Scandinavian (Nordic) programs

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Medicon Valley Alliance

Region Hovedstaden

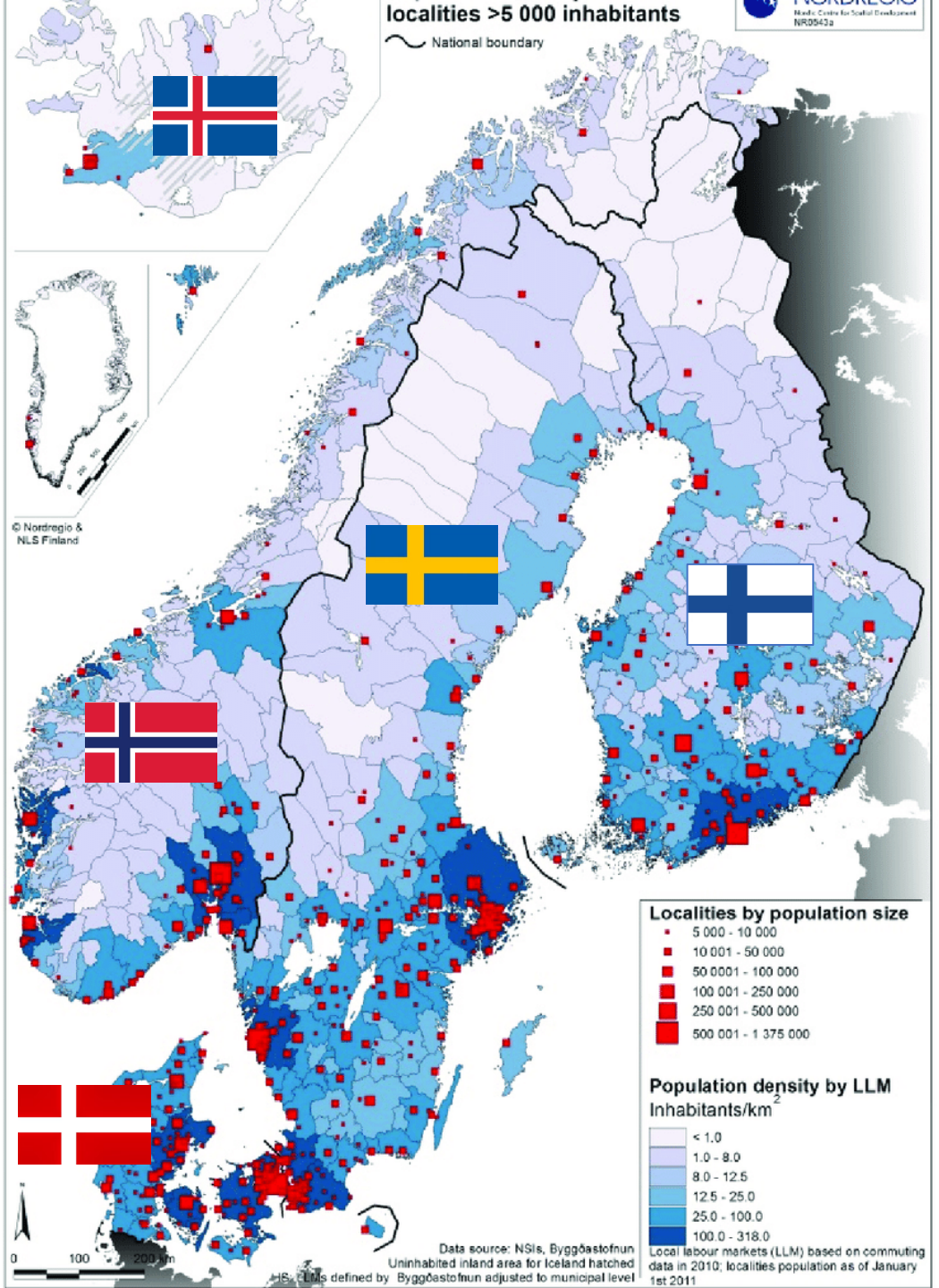
Region Skåne

Conflicts of interest

