

The ISEC

(Islet autoantibody **S**creening and referral **E**cosystem **C**ompendium)

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Introduction and Scope

The Islet autoantibody Screening and referral Ecosystem Compendium (ISEC) is intended as a tool to support healthcare practitioners in establishing screening programs in their countries. Successful early detection of type 1 diabetes (T1D) requires the implementation of care pathways to access confirmatory testing, as well monitoring and ongoing specialist support.

The ISEC is intended as a living document compiling available and potential care pathways that may be accessed when initiating a screening program. This has been developed by Sanofi based on research into existing screening programs and early-detection initiatives but is by no means exhaustive.

Please note that the information in this document is current as of 14th of August 2026.

If there are pathways currently not covered by this document in your country, we would be grateful if you could contact your local Sanofi representative with the relevant details so this document can be updated.

Intended Use

The ISEC aggregates relevant information by country, highlighting existing pathways to access confirmatory testing, and referral pathways for subsequent monitoring.

To explore this document, please use the table of contents to find your country page.

- The information provided in this document is intended as a reference guide only, to illustrate how care pathways following screening have been implemented around the world

If there are available pathways in your country that have not been included in the ISEC, then please contact your local Sanofi representative and this will be updated accordingly

Countries

Introduction and scope



Intended use



Global T1D Early Detection
Policy Momentum



Argentina



Australia



Belgium



Canada



China



Czech
Republic



Denmark



Finland



France



Germany



Gulf Countries
(KSA, UAE, and others)



Israel



Italy



Japan



Netherlands



Norway



Poland



Portugal



Russia



Spain



Sweden



UK



USA

Global T1D Early Detection Policy Momentum

Momentum for T1D early detection is accelerating across countries, driven by parliamentary engagement, calls to action and white papers, and the formalization of T1D multi-stakeholder alliances.



GLOBAL

[IDF-ISPAD Policy Brief: “Detect early, act early: Improving diagnosis of type 1 diabetes”](#) (Feb 2026)



US

[18 State-Level Legislative Developments on T1D Educational Laws](#)
[Cost of not Knowing Survey](#) (Jun 2024)



NORTH EUROPE

Country Multi-stakeholder Alliances for Early Detection of T1D
DK: [DiaUnion & MEP Stine Bosse Call to Action on T1D Early Detection](#) (Feb 2026)



UK

[MP Question to UK Prime Minister](#) (Jun 2025)
[Breakthrough T1D UK White Paper on T1D Early Detection](#) (Oct 2025)
[Parliamentary Debate on Lyla’s Law and T1D Early Detection](#) (Mar 2026)



GERMANY

[FRIDA Position Paper](#) (Jan 2025)
[VFA Position Paper: Prevention as an investment in health](#) (Jul 2025)



FRANCE

[French Experts SFD, SFEDP, AJD Position Paper](#) (Dec 2024)
[French Medical Biologists Call to Action](#) (Nov 2025)



ITALY

[National Law on T1D Screening](#) (Sep 2023)
[Diabetes Vision of ScrEening \(DIVE\) White Paper](#) (Sep 2024)
[Multistakeholder Booklet on emerging T1D treatments](#) (Feb 2026)



SPAIN

[Creceer sin Diabetes Platform & White Paper on T1D Screening](#) (Jul 2025)
[SESIDA & Observatory of Health Outcomes in Autoimmune T1D Position Paper with Recommendations to advance T1D screening implementation](#) (Feb 2026)



EUROPEAN UNION

[White Paper: Presidency of the Council of the European Union 2025. Healthcare Policy Recommendations](#) (Feb 2025)
[EU Parliament Event on T1D Early Detection](#) organized by EUDF, EDENTIFI, and the Danish Presidency of the Council of European Union (Nov 2025)
[EUDF x EDENTIFI Call to Action on T1D Early Detection & Euractiv Op-ed](#) (Nov 2025)
[MEP Question to the EU Commission on Teplizumab](#) (Nov 2025)
[MEP Questions to the EU Commission on EU Strategy for T1D Early Detection](#) (Dec 2025) and [answer from the EU Commission](#)
[IDF-Europe Policy Paper: Int. Consensus on screening and monitoring early-state T1D: A roadmap for European Implementation](#) (Mar 2026)



AUSTRALIA

[Cost of not Knowing Survey and Parliamentarian launch event](#) (Nov 2025)

Note: To access the links to policy information, please download the ISEC



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

Argentinian Guidelines on screening, monitoring, and management of population at high risk of type 1 diabetes (T1D) were released in October 2025, and provide guidance on the standard screening and monitoring processes (based on ISPAD guidelines).¹

1 SCREENING

LOCATION

Diabetologist and Endocrinologist in their clinical practices offer IAb screening, or refer to another lab

LOGISTICS

Venous: clinical practice/testing lab

RESULTS COMMUNICATION & NEXT STEPS

HCP who requested the test (Diabetologist) follows results and talks with patient/caregivers

COST TO INDIVIDUAL/CAREGIVER

Test reimbursed for some prepay/ social works (except for ZnT8A – not widely reimbursed); some healthcare providers grant full coverage; others include only some IAbs (not all four)

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Normally, the HCP who requested first testing	NA
METHODOLOGY (assay & sample type)	Thought leaders and HCPs are aware of the confirmatory testing needed, if the patient could pay (out of pocket) or have access, HCP suggest other methodology. In some cases, the confirmatory is the same test (ELISA only in some cities)	ELISA
TESTING LAB	To be defined; confirmatory tests could be performed at private centers or CoEs	ELISA: laboratory with multiplex panel.
GUIDELINES FOLLOWED	SAD 2025 ¹	SAD 2025 ¹
COST TO INDIVIDUAL/CAREGIVER	Depends on access to prepaid/out of pocket	Depends on local HCP

3 MONITORING

LOCATION

The HCP who requested IAb testing

PREFERRED METHODOLOGY

Depends on HCP preference (OGTT or CGM)

GUIDELINES FOLLOWED

SAD 2025¹

COST TO INDIVIDUAL/CAREGIVER

Not yet determined

SINGLE IAB MONITORED?

No

Disclaimer: Please note the information in this document is current as of 14 August 2026.
CGM, continuous glucose monitoring; CoE, Center of Excellence; ELISA, enzyme-linked immunosorbent assay; HCP, healthcare practitioner; IAb, islet autoantibody; ISPAD, International Society for Pediatric and Adolescent Diabetes; NA, information not available; OGTT, oral glucose tolerance test; SAD, Sociedad Argentina de Diabetes; ZnT8A, zinc transporter 8 autoantibody.
1. Trifone L, et al. Revista de la Sociedad Argentina de Diabetes. 2025;59:176–92.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

PILOT
SCREENING

Pilot screening programs focused on screening first-degree relatives of people with type 1 diabetes (T1D) and, potentially, people with other autoimmune diseases are being developed. 2026: DBS Pilot with ADAP methodology (in 4 centers), 3 medical contributions (SAD Screening Project, SAEM Screening Project, Cordoba City Screening Project)

1 SCREENING

LOCATION

4 cities in Argentina (La Plata, Mar del Plata, Corrientes, Rosario)

LOGISTICS

DBS Pilot in 4 centers (April–July 2026): Enable as vendor

RESULTS COMMUNICATION &
NEXT STEPS

Treating HCP participating in the pilot screening program

COST TO INDIVIDUAL/CAREGIVER

Sponsored by Sanofi

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Champion of Pilot DBS or medical contribution	Champion of Pilot DBS or medical contribution
METHODOLOGY (assay & sample type)	ELISA in Cordoba contribution, RBA in SAD–SAEM contribution, ADAP in Pilot DBS	ELISA
TESTING LAB	ELISA: laboratory with multiplex panel. RBA: Biochemist Department in National University (UBA)	ELISA: laboratory with multiplex panel
GUIDELINES FOLLOWED	SAD 2025 ¹	SAD 2025 ¹
COST TO INDIVIDUAL/CAREGIVER	Free, with Sanofi financial support if the patient was included in DBS Pilot or local medical contribution	Depends access to prepaid/out of pocket.

3 MONITORING

LOCATION

HCP who prescribed IAb testing (Endocrinologist or Diabetologist)

PREFERRED METHODOLOGY

Depends on HCP criteria (OGTT or CGM)

GUIDELINES FOLLOWED

SAD 2025¹

COST TO INDIVIDUAL/CAREGIVER

Depends access to prepaid/out of pocket

SINGLE IAB MONITORED?

No

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ADAP, antibody detection by agglutination–PCR; DBS, dried blood spot; ELISA, enzyme–linked immunosorbent assay; HCP, healthcare practitioner; IAb, islet autoantibody; OGTT, oral glucose tolerance test; PCR, polymerase chain reaction; RBA, radio–binding assay; SAD, Sociedad Argentina de Diabetes; SAEM, Sociedad Argentina de Endocrinología y Metabolismo; T1D, type 1 diabetes.

1. Trifone L, et al. Revista de la Sociedad Argentina de Diabetes. 2025;59:176–92.



If you have any questions or considerations around Early Detection Referral Pathways or the information in this document, please use the details listed below to contact your local Sanofi representative

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RESEARCH INITIATIVE

TYPE1SCREEN

Type1Screen is a nationwide type 1 diabetes (T1D) screening program offering islet autoantibody (IAb) testing to children aged ≥2 years and young adults across Australia to determine whether they are at risk of developing T1D. It is open to those that have a relative diagnosed with T1D or have previously had a positive IAb test. Following the introduction of in-home blood spot screening, two-year (2022–2024) outcomes results showed its feasibility, particularly for younger, remotely based participants, with >99% of returned samples testable.¹ In February 2026, Breakthrough T1D announced additional funding for a three-year initiative to build the infrastructure for a sustainable, scalable T1D screening program in Australia, including expansion of screening for individuals with a family history of T1D, through Type1Screen.²

1 SCREENING

LOCATION

Home test or by Local Pathology Collection Centre

LOGISTICS

DBS or venous blood

RESULTS COMMUNICATION & NEXT STEPS

Endocrinologist at Royal Melbourne Hospital by phone for positive results, program email for negative screens

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Endocrinologist at Royal Melbourne Hospital	NA
METHODOLOGY (assay & sample type)	Venous blood	NA
TESTING LAB	Royal Melbourne Hospital	NA
GUIDELINES FOLLOWED	ADA/EASD 2024 consensus ³	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Adults: Endocrinologist at Royal Melbourne Hospital. Children: CoEs

PREFERRED METHODOLOGY

IAb, random capillary glucose, HbA1c, ± CGM

GUIDELINES FOLLOWED

Program protocol⁴

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

Yes

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ADA, American Diabetes Association; CGM, continuous glucose monitoring; CoE, Center of Excellence; DBS, dried blood spot; EASD, European Association for the Study of Diabetes; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; T1D, type 1 diabetes.

1. Wentworth JM, et al. Diabetes Care. 2025;48(4):556–63. 2. BreakthroughT1D. <https://breakthrought1d.org.au/news/national-type-1-diabetes-screening-supported-with-10m-from-breakthrough-t1d/>. Accessed August 2026. 3. Phillip M, et al. Diabetologia. 2024;67(9):1731–59. [simultaneously published in Diabetes Care. 2024;47(8):1276–98]. 4. Bell KJ, et al. Diabet Med. 2024;41(11):e15419.

RESEARCH INITIATIVE

T1D NATIONAL
SCREENING PILOT

The National Screening Pilot initially evaluated the feasibility, acceptability, and costs of three models for routine screening of children at risk of T1D in a population-wide screening program in Australia. It was conducted between July 2022 and June 2024.¹ In February 2026, following the pilot phase, Breakthrough T1D announced additional funding for a 15-month initiative to screen 7500 children aged 4–12 in schools, assessing the effectiveness, feasibility, acceptability, and cost-effectiveness of IAb screening for T1D.²

1 SCREENING

LOCATION

Nationwide select locations

LOGISTICS

Newborn heel prick: hospital saliva
swab: home, GP, pharmacy

RESULTS COMMUNICATION &
NEXT STEPS

GP and online portal

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Endocrinologist at Walter & Eliza Hall Inst. of Medical Research	NA
METHODOLOGY (assay & sample type)	Venous blood	NA
TESTING LAB	Walter & Eliza Hall Inst. of Medical Research	NA
GUIDELINES FOLLOWED	ADA/EASD 2024 consensus ³	NA
COST TO INDIVIDUAL/ CAREGIVER	None	NA

3 MONITORING

LOCATION

Endocrinologist at Walter & Eliza Hall Inst. of
Medical Research

PREFERRED METHODOLOGY

IAb, random capillary glucose, HbA1c, ± CGM

GUIDELINES FOLLOWED

Program protocol¹

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

Yes

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ADA, American Diabetes Association; CGM, continuous glucose monitoring; CoE, Center of Excellence; DBS, dried blood spot; EASD, European Association for the Study of Diabetes; GP, general practitioner; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; T1D, type 1 diabetes.
1. Bell KJ, et al. Diabet Med. 2024;41(11):e15419. 2. Breakthrough T1D. <https://breakthrought1d.org.au/news/national-type-1-diabetes-screening-supported-with-10m-from-breakthrough-t1d/>. Accessed August 2026. 3. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.

RESEARCH INITIATIVE

AusDAP

This project aims to determine which model of care for early-stage T1D monitoring works best in different healthcare settings, in preparation for general-population screening for T1D. In evaluating eight early-stage T1D monitoring centers (7 for children and 1 for adults), the researchers will consider how to build the capacity of staff and identify elements that are critical for integrating screening and monitoring into the health service. In this way, the team will develop the best model of care to be delivered by the Australian health care system. Existing telehealth approaches will be evaluated and refined to increase equity of access to care, education and support, particularly for families in rural and remote areas.^{1,2}

1 SCREENING

LOCATION
Nationwide select centers
LOGISTICS
Variable depending on center
RESULTS COMMUNICATION & NEXT STEPS
Variable depending on center
COST TO INDIVIDUAL/CAREGIVER
None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Endocrinologist-led	NA
METHODOLOGY (assay & sample type)	ADAP if sent to Type1Screen (venous blood)	NA
TESTING LAB	Type1Screen or others	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION
Nationwide select centers
PREFERRED METHODOLOGY
NA
GUIDELINES FOLLOWED
NA
COST TO INDIVIDUAL/CAREGIVER
None
SINGLE IAB MONITORED?
NA

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ADAP, antibody detection by agglutination-PCR; IAB, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; T1D, type 1 diabetes.

1. Breakthrough T1D. <https://breakthrought1d.org.au/news/national-type-1-diabetes-screening-supported-with-10m-from-breakthrough-t1d/>. Accessed August 2026. 2. Breakthrough T1D. <https://breakthrought1d.org.au/research-project/implementing-the-best-care-for-people-with-early-stage-t1d/>. Accessed August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

BEAT T1D **BEAT T1D (Belgian Early Awareness and Testing for Type 1 Diabetes) is soon to be standard clinical practice in Belgium.** BEAT T1D aims to organize structured, coordinated, and independent early-stage screening for T1D across the country.¹ The Belgian screening framework consists of multiple phases. Learnings are applied throughout the journey, both from the Belgian context as well as international projects such as EDENTIFI. The first phase in 2026 will focus on first degree relatives (FDRs) of patients with T1D. In a second phase, people with an increased risk for autoimmune diseases will be included in the target group for T1D screening, including people with other autoimmune diseases, people with an increased genetic risk score (GRS), people with HLA DR3-DR4, and people with Down-syndrome.²

1 SCREENING

LOCATION

Hospitals

LOGISTICS

Initial test: Venous blood or capillary blood sample. ELISA-RSR 3-screen assay; GADA/IA-2A/ZnT8A (3-in-one panel)

RESULTS COMMUNICATION & NEXT STEPS

Endocrinologist (result available on platform)

COST TO INDIVIDUAL/CAREGIVER

Reimbursed (with little co-payment for patient)
Dossier currently in process for reimbursement with authorities

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Endocrinologists	Endocrinologist
METHODOLOGY (assay & sample type)	Confirmation test: Venous blood (new sample) IAA: sensitive RBA — gold standard for insulin autoantibodies GADA, IA-2A, ZnT8A: singleplex ELISA (or best available IASP-accredited method) Staging: OGTT	NA
TESTING LAB	List of labs to be defined	List of labs to be defined
GUIDELINES FOLLOWED	International guidelines; Belgian guidelines to be published soon	International guidelines; Belgian guidelines to be published soon
COST TO INDIVIDUAL/CAREGIVER	Reimbursed (with little co-payment for patient) Dossier currently in process for reimbursement with authorities	Reimbursed (with little co-payment for patient) Dossier currently in process for reimbursement with authorities

3 MONITORING

LOCATION

Hospitals (diabetes centers)

PREFERRED METHODOLOGY

OGTT; FPG/HbA1c; CGM

GUIDELINES FOLLOWED

International guidelines; Belgian guidelines to be published soon

COST TO INDIVIDUAL/CAREGIVER

Reimbursed as patient is associated with diabetes center

SINGLE IAB MONITORED?

