ANNUAL REPORT 2025 - 2026

Australian NPC Disease Foundation Inc

ABN: 87 767 010 514

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C/- 3 WALLER STREET, BENALLA VIC 3672

PRESIDENT'S REPORT

2025-2026 Annual General Meeting

Prepared by Mandy Whitechurch

As we reflect on the period from **February 2025 to November 2025**, it is my pleasure to present the President's Report for the Australian NPC Disease Foundation (ANPDF). This report provides an overview of our achievements, challenges, and transitions as we continue our mission to support families and advocate for improved understanding, care, and treatment of Niemann-Pick Disease.

This has been a year of progress, collaboration, and change. With the Foundation's annual reporting period now aligned to the ACNC cycle, we have strengthened our governance and strategic focus, ensuring our operations remain transparent, sustainable, and effective for the years ahead.

Achievements

Financially

Over the past year, the Foundation has continued to maintain its financial stability through careful management and community generosity. Regular quarterly contributions were made to The Florey Institute in support of Dr Ya Hui Hung's mRNA therapy research, ensuring that Australian-led scientific progress remains a core focus of our funding support. The ongoing engagement of Ellie Van Velsen as Project Coordinator for the National Care and Guidelines Project has allowed continuity in this key initiative, while community fundraisers, monthly donors, and one-off contributions have sustained operational needs.

Throughout this period, the Foundation has navigated a transition in administrative structure. The decision to conclude the General Manager position at the end of 2025 was made after careful consideration of our future sustainability. This change reflects our commitment to ensuring a strong, volunteer-led organisation that can continue to deliver on its mission with efficiency and accountability. We have also been in a position to support global initiatives that would impact Niemann-Pick disease awareness; the Global Consensus Project by Childhood Dementia Initiative and supporting the rebuilding of Niemann-Pick UK.

Development of the NPC Care Guidelines

The **National Care and Guidelines for Niemann-Pick Disease Type C** project has continued to progress toward publication. Under the coordination of Ellie Van Velsen, this project has been developed with valuable input from clinicians, researchers, and families across the country. The Medical and Scientific Advisory Committee has provided ongoing expert oversight and review, ensuring that the Guidelines meet high clinical standards.

Importantly, the lived experiences of families have remained central to this work. Through surveys and community consultations, patient and carer voices have shaped the content and direction of the Guidelines, ensuring they provide practical, compassionate, and relevant information. The publication of this document will be a landmark moment for the Foundation, offering Australia's first unified guidance on care and management for Niemann-Pick Disease Type C.

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Community Engagement and Advocacy

This year has seen strong participation from the Foundation in both national and international advocacy activities. The **2025 Australian Niemann-Pick Conference**, held in Melbourne in June, brought together families, clinicians, and researchers for two days of learning, collaboration, and community connection. The event showcased not only the scientific and medical progress being made globally but also the resilience and strength of our local community.

Beyond the conference, the Foundation continued to ensure representation at key sector events. We attended the **Lysosomal Storage Disorder Summit** in Sydney, participated in the **International Niemann-Pick Disease Alliance (INPDA) Summit** in September, and had representatives at the **Genetic Support Network of Victoria (GSNV) Conference**. In addition, we were represented at **Parliament House in Canberra** for the launch of the **Neurological Alliance Australia Blueprint**, a key national initiative advocating for improved recognition and support across neurological conditions.

Our collaboration with the **Childhood Dementia Initiative** has continued to ensure that the Niemann-Pick community is included in broader advocacy discussions at the national level. The Foundation has also benefited from the ongoing support of volunteers and university placement students, whose contributions have enhanced our communications and project delivery throughout the year.

Fundraising Events

Although this year saw a smaller fundraising calendar, our community spirit and generosity have remained unwavering. Early in the year, Amy Leddick led a **Swimming Challenge**, which encouraged participation and awareness among families and supporters across the country. We launched the **Charity Golf Day** in Melbourne and the Annual **Poker Tournament** in Benalla was once again a highlight, bringing together the local community and raising important funds to support our mission.

