10 YEARS:
10 STORIES OF IMPACT

CASE STUDY 6

Fast-tracking immunotherapy treatment options towards a cure

Autoimmunity against pancreatic beta cells is the principal mechanism leading to type 1 diabetes (T1D). As such, research efforts are directed towards intercepting this destructive process, with the intervention of immunotherapies before beta cell loss reaches a critical threshold. Australian strengths in immunology research are world-recognised, however moving potential immune therapies from a lab to clinical trials requires a consolidated, coordinated effort from a multidisciplinary team of experts.

The Australian Type 1 Diabetes Clinical Research Network (T1DCRN) funded the establishment of the Australasian Type 1 Diabetes Immunotherapy Collaborative (ATIC) to provide the infrastructure to support such efforts. ATIC has supported Australia's immunotherapy talent and cemented Australia as an attractive site for immunotherapy clinical trials. Following on from its inception, ATIC has one prevention study and three clinical trials operating within its network.

Australian Type 1 Diabetes Clinical Research Network

JDRF IMPROVING LIVES. CURING TYPE 1 DIABETES.

WHAT PROBLEM DO WE NEED TO SOLVE?

Since the 1970s, beta cell autoimmunity has been recognised as the principal mechanism leading to T1D. Decades of research has since identified subsets of immune cells, in particular T lymphocytes, some of which participate in the damage of pancreatic beta cells, and others, such as T regulatory cells, which can suppress excessive immune response and ultimately protect beta cells from destruction.

Many research projects have been dedicated to the development of therapies that can target the subsets of immune cells capable of suppressing or halting immune attack before beta cells are destroyed, aiming to delay the insulin dependent stage of T1D, and ultimately prevent its onset altogether.

Many years of research discovery and clinical testing led to the historic approval by the FDA of teplizumab in 2022. Teplizumab blocks the damaging action of T lymphocytes on beta cells. Infusion of this therapy delays the onset of symptomatic, insulin-requiring Stage 3 of the condition.

This breakthrough was the first new therapy approved for T1D since insulin some 100 years prior, and was proof that immunotherapies are a viable treatment option for the T1D community.

For more of these discoveries to be fast-tracked, infrastructure is needed to support a coordinated effort within Australia and globally to move potential therapies through the clinical trial phase. Robust investment in local capacity is needed for Australia to be at the forefront of these breakthroughs and their adoption into affordable clinical care.

WHAT WAS FUNDED BY THE T1DCRN, AND WHY?

Efforts to address this led to the establishment by the T1DCRN of the Australasian Type 1 Diabetes Immunotherapy Collaborative (ATIC), a consortium connecting experts and clinical sites in Australia and New Zealand to accelerate breakthroughs.

Coordinated by St Vincent's Institute of Medical Research and led by **Professor Thomas Kay and Associate Professor John Wentworth**, both of whom are globally renowned for their T1D research, the principal goal of ATIC is to offer most individuals diagnosed with Stage 1, 2, or 3 T1D in Australia and New Zealand access to an immunotherapy clinical trial.

Commencing in 2021 with a $2.4 million grant, it is a national clinical trials network that brings together adult and paediatric endocrinologists, immunologists, clinical triallists, and members of the T1D community across the country and internationally. As of March 2023, ATIC comprises a network of 24 clinical sites and 15 medical research institutes throughout Australia and New Zealand (Figure 1).

The T1DCRN funding of ATIC covers specialised personnel to operate and administer the network, align research procedures with other global clinical networks, include T1D community members in decision making, mentor future clinicians and work with regulatory bodies to accelerate local approvals of new therapies. Additional leveraged funding is sought by ATIC from a variety of sources to conduct trials through the network.

ATIC is the first and only immunology-focused clinical trials platform within Australia and has the capacity to facilitate the conduct of clinical trials in line with international standards, in turn cementing Australia as an attractive site for immunotherapy clinical trials.

