

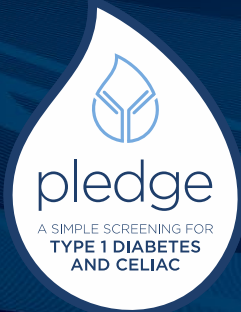
# The Sanford PLEDGE Study

## Integrating Screening into Routine Pediatric Care Across a Health System

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Director of Clinical Trials  
Sanford Health  
Sioux Falls, South Dakota

6<sup>th</sup> Childhood Diabetes Prevention Symposium  
Barbara Davis Center  
10 November 2023



In Partnership with

THE LEONA M. AND HARRY B.  
**HELMSLEY**  
CHARITABLE TRUST

**SANFORD**  
RESEARCH

# Past Screening Efforts Miss Most People at Risk

## Diabetes TrialNet

- Screen for autoantibodies in family members of people with T1D
- ~250,000 people screened over 18 years

### BUT:

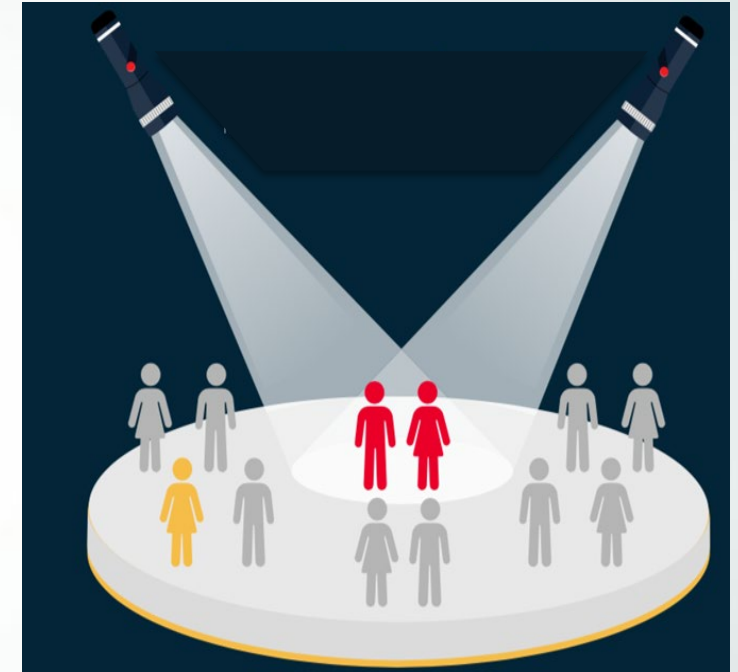
- 92% who will get T1D have no family history
- Not eligible for TrialNet screening
- Expect 1 in 200 people



# Sanford PLEDGE: General Population Screening

Novel, Pragmatic Design:

- Minimize burden on:
  - Providers & Staff
  - Families
  - Research Coordinators
- Integrated into routine clinic visits
- Leverage existing Epic electronic record system and
- MyChart patient messaging for enrollment & questionnaires
- Economic analyses and modeling
- No cost to families



# Goals

- Prevent initial diabetic ketoacidosis
- Identify patients for possible intervention:
  - Teplizumab when appropriate
  - Stage 1 / 2 intervention trials
- Generate evidence to support including T1D screening
  - Demonstrate feasibility of *integration into routine pediatric care*
  - Prospective validation of GRS and assessment of utility to focus screening
  - Assess cost effectiveness of general population screening

# PLEDGE Overview of Procedures

Entry before 6<sup>th</sup> birthday  
OR once 9 -16 y.