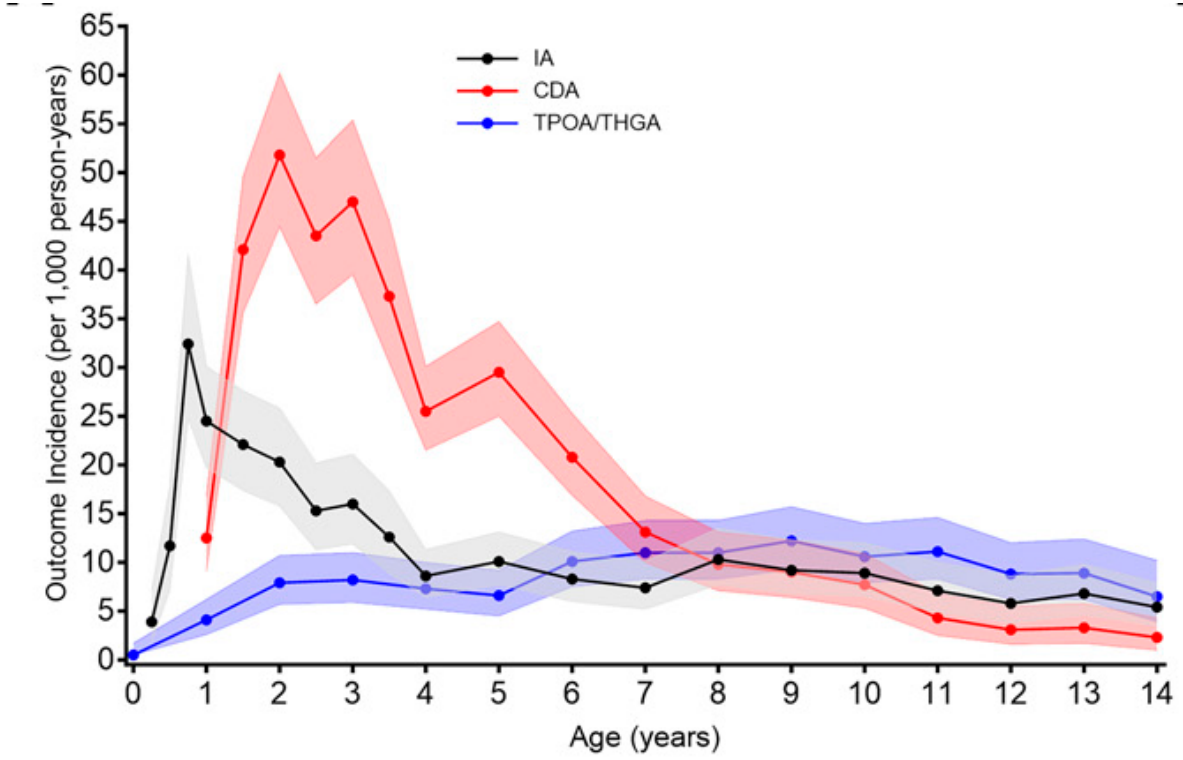
- Co-inventor of patent with Probi AB, Sweden
- Principal Investigator DiaUnion supported by Sanofi
- Scientific Advisory Board for Allero Therapeutics and Sanofi