No

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CGM, continuous glucose monitoring; ELISA, enzyme-linked immunosorbent assay; FPG, fasting plasma glucose; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; HLA, human leukocyte antigen; IA-2A, insulinoma-associated antigen 2 autoantibody; IAB, islet autoantibody; IASP, Islet Autoantibody Standardization Program; NA, information not available; OGTT, oral glucose tolerance test; RBA, radio-binding assay; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.
1. KU Leuven. <https://leuveniabeteslab.com/news/beat-t1d-officially-launched-belgium-takes-a-major-step-toward-early-detection>. Accessed August 2026. 2. BEAT T1D. <https://beatt1d.be/>. Accessed August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

BDR The Belgian Diabetes Registry (BDR) is a national, collaborative network of physicians, researchers and their teams founded in 1989. The BDR collects data from patients aged <40 years with recent-onset diabetes (particularly type 1 diabetes [T1D]), together with their first-degree relatives, for longitudinal data and sample storage with the ultimate goal of improving treatment, and finding a cure and an effective prevention of the disease.^{1,2}

1 SCREENING

LOCATION

Nationwide hospitals and transfusion centers

LOGISTICS

Venous blood sample analyzed at UZ Brussels lab: ELISA + RBA for initial screening

RESULTS COMMUNICATION & NEXT STEPS

In most cases, the BDR

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	BDR Investigators	NA
METHODOLOGY (assay & sample type)	RBA	NA
TESTING LAB	UZ Brussels lab (Center of Excellence)	NA
GUIDELINES FOLLOWED	Screening for ~25 years ¹ as per Greenbaum CJ, et al. (1992) ³	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

The BDR (UZ Brussels)

PREFERRED METHODOLOGY

OGTT but CGM under evaluation

GUIDELINES FOLLOWED

Institutional protocol: Belgian Diabetes Registry: Prédiction du risque (unpublished)

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

NA

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BDR, Belgian Diabetes Registry; CoE, Center of Excellence; CGM, continuous glucose monitoring; ELISA, enzyme-linked immunosorbent assay; IAB, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; RBA, radio-binding assay; T1D, type 1 diabetes. 1. Belgian Diabetes Registry. <http://www.bdronline.be/index.php?id=55&sid=55&taal=E&mn=1>. Accessed August 2026. 2. University of Antwerp. LEMP. <https://www.uantwerpen.be/en/research-groups/laboratory-of-experimental-medicine-and-pediatrics/lemp-clinical-research/endocrinology--diabetology/>. Accessed August 2026. 3. Greenbaum CJ, et al. J Clin Endocrinol Metab. 1992;74(5):1040-4.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

INNODIA The INNOvative approach towards understanding and arresting type 1 DIAbetes (INNODIA) consortium was established to develop a European infrastructure for the recruitment, detailed clinical phenotyping and biosampling of a large cohort of newly diagnosed individuals with T1D and unaffected family members using the INNODIA Master protocol.^{1,2} INNODIA aims to establish an optimal “T1D prevention ecosystem.” INNODIA offers its Members a clinical center-based early-stage T1D detection program for relatives and friends (aged 1–45 years) of individuals living with symptomatic T1D through the INNODIA DETECT protocol. All individuals with IAbs identified through the INNODIA DETECT protocol – or via other means, such as local screening initiatives – become a clinical responsibility. However, INNODIA supports their ongoing care through the INNODIA MONITOR initiative.^{3–5}

1 SCREENING

LOCATION

UZ Brussels

LOGISTICS

Capillary or venous blood on DBS cards shipped to central test hub in Lund, Sweden

RESULTS COMMUNICATION & NEXT STEPS

UZ Leuven Investigators

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	UZ Leuven Investigators	NA
METHODOLOGY (assay & sample type)	ELISA	NA
TESTING LAB	UZ Leuven immunology lab	NA
GUIDELINES FOLLOWED	Internal validation based on Van Aelst S, et al. (2022) ⁶	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

UZ Leuven

PREFERRED METHODOLOGY

INNODIA Protocol²

GUIDELINES FOLLOWED

Fr1da, GPPAD, INNODIA consensus guidance⁷

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

NA

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ADA, American Diabetes Association; CoE, Center of Excellence; DBS, dried blood spot; Fr1da, Typ-1-Diabetes: Früh erkennen; GPPAD, Global Platform for the Prevention of Autoimmune Diabetes; HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; T1D, type 1 diabetes.

1. Marcovecchio ML, et al. Diabetologia. 2024;67(6):995–1008. 2. Dunger DB, et al. Trials. 2022;23:414. 3. INNODIA. https://www.innodia.org/sites/default/files/2025-03/1.%20INNODIA_early-stage%20T1D%20PROGRAM.pdf. Accessed August 2026. 4. INNODIA-DETECT. https://www.innodia.org/sites/default/files/2025-03/2.%20INNODIA_DETECT_%20protocol_FINAL.pdf. Accessed August 2026. 5. INNODIA MONITOR. https://www.innodia.org/sites/default/files/2025-03/3.%20INNODIA_MONITOR_%20initiative_FINAL.pdf. Accessed August 2026. 6. Van Aelst S, et al. J Appl Lab Med. 2022;7(1):66–74. 7. Hendriks AEJ, et al. Diabetes Metab Res Rev. 2024;40(2):e3777

RESEARCH INITIATIVE

TRIALNET

In all TrialNet prevention studies, “Pathway to Prevention” screening is the first step offered at no cost to eligible individuals to evaluate their personal risk of developing T1D. Eligible individuals are aged 2–45 years and have a parent, brother/sister, or child with T1D, or, aged 2–20 years and have an aunt/uncle, cousin, grandparent, niece/nephew, or half-brother/sister with T1D. As of World Diabetes Day 2024, over 250,000 people had been screened through TrialNet, and 8937 participants were enrolled in long-term monitoring. Individuals who test positive for T1D-related IABs through TrialNet are offered ongoing monitoring and may enroll in the Long-Term Investigative Follow-Up in TrialNet (LIFT) Study, which tracks participants before, during, and after diagnosis. LIFT participants receive annual in-person assessments including a Health Status Questionnaire, HbA1c, mixed-meal tolerance test, and other lab tests.^{1–3}

1 SCREENING

LOCATION

Home test kit or at local TrialNet hospital-site lab

LOGISTICS

Home: finger-prick
Lab: venous blood

RESULTS COMMUNICATION & NEXT STEPS

Research nurse or Endocrinologist

COST TO INDIVIDUAL/CAREGIVER

None if eligible for TrialNet

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	TrialNet site nurse coordinator	NA
METHODOLOGY (assay & sample type)	Venous blood	NA
TESTING LAB	Sent to US lab for analysis	NA
GUIDELINES FOLLOWED	No appropriate Canada-specific guidelines TrialNet Protocol ^{4,5}	No appropriate Canada-specific guidelines. TrialNet does not offer routine annual rescreening to children who initially screen negative for IABs. Limited rescreening is available for those under the age of 18 years ^{1,5}
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

TrialNet research team

PREFERRED METHODOLOGY

Once/twice annually pending results; at visit, blood test and OGTT

GUIDELINES FOLLOWED

TrialNet Protocol^{4,5}

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note that early detection screening and referral pathways for T1D are not carried out as part of standard clinical practice at present in Canada. Information in this document is current as of 14 August 2026.

HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; T1D, type 1 diabetes.

1. TrialNet. <https://www.trialnet.org/our-research/risk-screening>. Accessed August 2026. 2. TrialNet-LIFT. <https://www.trialnet.org/our-research/long-term-investigative-follow-trialnet-lift>. Accessed August 2026. 3. Jacobsen LM, et al. Diabetes Care. 2025;48(7):1112–24. 4. Sims EK, et al. Diabetes Care. 2019;42:2228–36. 5. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT00097292>. Accessed August 2026.

RESEARCH INITIATIVE

SANOFI PROGRAM
(UNCOVERT1D)

The Sanofi Program (started Q3 2025) screening of first- or second-degree relatives of individuals with T1D, personal or family history of other autoimmune conditions (e.g., celiac, thyroid), and/or pre-diabetes/dysglycemic. The UncoverT1D Early Detection Program is a comprehensive testing program that supports the detection of autoantibodies (AABs) that may indicate early stages of autoimmune type 1 diabetes (T1D). The screening program is sponsored by Sanofi Canada, with testing services provided by Revvity Omics. The Program includes: Autoantibody testing: Comprehensive testing solution that covers 4 key diabetes-associated autoantibodies GADA, IA-2A, ZnT8A, and IAA to assess the presence of autoimmunity associated with T1D. First-time screen testing: Available for eligible individuals being screened for aT1D autoantibodies for the first time. Confirmatory testing: Performed to validate previous positive results. Follow-up testing: For individuals who have had a single positive or negative result in the past, ensuring continued monitoring for the development of additional autoantibodies!²

1 SCREENING

LOCATION

Physician clinic/POC or hospital, private laboratories (e.g., LifeLabs), mobile phlebotomy (e.g., ExamOne)

LOGISTICS

Capillary DBS assay or whole blood draw

RESULTS COMMUNICATION & NEXT STEPS

Endocrinologist/primary care provider (PCP; general physician or nurse practitioner). If autoantibody present, endocrinologist referral

COST TO INDIVIDUAL/CAREGIVER

None during pilot phase, (Sanofi-Revvity partnership)

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Ordering HCP (endocrinologist, PCP – general physician or nurse practitioner)	Ordering HCP (endocrinologist, PCP – general physician or nurse practitioner)
METHODOLOGY (assay & sample type)	Different method of confirmation (DBS or whole blood)	Capillary DBS assay or whole blood draw
TESTING LAB	Depending on ordering HCP (hospital or commercial laboratory)	NA
GUIDELINES FOLLOWED	ADA/EASD 2024 consensus ³	NA
COST TO INDIVIDUAL/CAREGIVER	None (pilot phase); sponsored until reimbursement available (\$300/test, incl. test assay, sample kit, sample shipping)	NA

3 MONITORING

LOCATION

PCP/ordering physician follow-up if 1 IAB; Endocrinologist referral, if 2 IABs

PREFERRED METHODOLOGY

SMBG, CGM, OGTT, random venous glucose, HbA1C, repeat IAB testing)

GUIDELINES FOLLOWED

ADA/EASD 2024 consensus³

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

NA

Disclaimer: Please note that early detection screening and referral pathways for T1D are not carried out as part of standard clinical practice at present in Canada. Information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; CGM, continuous glucose monitoring; DBS, dried blood spot; EASD, European Association for the Study of Diabetes; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, health care practitioner IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAB, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; PCP, primary care practitioner; POC, point of care; SMBG, self-monitoring of blood glucose; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.

1. Revvity. <https://www.revvity.com/category/autoimmune-type-1-diabetes-early-detection-program> Accessed August 2026. 2. UncoverT1D. <https://www.uncovert1d.ca/en-ca/patient/Screening>. Accessed August 2026. 3. Phillip M, et al. Diabetologia. 2024;67(9):1731-59.

RESEARCH INITIATIVE

CANSCREENT1D

CanScreenT1D is a national consortium (established by Breakthrough T1D Canada in partnership with the Canadian Institutes of Health Research) launched in 2023 and running through 2028, exploring screening for T1D in collaboration with people living with diabetes, their families, healthcare providers, and other experts across Canada. The initiative is conducting pilot studies to evaluate two screening strategies: a genetic approach in newborns and an autoantibody-based approach in children of various ages, aligned with international efforts. Findings will inform a pilot screening program, expected to launch in 2026.¹⁻⁴

1 SCREENING

LOCATION
NA
LOGISTICS
NA
RESULTS COMMUNICATION & NEXT STEPS
NA
COST TO INDIVIDUAL/CAREGIVER
NA

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	NA	NA
METHODOLOGY (assay & sample type)	NA	NA
TESTING LAB	NA	NA
GUIDELINES FOLLOWED	No appropriate Canada-specific guidelines	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION
NA
PREFERRED METHODOLOGY
NA
GUIDELINES FOLLOWED
NA
COST TO INDIVIDUAL/CAREGIVER
NA
SINGLE IAB MONITORED?
NA

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HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; T1D, type 1 diabetes.
1. Chen C, et al. BMJ Open. 2025;15:e099537. 2. Senior PA, et al. Can J Diabetes. 2026;50:58–61. 3. CanScreenT1D. <https://canscreent1d.ca/>. Accessed August 2026. 4. Breakthrough T1D. <https://breakthrought1d.ca/canscreent1d-screening-research-consortium-in-canada-announced/>. Accessed September 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

The Chinese expert consensus on screening, monitoring, and management of population at high risk of type 1 diabetes (T1D) was released on November 20, 2024, and provides guidance on the standard screening and monitoring processes.¹

1 SCREENING

LOCATION

Hospitals

LOGISTICS

Venous: clinical practice/third-party testing platform

RESULTS COMMUNICATION & NEXT STEPS

HCPs

COST TO INDIVIDUAL/CAREGIVER

Depends on local hospitals; mostly self-pay in China

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	HCP who prescribed first testing	HCP who prescribed first testing
METHODOLOGY (assay & sample type)	RBA, or ECL and bridging ELISA as evaluated by IASP ¹	RBA or ECL and bridging ELISA as evaluated by IASP ¹
TESTING LAB	Hospitals	Hospitals
GUIDELINES FOLLOWED	The Chinese expert consensus on screening, monitoring, and management of population at high risk of T1D	The Chinese expert consensus on screening, monitoring, and management of population at high risk of T1D
COST TO INDIVIDUAL/CAREGIVER	Depends on local hospitals; mostly self-pay	Depends on local hospitals; mostly self-pay

3 MONITORING

LOCATION

HCP who prescribed first testing

PREFERRED METHODOLOGY

RBA, or ECL and bridging ELISA as evaluated by IASP²

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

Depends on local hospitals; mostly self-pay in China

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ECL, electrochemiluminescence; ELISA, enzyme-linked immunosorbent assay; HCP, healthcare practitioner; IAB, islet autoantibody; IASP, Islet Autoantibody Standardization Program; NA, information not available; RBA, radio-binding assay; T1D, type 1 diabetes.

1. Chinese Expert Consensus. <https://www.sinomed.ac.cn/article.do?ui=2025131664>. Accessed August 2026. 2. Marzotto I, et al. Diabetologia. 2023;66:897-912.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

CARED The pilot screening program – CARED (China At-Risk Early Detection) – focused on screening first-degree relatives of people with T1D, included four pilot hospitals in China and screened more than 480 individuals within 8 months. Chinese guidelines on the prevention and treatment of diabetes mellitus exist.¹

1 SCREENING

LOCATION

4 pilot hospitals within CARED program

LOGISTICS

Venous: clinical practice

RESULTS COMMUNICATION & NEXT STEPS

HCPs participating in CARED program

COST TO INDIVIDUAL/CAREGIVER

Free. CARED initiated by Beijing Great Physician Commonwealth Foundation (BGPCF), with Sanofi financial support

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	HCPs within CARED program	HCPs within CARED program
METHODOLOGY (assay & sample type)	RBA	RBA
TESTING LAB	Lab with RBA	Lab with RBA
GUIDELINES FOLLOWED	ADA/EASD 2024 Consensus ²	The Chinese expert consensus on screening, monitoring, and management of population at high risk of T1D ¹
COST TO INDIVIDUAL/CAREGIVER	Free. CARED initiated by BGPCF, with Sanofi financial support	Free. CARED initiated by BGPCF, with Sanofi financial support

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; CoE, Center of Excellence; BGPCF, Beijing Great Physician Commonwealth Foundation; DBS, dried blood spot; EASD, European Association for the Study of Diabetes; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAB, islet autoantibody; RBA, radio-binding assay; T1D, type 1 diabetes.

1. Dalong Z, et al. Chin J Diabetes Mellitus. 2025;17:16–138. (<https://rs.yiigle.com/cmaid/1525739>). Accessed August 2026. 2. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

DPS

DPS: First revelation of T1D disease progression patterns in China. This natural history study has been designed to clarify this picture in China, enhancing understanding of the demographic, immunologic, and metabolic characteristics of individuals at risk for developing T1D in the country.

1 SCREENING

LOCATION

50 sites

LOGISTICS

Venous blood, ELISA (RSR)

RESULTS COMMUNICATION & NEXT STEPS

Research Nurse/Clinician in DPS study

COST TO INDIVIDUAL/CAREGIVER

Free, with Sanofi sponsorship

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Research Nurse/Clinician	Research Nurse/Clinician
METHODOLOGY (assay & sample type)	ELISA, Venous blood	ELISA, Venous blood
TESTING LAB	Central Lab	Central Lab
GUIDELINES FOLLOWED	The Chinese expert consensus on screening, monitoring, and management of population at high risk of T1D ¹	The Chinese expert consensus on screening, monitoring, and management of population at high risk of T1D ¹
COST TO INDIVIDUAL/CAREGIVER	Free, with Sanofi sponsorship	Free, with Sanofi sponsorship

3 MONITORING

LOCATION

50 sites

PREFERRED METHODOLOGY

Venous blood
IAb, HbA1c, OGTT

GUIDELINES FOLLOWED

The Chinese expert consensus on screening, monitoring, and management of population at high risk of T1D¹

COST TO INDIVIDUAL/CAREGIVER

Free, with Sanofi sponsorship

SINGLE IAB MONITORED?

