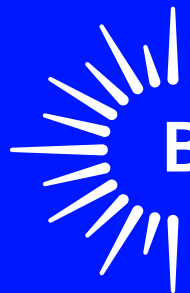


# The Australian Vision for Early T1D Screening

Dorota Pawlak, PhD  
Chief Scientific Officer  
BT1D Australia



**Breakthrough T1D™**

Formerly JDRF



*Disclosure: no-commission consultation for Sanofi Australia*

# Breakthrough T1D Type 1 Diabetes Clinical Research Network

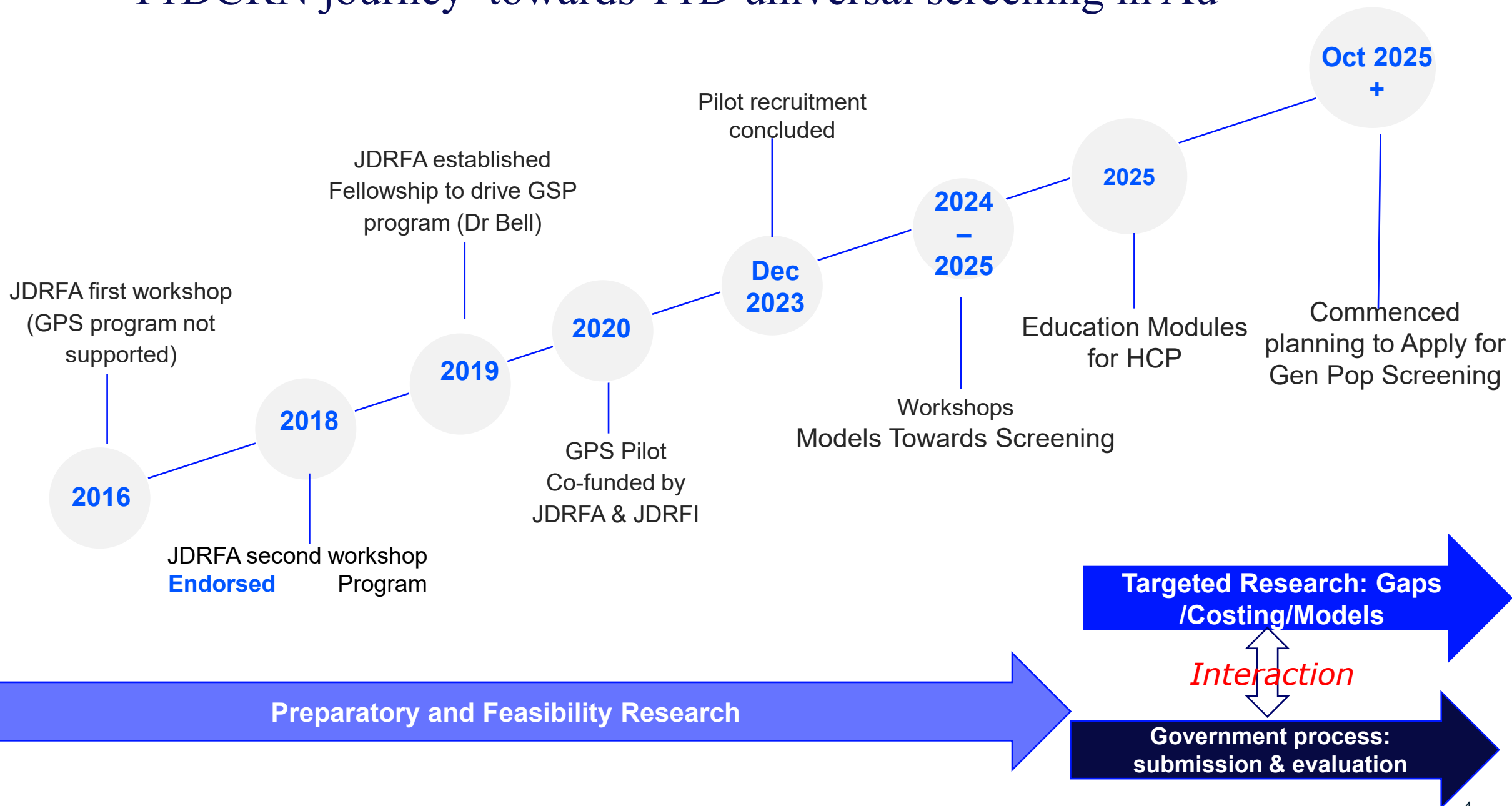
## T1DCRN



The T1DCRN was initially launched in June 2010 with \$5m from the Australian Government, followed by further \$110m of continued investment.

This established the highly successful virtual research network, aimed to drive better health outcomes for people with T1D, bringing beneficial change to health practice and increasing research collaboration nationally and internationally.