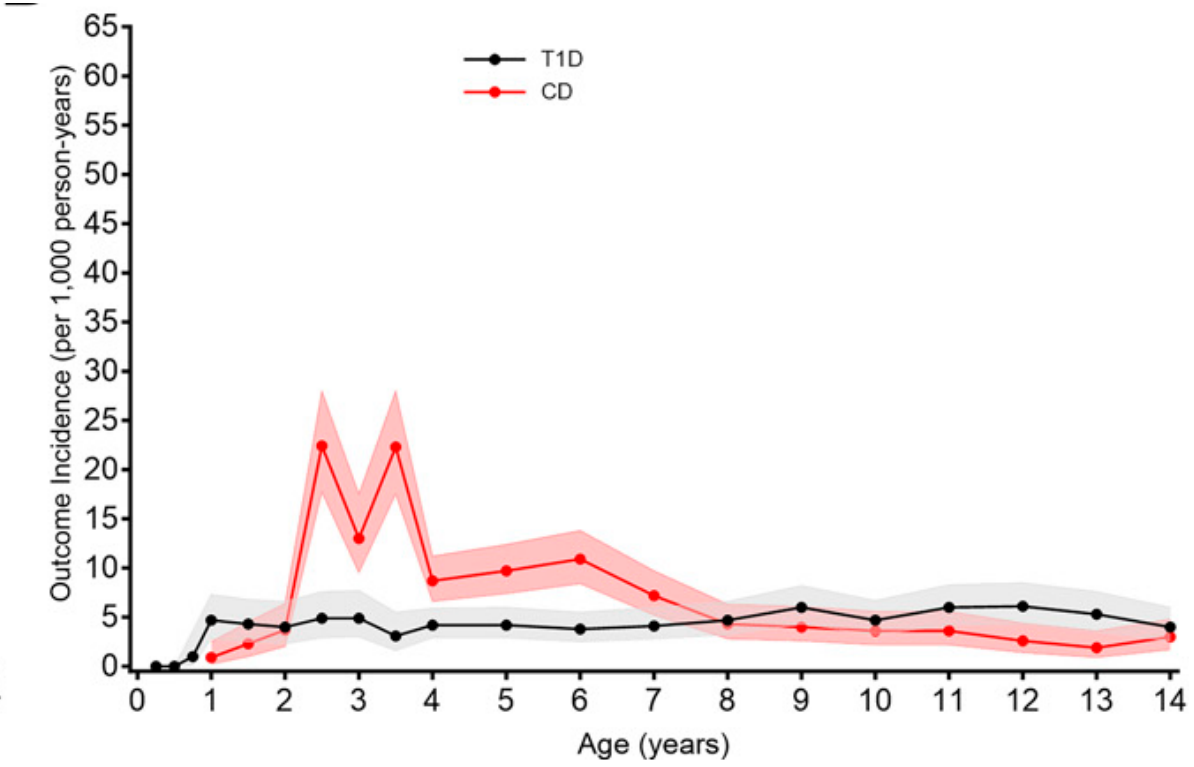
Scandinavia

- Scandinavia (Sweden, Denmark, Norway) has a total population of 22 million people
- **Total population (Nordic region) 28–29 million people** including Finland + Iceland
- Similar health care systems:
  - Public available
  - Majority of health care sector is governmental
  - Politics and taxpayers decide
- Health equality is high
- Nationwide patient registries
- Similar screening policies (but not for T1D)



TEDDY followed >7000 HLA-risk children to age 15 years between 2004 and 2025





Rewers et al. Diabetes Care, 2025.

TEDDY
The Environmental Determinants of Diabetes in the Young


DIPP
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Sweden screens general population age 2-14 years

Denmark screens first-degree relatives with T1D

Started 2020 in Malmö (Sweden) & in Copenhagen (Denmark)