Yes

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ELISA, enzyme-linked immunosorbent assay; HbA1c, glycated hemoglobin; HCP, health care practitioner; IAb, islet autoantibody; OGTT, oral glucose tolerance test; T1D, type 1 diabetes.

1. Dalong Z, et al. Chin J Diabetes Mellitus. 2025;17:16–138. (<https://rs.yiigle.com/cmaid/1525739>). Accessed August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

In the Czech Republic, screening standard clinical practice is currently performed on an *ad hoc* basis by clinicians for differential diagnosis of T1D and T2D.

1 SCREENING

LOCATION

In clinical settings for differential diagnosis

LOGISTICS

Venous blood clinic

RESULTS COMMUNICATION & NEXT STEPS

Ordering clinician

COST TO INDIVIDUAL/CAREGIVER

State Health Institute Clinics

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	NA	NA
METHODOLOGY (assay & sample type)	NA	NA
TESTING LAB	NA	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; T1D, type 1 diabetes; T2D, type 2 diabetes.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

EDENTIFI The β etty study aims to explore the feasibility and acceptability of screening 20,000 children aged 2–18 years for T1D.^{1,2} These individuals will be enrolled in the European action for the Diagnosis of Early Non-clinical Type 1 diabetes For disease Interception (EDENTIFI) Registry, metabolically staged, and invited to participate in an educational program.^{1,2} They will also be offered participation in studies examining the psychological burden of screening, as well as monitoring and intervention studies.¹ In the first year of the β etty study, 11,486 samples were obtained through a network of more than 200 collaborating health care providers.³

1 SCREENING

LOCATION

Research sites
(<https://projektbetty.cz>)

LOGISTICS

Capillary blood (triple ELISA)

RESULTS COMMUNICATION & NEXT STEPS

EDENTIFI Investigators

COST TO INDIVIDUAL/CAREGIVER

Free to participate

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Invited into testing centers	NA
METHODOLOGY (assay & sample type)	Venous blood (LIPS and RBA)	NA
TESTING LAB	EDENTIFI core lab	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Research Nurse/Clinician

PREFERRED METHODOLOGY

Venous blood

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

Minimal to none

SINGLE IAB MONITORED?

Yes, it is being offered

Disclaimer: Please note the information in this document is current as of 14 August 2026.
ELISA, enzyme-linked immunosorbent assay; HCP, healthcare practitioner; IAB, islet autoantibody; LIPS, luciferase immunoprecipitation system; NA, information not available; RBA, radio-binding assay; T1D, type 1 diabetes.
1. Hoffmann L, et al. BMJ Open. 2025;15(1):e088522. 2. β etty. <https://projektbetty.cz/pro-lekare/>. Accessed August 2026. 3. Berka B, et al. Oral presentation at the 51st ISPAD Annual Conference, 5–8 November 2025, Montreal, Canada.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

Denmark has a close to 100% tax-financed healthcare system. Currently no standard clinical practice is available for screening, testing and referral. However, the ADAP method (multiplex) can be ordered from all hospital departments. Due to pricing, the method is only used for differential diagnosis. If clinicians suspect T1D, some hospitals also use sequential analysis starting by analyzing GADA → IA-2A → ZnT8A → IAA. The last two IAbs are not measured outside Denmark.

1 SCREENING

LOCATION

Hospital department for differential diagnostic only

LOGISTICS

Capillary blood samples (Enable Biosciences, ADAP multiplex)
Sampling at local hospital, samples send via existing national sample transport system to the Core Lab at Steno Diabetes Centre Copenhagen

RESULTS COMMUNICATION & NEXT STEPS

All results are communicated via the nationwide e-journal and lab results. Results are available for both clinicians and patient at the same time

COST TO INDIVIDUAL/CAREGIVER

The country is divided in two payment systems; either the ordering clinical department or the lab covers costs of testing for IAbs. This varies from hospital to hospital also within each of the five regions

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Endocrinologist or clinicians at one of the five Steno Centers	NA
METHODOLOGY (assay & sample type)	ADAP, RBA or CLIA (GADA and IA-2A)	NA
TESTING LAB	The Core lab at Steno Diabetes Center Copenhagen (ADAP). RBA is conducted outside Denmark	NA
GUIDELINES FOLLOWED	No established guidelines but follow ADA/EASD or ISPAD. ^{2,3}	NA
COST TO INDIVIDUAL/CAREGIVER	The country is divided in two systems; either the ordering department or the lab covers costs of testing. This varies between hospitals	NA

3 MONITORING

LOCATION

Local hospital department

PREFERRED METHODOLOGY

OGTT, CGM, and HbA1c

GUIDELINES FOLLOWED

INNODIA Protocol.¹

COST TO INDIVIDUAL/CAREGIVER

Part of public system

SINGLE IAB MONITORED?

Yes and No

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; ADAP, antibody detection by agglutination-PCR; CGM, continuous glucose monitoring; CLIA, chemiluminescence immunoassay; EASD, European Association for the Study of Diabetes; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAb, islet autoantibody; ISPAD, International Society for Pediatric and Adolescent Diabetes; NA, information not available; OGTT, oral glucose tolerance test; PCR, polymerase chain reaction; RBA, radio-binding assay; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.

1. Dunger DB, et al. Trials. 2022;23:414. 2. Phillip M, et al. Diabetologia. 2024;67(9):1731-59. 3. Haller MJ, et al. Horm Res Paediatr. 2024;97(6):529-45.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

DIAUNION 2.0

The DiaUnion autoantibody screening 2.0 (DiaUnion 2.0) program was established in 2024, collaborating with INNODIA, to identify people with presymptomatic T1D and the related autoimmune diseases, celiac disease and autoimmune thyroid disease.¹ On a European level, DiaUnion also collaborates with other initiatives aimed at accelerating early detection of T1D, including the European Diabetes Forum (EDF) and European action for the Diagnosis of Early Non-clinical T1D For disease Interception (EDENTIFI).² In Denmark, DiaUnion is led by the Steno Diabetes Center Copenhagen.² First-degree relatives aged <40 years of individuals from the DSDB (Danish Registry for Child and Adolescent with Diabetes) cohort are targeted. Under DiaUnion 2.0, the IAb screening program is expected to identify 7030 individuals with positive IAbs over 3 years across Sweden and Denmark. Among these, 2196 are projected to test positive for IAbs, including 1244 individuals with two or more IAbs (Stage 1 or 2).³

1 SCREENING

LOCATION

Home test and lab

LOGISTICS

4 µL capillary blood samples;
ADAP multiplex

RESULTS COMMUNICATION &
NEXT STEPS

Letter from DiaUnion Investigators or
webpage sign-up

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	DiaUnion Investigators	NA
METHODOLOGY (assay & sample type)	RBA singleplex	NA
TESTING LAB	Lund University Clinical Research Center (CoE), Sweden	NA
GUIDELINES FOLLOWED	INNODIA Protocol. ⁴	NA
COST TO INDIVIDUAL/ CAREGIVER	None	NA

3 MONITORING

LOCATION

Pediatric Endocrinologist

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

INNODIA Protocol.⁴

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADAP, antibody detection by agglutination-PCR; CoE, center of excellence; HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; RBA, radio-binding assay; T1D, type 1 diabetes.

1. DiaUnion. <https://diaunion.org/en/about-us/>. Accessed August 2026. 2. DiaUnion DSDB. <https://diaunion.org/en/for-health-professionals/>. Accessed August 2026. 3. DiaUnion. <https://diaunion.org/en/breaking-news-diaunion-2-0-is-now-a-reality/>. Accessed August 2026.

4. Dunger DB, et al. Trials. 2022;23:414.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

DIAUNION 3.0

DIAUNION 3.0 Nationwide Danish Screening program. * **To be initiated Q3 2026** * To be rolled out on all Steno Diabetes Centers in Denmark, with different work packages in different locations. All centers will do early detection of FDRs from 8–40 years. Further info – Work Package Overview: WP1: Early detection of T1D. WP2: Clinical follow-up and monitoring. WP3: Psycho-social aspects of early detection. WP4: Biomarkers – progression prediction Platform Trials. WP5: The gut microbiome. WP6: Diet and physical activity.

1 SCREENING

LOCATION

Home test and Lab. Teams at all Steno centers dedicated for DiaUnion early detection in FDRs

LOGISTICS

4 µL capillary blood samples; ADAP multiplex

RESULTS COMMUNICATION & NEXT STEPS

Letter from DiaUnion Investigators or webpage sign-up

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	NA	NA
METHODOLOGY (assay & sample type)	NA	NA
TESTING LAB	NA	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
ADAP, antibody detection by agglutination-PCR; FDR, first-degree relative; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; T1D, type 1 diabetes.

If you have any questions or considerations around Early Detection Referral Pathways or the information in this document, please use the details listed below to contact your local Sanofi representative

Name	Location	Shared inbox address
Lina Keller	TBC	lina.keller@sanofi.com

Disclaimer: Please note the information in this document is current as of 14 August 2026.

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

DIPP

The Type 1 Diabetes Prediction and Prevention (DIPP) research program is based on the screening of newborns for increased genetic risk for T1D. Since 1994, the DIPP study has screened more than 250,000 newborns for genetic risk of T1D (HLA genotyping followed by RBA) and about 17,000 children have participated in the follow-up that includes regular visits, interviews and collection of various kinds of biological samples until the age of 15 years or diagnosis of T1D.^{1,2}

1 SCREENING

LOCATION

DIPP centers in Oulu, Turku, and Tampere

LOGISTICS

Cord blood at birth (genetic screening)
Venous blood (IAb) testing of people at high genetic risk according to HLA genotype)

RESULTS COMMUNICATION & NEXT STEPS

DIPP centers in Oulu, Turku, and Tampere

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	DIPP study Investigators	NA
METHODOLOGY (assay & sample type)	RBA	NA
TESTING LAB	Oulu University lab	NA
GUIDELINES FOLLOWED	DIPP Protocol ³	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

DIPP centers in Oulu, Turku and Tampere

PREFERRED METHODOLOGY

According to study protocol (OGTT, CGM, HbA1c)

GUIDELINES FOLLOWED

DIPP Protocol³

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

NA

Disclaimer: Please note that early detection screening and referral pathways for T1D are not carried out as part of standard clinical practice at present in Finland. Information in this document is current as of 14 August 2026.
CGM, continuous glucose monitoring; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; HLA, human leukocyte antigen; IAB, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; RBA, radio-binding assay; T1D, type 1 diabetes.
1. DIPP/TEDDY/INNODIA. https://dipp.fi/?page_id=7299&lang=en. Accessed August 2026. 2. Agardh D. https://medschool.cu.anschutz.edu/docs/librariesprovider48/conferences-and-events/2025-8th-symposium-on-general-population-t1d-screening/3-2_scandinavian-programs_agardh-d.pdf?sfvrsn=772cdb4_1. Accessed August 2026. 3. Ghalwash M, et al. Diabetes Care. 2024;47(8):1424-31.

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

FINTIDAS

FINTIDAS is a general-population screening pilot for children aged 2 and 6 years in the cities of Oulu and Turku. Recruitment initiated in 2025.^{1,2}

1 SCREENING

LOCATION

Recruitment: cities of Oulu and Turku,
Sample collection: any clinical
biology lab in those cities;
Analysis: Oulu University lab

LOGISTICS

Invitation letter sent to all children at
2 and 6 years of age (child health
centers involved in promotion)
Venous blood sample

RESULTS COMMUNICATION &
NEXT STEPS

DIPP centers in Oulu and Turku

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	FINTIDAS study Investigators	NA
METHODOLOGY (assay & sample type)	RBA	NA
TESTING LAB	Oulu University lab	NA
GUIDELINES FOLLOWED	FINTIDAS protocol ²	NA
COST TO INDIVIDUAL/ CAREGIVER	None	NA

3 MONITORING

LOCATION

DIPP centers in Oulu and Turku

PREFERRED METHODOLOGY

According to study protocol

GUIDELINES FOLLOWED

FINTIDAS protocol²

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note that early detection screening and referral pathways for T1D are not carried out as part of standard clinical practice at present in Finland. Information in this document is current as of 14 August 2026.

DIPP, Type 1 Diabetes Prediction and Prevention; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; RBA, radio-binding assay; T1D, type 1 diabetes.

1. Agardh D. https://medschool.cuanschutz.edu/docs/librariesprovider48/conferences-and-events/2025-8th-symposium-on-general-population-t1d-screening/3-2_scandinavian-programs_agardh-d.pdf?sfvrsn=772cdb4_1. Accessed August 2026. 2. Ghalwash M, et al. Diabetes Care. 2024;47(8):1424-31.

If you have any questions or considerations around Early Detection Referral Pathways or the information in this document, please use the details listed below to contact your local Sanofi representative

Name	Location	Shared inbox address
Lina Keller	TBC	lina.keller@sanofi.com

Disclaimer: Please note the information in this document is current as of 14 August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

In French standard clinical practice, ‘opportunistic’ screening in first-degree relatives (FDRs) is carried out, i.e., individual screening of FDRs upon HCPs’ proposal or at family’s request. Of note: some French expert centers systematically propose to all FDRs of their T1D patients to be screened (with pediatric/adult referral pathway).

1 SCREENING

LOCATION

Public Hospitals, mainly

LOGISTICS

Venous blood, mainly

RESULTS COMMUNICATION & NEXT STEPS

Hospital Diabetologists & Endocrinologists

COST TO INDIVIDUAL/CAREGIVER

None (hospital costs covered by health insurance)

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Referring prescriber (Specialized HCP, hospital based)	NA
METHODOLOGY (assay & sample type)	Venous blood	NA
TESTING LAB	Hospital lab, mainly	NA
GUIDELINES FOLLOWED	National Recommendations (in French, ¹ and in English ²)	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Specialized HCP, hospital based

PREFERRED METHODOLOGY

Metabolic/glycemic follow-up as per national guidelines + hospital practices (e.g., OGTT, glycemia ± HbA1c)

GUIDELINES FOLLOWED

National Recommendations (in French,¹ and in English²)

COST TO INDIVIDUAL/CAREGIVER

None (hospital costs covered by health insurance)

SINGLE IAB MONITORED?

Yes, as per National recommendations (immunometabolic monitoring)

Disclaimer: Please note the information in this document is current as of 14 August 2026.

FDR, first-degree relative; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; T1D, type 1 diabetes.