Genetic Risk Score  
GRS2 Once at study entry  
(blood spot; can be with Newborn Screening)

Anxiety Survey  
Entry & Annually

T1D AutoAb

Celiac Testing



Birth

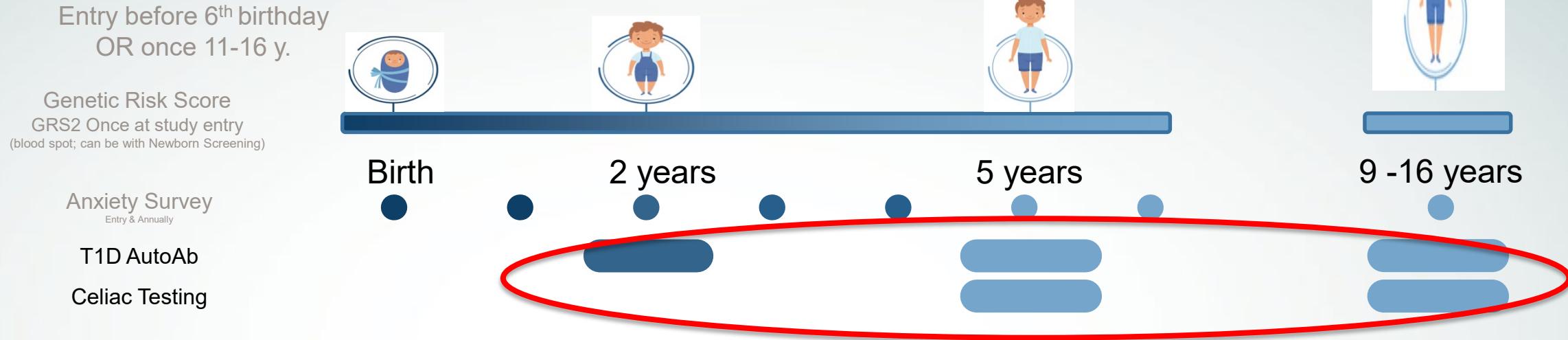
2 years

5 years

9 -16 years

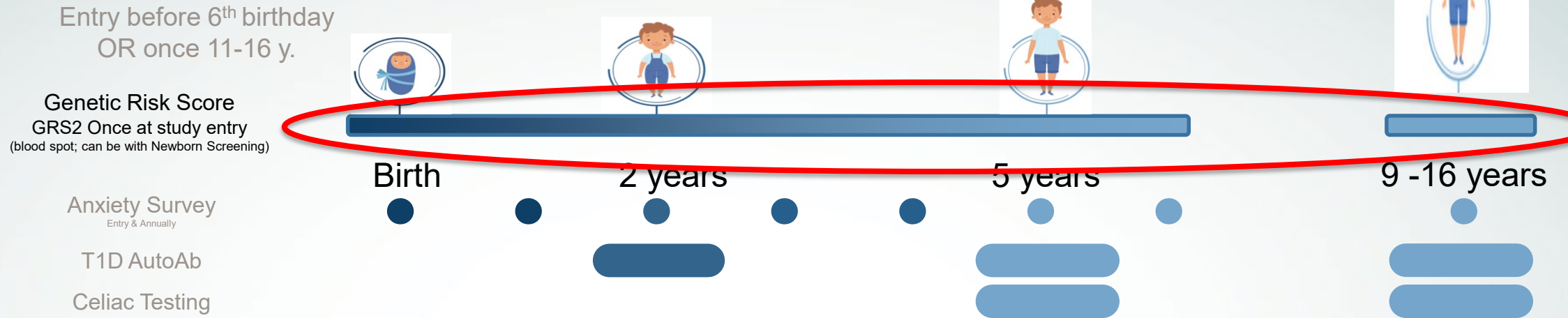


# PLEDGE Overview of Procedures



Antibody Screening at ~2, ~ 5, and 9-16 years of age

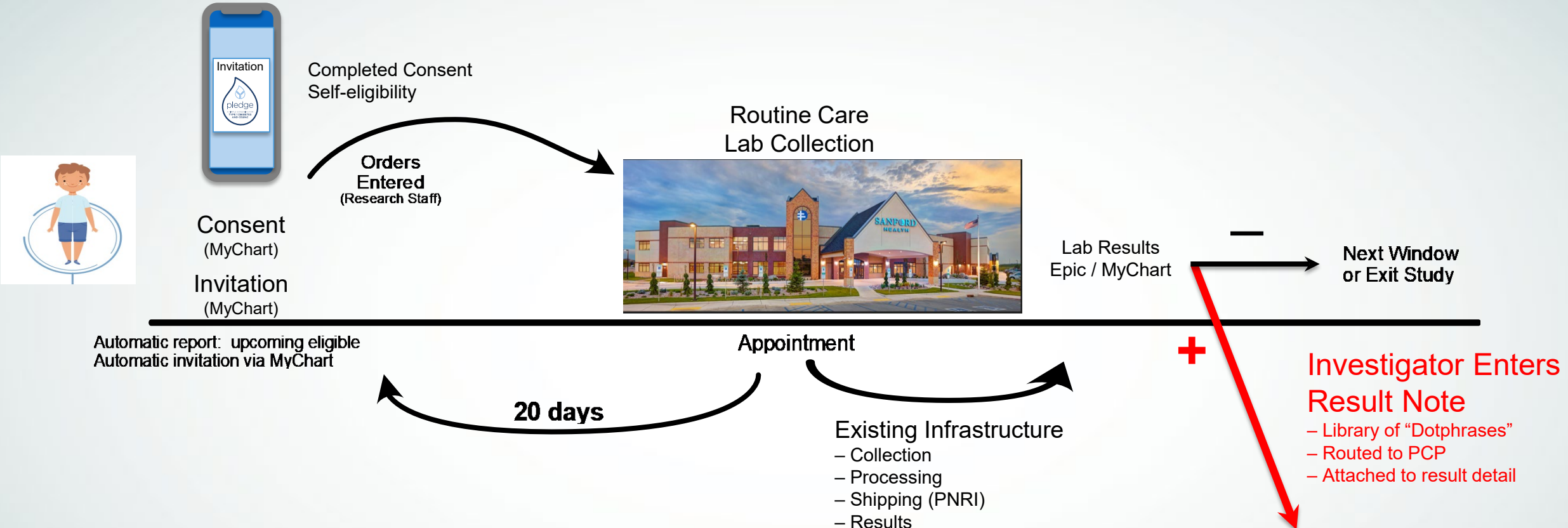
# PLEDGE Overview of Procedures



## GRS2 at study entry

- SNP-based risk score for T1D and Celiac autoimmunity
- Can enroll before birth and collect with newborn screens

# Innovation and Infrastructure



Integration into routine care  
 Leverage existing processes and infrastructure  
 Automation of invitation, enrollment, and messaging

**Research Staff will:**

- Contact Family & Explain
- Retest
- If persistent:
  - Monitoring Protocol for T1D
  - Clinical referral to peds GI for celiac





# Epic Notifications

“BPA” [light] in Storyboard

Callie K. Bear  
Female, 31yr, 7/21/1989  
MRN: E20327  
Code: Not on file (no ACP docs)  
Adv Direct/POLST: None  
HAR: None  
Phone: 608-555-4578

Isolation: None  
TDAP vaccination due  
Patient due for the following HM topic  
More Advisories (2)  
OB Providers: None found  
Coverage: SHP-SANFORD H...  
Allergies: No Known Allergies  
CrCl: None

Specialty Comments  
No comments regarding your specialty

Patient  
Callie Katie Bear  
31 year old  
Legal sex: female  
7/21/1989

Recent Visits with You in this Dept  
More...<sup>5</sup>

Consider HIV screening today  
May qualify for SH-PLUDGE Study

Raven, Claudia  
SANFORD HEALTH TRAIN TERRY B. EpicCare

Chart Review Review Flow... Results Allergies History Problems Patient...

Patient Chart Advisories  
Take notice of the following advisories for this patient before you continue.