# T1DCRN journey towards T1D universal screening in Au

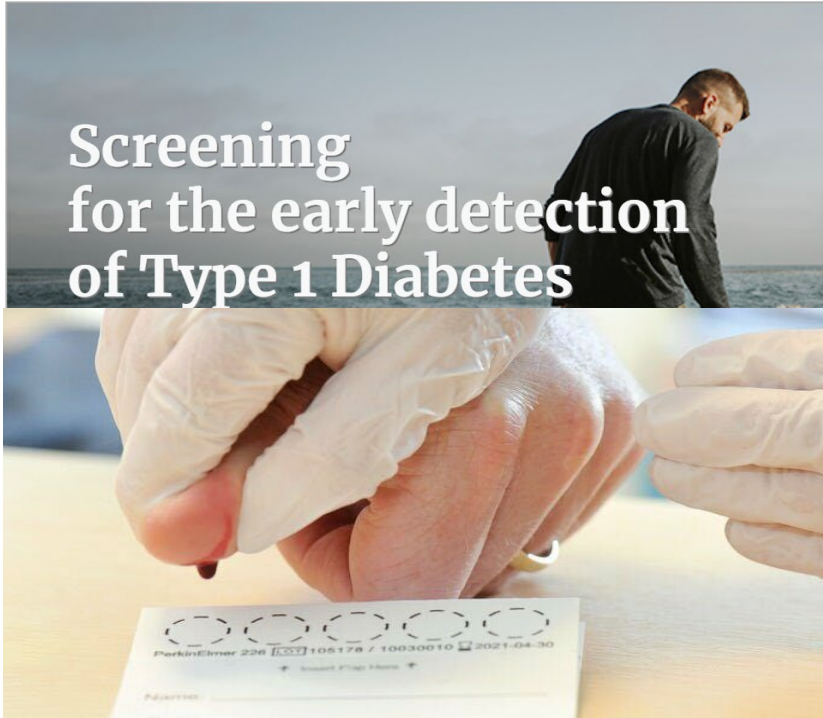


# Early Detection Programs in Australia T1D (as of 2025)

For Individuals with Family History  
(Ongoing)



Home About Us Getting Involved Support Us Resource



General Population Screening Pilot  
(recruitment ended in 2023)

**SIMPLE TEST**

**BIG OUTCOMES**  
TEST FOR TYPE 1 DIABETES

Babies born in this hospital will be offered screening for type 1 diabetes.

Screening is free, simple and safe.

A simple heel prick test when your baby is born helps find and care for these kids as early as possible, before they become very sick.

The Type 1 Diabetes National Screening Pilot is a research study aiming to find the best way to offer screening for type 1 diabetes to children in Australia.