1. Mallone R, et al. Med Mal Metab. 2024;18(5):405–32. 2. Mallone R, et al. Diabetes Metab. 2025;51(1):101603.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

INNODIA The INNOvative approach towards understanding and arresting type 1 DIAbetes (INNODIA) consortium was established to develop a European infrastructure for the recruitment, detailed clinical phenotyping and biosampling of a large cohort of newly diagnosed individuals with T1D and unaffected family members using the INNODIA Master protocol.^{1,2} INNODIA aims to establish an optimal “T1D prevention ecosystem.” INNODIA offers its Members a clinical center-based early-stage T1D detection program for relatives and friends (aged 1–45 years) of individuals living with symptomatic T1D through the INNODIA DETECT protocol. All individuals testing positive for IABs through the INNODIA DETECT protocol – or via other means, such as local screening initiatives – become a clinical responsibility. However, INNODIA supports their ongoing care through the INNODIA MONITOR initiative.^{3–5}

1 SCREENING

LOCATION

Home- and hospital-based throughout France (approx. 25 INNODIA DETECT investigator centers)

LOGISTICS

Fingerstick capillary blood sample collected in microtubes on site or at home + centralized testing by ADAP at Cochin Hospital (Paris)

RESULTS COMMUNICATION & NEXT STEPS

INNODIA Investigators

COST TO INDIVIDUAL/CAREGIVER

None (covered by the clinical study)

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	INNODIA Investigator but not as part of INNODIA Detect	NA
METHODOLOGY (assay & sample type)	Venous blood	NA
TESTING LAB	Hospital lab, mainly	NA
GUIDELINES FOLLOWED	Clinical practice (INNODIA DETECT does not cover confirmatory testing in France)	NA
COST TO INDIVIDUAL/CAREGIVER	None (covered by the hospital)	NA

3 MONITORING

LOCATION

None as part of INNODIA (INNODIA Monitor has not started yet in France)

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
ADAP, antibody detection by agglutination-PCR; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; T1D, type 1 diabetes.
1. Marcovecchio ML, et al. Diabetologia. 2024; 67(6):995–1008. 2. Dunger DB, et al. Trials. 2022; 23:414. 3. INNODIA. https://www.innodia.org/sites/default/files/2025-03/1.%20INNODIA_early-stage%20T1D%20PROGRAM.pdf. Accessed August 2026. 4. INNODIA DETECT. https://www.innodia.org/sites/default/files/2025-03/2.%20INNODIA_DETECT_%20protocol_FINAL.pdf. Accessed August 2026. 5. INNODIA MONITOR. https://www.innodia.org/sites/default/files/2025-03/3.%20INNODIA_MONITOR_%20initiative_FINAL.pdf. Accessed August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

PRÊTID The Projet national de dépistage et prise en charge du diabète de type 1 présymptomatique (PRÊTID) is a national pilot study sponsored by the Fondation Francophone pour la Recherche sur le Diabète FFRD (PI: Prof Mallone) which aims to evaluate IAb screening and early management of presymptomatic T1D in 30,000 first-degree relatives of people living with T1D, aged 2–45 years recruited in approx. 29 hospitals/expert centers. The study is expected to start end of 2026, until 2030 (last patient out), following a pilot phase with INNODIA DETECT.¹

1 SCREENING

LOCATION

Home- and hospital-based throughout France (approx. 29 PRÊTID Investigator centers)

LOGISTICS

Fingerstick capillary blood sample collected in microtubes on site or at home + centralized testing by ADAP at Cochin Hospital (Paris)

RESULTS COMMUNICATION & NEXT STEPS

PRÊTID Investigators (29 CoEs)

COST TO INDIVIDUAL/CAREGIVER

None (covered by the clinical study)

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	PRÊTID Investigators	NA
METHODOLOGY (assay & sample type)	Venous blood	NA
TESTING LAB	Hospital lab, mainly	NA
GUIDELINES FOLLOWED	PRÊTID protocol (not publicly available yet), which will follow the National Recommendations (in French, ² and in English ³)	NA
COST TO INDIVIDUAL/CAREGIVER	None (covered by the clinical study)	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
ADAP, antibody detection by agglutination-PCR; CoE, Center of Excellence; HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; PI, principal investigator; T1D, type 1 diabetes.
1. PRÊTID. <https://www.ffrdiabete.org/en/type-2-diabetes-cure-or-remission-can-it-happen/>. Accessed August 2026. 2. Mallone R, et al. Med Mal Metab. 2024;18(5):405–32. 3. Mallone R, et al. Diabetes Metab. 2025;51(1):101603.

If you have any questions or considerations around Early Detection Referral Pathways or the information in this document, please use the details listed below to contact your local Sanofi representative

Name	Location	Shared inbox address
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Amar Bahloul	Medical Head, France	amar.bahloul@sanofi.com

Disclaimer: Please note the information in this document is current as of 14 August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

IAb screening is possible in standard clinical practice if there is a corresponding reason/risk of developing T1D. This can be a close family member of an individual with T1D (mainly first-degree relative). Further risk factors may be required (for example dysglycemia in adults). It is up to the HCP to decide whether there is sufficient risk to require IAb screening in Germany.

1 SCREENING

LOCATION

Across Germany, Endocrinologists and Pediatric Endocrinologists, (Pediatricians and GPs can also perform screening)

LOGISTICS

Venous blood

RESULTS COMMUNICATION & NEXT STEPS

HCP who ordered the test

COST TO INDIVIDUAL/CAREGIVER

Can be covered by health insurance (statutory and private health insurance) - depends on region/insurance, test can also be offered as self-pay service

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	HCP who ordered the test (if performed)	NA
METHODOLOGY (assay & sample type)	Venous blood (if performed)	NA
TESTING LAB	Same lab as screening lab (if performed)	NA
GUIDELINES FOLLOWED	ADA/EASD 2024 consensus ¹	NA
COST TO INDIVIDUAL/CAREGIVER	Covered by health insurance (statutory and private health insurance) if performed	NA

3 MONITORING

LOCATION

Endocrinologists / Pediatric Endocrinologists

PREFERRED METHODOLOGY

Monitoring as per hospital practices (e.g., HbA1c, FPG value)

GUIDELINES FOLLOWED

ADA/EASD 2024 consensus¹

COST TO INDIVIDUAL/CAREGIVER

Covered by health insurance (statutory and private health insurance)

SINGLE IAB MONITORED?

Only in rare cases

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; EASD, European Association for the Study of Diabetes; FPG, fasting plasma glucose; GP, general practitioner; HbA1c, glycated hemoglobin; HCP, health care practitioner; IAb, islet autoantibody; NA, information not available; T1D, type 1 diabetes.

1. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

FRIDA

The FrIda study aims to assess whether early staging of T1D is feasible at a population-based level, prevents severe metabolic decompensation observed at the clinical manifestation of T1D and reduces psychological distress through preventive teaching and care.¹ Since 2022, the FrIda study center in Munich, Bavaria has partnered with centers in Dresden and Hanover to form the FrIdaplex network. This network unites FrIda screening studies across Bavaria, Saxony, and Lower Saxony/Hamburg, with children testing positive for multiple islet autoantibodies (IAbs) being entered into a shared database.² Since May 2025, FrIda-screening has also been possible in Rhineland-Palatinate and Hesse.³ From May 2026, the study will expand its program by five additional federal states, bringing the total to 12: Berlin, Brandenburg, Mecklenburg-Western Pomerania, Saxony-Anhalt, and Thuringia will be added.⁴ As of 25 May 2026, approximately 240,000 children aged 2–10 years have participated in the IAb screening at least once.⁵

1 SCREENING

LOCATION

Available in 12 federal states, among others: Bavaria (227,331), Rhineland-Palatinate (1795), Hesse (3707), Saxony (11,080), Lower Saxony & Hamburg (7271).⁵

LOGISTICS

200 µL capillary blood

RESULTS COMMUNICATION & NEXT STEPS

Pediatrician

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Helmholtz Munich/regional FrIda center	Helmholtz Munich/regional FrIda center
METHODOLOGY (assay & sample type)	RBA/LIPS	RBA/LIPS
TESTING LAB	Helmholtz Munich (CoE)/ CRTD Dresden (Prof. Bonifacio lab, regional FrIda center Saxony)	Helmholtz Munich (CoE)/ CRTD Dresden (Prof. Bonifacio lab, regional FrIda center Saxony)
GUIDELINES FOLLOWED	FrIda Protocol ^{1,6}	FrIda Protocol ^{1,6}
COST TO INDIVIDUAL/CAREGIVER	None	None

3 MONITORING

LOCATION

Local FrIda center

PREFERRED METHODOLOGY

According to study protocol (glucose-urine-test, blood glucose meter, HbA1c, OGTT)

GUIDELINES FOLLOWED

FrIda Protocol^{1,6}

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

Yes (only in parts, e.g., re-testing offered)

Disclaimer: Please note the information in this document is current as of 14 August 2026.

CoE, Center of Excellence; FrIda, Typ-1-Diabetes: Früh erkennen; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAb, islet autoantibody; LIPS, luciferase immunoprecipitation system; NA, information not available; OGTT, oral glucose tolerance test; RBA, radio-binding assay; T1D, type 1 diabetes.

1. Raab J, et al. BMJ Open. 2016;6(5):e011144. 2. FrIda Science Newsletter Issue 06 – October 2024. 3. FrIda study participation. <https://www.typ1diabetes-frueherkennung.de/teilnahme-frida-studie/index.html>. 4. <https://www.helmholtz-munich.de/en/newsroom/news-all/artikel/frida-study-expands-early-diabetes-detection-to-12-german-federal-states> Accessed August 2026. 5. FrIda Dashboard. FrIda enrollment numbers: https://dashboard.typ1diabetes-frueherkennung.de/app/frida-progression-dashboard?sp_hide_navbar=true. Accessed August 2026. 6. Winkler C, et al., JAMA. 2026;335(23):2046–56.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

FRIDA-FDR

The Frlda For Relatives (FRIDA-FDR) Program has not yet had any data published.

1 SCREENING

LOCATION

Germany, GP, Pediatrician or Endocrinologist, via Helmholtz Munich

LOGISTICS

Venous blood/capillary blood

RESULTS COMMUNICATION & NEXT STEPS

Helmholtz Munich (Frlda team)/ treating physician

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Helmholtz Munich	NA
METHODOLOGY (assay & sample type)	RBA/LIPS	NA
TESTING LAB	Helmholtz Munich (CoE)	NA
GUIDELINES FOLLOWED	Frlda Protocol ¹	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Helmholtz Munich or local Pediatric Endocrinologist

PREFERRED METHODOLOGY

According to study protocol (glucose-urine-test, blood glucose meter, HbA1c, OGTT)

GUIDELINES FOLLOWED

Frlda Protocol¹

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note the information in this document is current as of 14 August 2026.

CoE, Center of Excellence; Frlda, Typ-1-Diabetes: Früh erkennen; FDR, first-degree relative; GP, general practitioner; HbA1c, glycated hemoglobin; HCP, health care practitioner; IAB, islet autoantibody; LIPS, luciferase immunoprecipitation system; NA, information not available; OGTT, oral glucose tolerance test; RBA, radio-binding assay; T1D, type 1 diabetes.

1. Raab J, et al. BMJ Open. 2016;6(5):e011144.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

The Sanofi Partnership Screening Project operates exclusively in KSA, targeting high-risk individuals (mainly FDRs) aged 1.5–45 years at selected CoEs (mainly tertiary care hospitals, Ministry of Defense hospitals and National Guard hospital) with a pilot of Ministry of Health hospitals. The project is activated in 9 centers. Other Gulf countries (Kuwait, and UAE) conduct screening through organic clinical practice only.

1 SCREENING	2 TESTING & STAGING	3 MONITORING																		
<div>LOCATION</div> <div>Hospital</div>	<table><tr><th></th><th>CONFIRMATORY TESTING (Detectable IABs on Screening)</th><th>RESCREENING (Undetectable IABs on Screening)</th></tr><tr><th>COORDINATING HCP/TEAM</th><td>Endocrinologist (Adult and Peds)</td><td>NA</td></tr><tr><th>METHODOLOGY (assay & sample type)</th><td colspan="2">Qatar: ADAP KSA, UAE and Kuwait : ELISA capillary puncture (fingerstick), IA-2A, IAA, ZnT8A, GADA And, for staging; HbA1c, CGM or OGTT</td></tr><tr><th>TESTING LAB</th><td>KSA: Enable Bioscience and Revvity UAE and Kuwait: test is conducted by hospitals in collaboration with different labs Qatar: Enable Bioscience (Dia Mena)</td><td>NA</td></tr><tr><th>GUIDELINES FOLLOWED</th><td>ISPAD Consensus¹ ADA Standards of Care in Diabetes²</td><td>NA</td></tr><tr><th>COST TO INDIVIDUAL/CAREGIVER</th><td>KSA and Kuwait: None UAE: Insurance covering</td><td>NA</td></tr></table>		CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)	COORDINATING HCP/TEAM	Endocrinologist (Adult and Peds)	NA	METHODOLOGY (assay & sample type)	Qatar: ADAP KSA, UAE and Kuwait : ELISA capillary puncture (fingerstick), IA-2A, IAA, ZnT8A, GADA And, for staging; HbA1c, CGM or OGTT		TESTING LAB	KSA: Enable Bioscience and Revvity UAE and Kuwait: test is conducted by hospitals in collaboration with different labs Qatar: Enable Bioscience (Dia Mena)	NA	GUIDELINES FOLLOWED	ISPAD Consensus ¹ ADA Standards of Care in Diabetes ²	NA	COST TO INDIVIDUAL/CAREGIVER	KSA and Kuwait: None UAE: Insurance covering	NA	<div>LOCATION</div> <div>Hospital</div>
	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)																		
COORDINATING HCP/TEAM	Endocrinologist (Adult and Peds)	NA																		
METHODOLOGY (assay & sample type)	Qatar: ADAP KSA, UAE and Kuwait : ELISA capillary puncture (fingerstick), IA-2A, IAA, ZnT8A, GADA And, for staging; HbA1c, CGM or OGTT																			
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GUIDELINES FOLLOWED	ISPAD Consensus ¹ ADA Standards of Care in Diabetes ²	NA																		
COST TO INDIVIDUAL/CAREGIVER	KSA and Kuwait: None UAE: Insurance covering	NA																		
<div>LOGISTICS</div> <div>KSA: ADAP UAE and Kuwait : ELISA capillary puncture (fingerstick), IA-2A, IAA, ZnT8A, GADA</div>		<div>PREFERRED METHODOLOGY</div> <div>As per clinical practice</div>																		
<div>RESULTS COMMUNICATION & NEXT STEPS</div> <div>Result communicated by lab to hospital , then hospital communicates the result with patients and explains next steps</div>		<div>GUIDELINES FOLLOWED</div> <div>ISPAD Consensus¹ ADA Standards of Care in Diabetes²</div>																		
<div>COST TO INDIVIDUAL/CAREGIVER</div> <div>KSA and Kuwait: None UAE: Insurance covering</div>		<div>COST TO INDIVIDUAL/CAREGIVER</div> <div>Dysglycemic testing covered by insurance</div>																		
		<div>SINGLE IAB MONITORED?</div> <div>No</div>																		

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; ADAP, antibody detection by agglutination-PCR; CGM, continuous glucose monitoring; CoE, Center of Excellence; ELISA, enzyme-linked immunosorbent assay; FDR, first-degree relative; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAB, islet autoantibody; ISPAD, International Society for Pediatric and Adolescent Diabetes; KSA, Kingdom of Saudi Arabia; NA, information not available; OGTT, oral glucose tolerance test; PCR, polymerase chain reaction; T1D, type 1 diabetes; UAE, United Arab Emirates; ZnT8A, zinc transporter 8 autoantibody.

1. Haller MJ, et al. Horm Res Paediatr. 2024;97(6):529-45. 2. ADA Standards of Care in Diabetes. Diabetes Care. 2025;48(Suppl.1):S50-S58.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

DETECT T1D GULF The Early Detection of Type 1 Diabetes in First Degree Relatives of Type 1 Diabetes Patients (DETECT T1D GULF) study will enroll approximately 3500 participants aged 1.5–18 years in Saudi Arabia (5 sites), the United Arab Emirates (2 sites), and Kuwait (1 site) who have an FDR with T1D. The Sanofi-sponsored study began in December 2025 and the estimated study completion date is Jun 2027. the confirmatory testing is conducted for subjects with at least 1 IAb.¹

1 SCREENING

LOCATION
Hospital
LOGISTICS
ELISA, capillary puncture (fingerstick), IA-2A, IAA, ZnT8A, GADA
RESULTS COMMUNICATION & NEXT STEPS
Revvity Lab to Endocrinologist
COST TO INDIVIDUAL/CAREGIVER
None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Endocrinologist	NA
METHODOLOGY (assay & sample type)	ADAP, capillary puncture (fingerstick), IA-2A, IAA, ZnT8A, GADA And, for staging; HbA1c, CGM or OGTT	NA
TESTING LAB	Enable Bioscience	NA
GUIDELINES FOLLOWED	ADA Standards of Care in Diabetes ²	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION
NA
PREFERRED METHODOLOGY
NA
GUIDELINES FOLLOWED
NA
COST TO INDIVIDUAL/CAREGIVER
NA
SINGLE IAB MONITORED?
NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
ADA, American Diabetes Association; ADAP, antibody detection by agglutination-PCR; CGM, continuous glucose monitoring; ELISA, enzyme-linked immunosorbent assay; FDR, first-degree relative; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAb, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; PCR, polymerase chain reaction; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.
1. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT07038473>. Accessed August 2026. 2. ADA Standards of Care in Diabetes. Diabetes Care. 2025;48(Suppl.1):S50–S58.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

DIA-MENA

The Type 1 Diabetes Islet Autoantibody Screening Program in the Middle East and North Africa (DIA-MENA) involves a pilot, cross-sectional, prospective cohort study entitled AL-DIAR2, which aims to build a national islet autoantibody (IAb) screening program for T1D, and to become a focal point in guiding future clinical trials in Qatar. The program is based at the Sidra Medicine Research Center in Doha, focuses on all children aged 1.5 to 5.5 years, and will serve as the basis for pre-type 1 diabetes screening in the pediatric general population in Qatar. It will also act as a model approach to T1D screening in the wider region. The screening combines IAb testing with genome wide-array genotyping (GRS); the intention is to inform and follow up high-risk children for development of autoimmunity and early-stage T1D, and design monitoring strategies and parent education and counselling plans. In future, the cohort will be expanded to include older age groups. The duration of the project is initially 1 March 2024 to 29 February 2028.¹

1 SCREENING

LOCATION

Sidra Medicine Research Center, Doha, Qatar

LOGISTICS

ADAP, capillary puncture (fingerstick), IA-2A, IAA, ZnT8A, GADA

RESULTS COMMUNICATION & NEXT STEPS

Result communicated by lab to hospital, then hospital communicates the result with patients and explains next steps

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Screening for all pediatrics visiting the hospitals in all specialties in Sidra hospital	NA
METHODOLOGY (assay & sample type)	ADAP, capillary puncture (fingerstick), IA-2A, IAA, ZnT8A, GADA And, for staging; HbA1c, CGM or OGTT	NA
TESTING LAB	Sidra Medicine Research Center, Doha, Qatar in collaboration with Enable Bioscience	Sidra Medicine Research Center, Doha, Qatar
GUIDELINES FOLLOWED	ISPAD Consensus ² ADA Standards of Care in Diabetes ³	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; ADAP, antibody detection by agglutination-PCR; CGM, continuous glucose monitoring; FDR, first-degree relative; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAB, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; PCR, polymerase chain reaction; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.
1. DIA-MENA. <https://www.breakthrought1d.org/grants/qatar/ar-rayyan/dia-mena-type-1-diabetes-islet-autoantibody-screening-program-in-the-mena-a-pilot-cross-sectional-prospective-cohort-study/>. Accessed June 2026. 2. Haller MJ, et al. Horm Res Paediatr. 2024;97(6):529-45. 3. ADA Standards of Care in Diabetes. Diabetes Care. 2025;48(Suppl.1):S50-S58.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

Current screening in Israeli standard clinical practice is done on an *ad hoc* basis by clinicians mainly for differential diagnosis of T1D and T2D.