**WARNING! Please see important patient care note in comments below: Special Patient Care Info**

This patient has pre-symptomatic TYPE 1 DIABETES (Stage 1- multiple T1D auto-antibodies with normal glucose tolerance) NOT yet requiring insulin, and is a participant in the PLEDGE Monitoring study.

PROVIDERS: If acutely ill or T1D symptoms present, consider screening for hyperglycemia & ketosis

Clinical Questions: Follow your clinic's policy for consultation with Pediatric Endocrinology  
Non-Urgent Study Questions: Contact the Sanford diabetes research team: (605) 312- 3309, M-F 0800am-4:30pm.

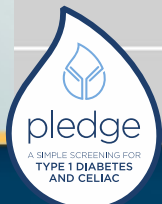
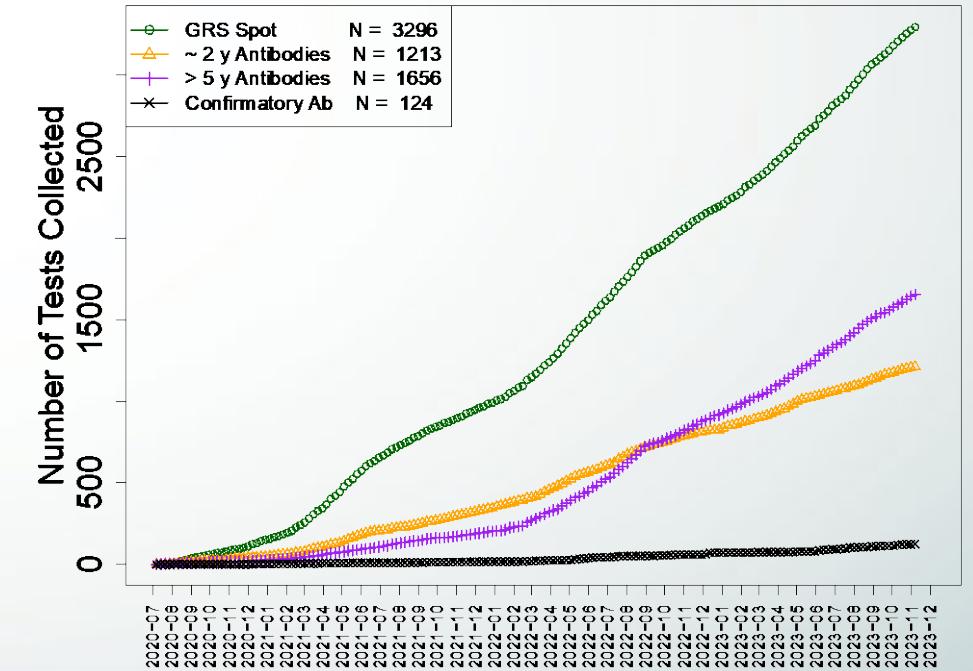
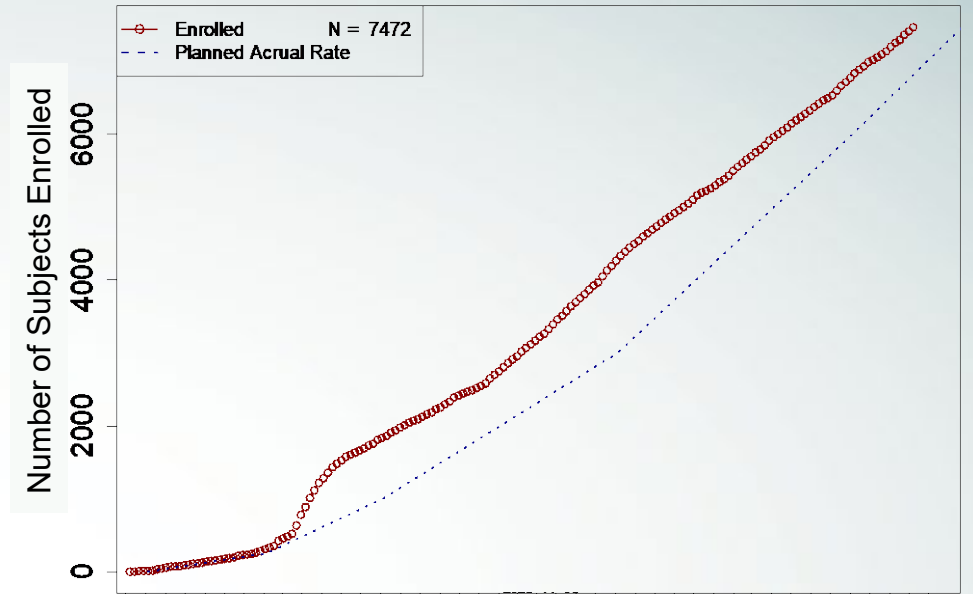
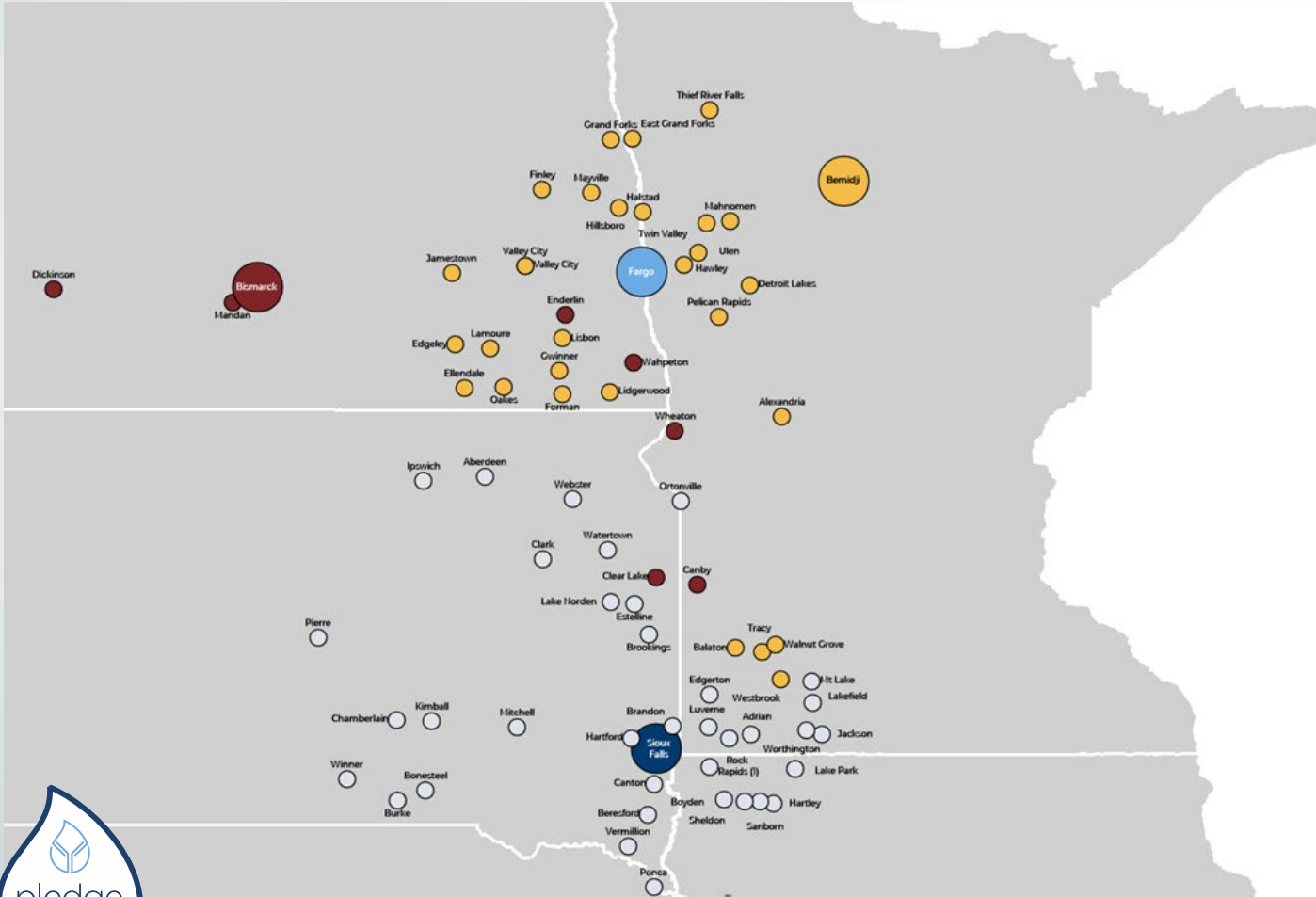
“Patient Chart Advisory”

