

A satellite night view of Europe, showing the continent illuminated by city lights against a dark background. The lights are concentrated in major urban centers and along coastlines, with a gradient from dark blue in the north to light blue in the south.

Scandinavian programs

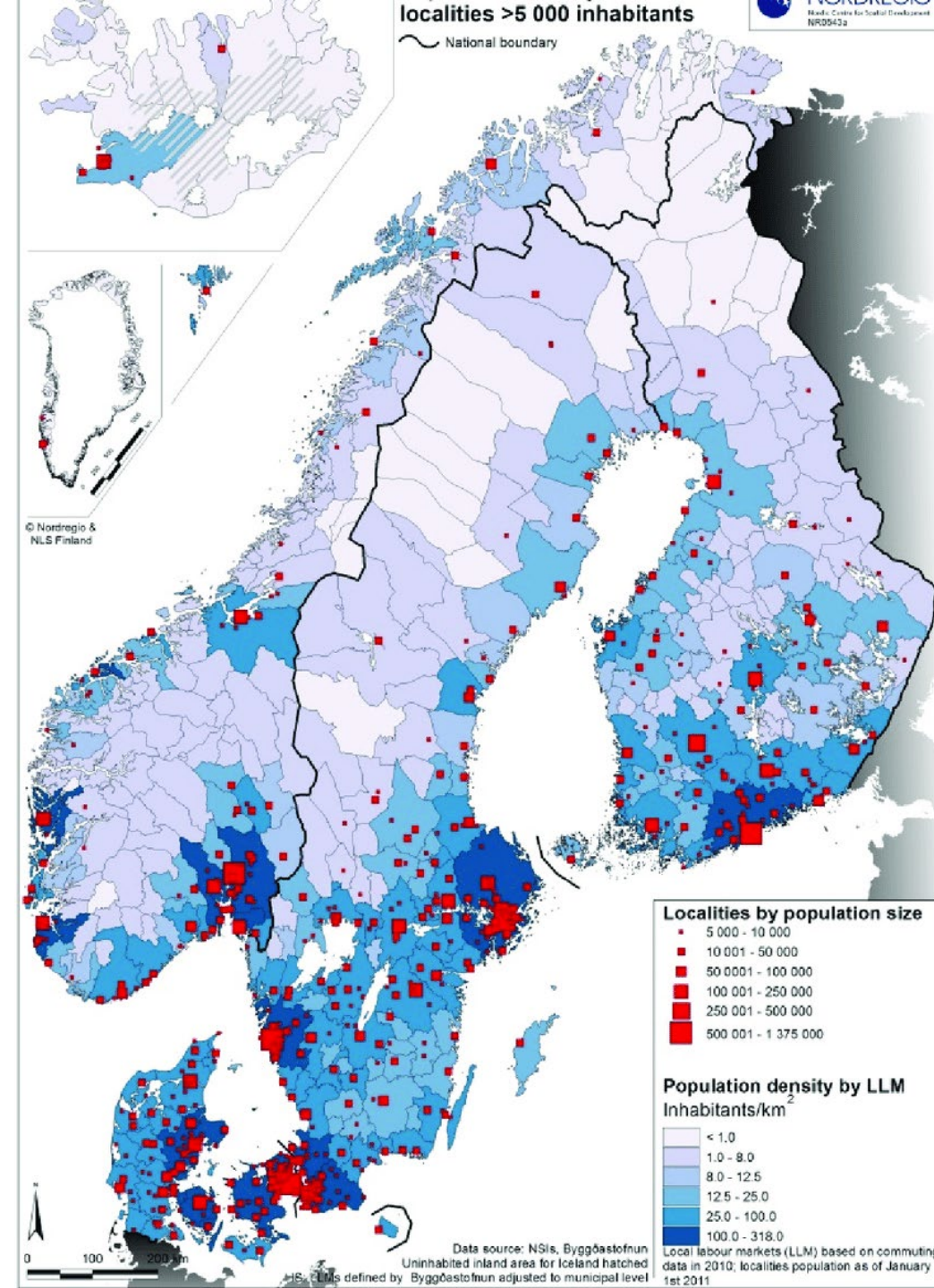
- Daniel Agardh, MD, PhD
- DiaUnion
- Lund University
- SWEDEN

