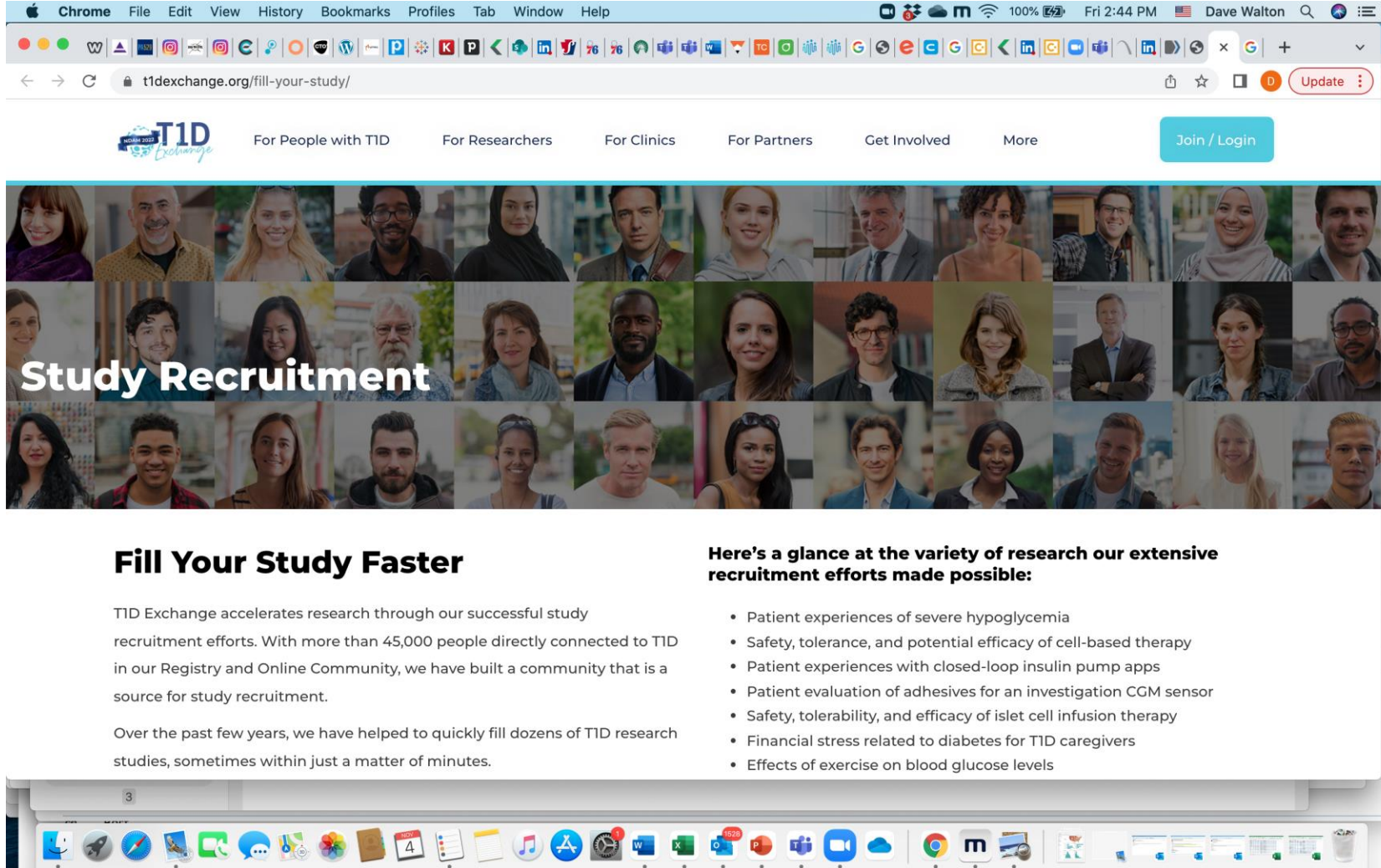
# T1D Exchange Online Community – Question of the Day

“Question of the Day” typically garners 300-400 responses from members of the online community





# Study Recruitment Assistance



**We can help accelerate virtually any study in which T1D participants are needed!**

**Please reach out!**

**Debbie Taylor**  
**dtaylor@t1dexchange.org**

**Courtney Holubiak**  
**cholubiak@t1dexchange.org**



# We have recruited for 56 studies in the past several years

## Overview

- Over past few years, we have helped to quickly fill dozens of T1D research studies: online surveys, virtual studies, in-person research, and clinical trials.
  - **19 partners for 32 studies (academic/CRO)**
  - **12 partners for 24 studies (industry)**
- T1D Exchange Registry participants are an engaged, characterized cohort who have consented to be contacted about research
- Online community members also participate on select studies depending on partner needs
- Recruitment solicitations may be targeted based on demographic and clinical characteristics
- Experience working with Coordinating Centers, industry partners and individual centers/PI's

