CASE STUDY

THE AUSTRALASIAN TYPE 1 DIABETES IMMUNOTHERAPY COLLABORATIVE

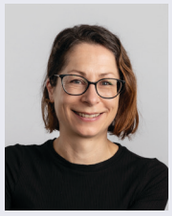
Showcasing novel collaboration models between CTNs and Industry

Australian Clinical Trials Alliance

The Australasian T1D Immunotherapy Collaborative (ATIC) is a clinical trials network supporting both investigator-initiated and commercially sponsored trials and research projects. Their work spans pre-clinical testing of new immune interventions, facilitating and conducting T1D clinical trials through collaborating hospitals, and collecting, storing, and analyzing clinical trial samples.

AUSTRALASIAN TYPE 1 DIABETES IMMUNOTHERAPY COLLABORATIVE

MICHAELA WAIBEL
CO-PROJECT MANAGER



Michaela Waibel received her PhD in 2007 from the University of Hohenheim, Germany, and held post-doctoral positions at the University Clinics Tuebingen and Peter MacCallum Cancer Centre, Melbourne. She later worked as a research project manager at St Vincent's Institute of Medical Research, focusing on islet transplantation and T1D therapies. At ATIC, Michaela is co-project manager and oversees the BANDIT (Baricitinib in new-onset type 1 diabetes) clinical trial, now entering an extended observational follow-up phase.

CANDICE HALL
CO-PROJECT MANAGER

Candice Hall completed a Bachelor of Nursing at Monash University in 2006 and developed an interest in diabetes management while working at St Vincent's Hospital. She became a research nurse at the Royal Melbourne Hospital, focusing on type 1 diabetes prevention, and led clinical trials in diabetes and endocrinology for over a decade. In 2018, Candice completed a Master of Public Health, researching breastfeeding and type 1 diabetes. Since 2022, she has been co-project manager at ATIC, supporting clinical trials and pre-clinical research on immune-modifying treatments for type 1 diabetes.

Please tell us about ATIC as a fairly new CTN and how the collaboration came about

Insulin has been the sole treatment for type 1 diabetes for the last 100+ years. Hosted by St Vincent's Institute of Medical Research (SVI), **ATIC** was established in 2022 with funding from Breakthrough T1D (formally JDRF).

The collaborative works across six distinct but interconnected domains to ensure maximum impact towards our vision: *to fast-track new immunotherapy treatment options for people with type 1 diabetes (T1D).* These domains include:

1. Clinical Trials;
2. Regulation and Government;
3. Education and Training;
4. Data Management;
5. Pre-clinical and Translation; and
6. Community Engagement.

ATIC's overarching remit is to:

- Expand site networks and build site capacity to conduct high-quality T1D immunotherapy trials in Australia and New Zealand.
- Ready the diabetes workforce for the implementation of immunotherapy treatment for T1D by providing health professional education and training.
- Work with the T1D community to ensure they are at the forefront in the process of planning and priority setting.

Please describe your roles at ATIC

As project managers of the network, we sit within the network's core coordinating team and are responsible for day-to-day operations as well as strategy and planning, facilitating steering committee meetings and reporting to the funding body.

What are some of the specific challenges of conducting clinical trials in the type 1 diabetes space?

One challenge is the reality that there is a consistent need for cross-over between paediatric and adult populations and trial inclusion criteria often span both childhood, adolescence and adulthood (eg 8-45 years). Therefore, we are working with endocrinologists in both paediatric and adult settings to ensure that, as a network we can meet recruitment targets across the required patient population for new trials.

Another challenge is raising awareness of clinical trial opportunities amongst the T1D healthcare workforce, given the potential for immunotherapies to change the treatment paradigm for T1D.

What are some of the challenges you face as a CTN more broadly?

Sustainable funding is an ongoing challenge for many CTNs, and a major priority of ours is to think innovatively about new revenue models to sustain ATIC into the future. Also, as we get busier, finding the capacity to implement new strategies and ideas is an ongoing challenge.

What is the mix of ATIC's trial portfolio in terms of IITs compared to commercially-sponsored studies and how have you gone about increasing engagement with industry?

At the moment, IITs and commercially-sponsored studies are split 50/50, but we are focused on growing our commercially sponsored trial portfolio, both as a means of offering Australians and New Zealanders the latest, cutting-edge international research, but also as a way to ensure ATIC's sustainability into the future.

We spent the first couple of years building an offering for industry as an independent service and we are essentially now moving towards commercialising some of the services we provide in an acknowledgement that in-kind work only stretches so far.

Please tell us more about how ATIC has partnered with Industry to be a service provider of choice

ATIC formalised a network of T1D clinicians and researchers who had worked together on clinical trials for over three decades, including establishing a steering committee of key opinion leaders in the field from around Australia and a Community Engagement Panel (CEP). ATIC's steering committee assessment and endorsement of new clinical trial proposals is of great value for industry, as it provides a centralised process for feedback, as well as opportunity to scope potential sites. Our offer also includes review/feedback of trial documents by the CEP.

In keeping with ATIC's focus on communication, ATIC has brought together an extensive group of health professionals, with a list of interested parties that is continuously growing, including new potential trial sites. In addition, we set up a mailing list for the T1D community from the outset and started taking enquiries from the day the website was launched. We now have a growing mailing list of members of the T1D community who have expressed interest in participating in research. Along with our web/social media presence, we offer clinical trial recruitment services from communications and advertising, through to participant enquiry management and triage services.

We have since increased our offering to consulting and advisory services including protocol development/trial design, support for trial/lab manual development and we partner with SVI's in-house CRO, Effica biolabs, for pre-clinical consulting and validation studies.

Most recently, ATIC has provided consultant and advisory support to two international biotech companies, leading to two phase I clinical trials which commenced recruitment in January 2025. In addition to steering committee endorsement and connecting sponsors with sites that have expertise in T1D clinical trials, we are also providing recruitment support with the expectation that this will fast-track recruitment for these trials.

We have now shown in two Australian IIT's, that the addition of centralised recruitment services can fast-track recruitment, with both the **BANDIT** and **IAA** trials reaching recruitment target ahead of schedule.

In essence, we feel that ATIC provides excellent value for money to Industry partners and we are focusing on advisory services as a part of a diversified approach to revenue generation.

How has being a member of ACTA and a member of SIGNet helped you as you have gotten ATIC off the ground?

Starting a CTN from the ground up has been a new challenge for both of us and there were many knowledge gaps to begin with. ACTA's online resources and SIGNet meetings helped us to both fill the knowledge gaps we knew we had, as well as understand what we 'don't know we don't know'.

The SIGNet network has allowed us to connect with CTNs that are at a similar stage and face similar challenges. This has allowed us to learn from others as part of a two-way knowledge exchange. It has also been invaluable for making new connections and avoiding reinventing the wheel.

What role do you think that ACTA can play in the future to support the broader national clinical trial ecosystem?

ACTA has such an important role to play in the national CTN space and we have benefitted from the great work it has already done in terms of providing education and resources and facilitating the sharing of knowledge between groups. The communities of practice that ACTA supports are wonderful for exchanging knowledge amongst peers in a collaborative way.

Future work sharing relevant CTN exemplars via case studies, promoting the sharing of lessons learned around key topics such as commercial agreements, sustainability funding and operational efficiencies would further enhance the ability for new CTN's to identify opportunities for industry collaboration.