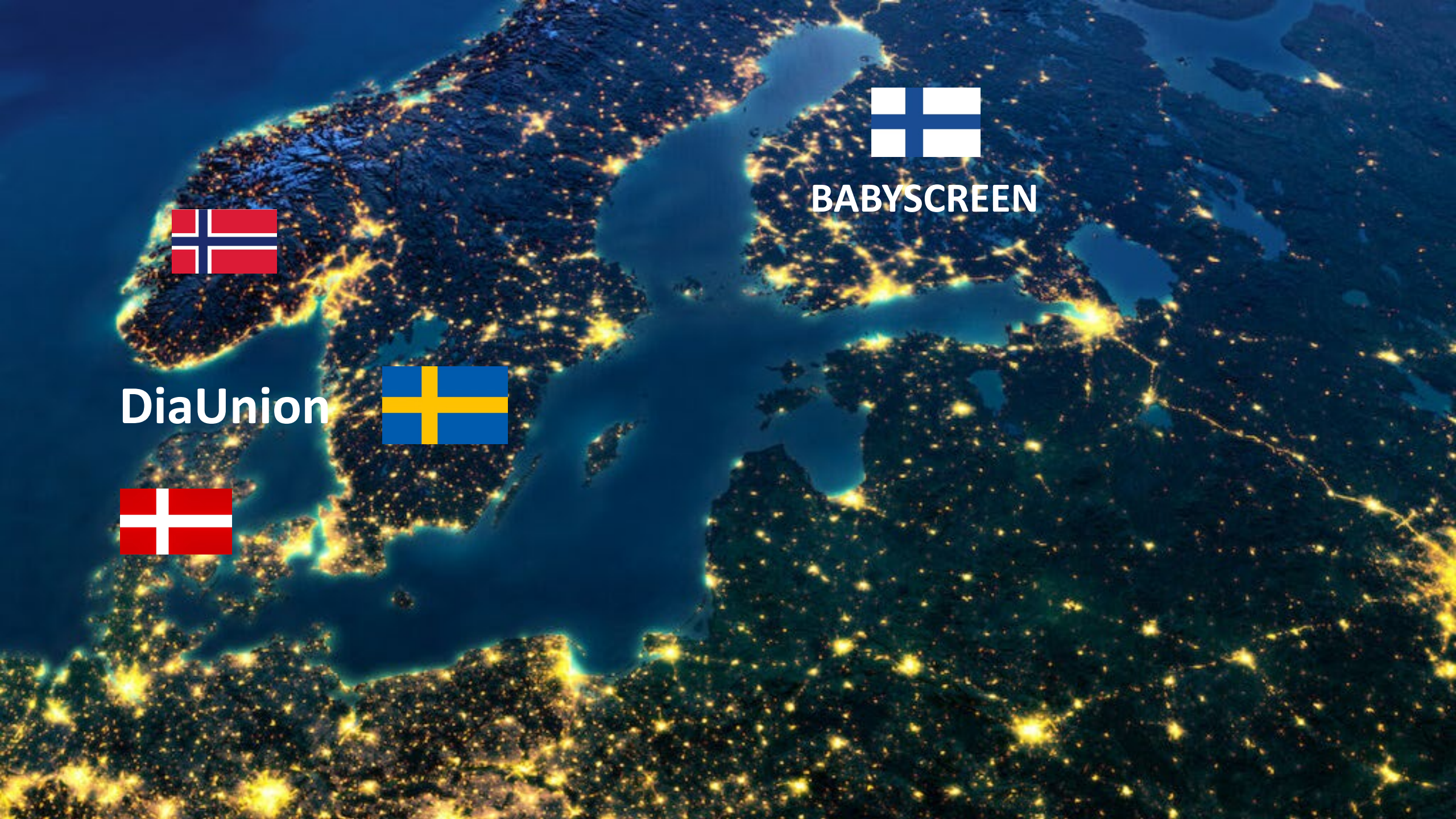
Conflicts of interest

- 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
- 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)