Aim: Early detection of T1D, celiac disease & autoimmune thyroiditis

Vision: Nation-wide screening in both countries

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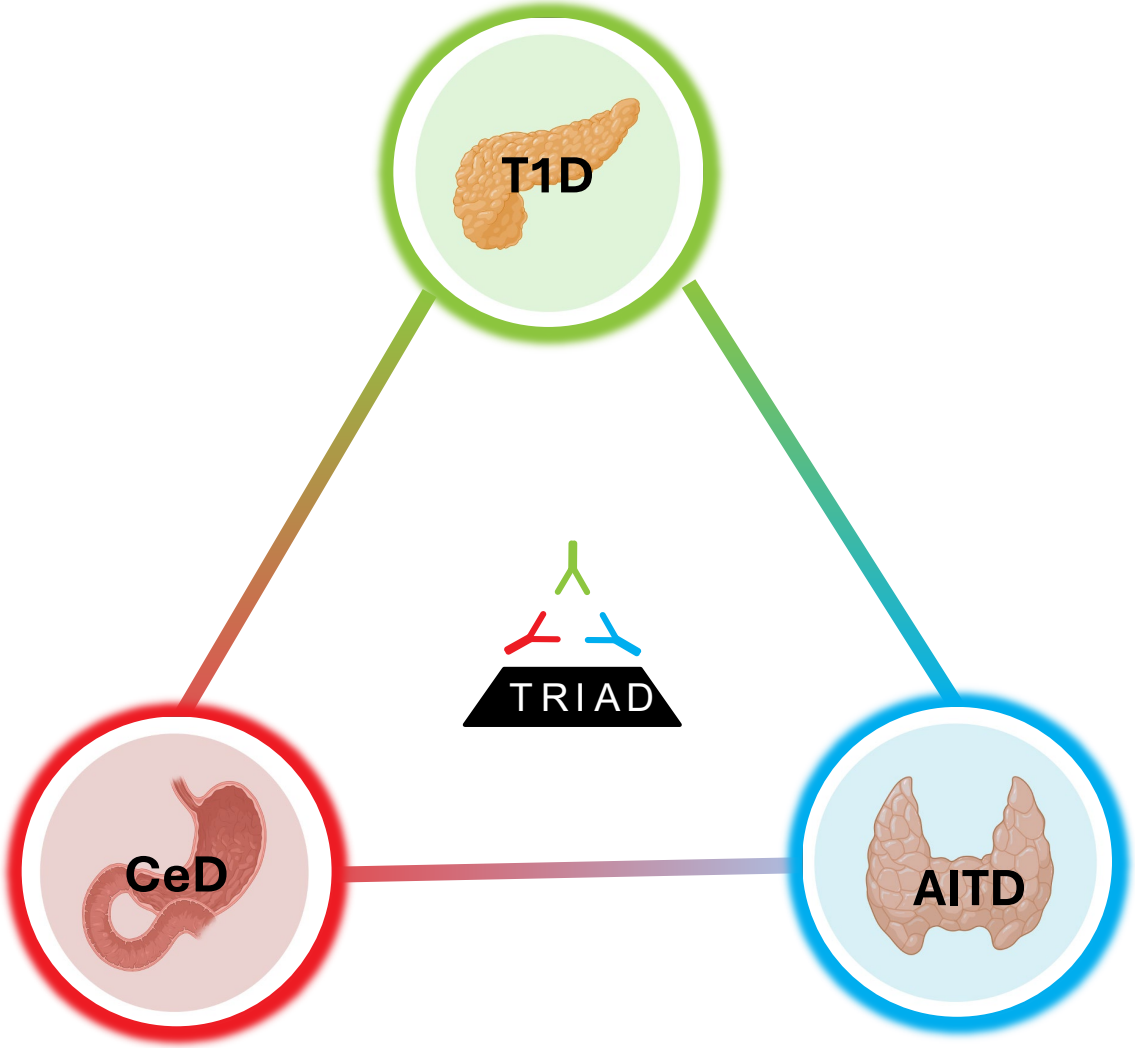
Screens for three diseases (TRIAD)