- Appears on opening chart
- Reminder to consider T1D
- Provides guidance
- Does not slow work
- Less intrusive than BPA

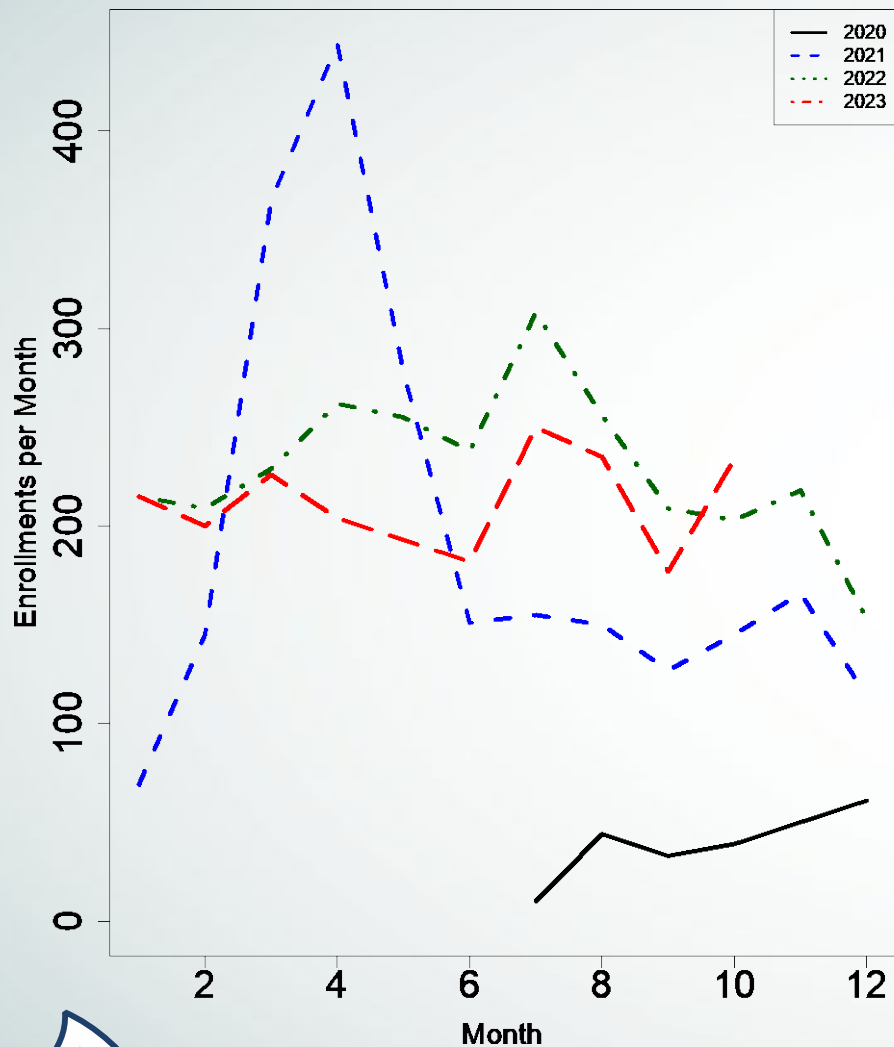
# Expansion and Enrollment

Now Open at every primary care clinic in Sioux Falls and Fargo

Still ahead of planned enrollment and budget



# Expansion and Enrollment



## Race

Caucasian	2344
African American	75
Native American	64
Asian	31
HI/Pacific Island	1