Several families and supporters also organised their own initiatives throughout the year, including workplace fundraisers, raffles, and online giving campaigns. These community-led efforts remain a vital part of our fundraising landscape, demonstrating the dedication and creativity of those connected to the Foundation. While the **Silver Raffle** did not proceed in 2025, planning is already underway for refreshed awareness and fundraising activities in 2026. Regular monthly donations and corporate giving programs continued to provide a reliable source of support for our ongoing operations and commitments.

Challenges

While the Foundation continues to achieve important milestones, several challenges have persisted throughout the year. Access to **Miglustat** remains restricted for new patients through the hospitals, which continues to cause distress and frustration for affected families. Changes within the **NDIS system** have also made it increasingly difficult for families to secure appropriate supports and therapies tailored to the complex needs associated with Niemann-Pick Disease. Although an alliance with the Childhood Dementia Initiative's program has eased this frustration.

Volunteer capacity remains an ongoing challenge, as many within our community balance caring responsibilities, employment, and Foundation commitments. The decision to conclude the General Manager role at the end of the year has also required the Executive Committee to re-evaluate internal processes and redistribute key responsibilities to ensure the organisation remains well-supported and active.

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Sustainability

The ANPDF continues to be driven by the dedication and compassion of its members and families. Our Foundation is built on shared experience and a deep understanding of the challenges that come with living alongside Niemann-Pick Disease. We continue to stand together, offering empathy, knowledge, and hope to one another.

As we transition into a new chapter without a formal General Manager, the Foundation's sustainability will rely on continued collaboration, clear communication, and the ongoing commitment of our volunteer leadership. We live with grief before we have lost, grief after we lose, and the uncertainty of what lies ahead — but we face it together. This unity remains our greatest strength and ensures the Foundation's continued presence and impact within the rare disease community.

Conclusion

As I conclude my term as President and prepare to transition into the role of **Immediate Past President**, I do so with deep pride, gratitude, and optimism. Serving as President of the ANPDF has been one of the greatest honours of my life. I am incredibly proud of what we have achieved together — not only through our projects and events but through the spirit of unity and compassion that defines this Foundation.

To the committee, volunteers, and families — thank you for your strength, your trust, and your kindness. To **Deanna Carpino**, our outgoing General Manager, I extend my heartfelt thanks for your leadership, professionalism, and dedication during this period of change and growth. Your contribution has left a lasting impact on the Foundation and on our community as a whole.

As I step aside from the presidency and into the role of Immediate Past President, I remain committed to supporting the Foundation and its future leaders as they continue to build on this foundation of love and perseverance. We do this because of those we love — and it is for them that we will always continue.

With sincere thanks and love,

Mandy Whitechurch
President
mandy@npcd.org.au

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SCIENTIFIC AND MEDICAL ADVISORY COMMITTEE (SMAC) REPORT

2025 Annual General Meeting

SMAC members for 2025:

* **Brendon Boot** (Australia) IP Group Pty Ltd; Kookaburra Bio Consulting; Harvard Medical School
* **Ashley BUSH** (Australia) Oxidation Biology Group, The Florey Institute of Neuroscience and Mental Health
* **Caroline HASTINGS** (USA) UCSF Bienoff Children's Hospital
* **Ya Hui HUNG** (Australia) Oxidation Biology Group, The Florey Institute of Neuroscience and Mental Health
* **Pip JOHNSTON** (Australia) Tenterfield Vet Clinic
* **Sharmila KISS** (Australia) Royal Children's Hospital
* **Felicity MUNRO** (Australia) Future Directions Fitness
* **Tina SOULIS** (Australia) Alithia Life Sciences
* **Ellie VAN VELSEN** (Australia) student, The University of Melbourne
* **Mark WALTERFANG** (Australia) Royal Melbourne Hospital

- The Medical Advisory Committee for the National Care and Guidelines project was invited to submit an Expression of Interest for membership on the SMAC. We are pleased to welcome the following new members:
  * **Shanti BALASUBRAMANIAM** (Australia) The Children's Hospital at Westmead
  * **Jacqueline IMRIE** (UK) International Niemann-Pick Disease Registry (retired)
  * **Maina KAVA** (Australia) Perth Children's Hospital
  * **Rebecca QUINN** (Australia) Royal Children's Hospital
  * **Heidi PETERS** (Australia) Royal Children's Hospital
  * **Michel TCHAN** (Australia) Westmead Hospital