DiaUnion



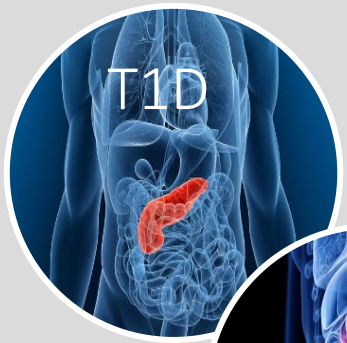
BABYSCREEN



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Steno Diabetes Center
Copenhagen



- **DiaUnion** started in 2020 and screens for Type 1 Diabetes (T1D), Celiac Disease (CD), Autoimmune Thyroid Disease (AITD) (i.e. TRIAD)
- **Steno Diabetes Center** in Denmark screens family members to T1D patients age <40 years
- **Lund University** in Sweden screens children from the general population age 2-14 years

1. ADAP screening assay

- Multiplex 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





Screened 4,000 children



In DiaUnion 1.0, performed during the pandemic in 2021-2022, radiobinding assays (RBA) was used as the first-line screening assay and evaluated antibody detection by agglutination-PCR (ADAP) as alternative multiplex method

In DiaUnion 1.5, performed after the pandemic in 2023-2024, **ADAP** was used as the screening assay and **RBA** as confirmation assay

DiaUnion 2.0, starts 2024 with the goal to screen 45,000 individuals over 5 years



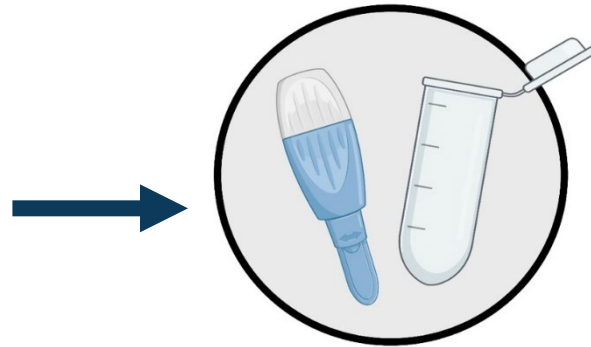
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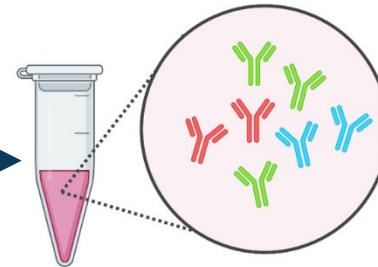
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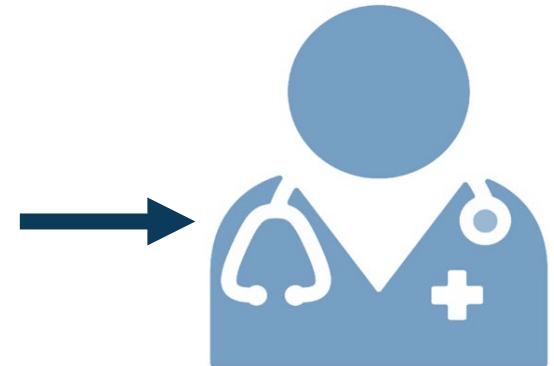
- **DiaUnion 1.0** invited 19,593 children born 2013/2014 (6-9 years) and 2006/2007 (13-16 years)
- **DiaUnion 1.5** invited 13,364 children born 2015/2016 (6-9 years) and 2008/2009 (13-14 years)