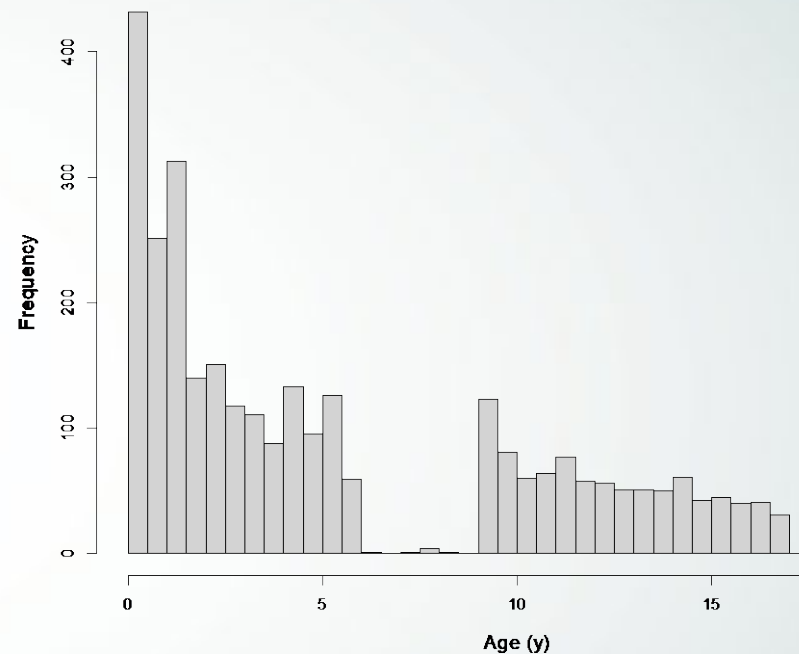
## Ethnicity

Not Hispanic	2390
Hispanic	117
Unknown	22

## Sex

Male	1262
Female	1273

Age at Entry (with collection)



# Screening Results

## Celiac Disease:

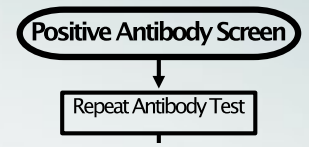
Positive Screens	92
Previously known CD	11
Repeat Testing Pending	3
<b>Persistent positives (to GI)</b>	<b>45</b>

## T1D:

Positive Screens	124
Repeat Testing Pending	2
<b>Persistent positive</b>	<b>36</b>
Single Antibody	25
RBA-only:	6
“High Affinity” RBA & ECL:	11
Multiple Antibodies	11
2 Antibodies	5
3 Antibodies	2
4 Antibodies	4
<b>Clinical Care</b>	<b>3</b>
<b>DKA at Diagnosis</b>	<b>0 ... so far</b>

