AusME Registry and Biobank

The Epicentre Driving Improved Outcomes for Long COVID and ME/CFS

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Behind every data point, there's a person, a story, and a chance for a better tomorrow.

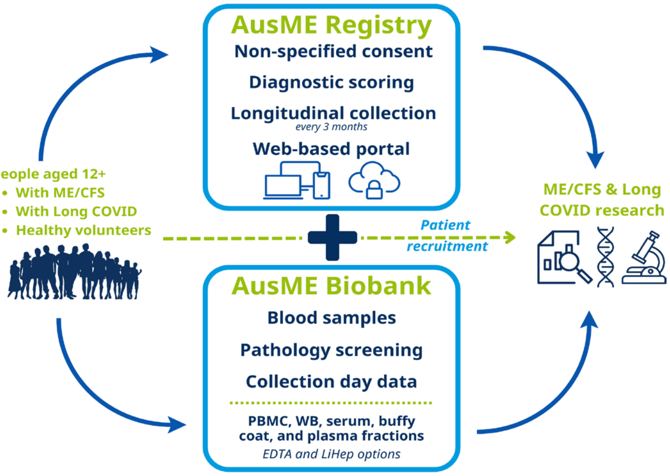
BACKGROUND

Historically, inconclusive ME/CFS research results stemmed from methodological flaws, small samples, and bias toward milder cases. The overlap between Long COVID and ME/CFS, where 50% progress to meet ME/CFS criteria[1-3], raises concern for similar Long COVID study limitations.

Establishing an online registry that compiles extensive data directly from individuals affected by these conditions holds the promise of revolutionising both ME/CFS and Long COVID research. Together with the associated biobank, the registry's capacity to comprehensively characterise a vast and diverse dataset from a heterogeneous study population will substantially enhance the quality of research outcomes, thereby facilitating the validation and identification of diagnostics and treatments.

Since 2021, Emerge Australia has been the custodian of the Australian ME/CFS Registry (You+ME, Aust.) and ME/CFS Biobank. Offering a comprehensive dataset of meticulously characterised study participants and biosamples derived from blood, Emerge Australia's ME/CFS Registry and biobank provides crucial support to Australian medical researchers and their endeavours, aimed at advancing knowledge and uncovering essential diagnostics and effective treatments for the individuals they represent.

In October 2023, the ME/CFS Registry and Biobank will rebrand as the Australian ME/CFS and Long COVID/PASC (AusME) Registry and Biobank, expanding to include those with Long COVID, as well as healthy/control volunteers, who may or may not have previously been infected with the SARS-CoV2 virus.



AusME Registry

- Non-specified consent
- Diagnostic scoring
- Longitudinal collection *every 3 months*
- Web-based portal

AusME Biobank

- Blood samples
- Pathology screening
- Collection day data

PBMC, WB, serum, buffy coat, and plasma fractions
EDTA and LiHep options

People aged 12+
- With ME/CFS
- With Long COVID
- Healthy volunteers

Patient recruitment

ME/CFS & Long COVID research

OBJECTIVES

1. To **empower those living with ME/CFS and Long COVID**, by recognising and recording their lived experience of these diseases.
2. To **foster patient-researcher-clinician-government collaboration** for evidence-based research and care, shaping patient-led medical advancements and enhancing healthcare and social support services.
3. To **unify data collection for ME/CFS and Long COVID**, bolstering research infrastructure to comprehensively study both conditions, expedite discoveries about their causes, progression, diagnostics, and treatments, and aid in identifying suitable participants for studies and trials.
4. To **establish an evidence base that will contribute to understanding the extent of individuals impacted by ME/CFS and Long COVID**; serving as a resource for the development of State and National policies to benefit those living with ME/CFS and Long COVID, while also aiding Australia in its readiness to address future challenges associated with post-infection diseases.

1,172 Registry participants

92.5% ME/CFS **7.5%** Controls

Mean age **49** years

Female 80.4%
Male 19.6%

29.3% House/Bed Bound

100+ Blood samples banked

10+ Australian Research Projects Supported

Participant locality

AusME Registry

Launched Oct 2023

380 participants enrolled in the first 7 days!

✓ ME/CFS ✓ Healthy
✓ Long COVID ✓ Paediatric

AusME protocol overview and vital statistics | *The AusME Registry algorithm ensures that ME/CFS and Long COVID participants meet strict diagnostic criteria (for 18+ ME/CFS: CCC, Fukuda, IoM and ICC; for ME/CFS <18: 2017 Paediatric primer and 2006 International Association of Chronic Fatigue Syndrome Pediatric Case Definition (Jason et al, 2006) and that all participants are well-characterised. Researchers seeking data for research, have their applications assessed by Emerge Australia's Medical and Scientific Advisory (MSAC) and Biobank Access Committees. The MSAC and Biobank Access Committees comprise ME/CFS experts, clinicians, scientists, and patient and carer representatives. Approved by La Trobe University's Human Ethics Committee, AusME data is stored securely via HIPAA-compliant Zoho interface in Sydney and Melbourne data centres. Data is deidentified, and researchers sign a Data Use Agreement for access.*

DISCUSSION

The Australian ME/CFS and Long COVID/PASC (AusME) Registry/Biobank will serve as an invaluable biorepository and resource for focused medical research on ME/CFS and Long COVID. With plans to engage a diverse group of well-characterized individuals, this data source has the potential to overcome historical limitations, significantly advancing our understanding of both diseases and discovering definitive diagnostics and treatments.

Through enabling translational research and establishing an evidence base, this initiative could shed light on the number of Australians affected and reveal challenges faced by those with Long COVID and ME/CFS. This information could also play a pivotal role in shaping policy development, essential for preparing Australia for a future with significant post-infection health considerations.

Acknowledgements:
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References: **1.** Kedor, C. *et al.* A prospective observational study of post-COVID-19 chronic fatigue syndrome following the first pandemic wave in Germany and biomarkers associated with symptom severity. *Nat Commun* **13**, 5104 (2022). **2.** C. (Linda) M. C. van Campen, P. C. R. and F. C. V. Orthostatic Symptoms and Reductions in Cerebral Blood Flow in Long-Haul COVID-19 Patients: Similarities with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. *Medicina (B Aires)* **58**, 1–18 (2022). **3.** Davis, H. E. *et al.* Characterizing long COVID in an international cohort: 7 months of symptoms and their impact. *EClinicalMedicine* **38**, 101019 (2021).