**TYPE 1 DIABETES**

**National Screening Pilot**

**Where can I find more information?**

Your midwife can help answer your questions

[www.KidsDiabetesScreen.com.au](http://www.KidsDiabetesScreen.com.au)  
1800 505 909

**TYPE 1 DIABETES National Screening Pilot**

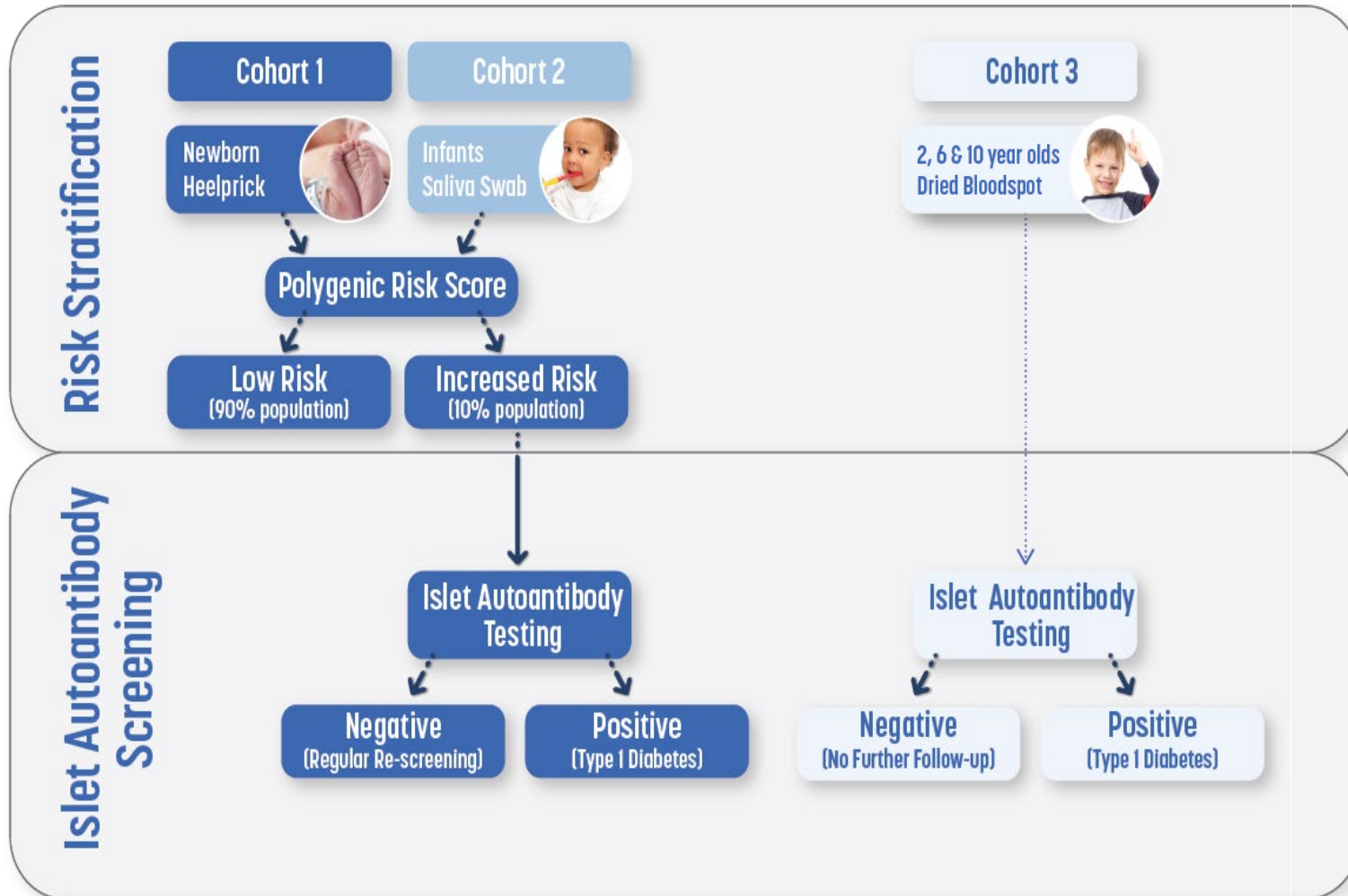
SUPPORTED BY:

This study has been approved by the Sydney Children's Hospitals Network Human Research Ethics Committee (Approval Number: 2022/ETH00637) and authorised at The Royal Hospital for Women by the Sydney South Eastern Local Health District (Authorisation Number: 2022/3518.0260). If you have any concerns or complaints you can contact the Research Ethics and Governance Officer on (02) 9362 3957 or 9324.86.402@health.nsw.gov.au.  
 TYPE 1 DIABETES NATIONAL SCREENING PILOT NEWSPAPER ADVERTISING POSTER MASTER V1.2 21/04/2022 BHW V1.0 06/06/2022

# Pilot for the Australian T1D National Screening Program



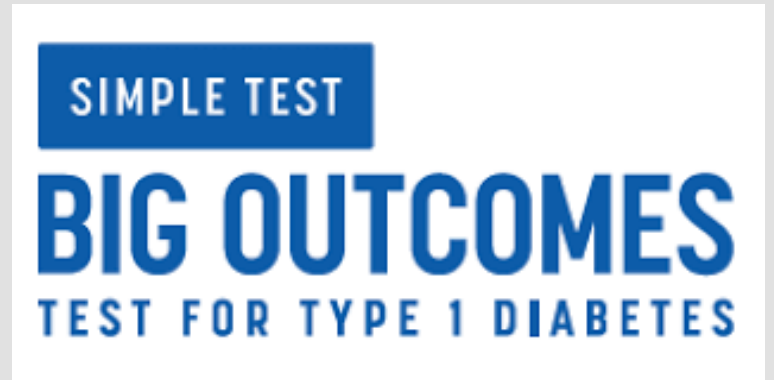
Dr Kirstine Bell



- ❑ 6700 participants registered across the three cohorts
- ❑ Manuscript with Pilot Results Submitted for Publication
- ❑ Health Economic analysis publication accepted

Protocol Published – Diabetic Medicine 2024, Bell KJ et al

Is it the right time to consider application for general population screening in Australia ?








# The importance of screening in public health setting

- The purpose of screening is to identify people in an **apparently healthy population** who are at higher risk of a health problem or condition.
- This can **enable early treatments or interventions**, and thereby reduce the incidence and/or mortality of the health problem or condition within the population.
- Screening is intended for all people, in an identified target population, who do not have symptoms of the disease or condition being screened for.
- The process can identify:
  - a pre-disease abnormality
  - early disease
  - disease risk markers.