- One hybrid meeting was held in 2025 on 12 June 2025, prior to the annual Australian Niemann-Pick Disease Conference, at the Florey and online via Zoom.
  * **Name Change and Membership:** The committee approved renaming the Scientific Advisory Board (SAB) to the Scientific and Medical Advisory Committee (SMAC) to reflect the inclusion of both clinicians and scientists. Members of the National Clinical Care and Guidelines project were invited to join (see above for new membership).
  * **Australian NP-C Clinical Guidelines Project:** A multidisciplinary team developed comprehensive national guidelines comprised of 22 consensus statements. Broader allied health involvement is planned for future work. Preferred journals for publication are *Developmental Medicine & Child Neurology* and *JIMD*. A clinical summary paper and accessible online resources are in development.
    - **Implementation and Communication:** Key strategies include conference presentations, clinician outreach, educational events, and engagement with patients and families.
    - **Resources and Evaluation:** Planned resources include educational videos for clinicians, establishing a clinical contact point on the ANPDF website, and evaluate outcomes over the next 1 – 2 years using REDCap. The Stroke Australia website is a good reference for resource development.
    - **Diagnostic Pathway Improvements:** Approaches to reducing diagnostic delays for NP-C were discussed, which included promoting inclusion of NP-C in ataxia and psychosis panels, and "Think NPC" campaign and the NP-C suspicion index to improve clinician NP-C awareness.

* 2025 meeting minutes and Clinical Care Guidelines update and implementation PowerPoint presented by Ellie Van Velsen are attached.

Sincerely,

Ya Hui Hung
Chair, SMAC
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PAEDIATRIC LIAISON REPORT

2025-2026 Annual General Meeting

To all within the Australian NPC Foundation community,

For those who I have not had the pleasure of meeting personally, I am writing this not just from a liaison role, but as a fellow traveller on this challenging path with Niemann-Pick Type C (NPC) disease. I am constantly inspired by the bravery of all our children and the immense strength, resilience and dedication of their families.

As parents, our mission is to support our children in thriving, despite the obstacles. This report is a testament to the strength and unwavering spirit of all our children. We aim to celebrate the progress made, acknowledge the difficulties faced, and look forward with hope to the treatments and support systems that are making a difference and those yet to come.

Family Updates:

This year has presented significant challenges for the eldest child in our South Australian family. He experienced the onset of seizures this year, requiring intensive monitoring, new management plans and juggling of medications to find effective treatment. Thankfully there has been stabilisation of seizures at the moment and the family is navigating their new 'normal'.

Another family are experiencing the challenging period of transitioning toward the adult system. Not just the hospital system obstacles, but also the personal obstacles of their children watching friends progress.

Our other families have continued to experienced a more stable year. Several children have shown no significant regression in their clinical signs, which is wonderful news and a source of hope for our entire community.

Trial Progress:

All of the children participating in the ongoing Cyclo Therapeutics trial are now on the open label extension period. Two of the children are receiving their fortnightly infusions at home, which has saved families at least a full day of travel every fortnight.

Melbourne and Adelaide children's hospitals will be sites for the upcoming nizubaglustat trials, however patient participation may be limited due to exclusion criteria.

These trials represent crucial steps in the ongoing search for effective treatments, and we remain hopeful for the positive impact they will have on our children's lives in the coming years.

Support Pathways:

CDI (Childhood Dementia Initiative) has successfully collaborated with NDIS (National Disability Insurance Scheme) to ensure a more efficient pathway. My personal experience has been a very quick NDIS renewal process, with extensive information gathered by a compassionate manager and subsequent programs put in place.

In closing, we will continue to build strong, positive connections within our community, offering peer support and shared resources, because no family should walk this path alone.

