Coordination of Screening and Early Detection Efforts

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November 15, 2024
7th Annual Diabetes Screening Symposium, Denver

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Our vision for early detection

A future where T1D is identified years before individuals need insulin, integrated into healthcare systems globally, and accompanied by effective preventive therapies.

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Breakthrough T1D is focused on driving early detection forward with three approaches

Research

Building evidence for the feasibility and acceptability of early detection and monitoring in the clinical setting

Enhance screening:
- Quality (PPV, cost, etc.)
- Reach (geography, cost, etc.)
- Populations (adults)

Health Policy

Affordable access to T1D early detection, monitoring, and disease modifying therapies

- USPSTF (data and advocacy)
- Private payers

Clinical Adoption

Health care provider education, clinical guidelines, and implementation science

- Recognized education program
- Clinical workflow, reimbursement and confirmation (BDC)
- Shared decision-making once AAb+

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Implementing Early Detection Recommendations for T1D

The strongest evidence for a T1D recommendation is in children with family history

There is robust evidence supporting early detection of T1D in the general pediatric population, and we continue to build evidence to support broader implementation

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Landscape of AAb Screening

CANScreenT1D Canada

DiaUnion Sweden/Denmark

ELSA UK

BABYDIAB Germany

Fr1DA Germany

INNODIA Europe

National Program Italy

EDENT1FI Europe

Autoimmunity Screening for Kids (ASK) USA

PLEDGE USA

Early Detection Pilot Clinic USA

TrialNet USA, Canada, Europe, Australia

ADIR Israel

AL-DIAR Qatar

DeteKta Costa Rica

Type1Screen Australia

Australian Type 1 Diabetes National Screening Pilot Australia

ENDIA Australia

First Degree Relatives (FDR)

General pediatric population

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We are building a global strategy based on evidence

Adult-onset

Nearly half of newly diagnosed cases of T1D are adult-onset, but we are limited in our understanding of the genetic, immunologic, and metabolic differences. Misdiagnosis with type 2 diabetes is common.

Genetics

Identifying individuals with highest genetic risk of developing T1D, who can be monitored for the presence and progression of autoimmunity. Responder stratification for specific therapies.

More than half of newly diagnosed cases of T1D are adult-onset, but our understanding of it is limited

T1DRA screening program (UK): Analyze prevalence and autoantibody positivity in the adult general population aged 18-70. TrialNet, ASK and the Early Detection Pilots provide valuable data on adult cases in the USA.