1 SCREENING

LOCATION

In clinical settings for differential diagnosis

LOGISTICS

Venous blood

RESULTS COMMUNICATION & NEXT STEPS

Ordering clinician

COST TO INDIVIDUAL/CAREGIVER

No cost – covered by the Health Management Organization (HMO)

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	NA	NA
METHODOLOGY (assay & sample type)	NA	NA
TESTING LAB	NA	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; T1D, type 1 diabetes; T2D, type 2 diabetes..

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

ADIR

The Antibody Detection Israeli Research (ADIR) study: A national screening program for children aged 9 months–5 years that will be tested for the presence of islet autoantibodies (IAbs). Up to 35,000 children will be screened by their primary care physician across Israel. The initial screening will be done at the age of 1 year (in conjunction with the routine collection of blood for complete blood cell count) and repeated at ages 2–5 years. The program comprises 65 community-based screening sites, six specialized diabetes centers following the children detected with preclinical T1D, a dedicated central laboratory, and a coordinating center. As of January 2025, 17,000 children (median age: 19 months) had been enrolled.^{1–3}

1 SCREENING

LOCATION

>45 screening sites (Clalit Health Management Organization [HMO]) nationwide

LOGISTICS

Capillary blood

RESULTS COMMUNICATION & NEXT STEPS

ADIR investigators

COST TO INDIVIDUAL/CAREGIVER

Free to participate

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	ADIR Investigators	ADIR Investigators
METHODOLOGY (assay & sample type)	Venous blood, combining ADAP, ELISA, and RBA	Capillary blood, ADAP
TESTING LAB	Schneider Children’s Medical Center of Israel	Schneider Children’s Medical Center of Israel
GUIDELINES FOLLOWED	ADA/EASD 2024 consensus ⁴	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

Venous blood

GUIDELINES FOLLOWED

ADA/EASD 2024 consensus⁴

COST TO INDIVIDUAL/CAREGIVER

None (covered by the HMO)

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; ADAP, antibody detection by agglutination-PCR; ADIR, Antibody Detection Israeli Research; EASD, European Association for the Study of Diabetes; ELISA, enzyme-linked immunosorbent assay; HCP, health care practitioner; IAB, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; RBA, radio-binding assay; T1D, type 1 diabetes.

1. Breakthrough T1D. <https://www.breakthrought1d.org/grants/israel/tel-aviv-gosh-dan/adir-part-2/>. Accessed August 2026. 2. Oron T, et al. <https://www.endocrine-abstracts.org/ea/0110/ea0110oc2.2>. Accessed August 2026. 3. Oron T, et al. *Pediatr Diabetes*. 2024;4238394. 4. Phillip M, et al. *Diabetologia*. 2024;67(9):1731–59.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

ADIR FAMILIES

The ADIR Families study: A national screening program to detect the presence of IABs in relatives of people with T1D, aged 2–45 years. Estimated enrollment is 20,000. Participants identified as part of the study with presymptomatic T1D (Stages 1 and 2) will be referred to complete an educational program emphasizing DKA prevention as part of routine medical care. During the study, cases of Stage 2 and Stage 3 T1D and DKA events will be documented in participants who have IABs.^{1–3}

1 SCREENING

LOCATION

>60 screening sites (all 4 Health Management Organizations [HMOs]) nationwide

LOGISTICS

Capillary blood

RESULTS COMMUNICATION & NEXT STEPS

ADIR Families investigators

COST TO INDIVIDUAL/CAREGIVER

Free to participate

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	ADIR families Investigators	NA
METHODOLOGY (assay & sample type)	Capillary blood & venous blood by ADAP, ELISA, and RBA	NA
TESTING LAB	Schneider Children’s Medical Center of Israel	NA
GUIDELINES FOLLOWED	ADA/EASD 2024 consensus ⁴	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

Diabetes clinics

PREFERRED METHODOLOGY

Venous blood

GUIDELINES FOLLOWED

ADA/EASD 2024 consensus⁴

COST TO INDIVIDUAL/CAREGIVER

None (covered by the HMO)

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; ADAP, antibody detection by agglutination-PCR; ADIR, Antibody Detection Israeli Research; DKA, diabetic ketoacidosis; EASD, European Association for the Study of Diabetes; ELISA, enzyme-linked immunosorbent assay; HCP, healthcare practitioner; HMO, Health Management Organization; IAB, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; RBA, radio-binding assay; T1D, type 1 diabetes.

1. ADIR Families Study. <https://ctv.veeva.com/study/the-israeli-study-for-islet-autoantibodies-screening-in-families-of-type-1-diabetes-patients>. Accessed August 2026. 2. ADIR Families Study. <https://ichgcp.net/clinical-trials-registry/NCT06665815>. Accessed August 2026.

3. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT05788341>. Accessed August 2026. 4. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

National screening (T1D and celiac disease) in the pediatric population aged from 1 to 17 years was approved in Italian law in September 2023.¹ The initial phase is underway: as a starting point, children aged 5–6 years will be screened and 3 IAbs will be tested on capillary blood samples (GADA, IA–2A, ZnT8A).^{2,3} Once fully licensed, the scale-up at regional level will begin. In clinical practice, single centers are setting up outpatient clinics to screen and monitor patients with presymptomatic T1D. Screening approaches vary between centers; the starting point is mostly FDR, then expanded to other high-risk populations, such as those with autoimmune thyroiditis, other endocrinopathies, or celiac disease.

1 SCREENING

LOCATION
NA
LOGISTICS
NA
RESULTS COMMUNICATION & NEXT STEPS
NA
COST TO INDIVIDUAL/CAREGIVER
NA

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Pediatric Diabetologists and Diabetologists in hub centers	Pediatric Diabetologists and Diabetologists in hub centers
METHODOLOGY (assay & sample type)	In pediatric setting, capillary blood is the most common sample type. Assay and IAbs tested may vary across centers and country (all regions have at least one referral center testing for all IAbs)	In pediatric setting, capillary blood is the most common sample type. Assay and IAbs tested may vary across centers and country (all regions have at least one referral center testing for all IAbs)
TESTING LAB	Where available, test is performed within the center of coordinating/requesting HCP	Lab work done within lab institution
GUIDELINES FOLLOWED	Italian Guidance ⁴	Italian Guidance ⁴
COST TO INDIVIDUAL/CAREGIVER	2 IAbs (GADA, IAA) are reimbursed under the NHS national tariffs (€8.5 each) and co-paid and 2 IAbs (ZnT8 and IA2) are reimbursed extra NHS national tariffs (EXTRA LEA – €30–40 each)	2 IAbs (GADA, IAA) are reimbursed under the NHS national tariffs (€8.5 each) and co-paid and 2 IAbs (ZnT8 and IA2) are reimbursed extra NHS national tariffs (EXTRA LEA – €30–40 each)

3 MONITORING

LOCATION
NA
PREFERRED METHODOLOGY
NA
GUIDELINES FOLLOWED
Good Clinical Practice Guidelines (ISS–SIEDP) ⁵
COST TO INDIVIDUAL/CAREGIVER
ICD–10 codes still not implemented (expected in Jan 2027 as per Internal ministerial Decree issued in Oct 2025) ⁶
SINGLE IAB MONITORED?
NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
FDR, first-degree relatives; GADA, glutamic acid decarboxylase autoantibody; HCP, healthcare practitioner; IAA, insulin autoantibody; IA–2A, insulinoma-associated antigen 2 autoantibody; IAb, islet autoantibody; NA, information not available; NHS, National Health Service; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.
1. Bosi E, et al. Lancet Diabetes Endocrinol. 2024;12(1):12–4. 2. Senato Della Repubblica. <https://www.senato.it/service/PDF/PDFServer/BGT/1506986.pdf>. Accessed August 2026. 3. Gazzetta Ufficiale Della Repubblica Italiana. <https://www.gazzettaufficiale.it/eli/gu/2023/09/27/226/sg/pdf> Accessed August 2026. 4. Cherubini V, et al. Diabetes Obes Metab. 2024;26:4197–202. 5. ISS–SIEDP. 12 Dec 2025. https://www.iss.it/documents/20126/10913326/RBPCA-00099_SIEDP+et+al_dic2025.pdf/86842841-5264-bcf3-4355-7e6a26f8dfb2?t=1779371507480. Accessed August 2026. 6. Ministero Della Salute. <https://www.mefop.it/cms/doc/29766/dm-salute-23-ottobre-2025.pdf>. Accessed August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SIRENA

The Standardized Italian netwoRk Enrolling iNdividuals with islet-Autoantibodies (SIRENA) is an Italian National Registry for patients with at least one IAb present. The registry includes both children and adult patients as this is promoted by a joint effort of major scientific societies involved in diabetes care (Italian society of Pediatric Endocrinology and Diabetology [SIEDP], Italian Society of Diabetology [SID], and Association of Medical Diabetology [AMD]). Being a registry, the data captured and screening methodology will reflect the standard practice of sites involved.^{1,2}

1 SCREENING

LOCATION
NA
LOGISTICS
NA
RESULTS COMMUNICATION & NEXT STEPS
NA
COST TO INDIVIDUAL/CAREGIVER
NA

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	NA	NA
METHODOLOGY (assay & sample type)	NA	NA
TESTING LAB	NA	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION
NA (EDENTIFI)
PREFERRED METHODOLOGY
NA
GUIDELINES FOLLOWED
NA
COST TO INDIVIDUAL/CAREGIVER
NA
SINGLE IAB MONITORED?
NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available.
1. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT07503366>. Accessed August 2026. 2. Sirena: <https://sirena-project.org/>. Accessed August 2026. [NOTE: website is in Italian, but a Google translation has been provided for reference purposes].

RESEARCH INITIATIVE

PREP-T1D PREP-T1D (Prevalence of Presymptomatic Type 1 Diabetes) is an observational study in Japan, targeting first-degree relatives (parents, brothers, sisters, and children) of individuals with Stage 1 T1D. The study began in September 2024 and plans to enroll 2000 children and adults aged 0–50 years. Follow-up of participants is ongoing.^{1,2}

1 SCREENING

LOCATION

71 participating sites (including clinics and hospitals)

LOGISTICS

Venous blood drawn at participating sites and sent to a centralized commercial lab for testing 4 individual IAbs (GADA, IA-2A, IAA, ZnT8A) using RSR ELISA kit

RESULTS COMMUNICATION & NEXT STEPS

Physicians at the clinics/hospitals who did screening communicate the results to screened individuals. If one or more IAbs are present, they go to second visit for OGTT, HLA genotyping etc.

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Same participating sites where individuals are screened, HCP/Team will also be same	NA
METHODOLOGY (assay & sample type)	No confirmatory testing OGTT is performed for staging	NA
TESTING LAB	No confirmatory testing OGTT is performed in participating sites (same sites as screening)	NA
GUIDELINES FOLLOWED	No local guideline available	No local guideline available
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Same participating sites where individuals are screened

PREFERRED METHODOLOGY

OGTT, IAb testing

GUIDELINES FOLLOWED

No local guideline available

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note that early detection screening and referral pathways for T1D are not carried out as part of standard clinical practice at present in Japan. Information in this document is current as of 14 August 2026.

ELISA, enzyme-linked immunosorbent assay; GADA, glutamic acid decarboxylase autoantibody; HCP, healthcare practitioner; HLA, human leukocyte antigen; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAb, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.

1. Sanofi press release. PREP-T1D. <https://www.sanofi.co.jp/assets/dot-jp/pressreleases/2024/241010.pdf>. Accessed August 2026. [NOTE: press release is in Japanese, but a Google translation has been provided for reference purposes].

2. JPRN Search Portal. https://rctportal.mhlw.go.jp/en/detail?trial_id=UMIN000055318. Accessed August 2026.

RESEARCH INITIATIVE

PRIDE-J

PRIDE-J: This study will start in Q4 2026 as a registry study led by Japan Diabetes Society as PREP-T1D finishes in Q3 2026. It will succeed monitoring of individuals with IAb(s) identified in PREP-T1D while newly screening FDR, SDR, AITD + dysglycemia, individuals known to have IAb(s) present or HLA high-risk.

1 SCREENING

LOCATION

We expect 71 PREP-T1D sites to continue and expand to more site

LOGISTICS

Venous blood drawn at participating sites and sent to a centralized commercial lab for testing 4 individual IAb(s) (GADA, IA-2A, IAA, ZnT8A) using RSR ELISA kit. Also, triplex RSR ELISA is tested for the first several cases

RESULTS COMMUNICATION & NEXT STEPS

Physicians at the clinics/hospitals who did screening communicate the results to screened individuals. If one or more IAb are positive, they go to second visit for OGTT, HLA genotyping etc.

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAb(s) on Screening)	RESCREENING (Undetectable IAb(s) on Screening)
COORDINATING HCP/TEAM	Same participating sites where individuals are screened	NA
METHODOLOGY (assay & sample type)	No confirmatory testing OGTT is performed for staging	NA
TESTING LAB	No confirmatory testing OGTT is performed in participating sites (same sites as screening)	NA
GUIDELINES FOLLOWED	No local guideline available	No local guideline available
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Same participating sites where individuals are screened

PREFERRED METHODOLOGY

HbA1c, FPG, less frequently with OGTT and IAb testing

GUIDELINES FOLLOWED

No local guideline available

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note that early detection screening and referral pathways for T1D are not carried out as part of standard clinical practice at present in Japan. Information in this document is current as of 14 August 2026.

AITD, autoimmune thyroid disease; ELISA, enzyme-linked immunosorbent assay; FDR, first-degree relative; FPG, fasting plasma glucose; GADA, glutamic acid de carboxylase auto antibody; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; HLA, human leukocyte antigen; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAb, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; SDR, second-degree relative; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.

RESEARCH INITIATIVE

INNODIA

The INNOvative approach towards understanding and arresting type 1 DIAbetes (INNODIA) consortium was established to develop a European infrastructure for the recruitment, detailed clinical phenotyping and biosampling of a large cohort of newly diagnosed individuals with type 1 diabetes (T1D) and unaffected family members using the INNODIA Master protocol.^{1,2} INNODIA aims to establish an optimal “T1D prevention ecosystem.” INNODIA offers its Members a clinical center-based early-stage T1D detection program for relatives and friends (aged 1–45 years) of individuals living with symptomatic T1D through the INNODIA DETECT protocol. All individuals testing positive for IAb through the INNODIA DETECT protocol – or via other means, such as local screening initiatives – become a clinical responsibility. However, INNODIA supports their ongoing care through the INNODIA MONITOR initiative.^{3–5}

1 SCREENING

LOCATION

NA

LOGISTICS

Capillary/venous blood on dried blood spot (DBS) cards shipped to central test hub in Lund, Sweden

RESULTS COMMUNICATION & NEXT STEPS

NA

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	NA	NA
METHODOLOGY (assay & sample type)	ADAP Multiplex	NA
TESTING LAB	TU Delft lab	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

INNODIA Protocol⁶

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note that early detection screening and referral pathways for T1D are not carried out as part of standard clinical practice at present in The Netherlands. Information in this document is current as of 14 August 2026.

ADAP, antibody detection by agglutination-PCR; DBS, dried blood spot; HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; T1D, type 1 diabetes.