Sincerely,

Pip Johnston
Paediatric Liaison
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FLOREY RESEARCH REPORT

2025 ANPDF Annual General Meeting

mRNA-based gene therapy for Niemann-Pick Disease Type C1

mRNA-based gene therapy aims to introduce functional NPC1 protein into NP-C1 cells using mRNA. This strategy represents one of the most effective treatment options for a genetic disease such as NP-C. In 2019 we showed normalisation of cellular cholesterol in NP-C1 patient cells *in vitro* after *NPC1* mRNA treatment. Following on from this promising result, research efforts have focused on optimising *NPC1* mRNA to make it more suitable as a therapeutic.

Research activities in 2025:

- Therapeutic *NPC1* mRNA design and optimisation with one variant identified to have NPC1 protein level equivalent to healthy control 10 days after transfection.
- *In vitro* and *in vivo* assessment of mRNA delivered using lipid nanoparticles (LNPs) and testing new LNP formulations.

Publications and manuscripts submitted/in preparation:

- Tchan, M., Smith, N., Peters, H., Van Velsen, E., Marraffa, C., Ellaway, C., Kruz, K., Mohammad, S., Kava, M., Lee, J., Balasubramaniam, S., Rahman, Y., Boot, B., Bush, A., Munro, F., Hamoy, L., **Hung, Y. H.**, Johnston, P., Carpino, D., Williams, M., Quin, R., Sutherland, I., and Walterfang, M. (submitted). An Australian standard of care for Niemann-Pick Disease Type C.
- Le Roux, L., Walterfang, M., Bush, A.I., **Hung, Y.H.** (in preparation). Current state of therapeutic developments for Niemann-Pick Disease Type C.

Grant applications:

- Successful:
    - Ya Hui Hung | 2025 | Financial assistance to enable Niemann-Pick Disease Type C patients and carers to participate at the 2026 Australian Niemann-Pick Disease Type C Conference | National Disability Conference Initiative 2025 – 2026, Australian Government Department of Social Services | AUD$10,000
    - Ya Hui Hung | 2025 | Florey Levelling Up Program | Career Development Award | AUD$3,000
    - NeuArtica (Louisa Bufardeci, Ya Hui Hung, Roshan Dhillon, Deanna Carpino) | 2025 | A-Maze-ing Brain! | ArtPlay, City of Melbourne | AUD $20,000
- Unsuccessful:
    - American Brain Foundation (CIA: Jaymin Upadhyay; CIs: Pui Y. Lee, Raquel van Gool, Mark Walterfang, Ya Hui Hung, Forbes D. Porter, and Walla Al-Hertani)
    - 2025 CASS Medicine/Science Grant Application (CIA: Ya Hui Hung; CIs: Colin Pouton)
    - 2025 CUREator+ Dementia & Cognitive Decline (CIA Ya Hui Hung; Mark Walterfang, Colin Pouton, Wei Xiang, Ashley Bush, Emilio Werden, and Deanne Greenwood)
- Pending:
    - NHMRC Ideas grant (CIA: Ya Hui Hung; CIB: Mark Walterfang; AIs: Ashley Bush, Akram Zamani, David Wright, Vinod Narayana, Colin Pouton, Leonid Churilov, Garron Dodd, Pawel Kalinowski)
    - NHMRC Ideas grant (CIA: Wah Chin Boon; CIB: Ya Hui Hung; CIC: Xin Huang; CID: Feng Chen)
    - SOAR NP-C EOI (CIA: Ya Hui Hung)

Research presentations:

- **Hung, Y. H.** Developing an mRNA-based Gene Therapy Strategy for Niemann-Pick Disease Type C1: A Blueprint to Treat Childhood Dementia | 2025 | Childhood Dementia Initiative Webinar (Online)
- **Hung, Y. H.** An mRNA gene therapy platform for childhood dementia: Initial findings with Niemann-Pick C and ongoing challenges | 2025 | NCL 2025 International Congress (Sunshine Coast, Australia)
- **Hung, Y. H.** An mRNA gene therapy for Niemann-Pick Disease Type C1: Preliminary results and ongoing challenges | 2025 | 3rd Annual Lysosomal Disease Summit (Sydney, Australia)