# PLEDGE Screening

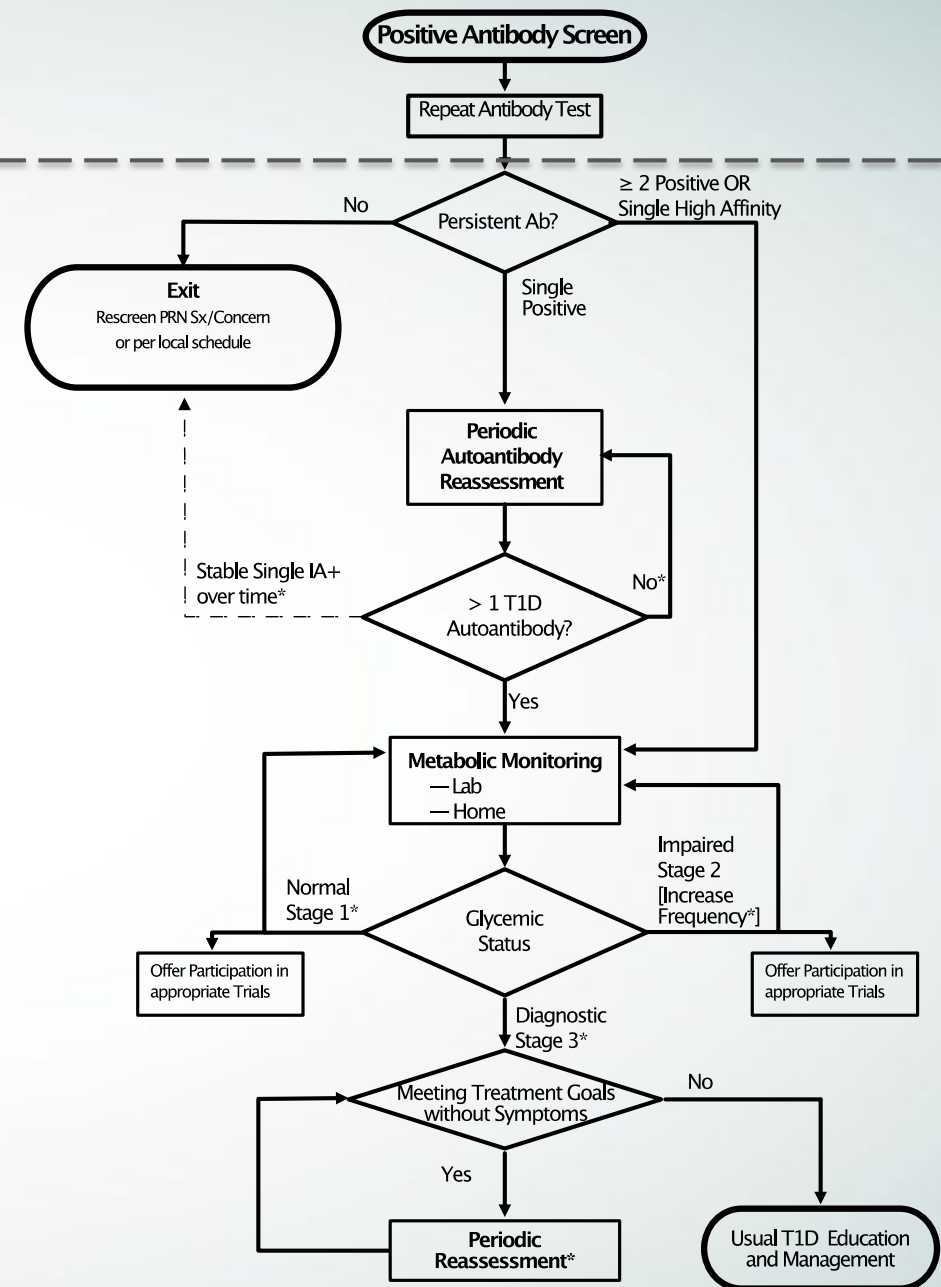
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# PLEDGE Screening

## PLEDGE Monitoring

- Separate Protocol and Consent after confirmation of persistent antibody.
- Tailor extent and frequency to expected risk
- 48 Children in enrolled



# Thank you

All the families who participate

## **The Sanford Project Team**

Ann Mays  
Magdalena Skon  
Lana Baerenwald  
Vanessa Williams  
Mary Berg  
Connie Hoffman  
Staci Schwinger

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Jennifer Richstmeier

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Kristin Little  
Holly McMahon

## **Sanford Health Plan**

Emily Griese

## **Collaborators & Advisors**

Bill Hagopian  
Richard Oram  
Marian Rewers

Faculty Positions Available

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