*WHO*

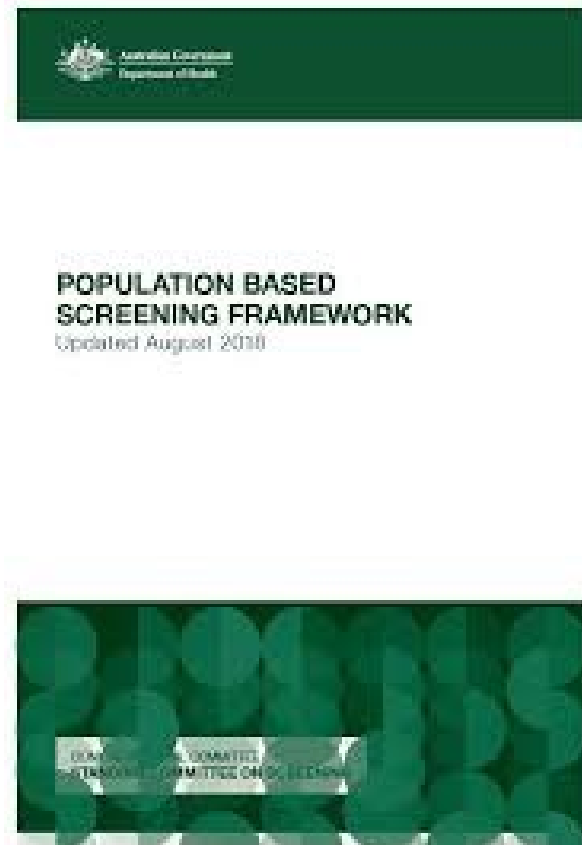


# National Screening Programs, uptake & impact (AU)

 <p>BreastScreen AUSTRALIA A joint Australian, State and Territory Government Program</p>	<p>Introduced in 1991</p> <p>Uptake 50%</p>	<p><b>40%</b> reduction in mortality since 1994</p>
 <p>NATIONAL CERVICAL SCREENING PROGRAM A joint Australian, State and Territory Government Program</p>	<p><b>Screening introduced in 1991, HPV Vaccination in 2007</b></p> <p><b>Uptake: Screening 73%; Vaccination 82%</b></p>	<p><b>75%</b> reduction in mortality (1982-2022)</p> <p>on track to eliminate cervical cancer by 2035</p>
 <p>NATIONAL BOWELCANCER SCREENING PROGRAM</p>	<p>Introduced in 2006; followed from <b>pilot program 2002-2004</b></p> <p>Uptake 40%</p>	<p><b>33%</b> reduction in mortality (2021 – 2024)</p>
 <p>NATIONAL LUNG CANCER SCREENING PROGRAM</p>	<p>Introduced July 2025, high risk individuals</p> <p>Uptake too early to assess</p>	<p>Impact too early to assess</p>
 <p>Newborn Hearing Screening</p>	<p>Initially state-based rollout; 2000 in WA, 2002 in NSW; Nationally in 2004</p> <p>Uptake 97%;</p>	<p>Impact not measured</p>
<p>Newborn Bloodspot Screening</p>	<p>Introduced in 1960s; it is run by states (inconsistent which conditions are included)</p> <p><b>Funding for expansion 2022-2028</b></p> <p>Uptake 99%</p>	<p>Impact not assessed</p>

# Process for evaluation of new screening programs

# Evaluation framework is based on Wilson & Jungner



## Population Based Screening Framework

- Introduced in 2006
- Revised in 2018
- Currently under revision with anticipated release in 2026
  - Morbidity
  - PROMs
  - Genomics

# Health Minister Decision informed by Expert Committee

## Medical Services Advisory Committee (MSAC)

Independent Committee to advise the government ie: Federal Health Minister on public funding for health services including screening

- **Minimum** timeframe from submission to FIRST decision is 16 months
- A positive recommendation from MSAC is not a guarantee of Ministerial approval and subsequent release of funding from Treasury for formal implementation
- There is no precedence for screening for a chronic condition in Australia

## Key input requirements are complex:

*(Guidelines Document is 309 pages long)*

- Clinical Evidence
- Economic Evidence including PRO
- Evidence of Value of Knowing (ie Risk and harms)
- Stakeholder acceptance
- Consumer acceptance
- Health Care Resources use
- Cost of Change

**Etc....**



# Advancing Public Health Policy

Clinical evidence meets the momentum in willingness to change health policy

- Strength of Evidence
- Clinical Effectiveness
- Economic Benefit



- Social Strategy
- Political Will
  - Public Understanding
  - Government Support

The best time to plant a  
tree was 20 years ago.

The second-best time is  
now

*A Chinese Proverb*



# Important milestones with relevance towards T1D Screening Policy



## Global Perspective

- Published Consensus Guidance for monitoring individuals with islet autoantibody-positive pre-stage 3 type 1 diabetes

**Diabetes Care.**  American Diabetes Association.

Consensus Guidance for Monitoring Individuals With Islet Autoantibody-Positive Pre-Stage 3 Type 1 Diabetes

- **EASD 2025:**
  - Recommendation population-based screening for T1D through testing for AAbs

- Italy 2023: legislation to establish a nationwide, screening program for T1D and celiac disease in children/adolescents aged 1-17 years
- 2025: Breakthrough T1D Submission to USPSTF
- Globally over 600,000 children in general population were screened for early T1D
- First therapy to delay Stage 3 approved in 2022

# Important milestones with relevance towards T1D Screening Policy



## National Perspective

### ➤ **Federal Government assigns screening as a priority for diabetes**

- July 2024: Parliamentary Inquiry into Diabetes: The State of Diabetes Mellitus in Australia in 2024