ATIC Collaborator Locations

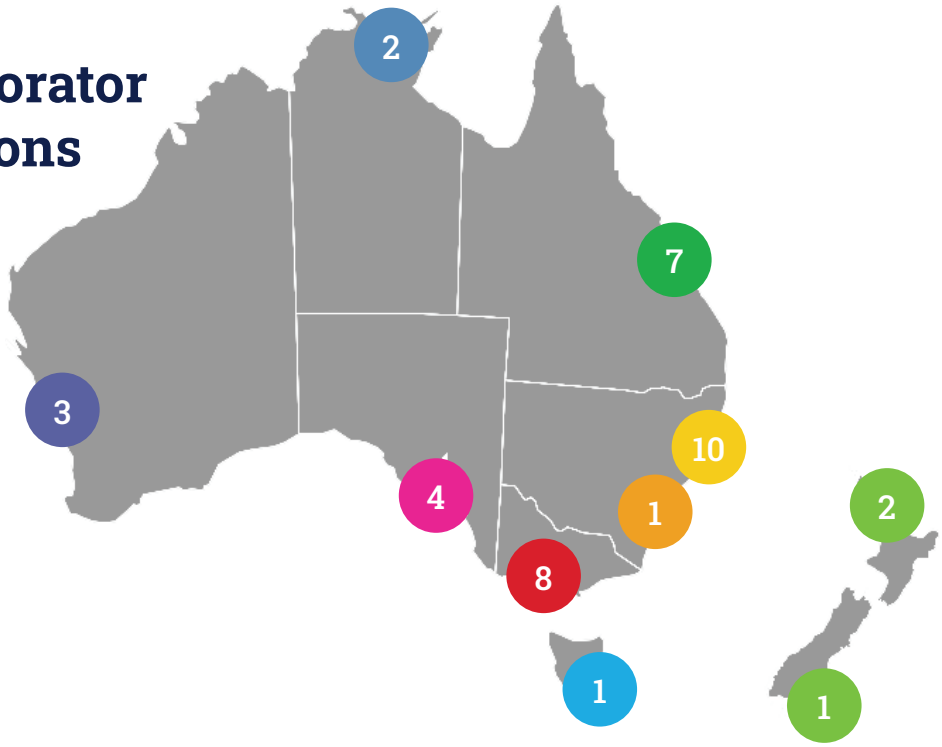

Figure 1: ATIC collaborator locations around Australia (image provided by ATIC)

WHAT HAS THIS DELIVERED?

Two years on from its inception, ATIC has one prevention study, and three clinical trials testing therapies to suppress beta cell destruction, operating within its network. These include:

Type1Screen: a screening program aimed at identifying individuals with pre-symptomatic T1D, who can be offered access to immunotherapy clinical trials

Insulin and Abatacept in Recently-diagnosed Type 1 Diabetes (IAA): combining two therapies, abatacept, an injectable immunotherapy currently in clinical use for rheumatoid arthritis and other autoimmune conditions, and nasal insulin

IMCY-0098 Proof of ACtion in Type 1 Diabetes (IMPACT): a trial testing a new experimental drug, known as IMCY-0098, an injectable peptide

Baricitinib in New-onset Type 1 Diabetes (BANDIT): a trial testing if a once-daily tablet of baricitinib, a therapy currently used for rheumatoid arthritis can be effective in T1D

WHAT DOES THIS MEAN?

The work of ATIC has cemented Australia as a leader in immunotherapies.

The progress that ATIC has achieved has:

- **increased capacity in clinical trials in T1D immunotherapies** through establishing the first immunotherapies clinical trial platform in Australia
- **established Australia as a recognised site for conducting international clinical trials,** already bringing together more than 10 expert investigators and 27 national partner organisations and international collaborators
- **advanced knowledge about how immunotherapies can be utilised,** including who responds to immunotherapies, why they respond, and what therapy dose is optimal.

The establishment of ATIC and its subsequent implementation of multiple clinical trials, provides hope for the T1D community. A future where people with T1D have treatment options, in addition to insulin, is closer than ever.

"JDRF's funding of the ATIC has been instrumental in building the necessary infrastructure to consolidate immunotherapy clinical trials for T1D in Australia. In only a few years, we have seen tremendous progress with multiple clinical trials now in operation, already showing promising results for the community. Without JDRF's support, this type of platform would not be possible.

Associate Professor John Wentworth,
ATIC Lead Investigator