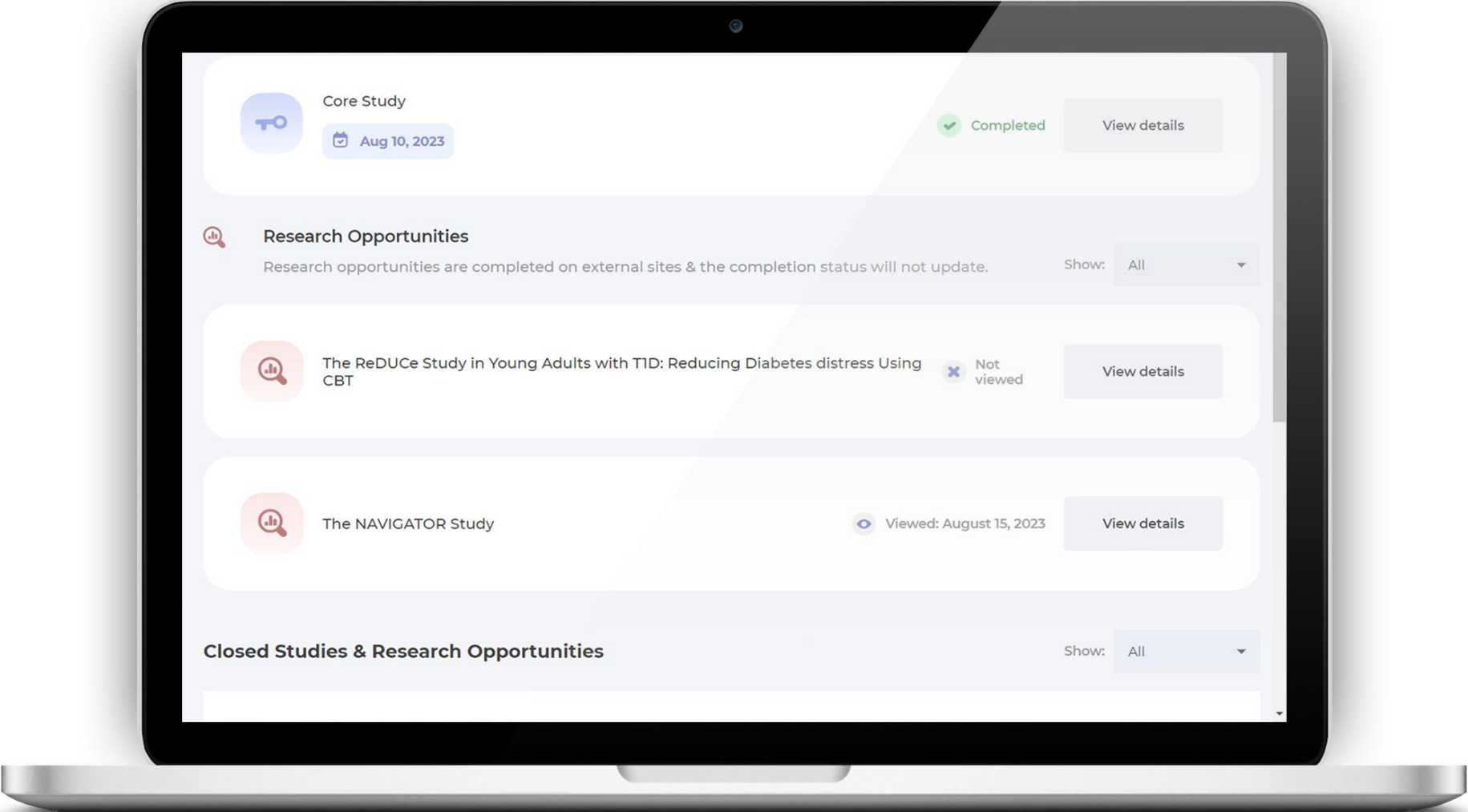


## Notable Examples

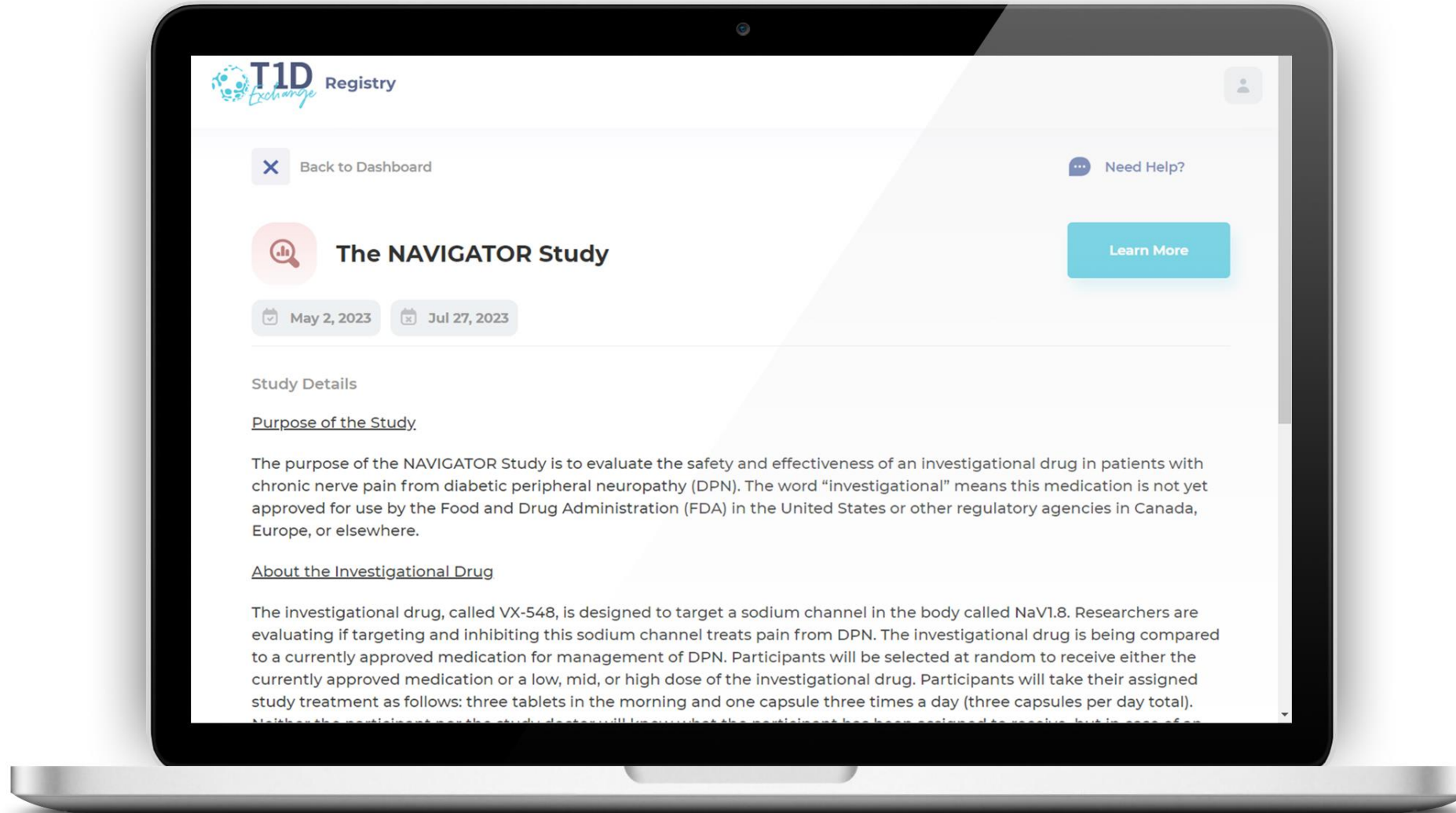
- At-home CGM and exercise study
- At-home study as part of a global evaluation of a new closed loop system
- Virtual focus groups to explore CGM user experience and unmet needs
- In-person phase 2 study of a novel biologic for newly diagnosed
- In-person phase 2 study of a cell therapy replacement for those with impaired hypoglycemia awareness
- At-home CGM adhesive studies for new longer-wear CGM sensor



# Research Opportunities Listed for Registry Participants...



# ...and Described in Understandable Language



# T1D Exchange Offers Additional Services if Needed

- Development and input on study documents – protocol and ICF
- Development of participant facing materials
- Development of study screener and surveys
- Coordination and execution of qualitative research – focus groups and interview
- Abstract/publication development & presentations
- Long-time relationship with central IRB (WCG)

# Study Recruiting Testimonials



“We are incredibly grateful to partner with T1D Exchange across several research projects. Partnering with T1D Exchange allowed us to include the perspectives of individuals with type 1 diabetes across the US to inform our understanding of diabetes distress.”