From pilot to full scale screening

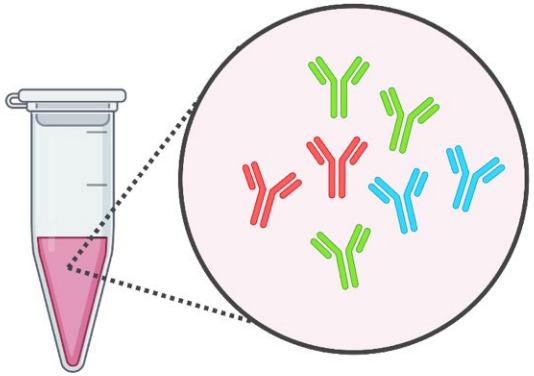
>60.000 invited

>10.000 accepted screening

>6.000 screened

Screening procedure

1. Invitation
2. Home capillary sampling
3. Antibody analysis
4. Follow-up

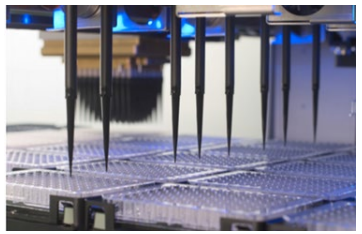


- **T1D**: IAA, GADA, IA-2A, ZnT8A
- **CD**: tTGA (IgA and IgG)
- **AITD**: TPOA

Screening assays

1. ADAP screening assay

- Mutiplex analysis for up to 8 autoantibodies
- 1-day assay
- Automated analysis (Hamilton robot)
- Sample volume is 4 ul
- Shelf-life DNA-conjugated antigens is 1 year



2. RBA confirmation assay

- Single plex analysis for each autoantibody
- 2-day assay, overnight incubation
- Includes radioactive tracers
- Sample volume for 6 autoantibodies is 68 ul
- Shelf-life for radiolabelled antigens is 28 days

Lind A, et al. EBioMedicine. 2024 Jun;104:105144.

”Rule of 2”

2 positive samples in 2 different assays

Sample 1

Sample 2

Screening: **ADAP** for 6 aab

- **T1D**: IAA, GADA, IA-2A, ZnT8A
- **CD**: tTGA (IgA and IgG)
- **AITD**: TPOA

Confirmation : **RBA** for positive aab (not TPOA)