Reliance on autoantibody positivity poses limitations, particularly given the slow progression of the disease in adulthood and single autoantibody positivity at disease onset, leading to near **40% of adult-onset T1D cases being misdiagnosed at disease onset**.
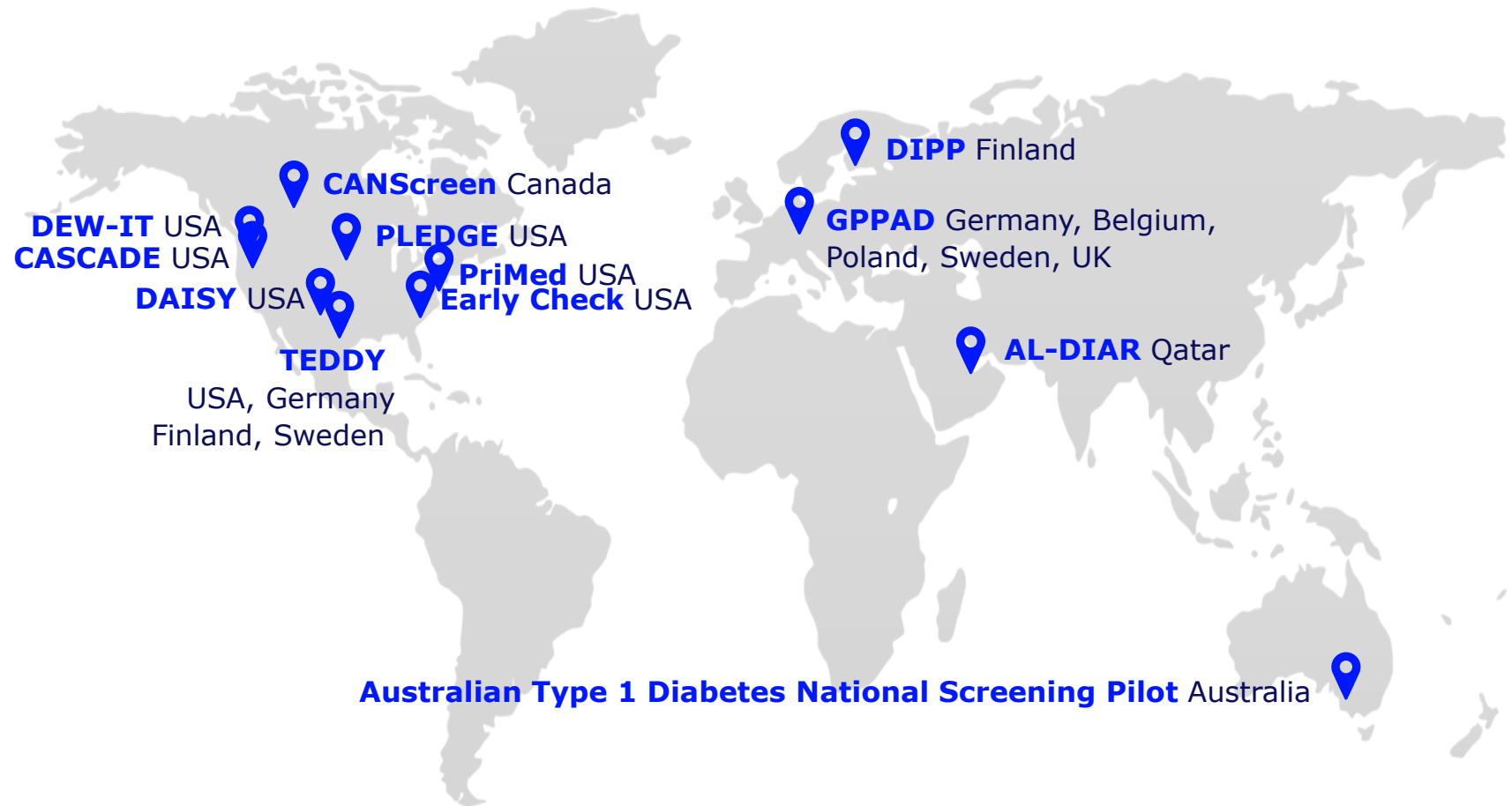
- IQVIA using a **machine learning approach to improve future diagnosis of T1D** so adults can benefit from clinical trials and therapies.

- Underscores potential need for genetic follow-up to enhance our understanding and management of adult-onset T1D.

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Current Landscape on Genetics

Stratifying high-risk individuals based on **HLA haplotypes** and/or **Genetic Risk Scores (GRS),** and monitoring their potential progression to T1D through autoantibody screening.

Genetics is also important to *potentially* identify responders to specific therapies.

Is this approach cost-effective for early detection of T1D?

DIPP Finland

GPPAD Germany, Belgium, Poland, Sweden, UK

CANScreen Canada

DEW-IT USA
CASCADE USA

PLEDGE USA

PriMed USA
Early Check USA

AL-DIAR Qatar

DAISY USA

TEDDY
USA, Germany
Finland, Sweden

Australian Type 1 Diabetes National Screening Pilot Australia

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Monitoring consensus guidance – What's Next?

- This is a **landmark publication** and was published in Diabetes Care and Diabetologia in June 2024.

- Breakthrough T1D seeks to implement recommendations from the consensus monitoring guidance, including alternatives for confirmatory testing in clinical practice.

- Need for coordination and analyses of all data sets to establish and iteratively enhance best practices.

- **SCREENING CONSENSUS GUIDANCE: Under Construction!**

Volume 63 | Number 6 | June 2020

Diabetologia
Journal of the European Association for the Study of Diabetes (EASD)

Springer

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Relevant monitoring approaches and identified gaps

- CGM data, when combined with individual characteristics, can **predict who will move from Stage 2 to Stage 3 earlier**

- RFA "Glycemic and Beta Cell Monitoring in Individuals at Risk of Type 1 Diabetes"

- Broader harmonization/standardization program is needed for current and emerging CGM devices to be implemented in early stages of T1D.

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Summary

Early detection and monitoring to:

√ **Reduce or eliminate DKA** at Stage 3 clinical diagnosis

√ **Accelerate clinical trial recruitment** and drug development

√ **Delay insulin dependence** through approved disease-modifying therapy

We are at a pivotal moment where greater coordination will supercharge our progress towards implementation of what we know now, and building the evidence for future early detection strategies

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