*R4: The Committee recommends that the Australian Government explores the potential for effective national screening programs for all forms of diabetes*

- **Stakeholder Support:** 2024-25 BT1D (AU) formed **Early T1D Working Group** (Co-Chaired by Prof Jennifer Couper and Dr Dorota Pawlak) comprised of all major diabetes organisation in AU

### ➤ **Changes in legislation**

- September 2025: Legislation to ban the use of adverse genetic testing results in life insurance; *(2007 - legislation to ban using genomics data in private health insurance)*

### ➤ **National Program and Data Collection**

- 2025: Data Analysis for Pilot for Australian T1D Diabetes National Screening Program Completed

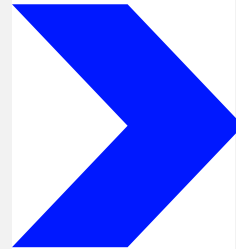
- **Potential for Therapy:** January 2025: Sanofi filed application to TGA for Teplizumab approval



# Two Pillar Approach towards National Health Screening Program in T1D

## ➤ **2025: Breakthrough T1D in Australia**

- Received \$50M funding for continuation of T1D Clinical Research Network
- Funding comes from Chronic Conditions Section of the Dep of Health, Federal Government
- **One of the key KPI:**
  - Develop a prevention screening pilot program for T1D in children



## ➤ **2-Pillar approach towards the Goal**

### ➤ **Pillar 1: Implementation Research**

- 2026: Comprehensive National Program for Screening, Monitoring and Interventions

### ➤ **Pillar 2: Policy Platform**

- BT1D AU partners with Axis Health Co. (Sciences and Healthcare Consultancy) to progress application submission to MSAC for universal screening for T1D in 2027

# Pillar 1: Australia-wide unique, coordinated approach towards T1D screening, monitoring & intervention



Prof Jennifer Couper

**Type 1 Screen<sup>1</sup>**

- Community screening of T1D relatives 2–35 years old
- 145 IA-positive screens<sup>1</sup>

**ENDIA<sup>2</sup>**

- First degree relative with T1D ENDIA graduates >10 years
- 110 IA positive – ongoing

**National Screening Pilot<sup>3</sup>**

- General population screening of 6–12 year olds – 2026 –



Prof John Wentworth

**Central islet autoantibody lab**  
The Royal Melbourne Hospital



Dr Kirstine Bell

**Associated studies**

QuEST – family experiences<sup>4</sup>  
TRACE-T1D – continuous glucose monitoring<sup>5</sup>

**Early T1D Monitoring Program**  
(8 centres [7 paediatric] & National Data Registry)<sup>6</sup>

- Health service delivery data
- Clinical and metabolic outcomes
- Fidelity to international guidelines

**Disease-modifying trials to preserve insulin production<sup>7</sup>**

AUSTRALASIAN TYPE 1 DIABETES IMMUNOTHERAPY COLLABORATIVE

Eligible children and young adults



Dr Aveni Haynes

**ENDIA**, Environmental Determinants of Islet Autoimmunity; **IA**, islet antibodies; **T1D**, type 1 diabetes  
**1.** Type1Screen. Screening for Type 1 Diabetes. Available at: <https://type1screen.org/> **2.** Walker GJ, et al. JAMA Pediatr. 2025;179:568–570. **3.** Bell KJ, et al. Diabet Med. 2024;41:e15419. **4.** Couper et al. Breakthrough T1D International study in progress. **5.** TRACE T1D. Launching TRACE T1D. Available at: <https://diabetes.thekids.org.au/news-and-events/trace-t1d/> **6.** Breakthrough T1D. New guidance set to change the way we diagnose type 1 diabetes. Available at: <https://breakthrought1d.org.au/news/new-guidance-for-early-stage-t1d/> **7.** ATIC. Clinical trials. Available at: <https://atic.svi.edu.au/clinical-trials/>.



Prof John Wentworth & Thomas Kay

# Pillar 2: Political Will Assessment

## Partnership with health consultancy to establish a Roadmap for Screening Program in T1D