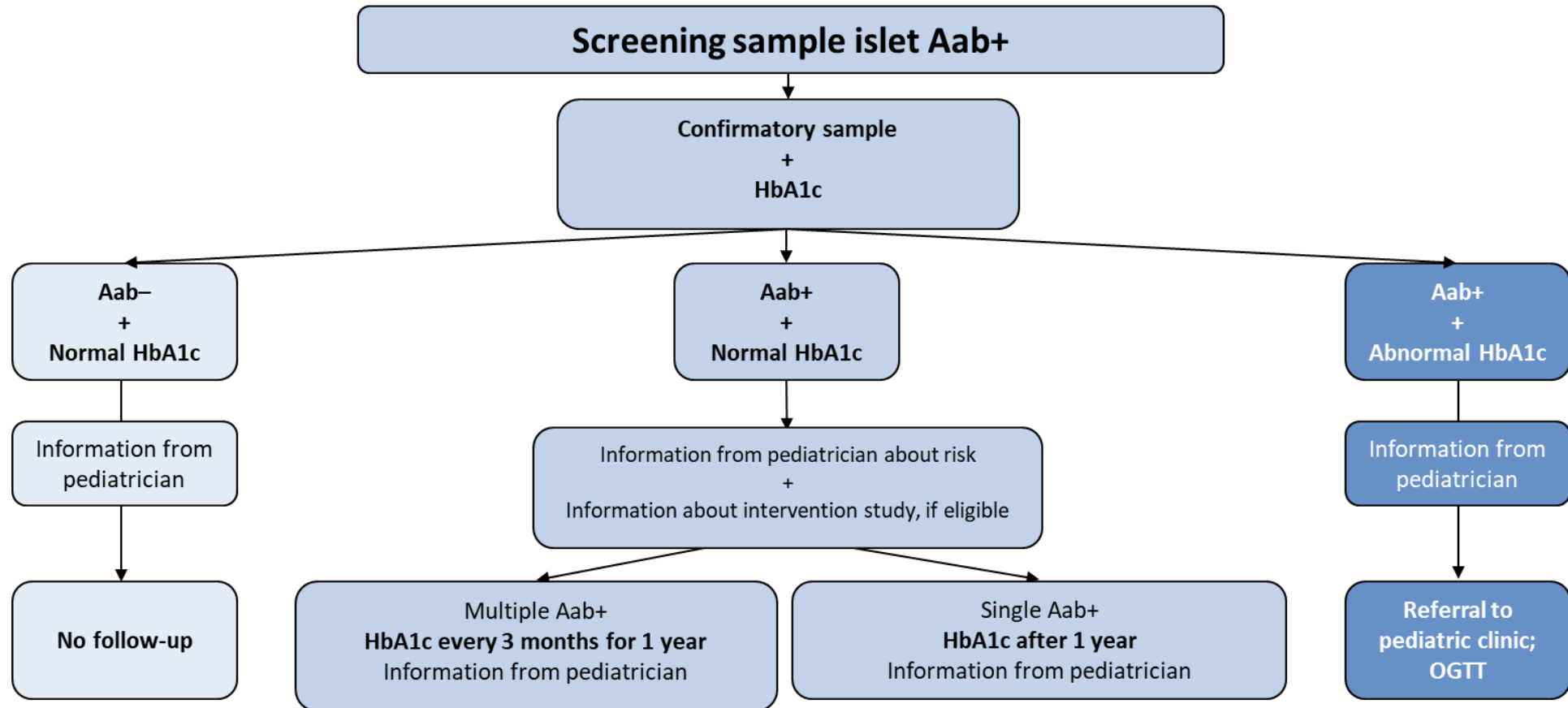
- Home capillary testing (250 uL) sent to CRC laboratory for analysis



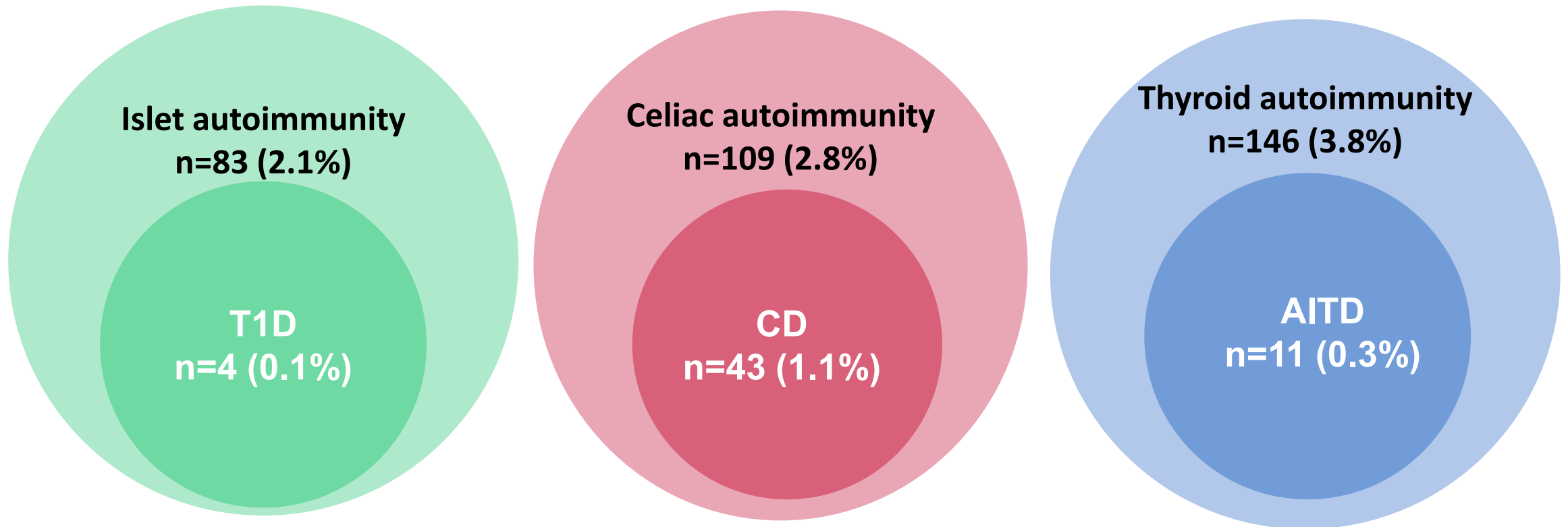
- **T1D** (IAA, GADA, IA-2A, ZnT8A)
- **CD** (IgA-tTG, IgG-tTG)
- **AITD** (TPOA; TGA only in DiaUnion 1.0)