1. Marcovecchio ML, et al. Diabetologia. 2024;67(6):995–1008. 2. Dunger DB, et al. Trials. 2022;23:414. 3. INNODIA. https://www.innodia.org/sites/default/files/2025-03/1.%20INNODIA_early-stage%20T1D%20PROGRAM.pdf. Accessed August 2026. 4. INNODIA DETECT. https://www.innodia.org/sites/default/files/2025-03/2.%20INNODIA_DETECT_%20protocol_FINAL.pdf. Accessed August 2026. 5. INNODIA MONITOR. https://www.innodia.org/sites/default/files/2025-03/3.%20INNODIA_MONITOR_%20initiative_FINAL.pdf. Accessed August 2026. 6. Dunger DB, et al. Trials. 2022;23:414.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

In Norwegian standard clinical practice, any general practitioner (GP) or specialist can prescribe islet autoantibody (IAb) testing in Norway, but a lack of guidance on who to screen, and how to follow-up for those who test positive hampers implementation; in practice, there is no monitoring.

1 SCREENING

LOCATION

Any medical practice

LOGISTICS

Venous blood clinic

RESULTS COMMUNICATION & NEXT STEPS

GP but in the absence of guidance to refer to a Specialist; management of positivity might be heterogenous

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	The prescriber of the first test: GP	NA
METHODOLOGY (assay & sample type)	ADAP	NA
TESTING LAB	National Hormone Lab at Oslo University Hospital (CoE)	NA
GUIDELINES FOLLOWED	Urgent need for screening & monitoring guidelines suited to local resources	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
ADAP, antibody detection by agglutination-PCR; CoE, Center of Excellence; GP, general practitioner; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; PCR, polymerase chain reaction.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

INNODIA The INNODIA approach towards understanding and arresting type 1 DIAbetes (INNODIA) consortium was established to develop a European infrastructure for the recruitment, detailed clinical phenotyping and biosampling of a large cohort of newly diagnosed individuals with T1D and unaffected family members using the INNODIA Master protocol.^{1,2} INNODIA aims to establish an optimal “T1D prevention ecosystem.” INNODIA offers its Members a clinical center-based early-stage T1D detection program for relatives and friends (aged 1–45 years) of individuals living with symptomatic T1D through the INNODIA DETECT protocol. All individuals testing positive for IAb through the INNODIA DETECT protocol – or via other means, such as local screening initiatives – become a clinical responsibility. However, INNODIA supports their ongoing care through the INNODIA MONITOR initiative.^{3–5}

1 SCREENING

LOCATION

Home

LOGISTICS

Capillary blood sample

RESULTS COMMUNICATION & NEXT STEPS

Specialists from the Norwegian Childhood Diabetes Registry Network (NCDR), which is part of the INNODIA Consortium

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Study investigators	NA
METHODOLOGY (assay & sample type)	ADAP Multiplex	NA
TESTING LAB	Oslo University Hospital Ullevål (Ullevål Hospital)	NA
GUIDELINES FOLLOWED	INNODIA Protocol ⁶	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Specialists from the NCDR

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

ISPAD for pediatricians⁷
National guidelines need updating for adults

COST TO INDIVIDUAL/CAREGIVER

Covered by study budget (no cost to participants)

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADAP, antibody detection by agglutination-PCR; HCP, healthcare practitioner; IAb, islet autoantibody; ISPAD, International Society for Pediatric and Adolescent Diabetes; NA, information not available; PCR, polymerase chain reaction; T1D, type 1 diabetes.

1. Marcovecchio ML, et al. Diabetologia. 2024;67(6):995–1008. 2. Dunger DB, et al. Trials. 2022;23:414. 3. INNODIA. https://www.innodia.org/sites/default/files/2025-03/1.%20INNODIA_early-stage%20T1D%20PROGRAM.pdf. Accessed August 2026. 4. INNODIA DETECT. https://www.innodia.org/sites/default/files/2025-03/2.%20INNODIA_DETECT_%20protocol_FINAL.pdf. Accessed August 2026. 5. INNODIA MONITOR. https://www.innodia.org/sites/default/files/2025-03/3.%20INNODIA_MONITOR_%20initiative_FINAL.pdf. Accessed August 2026. 6. Dunger DB, et al. Trials. 2022;23:414. 7. Haller MJ, et al. Horm Res Paediatr. 2024;97(6):529–45.

If you have any questions or considerations around Early Detection Referral Pathways or the information in this document, please use the details listed below to contact your local Sanofi representative

Name	Location	Shared inbox address
Lina Keller	TBC	lina.keller@sanofi.com

Disclaimer: Please note the information in this document is current as of 14 August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

Current screening in Polish standard clinical practice is performed on an *ad hoc* basis by clinicians for differential diagnosis of T1D and T2D.

1 SCREENING

LOCATION

In clinical settings for differential diagnosis

LOGISTICS

Venous blood clinic

RESULTS COMMUNICATION & NEXT STEPS

Ordering clinician

COST TO INDIVIDUAL/CAREGIVER

National Health Fund Clinics

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	NA	NA
METHODOLOGY (assay & sample type)	NA	NA
TESTING LAB	NA	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; T1D, type 1 diabetes; T2D, type 2 diabetes.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

EDENTIFI

The European action for the Diagnosis of Early Non-clinical Type 1 diabetes For disease Interception (EDENTIFI) study¹ in Poland aims to explore the feasibility and acceptability of screening 30,000 children aged 2–17 years for T1D. These individuals will be enrolled in the EDENTIFI Registry,¹ metabolically staged, and invited to participate in an educational program. They will also be offered participation in studies examining the psychological burden of screening, as well as monitoring and intervention studies.

1 SCREENING		2 TESTING & STAGING		3 MONITORING	
LOCATION			CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)	LOCATION
Research sites					Research Nurses/Clinician
LOGISTICS		COORDINATING HCP/TEAM	Invited to testing centers	NA	PREFERRED METHODOLOGY
Capillary blood		METHODOLOGY (assay & sample type)	Venous blood	NA	Venous blood
RESULTS COMMUNICATION & NEXT STEPS		TESTING LAB	EDENTIFI core lab	NA	GUIDELINES FOLLOWED
EDENTIFI Investigators		GUIDELINES FOLLOWED	NA	NA	NA
COST TO INDIVIDUAL/CAREGIVER		COST TO INDIVIDUAL/CAREGIVER	None	NA	COST TO INDIVIDUAL/CAREGIVER
Free to participate					Minimal to none
					SINGLE IAB MONITORED?
					Yes

Disclaimer: Please note the information in this document is current as of 14 August 2026.
HCP, health care practitioner; IAB, islet autoantibody; NA, information not available; T1D, type 1 diabetes.
1. Hoffman L, et al. BMJ Open. 2025;15(1):e088522.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

INNODIA-DETECT

The INNOvative approach towards understanding and arresting type 1 DIAbetes (INNODIA) consortium was established to develop a European infrastructure for the recruitment, detailed clinical phenotyping and biosampling of a large cohort of newly diagnosed individuals with type 1 diabetes and unaffected family members using the INNODIA Master protocol.^{1,2} INNODIA aims to establish an optimal “T1D prevention ecosystem.” INNODIA offers its Members a clinical center-based early-stage T1D detection program for relatives and friends (aged 1–45 years) of individuals living with symptomatic T1D through the INNODIA DETECT protocol. All individuals testing positive for IAb through the INNODIA DETECT protocol – or via other means, such as local screening initiatives – become a clinical responsibility. However, INNODIA supports their ongoing care through the INNODIA MONITOR initiative.^{3–6}

1 SCREENING

LOCATION

Medical University of Silesia

LOGISTICS

ADAP, RBA (dried blood spot)

RESULTS COMMUNICATION & NEXT STEPS

INNODIA-DETECT Investigators

COST TO INDIVIDUAL/CAREGIVER

Free to participate

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	INNODIA-DETECT Investigators	NA
METHODOLOGY (assay & sample type)	Re-test venous blood (standardized local methods)	NA
TESTING LAB	INNODIA Hub	NA
GUIDELINES FOLLOWED	INNODIA Protocol ²	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Medical University of Silesia (NA)

PREFERRED METHODOLOGY

Capillary/venous blood
OGTT and CGM

GUIDELINES FOLLOWED

ISPAD guidelines⁷

COST TO INDIVIDUAL/CAREGIVER

None (NA)

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADAP, antibody detection by agglutination-PCR; CGM, continuous glucose monitoring; HCP, healthcare practitioner; IAb, islet autoantibody; ISPAD, International Society for Pediatric and Adolescent Diabetes; NA, information not available; OGTT, oral glucose tolerance test; RBA, radio-binding assay; T1D, type 1 diabetes.

1. Marcovecchio ML, et al. Diabetologia. 2024;67(6):995–1008. 2. Dunger DB, et al. Trials. 2022;23:414. 3. INNODIA. https://www.innodia.org/sites/default/files/2025-03/1.%20INNODIA_early-stage%20T1D%20PROGRAM.pdf. Accessed August 2026. 4. INNODIA DETECT. https://www.innodia.org/sites/default/files/2025-03/2.%20INNODIA_DETECT_%20protocol_FINAL.pdf. Accessed August 2026. 5. INNODIA MONITOR. https://www.innodia.org/sites/default/files/2025-03/3.%20INNODIA_MONITOR_%20initiative_FINAL.pdf. Accessed August 2026. 6. Małachowska M, et al. Adv Clin Exp Med. 2026;35(4):599–609. 7. Haller MJ, et al. Horm Res Paediatr. 2024;97(6):529–45.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

Screening of first-degree relatives (FDR) of people with T1D is heterogeneous across different regions and hospitals in Portugal. Some hospitals conduct screening of FDR of pediatric patients with T1D. Others perform screening occasionally, for both children and adults. The Direção-Geral da Saúde (DGS; Portuguese Health Authority) has prepared a guidance document aimed at standardizing protocols, defining referral pathways and ensuring equitable access, which is pending publication. Additionally, a scientific consensus document involving 7 medical societies and 2 PAGs is also pending publication shortly.

1 SCREENING

LOCATION

Public Hospitals

LOGISTICS

Heterogenous, depending on the hospital/region. Some use 3Screen ELISA. Others test for 4 autoantibodies individually, using different methods

RESULTS COMMUNICATION & NEXT STEPS

Endocrinologist/Endopediatrician

COST TO INDIVIDUAL/CAREGIVER

None (public health system is free)

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Endocrinologist/ Endopediatrician	Endocrinologist/ Endopediatrician
METHODOLOGY (assay & sample type)	Heterogenous, depending on the hospital/region. Some hospitals do not re-test until the next follow-up appointment	Heterogenous, depending on the hospital/ region
TESTING LAB	Usually hospital laboratory, or other facility if protocolized (similarly to confirmation of traditional Stage 3 diagnosis)	Usually hospital laboratory, or other facility if protocolized (similarly to confirmation of traditional Stage 3 diagnosis)
GUIDELINES FOLLOWED	ADA/EASD 2024 Consensus, ¹ with local adaptations	ADA/EASD 2024 Consensus, ¹ with local adaptations
COST TO INDIVIDUAL/CAREGIVER	None	None

3 MONITORING

LOCATION

Public Hospitals

PREFERRED METHODOLOGY

Usually hospital laboratory, or other facility if protocolized (similarly to confirmation of traditional Stage 3 diagnosis)

GUIDELINES FOLLOWED

ADA/EASD 2024 Consensus,¹ with local adaptations

COST TO INDIVIDUAL/CAREGIVER

None (public health system is free)

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; EASD, European Association for the Study of Diabetes; ELISA, enzyme-linked immunosorbent assay; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; PAG, patient advocacy group; T1D, type 1 diabetes.

1. Phillip M, et al. Diabetologia. 2024;67(9):1731-59.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

PILOT PROJECT

A pilot project for screening in the general pediatric population is underway, with plans to screen 4500 children across three regions of the country. Samples are to be collected at primary care health centers in each region, taking advantage of the routine 5-year vaccination appointment. Samples are then transported to and analyzed at the central laboratory of each of the three regions. Positive results are communicated by the endopediatrician at the respective hospital. In parallel, driven by the EDENTIFI initiative, some regions have also initiated or plan to initiate school-based screening programs in their areas during the next school year, with coordination between hospital pediatrics and school health services.

1 SCREENING

LOCATION

Primary care centers

LOGISTICS

Capillary blood sample, ELISA triplex – GADA, ZnT8A, IA-2A

RESULTS COMMUNICATION & NEXT STEPS

Endopediatrician

COST TO INDIVIDUAL/CAREGIVER

None (public health system is free)

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Endopediatrician	Endopediatrician
METHODOLOGY (assay & sample type)	Venous sample, 4 IABs tested individually	Venous sample, 4 IABs tested individually
TESTING LAB	Hospital lab	Hospital lab
GUIDELINES FOLLOWED	ADA/EASD 2024 Consensus, ¹ with local adaptations	ADA/EASD 2024 Consensus, ¹ with local adaptations
COST TO INDIVIDUAL/CAREGIVER	None	None

3 MONITORING

LOCATION

Hospital

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

ADA/EASD 2024 Consensus,¹ with local adaptations

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American diabetes Association; EASD, European Association for the Study of Diabetes; ELISA, enzyme-linked immunosorbent assay; GADA, glutamic acid decarboxylase autoantibody; HCP, healthcare practitioner; IA-2A, insulinoma-associated antigen 2 autoantibody; IAB, islet autoantibody; NA, information not available; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.

1. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

EDENTIFI

The Early Non-clinical Type 1 diabetes For disease Interception (EDENTIFI) Study follows the FrIda model, aiming to improve clinical care for children and adolescents by diagnosing type 1 diabetes (T1D) at an early presymptomatic stage; ~200,000 participants aged 1–17 years are to be screened for islet autoantibodies (IAbs) in the Czech Republic, Denmark, Germany, Italy, Poland, Portugal, Sweden and the UK between Nov 2023 and Oct 2028! Current target in Portugal is to screen 20,000 children. APDP is the coordinating center, but other health units across the country are also participating: ULS Matosinhos, ULSBaixo Alentejo, ULS Barcelos/Esposende, and Ilha São Miguel. Other health units are also in the process of joining (ULS Lezíria, Ilha Terceira, Tamega e Sousa).

1 SCREENING

LOCATION

Schools, football schools, sports events & other events gathering youth
APDP Lab

LOGISTICS

200 µL capillary blood

RESULTS COMMUNICATION & NEXT STEPS

Pediatric Endocrinologist

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Pediatric Endocrinologist	Pediatric Endocrinologist
METHODOLOGY (assay & sample type)	EDENTIFI Protocol ¹	Venous sample
TESTING LAB	Milan Central Lab + APDP Lab	Milan Central Lab + APDP Lab
GUIDELINES FOLLOWED	EDENTIFI Protocol, ¹ with local adaptation	EDENTIFI Protocol, ¹ with local adaptation
COST TO INDIVIDUAL/CAREGIVER	None	None

3 MONITORING

LOCATION

Pediatric Endocrinologist

PREFERRED METHODOLOGY

OGTT

GUIDELINES FOLLOWED

ADA/EASD 2024 Consensus²

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note the information in this document is current as of 14 August 2026.
ADA, American diabetes Association; APDP, Associação Protectora dos Diabéticos de Portugal; EASD, European Association for the Study of Diabetes; HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; T1D, type 1 diabetes.
1. Hoffmann L, et al. BMJ Open. 2025;15(1):e088522. 2. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

RADAR1 (ADULTS)

RADAR1 is a consultation launched in 2023 by the APDP. It was initially created to screen the family members of children followed at APDP. Subsequently, screening of children and young people aged 3–18 years old was incorporated into the EDENTIFI project, while RADAR1 became focused on adults. Its objective is to screen risk groups — namely FDR and other AI diseases — while also opportunistically including people from the general population.^{1,2}

1 SCREENING

LOCATION

APDP & other opportunistic locations

LOGISTICS

Venous sample (at APDP Lab) or 200 µL capillary blood

RESULTS COMMUNICATION & NEXT STEPS

Endocrinologist

COST TO INDIVIDUAL/CAREGIVER

€60 (includes retest if IAbs detected)

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Endocrinologist	Endocrinologist
METHODOLOGY (assay & sample type)	Venous sample (if at APDP Lab) or 200 µL capillary blood	NA
TESTING LAB	APDP Lab	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	€60 (includes retest if IAbs detected)	NA

3 MONITORING

LOCATION

APDP Endocrinologist or other for follow-up, according to patient preference

PREFERRED METHODOLOGY

OGTT

GUIDELINES FOLLOWED

ADA/EASD 2024 Consensus³

COST TO INDIVIDUAL/CAREGIVER

Unknown
Covered by NHS if T1D diagnosis is registered in public system

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
ADA, American diabetes Association; AI, autoimmune; APDP, Associação Protectora dos Diabéticos de Portugal; EASD, European Association for the Study of Diabetes; FDR, first-degree relative; HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; NHS, national health service; OGTT, oral glucose tolerance test; T1D, type 1 diabetes.
1. RADAR1. <https://saudeonline.pt/apdp-lanca-radar1-para-avaliar-risco-de-diabetes-tipo-1-em-criancas-e-jovens/> Accessed August 2026. 2. RADAR1. <https://apdp.pt/clinica/rastreios/> Accessed August 2026. 3. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.