- **Hung, Y. H.** | 2025 | International Niemann-Pick Disease Alliance Face-to-Face Meeting (Puerto Iguazu, Argentina)
- **Hung, Y. H.**, Zhang, Y., Mhatre, M., Brook, S., and Nategh, L. NeuMessenger: Gene therapy for childhood dementia | 2025 | CSIRO ON Prime Showcase
- **Hung, Y. H.** Medical Ethics & Rare Diseases: A Fight for Fairness (panel discussion member) | 2025 | Melbourne MD Student Conference (Melbourne, Australia)
- **Hung, Y. H.** The Florey mRNA gene therapy project for Niemann-Pick Disease Type C1: An update| 2025 | 2025 Australian NP-C Conference (Melbourne, Australia)
- Mhatre, M., Zhang, T., Fabb, S., Le Roux, L., Pouton, C., and **Hung, Y. H.** Delivering *NPC1* mRNA to treat Niemann-Pick Disease Type C1 (NP-C1), a childhood dementia | 2025 | International Conference on Central Nervous System Disorders: From Mechanisms to Medicine (Ahmedabad, India)

Other activities:

- Student supervision (continuing): 2x PhD students, 1x Master of Biomedical Science students, 1x Master of Biotechnology student
- Student completions: 1x Master of Biomedical Science student, 1x 3rd year Research Project student, 1x Science and Technology Internship student
- Participated in CSIRO ON Prime 17 program

Projected research activities for 2026:

- Continuing with testing new *NPC1* mRNA therapeutic designs *in vitro* in NP-C1 patient cell lines.
- Proof of concept pilot study of *NPC1* mRNA-LNP treatment in Npc1 mice.
    - Investigation of different LNP formulations with potential to cross the blood-brain barrier against a benchmark LNP formulation (not capable of crossing the blood-brain barrier).
    - Investigation of mRNA-LNP delivery directly to brain cells by intracerebroventricular injection.
    - Determine dosing regimen of *NPC1* mRNA-LNP.
    - Commence chronic treatment toxicity study and outcomes to assess *NPC1* mRNA therapeutic efficacy.

Sincerely,

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NP-C CARE & GUIDELINES PROJECT REPORT

2025 ANNUAL GENERAL MEETING

Summary

The NPC Care & Guidelines project was developed to assist health professionals to better identify, diagnose, manage and support individuals impacted by Niemann-Pick disease and their families. The project was formed to address the critical gap in healthcare education for NPC disease in Australia and is working towards the publication of a new consensus-based standard of care that can be utilised nationally.

The project formally began in June 2024 with the approval of the executive committee and appointment of a project coordinator, Ellie Van Velsen. A project plan was developed and is continuing to be delivered. The estimated project cost is predicted to be $29,000, which is $11,000 less than the original allocated budget of $40,000.

Following extensive collaboration with medical and community advisory boards, the '*Australian standard of care for Niemann-Pick disease type C'* manuscript was submitted on the 23rd of July 2025 to the Journal of Inherited Metabolic Diseases (JIMD). The JIMD provided favourable feedback to the authors but ultimately decided not the publish the manuscript. The author group has chosen to resubmit the paper to the Internal Medicine Journal (IMJ), following in the footsteps of other rare groups that have had their papers published in this journal.

Phase 1 of the project has been extended from July 2025 to December 2025 to accommodate journal review times. After the manuscript publication is finalised, the project will progress to phase 2, which includes the creation of an additional clinical guideline summary paper and community resources. Activities for 2025/2026 will focus on the delivery of all outputs and the creation of stakeholder implementation and impact evaluation plans.

Overview

Objective: Create and Publish Australian Diagnosis and Disease Management Consensus Guidelines for Niemann-Pick Type C Disease

Estimated Outputs & Completion Dates:

Since the previous AGM, the project has now been divided into two phases as described below:

- **Phase 1:** Manuscript Publication

- Estimated completion date: 30th December 2025*
- Output: 'Position Paper: Australian standard of care for Niemann-Pick disease type C', an open-access journal publication

- **Phase 2:** Clinical Summary & Community Resource Development
  - Estimated completion date: 30th July 2026*
  - Outputs*:*
    - Australian Care Guidelines for Niemann-Pick type C disease – A Clinical Summary (title not formalised), an open-access journal publication
    - NPC Care & Guidelines – A Community Resource – to be published on the ANPDF website