- Autoantibody positive children
- Second sample collected:
- Re-analysed for Aab+
- **HbA1c/tTGA/TSH**
- Referral to pediatrician for:
- **OGTT/Endoscopy/Ultrasound**

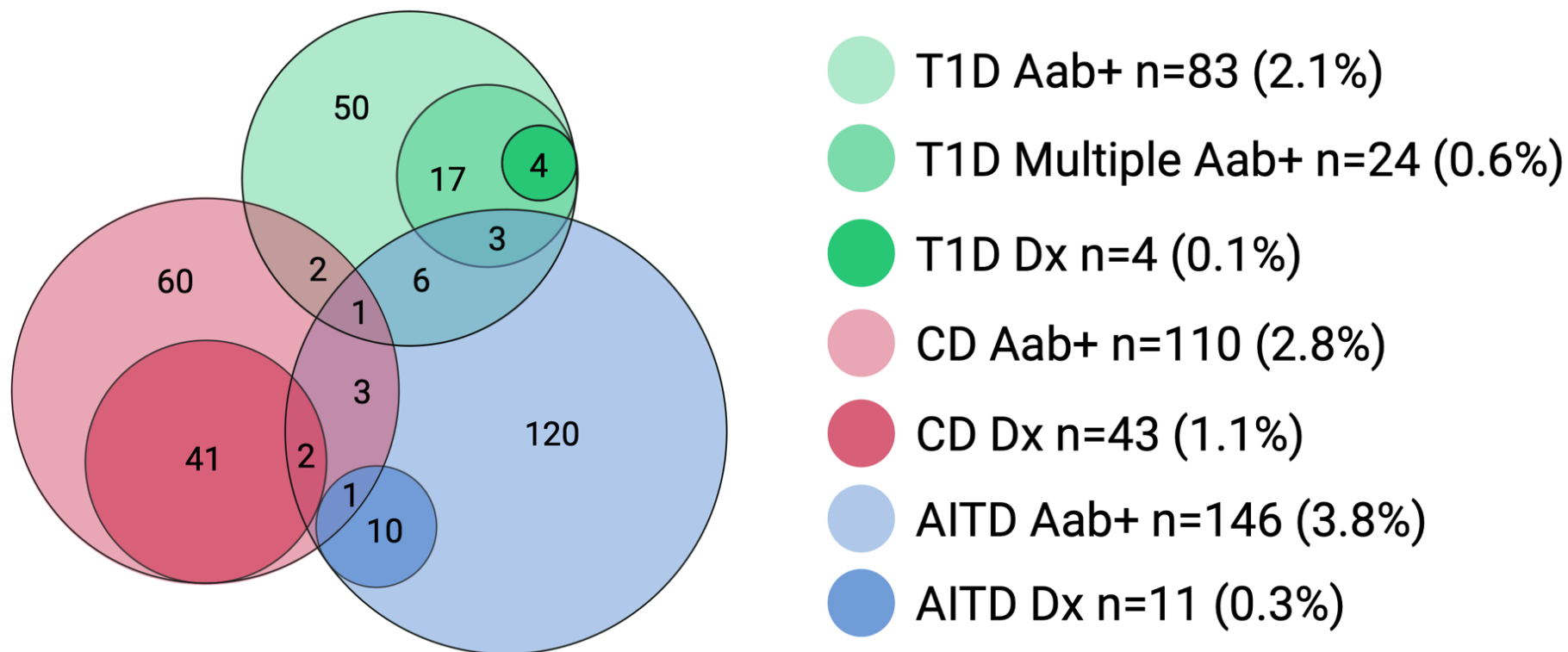


320/3,877 (8.3%) screened positive of whom 58/3,877 (1.5%) were diagnosed with a disease*:

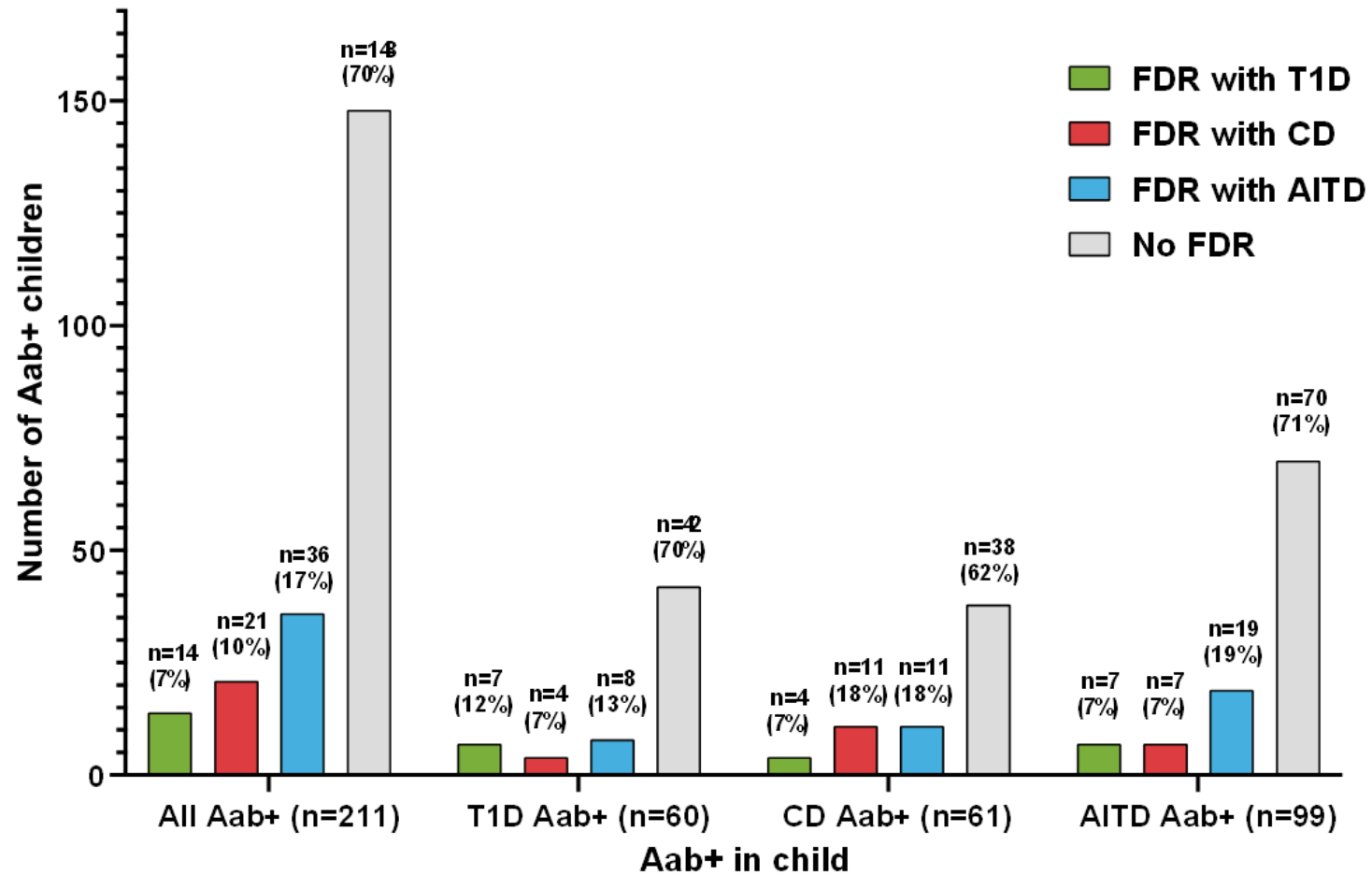


**Seven participants are still under investigation for CD (n=3), or AITD (n=4)*

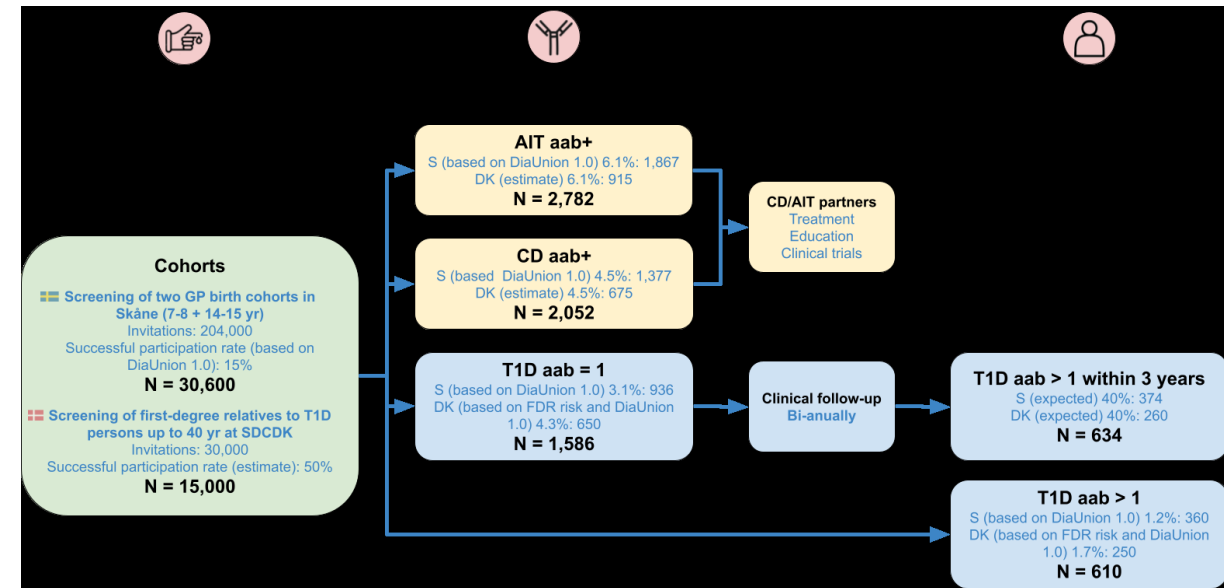
Occurrence of autoimmunity and screening-detected diagnosis among 3,875 screened



Seven participants are still under investigation for CD (n=3), or AITD (n=4)



- Goal is to screen 45,000 individuals over the next 5 years
- Involve all Steno Diabetes Centers in Denmark
- Lund University will expand screening to age 2-14 years
- Örebro University (Sweden) and University of Oslo (Norway) will be new sites of DiaUnion and start screening in 2025



Type 1 Diabetes and Celiac Disease and Prospective Follow-up Study (BABYSCREEN)

Genetic screening of infants for T1D/CD HLA-risk genotypes: 9,781 of 31,200 (31%) have been screened

Identified 1618 risk infants (16.5% tested for autoantibodies at the age of 1, 2 and 3 years)

26 of 677 (3.9%) with HLA-T1D-risk had multiple islet autoantibodies

42 of 1214 (3.9%) with HLA-CD-risk had tTGA (RBA) and 15/42 (35.7%) Ema+

By age 3 years:

23 of 677 (3.4%) children diagnosed with T1D

16 of 1214 (1.3%) diagnosed with CD

<https://www.helsinki.fi/en/researchgroups/babyscreen>



Thank you!

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