If you have any questions or considerations around Early Detection Referral Pathways or the information in this document, please use the details listed below to contact your local Sanofi representative

Name	Location	Shared inbox address
Joana Malta Vacas	TBC	joana-malta.vacas@sanofi.com

Disclaimer: Please note the information in this document is current as of 14 August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

In Russian standard clinical practice, autoantibody testing is performed for differential diagnosis of T1D and T2D; clinical guidelines for children with type 1 diabetes include a recommendation to conduct antibody screening in first-degree relatives; the test is not included in reimbursement, but is planned for inclusion for a specific category in 2027; commercial laboratories offer the ability to test for 4 autoantibodies (ICA, IA-2A, IAA, GADA), ZnT8A only for research purposes (for example, at the Endocrinology Research Center); antibody tests are mainly performed using the ELISA method, ECL is available in select regions (limited), local ELIS A reagents are being prepared for registration.

1 SCREENING

LOCATION

At hospital

LOGISTICS

ELISA (ECL in few regions), venous blood sample, 4 IAbs (GADA, IA-2A, ICA, IAA)

RESULTS COMMUNICATION & NEXT STEPS

Pediatric Endocrinologist (mostly regional leaders of screening)

COST TO INDIVIDUAL/CAREGIVER

Reimbursed by hospital (special compulsory medical insurance service with limited quotas), some amount out of pocket ~50 euro for 4 IAbs

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Pediatric Endocrinologist	NA
METHODOLOGY (assay & sample type)	ELISA (ECL in few regions), venous blood sample, 4 IAb (GADA, IA-2A, ICA, IAA), HbA1c (high-performance liquid chromatography), OGTT	NA
TESTING LAB	1. Lab work done within lab institution 2. Early diagnostic program sponsored by Sanofi (Invitro lab)	NA
GUIDELINES FOLLOWED	Type 1 Diabetes in Children ¹	NA
COST TO INDIVIDUAL/CAREGIVER	Reimbursed by hospital (special compulsory medical insurance service with limited quotas), HbA1c, FPG, OGTT –reimbursed by compulsory medical insurance	NA

3 MONITORING

LOCATION

61 regions (accounts)

PREFERRED METHODOLOGY

HbA1c (high-performance liquid chromatography), FPG

GUIDELINES FOLLOWED

Type 1 Diabetes in Children¹
ADA/EASD 2024 Consensus²

COST TO INDIVIDUAL/CAREGIVER

HbA1c, FPG – reimbursed by compulsory medical insurance

SINGLE IAB MONITORED?

No

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; EASD, European Association for the Study of Diabetes; ECL, electrochemiluminescence; ELIS A, enzyme-linked immunosorbent assay; FPG, fasting plasma glucose; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAb, islet autoantibody; ICA, islet cell autoantibody; NA, information not available; OGTT, oral glucose tolerance test; T1D, type 1 diabetes; T2D, type 2 diabetes; ZnT8A, zinc transporter 8 autoantibody.

1. Type 1 Diabetes in Children. https://cr.minzdrav.gov.ru/preview-cr/287_3. Accessed August 2026. 2. Phillip M, et al. Diabetologia. 2024;67(9):1731-59.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

NMRC (i)

Federal State Budgetary Institution "NMRC of Endocrinology named after Academician I.I. Dedov" Ministry of Health of Russia screening program: "Ethnic, genetic, cellular and environmental factors in the formation of various forms of autoimmune diabetes". First degree relatives of people with T1D can participate in the study: children and their parents (under the age of 45), as well as siblings of children with diabetes. At the first stage, biomaterial is taken for autoantibodies to pancreatic cells that produce insulin, and a questionnaire is filled out with information about your health and family history. Patients who have a high titer of autoantibodies to pancreatic cells, depending on their number and level, will undergo additional examination.

1 SCREENING

LOCATION

At NMRC for participants from Moscow and ~46 regional hospital/polyclinic

LOGISTICS

ELISA, venous blood sample, 5 IABs (GADA, IA-2A, ICA, IAA, ZnT8A). HbA1c isn't captured at screening

RESULTS COMMUNICATION & NEXT STEPS

Pediatric Endocrinologist

COST TO INDIVIDUAL/CAREGIVER

The scientific program is free for participants

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Pediatric Endocrinologist	NA
METHODOLOGY (assay & sample type)	ELISA, venous blood sample, 5 IAB (GADA, IA-2A, ICA, IAA, ZnT8A). HbA1c, OGTT performed after receiving confirmation of ≥2 IABs	NA
TESTING LAB	Lab work done within lab institution	NA
GUIDELINES FOLLOWED	Institute of Pediatric Endocrinology, Department of Pediatric Diabetes protocols ¹	NA
COST TO INDIVIDUAL/CAREGIVER	The scientific program is free for participants	NA

3 MONITORING

LOCATION

Pediatric endocrinologist at NMRC for participants from Moscow and ~46 regional hospital/polyclinic

PREFERRED METHODOLOGY

HbA1c, FPG, PPG

GUIDELINES FOLLOWED

Type 1 Diabetes in Children²

COST TO INDIVIDUAL/CAREGIVER

The scientific program is free for participants

SINGLE IAB MONITORED?

Yes

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ELISA, enzyme-linked immunosorbent assay; FPG, fasting plasma glucose; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, healthcare practitioner; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAB, islet autoantibody; ICA, islet cell autoantibody; NA, information not available; NMRC, National Medical Research Radiological Centre; OGTT, oral glucose tolerance test; PPG, postprandial glucose; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.

1. Institute of Pediatric Endocrinology, Department of Pediatric Diabetes protocols. <https://www.endocrin-centr.ru/departments/institut-detskoy-endokrinologii/otdel-detskogo-saharnogo-diabeta>. Accessed August 2026. 2. Type 1 Diabetes in Children. https://cr.minzdrav.gov.ru/preview-cr/287_3. Accessed August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

NMRC (ii)

The study involves children FDR and children with autoimmune thyroid diseases. Screening for antibodies, FPG and HbA1c is carried out, then children with ≥1 IAb can undergo a confirmatory test as part of the Sanofi-sponsored early diagnosis program of preclinical stages of T1D.

1 SCREENING

LOCATION

I.N. Grigovich Children's Republican Hospital, Petrozavodsk

LOGISTICS

ELISA, venous blood sample, 4 IAbs (GADA, IA-2A, ICA, IAA). HbA1c and FPG

RESULTS COMMUNICATION & NEXT STEPS

Pediatric Endocrinologist

COST TO INDIVIDUAL/CAREGIVER

The scientific program is free for participants

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Pediatric Endocrinologist	NA
METHODOLOGY (assay & sample type)	ELISA, venous blood sample, 4 IAbs (GADA, IA-2A, ICA, IAA). HbA1c and FPG in Sanofi-sponsored early detection program	NA
TESTING LAB	Early diagnostic program sponsored by Sanofi (Invitro lab)	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	Sanofi sponsored	NA

3 MONITORING

LOCATION

Early diagnostic program sponsored by Sanofi (Invitro lab-145 laboratories in 67 regions)

PREFERRED METHODOLOGY

HbA1c and FPG in Sanofi-sponsored early detection program

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

Sanofi sponsored

SINGLE IAB MONITORED?

Yes, if participant has 1 IAb and dysglycemia

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ELISA, enzyme-linked immunosorbent assay; FPG, fasting plasma glucose; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, health care practitioner; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAb, islet autoantibody; ICA, islet cell autoantibody; NA, information not available; OGTT, oral glucose tolerance test; T1D, type 1 diabetes.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

NMRC (iii)

The study involves children FDR and children with autoimmune diseases. Screening for antibodies, FPG and HbA1c is carried out, then children with 1 and more IAb can undergo a confirmatory test as part of the Sanofi-sponsored early diagnosis program of T1D.

1 SCREENING

LOCATION

Novosibirsk State University (Regions: Novosibirsk, Tomsk, Kemerovo, Barnaul)

LOGISTICS

ELISA, venous blood sample, 4 IAbs (GADA, IA-2A, ICA, IAA). HbA1c and FPG

RESULTS COMMUNICATION & NEXT STEPS

Pediatric Endocrinologist

COST TO INDIVIDUAL/CAREGIVER

The scientific program is free for participants

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	Pediatric Endocrinologist	NA
METHODOLOGY (assay & sample type)	ELISA, venous blood sample, 4 IAbs (GADA, IA-2, ICA, IAA). HbA1c and FPG in Sanofi-sponsored ED program	NA
TESTING LAB	Early diagnostic program sponsored by Sanofi (Invitro lab)	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	Sanofi sponsored	NA

3 MONITORING

LOCATION

Early diagnostic program sponsored by Sanofi (Invitro lab-145 laboratories in 67 regions)

PREFERRED METHODOLOGY

HbA1c and FPG in Sanofi-sponsored early detection program

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

Sanofi sponsored

SINGLE IAB MONITORED?

Yes, if participant has 1 IAb and dysglycemia

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ELISA, enzyme-linked immunosorbent assay; FPG, fasting plasma glucose; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; HCP, health care practitioner; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen 2 autoantibody; IAb, islet autoantibody; ICA, islet cell autoantibody; NA, information not available; OGTT, oral glucose tolerance test; T1D, type 1 diabetes.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

In standard clinical practice in Spain, any adult endocrinologist or pediatric endocrinology specialist can order IAb testing for individuals at risk of developing T1D), in accordance with the criteria of the specific hospital or healthcare provider. Several public hospitals are already conducting screening programs targeting first-degree relatives. National consensus guidelines from scientific societies (SED, SEEN, and SEEP) were published in July 2025.¹

1 SCREENING

LOCATION

Hospital setting

LOGISTICS

Venous blood sample at medical practice

RESULTS COMMUNICATION & NEXT STEPS

Endocrinologist/Pediatric Endocrinologist

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Endocrinologist/Pediatric Endocrinologist	Individuals with no IAB are not followed
METHODOLOGY (assay & sample type)	Commercial IAb tests (can differ hospital by hospital) Commercial autoantibody tests (may vary by hospital). Options range from the 3-plex capillary ELISA (GADA, ZnT8A, IA-2A) and the ELISA for the 4 individual antibodies to the CLIA technique.	NA
TESTING LAB	Hospital Lab	NA
GUIDELINES FOLLOWED	ADA/EASD 2024 Consensus ²	No local guideline available
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Hospital setting

PREFERRED METHODOLOGY

Commercial IAb tests (can differ hospital by hospital). Commercial autoantibody tests (may vary by hospital). Options range from the 3-plex capillary ELISA (GADA, ZnT8A, IA-2A) and the ELISA for the 4 individual antibodies to the CLIA technique

GUIDELINES FOLLOWED

SED/SEEN/SEEP National Consensus Guidelines July 2025¹

COST TO INDIVIDUAL/CAREGIVER

Not applicable

SINGLE IAB MONITORED?

Yes

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ADA, American Diabetes Association; CLIA, chemiluminescence immunoassay; EASD, European Association for the Study of Diabetes; ELISA, enzyme-linked immunosorbent assay; GADA, glutamic acid decarboxylase autoantibody; HCP, healthcare practitioner; IA-2A, insulinoma-associated antigen 2 autoantibody; IAb, islet autoantibody; NA, information not available; PAG, patient advocacy group; SED, Sociedad Española de Diabetes; SEEN, Sociedad Española de Endocrinología y Nutrición; SEEP, Sociedad Española de Endocrinología Pediátrica; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.

1. SED/SEEN/SEEP National Consensus Guidelines. <https://isanidad.com/wp-content/uploads/2025/07/Consenso-DMI-completo-sociedades-protect.pdf>. Accessed August 2026. 2. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

SCREEND1A

SCREEND1A was launched in 2025 and aims to screen >6000 people in Basque Country, Spain, including the general pediatric population and first-degree relatives (FDR) of people with type 1 diabetes (T1D). These individuals comprise 4000 children (3–13 years old) included in pediatric check-ups in centers in Araba, Bizkaia and Gipuzkoa, and 2000 first-degree relatives, adults and children, evaluated in Pediatric Endocrinology and Nutrition consultations in hospitals. Funded by Osakidetza, the program will launch at the Ezkerraldea-Enkarterri-Cruces, OSI Bilbao-Basurto, and OSI Uribe centers, with plans to expand to Araba and Gipuzkoa.^{1–3} Various nodes are currently being established across Spain; the Asturias node is already open, and nodes in Extremadura, Andalusia, Madrid, and Valencia will open soon.

1 SCREENING

LOCATION

Primary Care Centers and referral Hospitals

LOGISTICS

Capillary and venous blood sample, depending on the center (ADAP) and verification by RBA

RESULTS COMMUNICATION & NEXT STEPS

Endocrinologist/Pediatric Endocrinologist

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Endocrinologist/Pediatric Endocrinologist	Individuals with no IAB are not followed
METHODOLOGY (assay & sample type)	Venous blood sample (RBA)	NA
TESTING LAB	RBA	NA
GUIDELINES FOLLOWED	NA	No local guideline available
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Endocrinologist/Pediatric Endocrinologist

PREFERRED METHODOLOGY

Commercial IAB tests (can differ hospital by hospital). Commercial autoantibody tests (may vary by hospital). Options range from the 3-plex capillary ELISA (GADA, ZnT8A, IA-2A) and the ELISA for the 4 individual antibodies to the CLIA technique.

GUIDELINES FOLLOWED

ADA/EASD 2024 Consensus⁴

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

Yes

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American diabetes Association; ADAP, antibody detection via agglutination-PCR; CLIA, chemiluminescence immunoassay; EASD, European Association for the Study of Diabetes; ELISA, enzyme-linked immunosorbent assay; GADA, glutamic acid decarboxylase autoantibody; HCP, healthcare practitioner; IA-2A, insulinoma-associated antigen 2 autoantibody; IAB, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; RBA, radio-binding assay; T1D, type 1 diabetes; ZnT8A, zinc transporter 8 autoantibody.

1. Highlights XXXVI Congreso FSED 2025. <https://pro.campus.sanofi/es/diabetes-tipo-1-presintomatica/eventos/highlights-sed-2025>. Accessed August 2026. 2. Bio-Bizkaia. <https://www.bio-bizkaia.eus/eu/-/euskadi-inicia-un-estudio-pionero-en-la-deteccion-de-la-diabetes-tipo-1>. Accessed August 2026. 3. Crecer sin Diabetes. <https://www.crecersindiabetes.com/2025/08/13/screend1a/>. Accessed August 2026. 4. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.

If you have any questions or considerations around Early Detection Referral Pathways or the information in this document, please use the details listed below to contact your local Sanofi representative

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Disclaimer: Please note the information in this document is current as of 14 August 2026.

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

DIAUNION 2.0

The DiaUnion autoantibody screening 2.0 (DiaUnion 2.0) program was established in 2024, collaborating with INNODIA, to identify people with presymptomatic T1D and the related autoimmune diseases, celiac disease and autoimmune thyroid disease. On a European level, DiaUnion also collaborates with other initiatives aimed at accelerating early detection of T1D, including the European Diabetes Forum and EDENTIFI.¹ In Sweden, DiaUnion is managed by Medicon Valley Alliance (MVA), with the TRIAD Study led by Lund University and Region Skåne.² Under DiaUnion 2.0, the islet autoantibody (IAb) screening program is expected to identify 7030 individuals with positive IAb status over three years across Sweden and Denmark. Among these, 2196 are projected to test positive for IAbs, including 1244 individuals with two or more IAbs (Stage 1 or 2).³

1 SCREENING

LOCATION

Home

LOGISTICS

4 µL capillary blood samples

RESULTS COMMUNICATION & NEXT STEPS

Pediatric Endocrinologist

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	DiaUnion Investigators	NA
METHODOLOGY (assay & sample type)	Antibody detection by ADAP Multiplex	NA
TESTING LAB	Lund University hospital (CoE)	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	None	NA

3 MONITORING

LOCATION

Pediatric Endocrinologist

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

INNODIA protocol⁴

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note that early detection screening and referral pathways for T1D are not carried out as part of standard clinical practice at present in Sweden. Information in this document is current as of 14 August 2026.

ADAP, antibody detection via agglutination-PCR; CoE, Center of Excellence; HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; PCR, polymerase chain reaction; T1D, type 1 diabetes.

1. DiaUnion. <https://diaunion.org/en/about-us/>. Accessed August 2026. 2. DiaUnion. <https://diaunion.org/en/for-health-professionals/>. Accessed August 2026. 3. DiaUnion. <https://diaunion.org/en/breaking-news-diaunion-2-0-is-now-a-reality/>. Accessed August 2026. 4. Dunger DB, et al. *Trials*. 2022;23:414.