- Danielle Hessler Jones, PhD, University of California San Francisco

“We had over 2,000 participants! I was hoping for at least 500, with a bigger goal of 1,000. I could have never surveyed 2,000 people with type 1 diabetes without a partnership with the T1D Exchange. It was essential and such an easy process.”

- Dr. Stephanie Crossen, MD, MPH, University of California Davis

“T1D Exchange saved our bacon and caught us up on recruitment for an NIH study for which we were way behind”

- Dr. Mark Clements, MD, PhD, Children’s Mercy Kansas City



# Thank you to our partners and collaborators!

## Funding Partners/ Collaborators

- **The Leona M. and Harry B. Helmsley Charitable Trust**
- **JDRF**
- **American Diabetes Association**
- **American Association of Diabetes Care & Education Specialists**
- **Children with Diabetes**
- **Diabetes Link (formerly CDN)**
- **SWEET**
- **DPV**

## Industry Members / Collaborators

- **Abbott Diabetes Care**
- **Abvance Therapeutics**
- **AdmetSys**
- **Bayer**
- **Dexcom**
- **Intuity Medical**
- **Janssen**
- **Lilly**
- **Lifescan**
- **Mannkind Corporation**
- **Medtronic Diabetes**
- **Sanofi (Provention Bio)**
- **Tandem Diabetes**
- **Vertex**
- **Xeris**
- **Zealand**