**Please note, these dates depend on journal review times and are therefore subject to change.*

Milestones & Completion Dates:

- Recruitment of Project Coordinator – June 2024
- Recruitment of Medical & Community Advisory Groups – August 2024
- Completion of Guideline Content Discussions – February 2025
- Submission of Guideline Manuscript to Journal – July 2025
- Publication of Guideline Manuscript by Journal – TBC
- Submission of Clinical Summary Manuscript to Journal – TBC
- Publication of Clinical Summary Manuscript in Journal - TBC
- Publication of Community Resources on ANPDF Website – TBC

Involved Contractors & Members:

- Paid contractors include a project coordinator and medical writer (Hazel Palmer, Scriptix)
- Members:
  - Lead Medical Team: 4 (Dr Michel Tchan, Dr Nick Smith, Dr Heidi Peters, Prof Mark Walterfang)
  - Community Liaison: 1 (Pip Johnston)
  - Medical Advisory Group: 30 (Dr Ya Hui Hung, Dr Sharmila Kiss, Lisette Curnow, Jackie Imrie, Felicity Munrow, Carly Heath, Joy Lee, Molly Williams, Dr Hugo Morales-Briceno, Dr Maina Kava, Rebecca Quin, Ashley Bush, Anita Inwood, Dr Yusof Rahman, Dr Drago Bratkovic, Dr Lia (Leniza) Hamoy, Dr Catherine Marraffa,

A/Prof Carolyn Ellaway, Dr Shanti Balasubramaniam, A/Prof Shekeeb Mohammad, Dr Brendon Boot, Dr Matthew (Matt) Lynch, Dr Anthony Herbert, Katrina Cruz, Sean Hosking, Ingrid Sutherland, Lei Chen, Karen Chidgey, Chante Niemand, Amy Sparks)

- Community Advisory Group: 6-7 (Renee Staska, Trina Sheehan, Amy Leddick, Marian Shoebridge, Dave Chamberlain, Mandy Whitechurch, Deanna Carpino)

Project Cost

Project Budget: $40,000 AUD *(Source: Australian NPC Disease Foundation Inc.)*

Cost to Date (end of October 2025): $20,485

Projected Total Cost: $29,000

- Includes:
  - Project coordinator's work hours. Due to a change in circumstances, the workdays of the project coordinator decreased from 2024 to 2025, with no significant impact on operations due to decreasing project time demands.
  - Medical writing fees for Hazel Palmer (Scriptix) for a total of $8000.
  - $5000 journal submission fee. This is a conservative estimate and may be reduced based on the ANPDF's charity status or the university affiliations of authors.

Difference: $11,000 surplus

Progress Metrics

Completed activities:

- Recruitment of a medical lead team, advisory board members, and a medical writer.
- A full revision of 39 statements and materials from the 2018 international guidelines via surveys and monthly meetings with advisory members.
  - Total meetings to date: 5 Medical Advisory Group, 4 Community Advisory Group, and 3 Lead Team.
- Presentations at the 2025 NPC Conference (Melbourne), Genetic Alliance Australia Annual Forum (via recorded video), Lysosomal Disease Summit (Sydney)

Notable Results:

- 75% average survey response rate across all groups and an average meeting attendance of 53% for the medical group (many reported time clashes with clinic days), and 77% for the community group.

- Development of a manuscript that included 22 consensus-based statements, and various figures and tables outlining diagnostic pathways, multidisciplinary care teams, management assessment guides and more.
- Drafting of a standard of care clinical summary manuscript (ON HOLD, awaiting the primary manuscript review, approval and publication)

Future Activities

- Adaptation of the primary manuscript into a resource for the community. These resources will be publicly accessible on the ANPDF website.
- Review, finalise and publish the clinical summary manuscript (intended for a clinical audience).
- Development, approval and execution of a plan to support the implementation of the guideline papers by key stakeholders and care providers.
- Development, approval and execution of an evaluation to assess awareness, implementation and impact of the guidelines.

Sincerely,

Ellie Van Velsen

Project Coordinator

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