If you have any questions or considerations around Early Detection Referral Pathways or the information in this document, please use the details listed below to contact your local Sanofi representative

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STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

Current screening in standard clinical practice is performed on an *ad hoc* basis by clinicians for differential diagnosis of T1D and T2D.

1 SCREENING

LOCATION

In clinical settings for differential diagnosis

LOGISTICS

Venous blood clinic

RESULTS COMMUNICATION & NEXT STEPS

Ordering clinician

COST TO INDIVIDUAL/CAREGIVER

None – covered by NHS Clinics

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	NA	NA
METHODOLOGY (assay & sample type)	NA	NA
TESTING LAB	NA	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

NA

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

NA

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; NHS, National Health Service; T1D, type 1 diabetes; T2D, type 2 diabetes.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

ELSA The Early Surveillance for Autoimmune diabetes (ELSA) study in the UK explored the feasibility and acceptability of screening 20,000 children aged 3–13 years for type 1 diabetes (T1D), with more than 17,000 children having completed the ELSA study as of June 2024. It is the largest T1D screening program for children in that age range in the UK general population. ELSA 2 started in January 2026 and will run into 2029, expanding screening to children aged 2–17 across the UK, with a focus on younger children (2–3 years) and older adolescents (14–17 years). The study aims to recruit 70,000 children and, as of November 2025, more than 37,000 families had signed up to the ELSA program.^{1–6}

1 SCREENING

LOCATION

Research sites/Online registration/
Schools/ Commercial Centers

LOGISTICS

Home kit/dried blood spot (DBS)

RESULTS COMMUNICATION &
NEXT STEPS

ELSA Investigators

COST TO INDIVIDUAL/CAREGIVER

Free to participate

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Invited to testing centers	NA
METHODOLOGY (assay & sample type)	University of Birmingham Research Labs	NA
TESTING LAB	University of Birmingham Research Labs	NA
GUIDELINES FOLLOWED	INNODIA protocol ⁷	NA
COST TO INDIVIDUAL/ CAREGIVER	None	NA

3 MONITORING

LOCATION

ARAD or NHS Clinics

PREFERRED METHODOLOGY

Finger-prick capillary

GUIDELINES FOLLOWED

ADA/EASD 2024 Consensus⁸
ADA 2026 Guidelines⁹

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; ARAD, At Risk of Autoimmune Diabetes; EASD, European Association for the Study of Diabetes; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; NHS, National Health Service; T1D, type 1 diabetes.
1. Quinn LM, et al. BMJ Open Diabetes Res Care. 2024;12(5):e004480. 2. Quinn LM, et al. Lancet Diabetes Endocrinol. 2026;14(3):197–9. 3. ELSA. <https://www.elsadiabetes.nhs.uk/about/>. Accessed August 2026. 4. ELSA. <https://www.elsadiabetes.nhs.uk>. Accessed August 2026.
5. <https://www.birmingham.ac.uk/news/2026/childhood-type-1-diabetes-screening-is-effective-and-could-prevent-thousands-of-emergency-diagnoses>. Accessed August 2026. 6. Narendran P. https://medschool.cuanschutz.edu/docs/librariesprovider48/conferences-and-events/2025-8th-symposium-on-general-population-t1d-screening/3-1_elsa-and-other-uk_narendran.pdf?sfvrsn=6f72cdb4_1. Accessed August 2026. 7. Dunger DB, et al. Trials. 2022;23:414. 8. Phillip M, et al. Diabetologia. 2024;67(9):1731–59.
9. ADA 2026 Guidelines. Diabetes Care. 2026;49(Suppl. 1):S27–S49.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

SANOFI COUNTRY CONTACTS

T1DRA The Type 1 Diabetes Risk in Adults (T1DRA) Study aims to screen 20,000 adults aged 18–70 years in the UK general population to determine how many are at increased risk of developing T1D, and to understand more about immune changes before symptoms appear. As of October 2025, 13,535 participants had been enrolled in the T1DRA study, of whom approximately a third were first-degree relatives.^{1,2}

1 SCREENING

LOCATION

Research center/online

LOGISTICS

Home kit/capillary blood

RESULTS COMMUNICATION & NEXT STEPS

T1DRA Investigators

COST TO INDIVIDUAL/CAREGIVER

None

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Invited to testing centers	NA
METHODOLOGY (assay & sample type)	Bristol Research Center (LIPS/RBA)	NA
TESTING LAB	Bristol Research Center	NA
GUIDELINES FOLLOWED	None	NA
COST TO INDIVIDUAL/CAREGIVER	NA	NA

3 MONITORING

LOCATION

ARAD or NHS Clinics

PREFERRED METHODOLOGY

Finger-prick capillary

GUIDELINES FOLLOWED

ADA/EASD 2024 Consensus³
ADA 2026 Guidelines⁴

COST TO INDIVIDUAL/CAREGIVER

None

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ADA, American Diabetes Association; ARAD, At Risk of Autoimmune Diabetes; EASD, European Association for the Study of Diabetes; HCP, healthcare practitioner; IAB, islet autoantibody; LIPS, luciferase immunoprecipitation system; NA, information not available;

NHS, National Health Service; RBA, radio-binding assay; T1D, type 1 diabetes.

1. T1DRA Study. <https://t1dra.bristol.ac.uk/research-so-far>. Accessed August 2026. 2. Narendran P. https://medschool.cuanschutz.edu/docs/librariesprovider48/conferences-and-events/2025-8th-symposium-on-general-population-t1d-screening/3-1_elsa-and-other-uk_narendran.pdf?sfvrsn=6f72cdb4_1. Accessed August 2026. 3. Phillip M, et al. Diabetologia. 2024;67(9):1731–59. 4. ADA 2026 Guidelines. Diabetes Care. 2026;49(Suppl. 1):S27–S49.

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STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

In standard clinical practice, T1D testing and referral pathways are available through different private and public channels in the USA.

1 SCREENING

LOCATION

Home, in clinic, lab

LOGISTICS

Fingerstick blood: home
Venous blood: clinic

RESULTS COMMUNICATION & NEXT STEPS

Ordering physician; Screening
Central telehealth provider if done
through platform

COST TO INDIVIDUAL/CAREGIVER

Depends on insurance

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Ordering physician	NA
METHODOLOGY (assay & sample type)	Up to ordering physician/ commercial lab	NA
TESTING LAB	Commercial labs (Quest/LabCorp) or DTC/Enable	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/ CAREGIVER	Depends on insurance	NA

3 MONITORING

LOCATION

Local physician (primary care provider or
specialist)

PREFERRED METHODOLOGY

Up to healthcare provider (HCP) discretion

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

Depends on insurance

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
DTC, diabetic testing center; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; T1D, type 1 diabetes.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

TRIALNET

In all TrialNet prevention studies, “Pathway to Prevention” screening is the first step offered at no cost to eligible individuals to evaluate their personal risk of developing T1D. Eligible individuals are aged 2–45 years and have a parent, brother/sister, or child with T1D, or, aged 2–20 years and have an aunt/uncle, cousin, grandparent, niece/nephew, or half-brother/sister with T1D. As of World Diabetes Day 2024, over 250,000 people had been screened through TrialNet, and 8937 participants were enrolled in long-term monitoring. Individuals who test positive for T1D-related IAbs through TrialNet are offered ongoing monitoring and may enroll in the Long-Term Investigative Follow-Up in TrialNet (LIFT) Study, which tracks participants before, during, and after diagnosis. LIFT participants receive annual in-person assessments including a Health Status Questionnaire, HbA1c, mixed-meal tolerance test, and other lab tests.¹⁻³

1 SCREENING

LOCATION

Home, lab, in clinic

LOGISTICS

Fingerstick blood: home
Venous blood: clinic

RESULTS COMMUNICATION &
NEXT STEPS

TrialNet Investigators

COST TO INDIVIDUAL/CAREGIVER

Free to eligible participants

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	TrialNet protocol ⁴	NA
METHODOLOGY (assay & sample type)	RBA	NA
TESTING LAB	TrialNet	NA
GUIDELINES FOLLOWED	TrialNet protocol ⁴	NA
COST TO INDIVIDUAL/CAREGIVER	Free to participants	NA

3 MONITORING

LOCATION

TrialNet (TN-01)

PREFERRED METHODOLOGY

TrialNet protocol⁴
(OGTTs are standard)

GUIDELINES FOLLOWED

TrialNet protocol⁴

COST TO INDIVIDUAL/CAREGIVER

Free to participants

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

HCP, healthcare practitioner; IAb, islet autoantibody; NA, information not available; OGTT, oral glucose tolerance test; RBA, radio-binding assay; T1D, type 1 diabetes.

1. TrialNet. <https://www.trialnet.org/our-research/risk-screening>. Accessed August 2026. 2. TrialNet. <https://www.trialnet.org/our-research/long-term-investigative-follow-trialnet-lift>. Accessed August 2026. 3. Jacobsen LM, et al. Diabetes Care. 2025;48(7):1112–24. 4. Sims EK, et al. Diabetes Care. 2019;42:2228–36.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

ASK

Autoimmunity Screening for Kids (ASK) is a health-screening program to detect T1D and celiac disease in all US children (aged 1–17 years) and adults with or without a family history of these conditions. As of November 2025, approximately 38,000 individuals have been screened through the ASK program since launch. Individuals who screen positive can access guidance and support through the ‘Ask the Experts’ program, which offers support including education, monitoring guidance, and referrals to local specialists for follow-up care and early intervention, in partnership with the Barbara Davis Center and clinical experts.^{1–3}

1 SCREENING

LOCATION

Home, lab, in clinic

LOGISTICS

Fingerstick blood: home
Venous blood: clinic

RESULTS COMMUNICATION & NEXT STEPS

ASK Investigators

COST TO INDIVIDUAL/CAREGIVER

Free to participants

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Per Protocol ⁴	NA
METHODOLOGY (assay & sample type)	ECL/RBA	NA
TESTING LAB	Local labs	NA
GUIDELINES FOLLOWED	Per Protocol ⁴	NA
COST TO INDIVIDUAL/CAREGIVER	Free to participants	NA

3 MONITORING

LOCATION

In-study or local Endocrinologist

PREFERRED METHODOLOGY

Per Protocol,⁴ or at discretion of HCP

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

Depending on insurance if local; free to participants if within the study

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ECL, electrochemiluminescence; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; RBA, radio-binding assay; T1D, type 1 diabetes.

1. ASK. <https://www.askhealth.org/>. Accessed August 2026. 2. Gesualdo P. [https://medschool.cuanschutz.edu/docs/librariesprovider48/conferences-and-events/2025-8th-symposium-on-general-population-t1d-screening/3-5_-autoimmunity-screening-for-kids-\(ask\)_gesualdo.pdf?sfvrsn=fe73cdb4_1](https://medschool.cuanschutz.edu/docs/librariesprovider48/conferences-and-events/2025-8th-symposium-on-general-population-t1d-screening/3-5_-autoimmunity-screening-for-kids-(ask)_gesualdo.pdf?sfvrsn=fe73cdb4_1). Accessed September 2026. 3. Ask the Experts. <https://www.asktheexperts.org/>. Accessed August 2026. 4. Steck AK, et al. Diabetes Care. 2022;45(2):365–71.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

PLEDGE

The Population Level Estimate of type 1 Diabetes risk GENes in Children (PLEDGE) study offers general-population screening for T1D and celiac autoantibodies; Sanford Health is seeking to enroll ~20,000 children, and Sanford patients under 6 years or between 9–16 years of age are eligible. As of November 2025, almost 15,000 individuals had consented to participate. The study includes GRS2 (a SNP–base risk score for T1D and celiac autoimmunity) at study entry, utilizing a blood spot, which may be collected with newborn screening.^{1,2}

1 SCREENING

LOCATION

Home, lab, in clinic

LOGISTICS

Fingerstick blood: home
Venous blood: clinic

RESULTS COMMUNICATION & NEXT STEPS

PLEDGE Investigators

COST TO INDIVIDUAL/CAREGIVER

Free to participants

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IABs on Screening)	RESCREENING (Undetectable IABs on Screening)
COORDINATING HCP/TEAM	Per Protocol ²	NA
METHODOLOGY (assay & sample type)	RBA	NA
TESTING LAB	Local labs	NA
GUIDELINES FOLLOWED	Per Protocol ²	NA
COST TO INDIVIDUAL/CAREGIVER	Free to participants	NA

3 MONITORING

LOCATION

In-study or local Endocrinologist

PREFERRED METHODOLOGY

Per Protocol²

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

Depending on insurance if local; free to participants if within the study

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

GRS2, Genetic Risk Score 2; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; RBA, radio-binding assay; SNP, small polynucleotide polymorphism; T1D, type 1 diabetes.

1. PLEDGE. <https://research.sanfordhealth.org/the-sanford-project/pledge>. Accessed August 2026. 2. Griffin KJ. https://medschoolcuanschutz.edu/docs/librariesprovider48/conferences-and-events/2025-8th-symposium-on-general-population-t1d-screening/3-4_pledge-platform_griffin.pdf?sfvrsn=e173cdb4_1. Accessed August 2026.



STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

CASCADE

The Combined Antibody Screening for Celiac And Diabetes Evaluation (CASCADE) Research Study estimates each child’s risk for T1D and celiac disease; it is currently enrolling newborns born in Washington State in the USA. The project will target 75,000 samples over a period of 5 years and will be using residual blood from NBS specimen cards to obtain samples. The estimated study completion date is June 2026.¹⁻³

1 SCREENING

LOCATION

Home, lab, in clinic

LOGISTICS

Fingerstick blood: home
Venous blood: clinic

RESULTS COMMUNICATION & NEXT STEPS

CASCADE Investigators

COST TO INDIVIDUAL/CAREGIVER

Free to participants

2 TESTING & STAGING

	CONFIRMATORY TESTING (Detectable IAbs on Screening)	RESCREENING (Undetectable IAbs on Screening)
COORDINATING HCP/TEAM	NA	NA
METHODOLOGY (assay & sample type)	LIPS	NA
TESTING LAB	Local labs or commercial labs	NA
GUIDELINES FOLLOWED	NA	NA
COST TO INDIVIDUAL/CAREGIVER	Free to participants	NA

3 MONITORING

LOCATION

In-study

PREFERRED METHODOLOGY

NA

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

Free to participants if within the study

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.
HCP, healthcare practitioner; IAb, islet autoantibody; LIPS, luciferase immunoprecipitation system; NBS, newborn blood spot; NA, information not available;; T1D, type 1 diabetes.
1. CASCADE. <https://cascadekids.org/>. Accessed August 2026. 2. Washington State Department of Health. <https://doh.wa.gov/you-and-your-family/infants-and-children/newborn-screening/research>. Accessed August 2026. 3. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT04677699>. Accessed August 2026.

STANDARD CLINICAL PRACTICE

RESEARCH INITIATIVE

EARLYCHECK

EarlyCheck is a statewide, voluntary study that aims to support the health of newborns and families in North Carolina; the study uses DNA sequencing to screen for ~200 serious health conditions (including many not covered by standard newborn screening) and can report the lifetime risk for T1D. Between September 2023 and June 2024, a total of 2125 newborns were enrolled.¹⁻³

1 SCREENING

LOCATION

Home, lab

LOGISTICS

Fingerstick blood: home
Venous blood: clinic

RESULTS COMMUNICATION &
NEXT STEPS

EarlyCheck Investigators

COST TO INDIVIDUAL/CAREGIVER

Free to participants

2 TESTING & STAGING

CONFIRMATORY TESTING
(Detectable IABs
on Screening)

RESCREENING
(Undetectable IABs
on Screening)

COORDINATING
HCP/TEAM

Per Protocol⁴NA

METHODOLOGY
(assay & sample type)

LabCorp/ELISA or ASK/ECL
(EarlyCheck)NA

TESTING LAB

Local labs or commercial
labsNA

GUIDELINES
FOLLOWED

Per Protocol⁴NA

COST TO INDIVIDUAL/
CAREGIVER

Free to participantsNA

3 MONITORING

LOCATION

In-study

PREFERRED METHODOLOGY

Per Protocol⁴

GUIDELINES FOLLOWED

NA

COST TO INDIVIDUAL/CAREGIVER

Free to participants if within the study

SINGLE IAB MONITORED?

NA

Disclaimer: Please note the information in this document is current as of 14 August 2026.

ASK, Autoimmunity Screening for Kids; DNA, deoxyribonucleic acid; ECL, electrochemiluminescence; ELISA, enzyme-linked immunosorbent assay; HCP, healthcare practitioner; IAB, islet autoantibody; NA, information not available; T1D, type 1 diabetes.
1. EarlyCheck. <https://earlycheck.org/home-2/>. Accessed August 2026. 2. EarlyCheck. <https://earlycheck.org/for-health-care-providers/type-1-diabetes-risk-screening/>. Accessed August 2026. 3. Cope HL, et al. Nat Med. 2025;31:3762–71. 4. Bailey DB, et al. BMC Pediatr. 2019;19(1):238