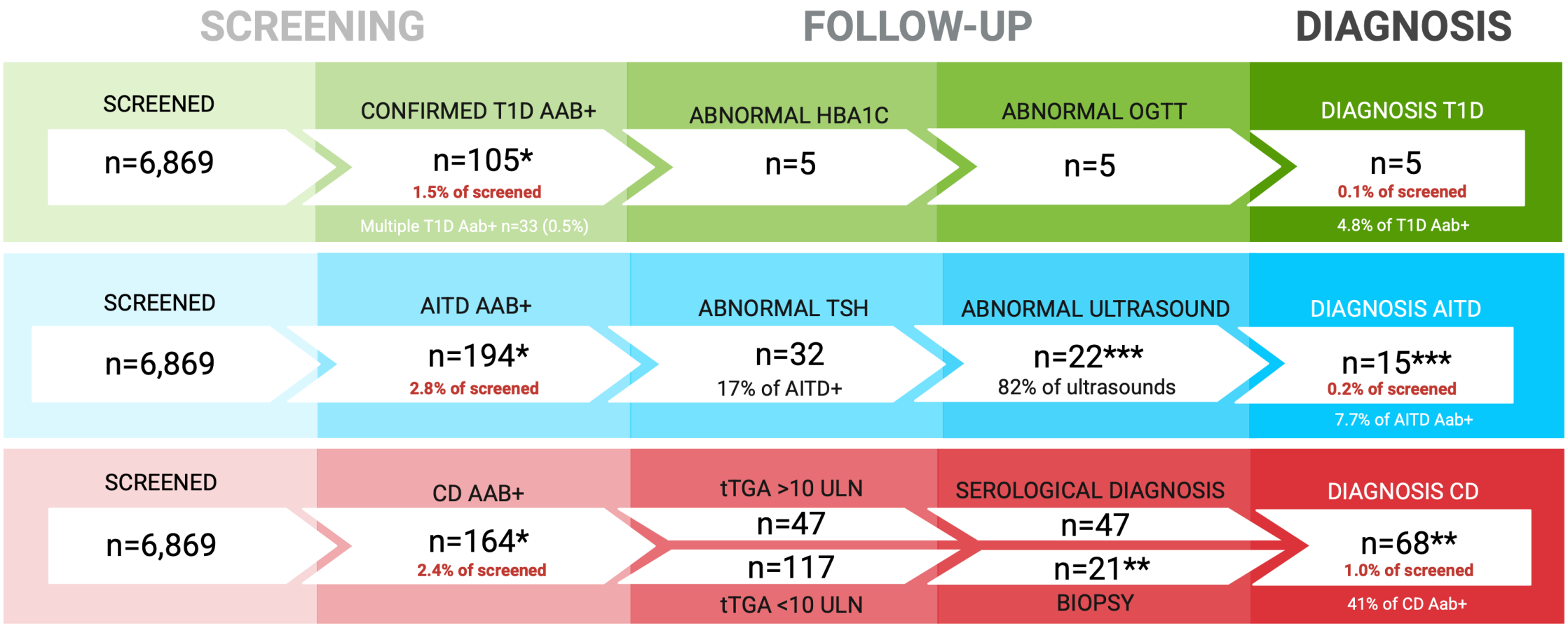
Follow-up

OGTT, HbA1c, Endoscopy, ultrasound

TRIAD study – Overview

Study	Age (years)	Screened (N)	Sampling	Methods
TRIAD 2021	**6-9 & 13-15**	**2,271**	**Home capillary**	**RBA first ADAP tested**
TRIAD 2023	**6-9 & 13-15**	**1,929**	**Home capillary**	**ADAP+RBA first RBA confirm**
TRIAD Sibling	**2-14**	**81**	**Home DBS**	**ADAP first RBA confirm**
TRIAD 2024	**2-14**	***>3000 (ongoing)***	**Home capillary**	**ADAP first RBA confirm**

What have we found so far?



**Preliminary results: 53 more T1D Aab+, 43 more CD Aab+, and 29 more AITD Aab+ waiting for analysis of confirmatory sample. **6 more children referred for endoscopy. ***4 more children referred for ultrasound.*

Family perspectives

- **Concern:** Highest among mothers, foreign-born individuals, and first-degree relatives.
- **Risk perception:** More accurate among those with higher education and among families with a history of the disease.
- **Satisfaction:** 70% were very satisfied with their participation.
- **Key point:** Clear communication and follow-up reduce anxiety.

Melin, M.J. Lund University (2023)

Education, staging and follow-up of islet antibody positive children

Follow-up of T1D Aab+ children in iT1D (”in Time”)

Genetically at risk	**Screening at Age 2, 6 and 10 years**	**Autoantibodies, HbA1c, Activity metrics, education, questionnaires**
Single IA positive	**Yearly**	**Autoantibodies, HbA1c, Activity metrics, education, questionnaires**
Multiple IA positive Stage 1 - 2	**Every 3 months**	**Autoantibodies, HbA1c, Activity metrics, education, questionnaires, OGTT, CGM**
Stage 3	**Annually for 5 yrs post-diagnosis**	**MMTT, CGM, HbA1c questionnaires**

The Diabetes Prediction and Prevention (DIPP) Study

- Ongoing since 1996 at 3 university hospitals (Turku, Helsinki, Oulu)
- >250,000 screened with HLA genotyping followed by RBA: IAA, GADA, IA-2A, ZnT8A
- Age 0.25–15 years with high-risk HLA genotypes
- All newborns with parental consent (~25% of birth cohort) receive cord blood HLA screening
- HLA-risk infants have agreed to follow-up AA screening at 3-12 month-intervals up to age 15 years
- % HLA-risk children with ≥2 AA+: 2.2% by 2 years; 3.5% by 5 years; 5.0% by 15 years.

DIPP TUTKIMUS

Finnish Type 1 Diabetes Autoantibody Screening Study (FINT1DAS)

Objective:

•Identify children at increased risk for type 1 diabetes (T1D) via autoantibody screening.

•Study early immunological and environmental risk factors.

Design:

•Population-based, prospective screening in **Oulu** & **Turku**, Finland.

•Target children aged **2 or 6 years**.

•Test for **T1D-associated autoantibodies** (GAD65, IA-2, insulin).

•Positive children receive longitudinal follow-up.

Started: Early 2025

FINT1DAS

Summary

Increasing number of sites are screening the general population for T1D in Scandinavia (Nordic countries).

Some screening programs also include other autoimmune diseases (celiac disease, autoimmune thyroiditis).

Education, staging and follow-up pave the way for prevention studies and clinical trials.