



Australian  
Dementia Network  
REGISTRY. CLINICS. TRIALS.

[www.australiandementianetwork.com](http://www.australiandementianetwork.com)

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# What is ADNeT?



Australian  
Dementia Network  
REGISTRY. CLINICS. TRIALS.

- Australian **D**ementia **N**eTwork= **ADNeT**
- Funding: \$18M government NHMRC-NNIDR (Boosting Dementia Research Grant) + \$2M philanthropy
- Network of national dementia research experts

## OUR PARTNERS



## SUPPORTED BY

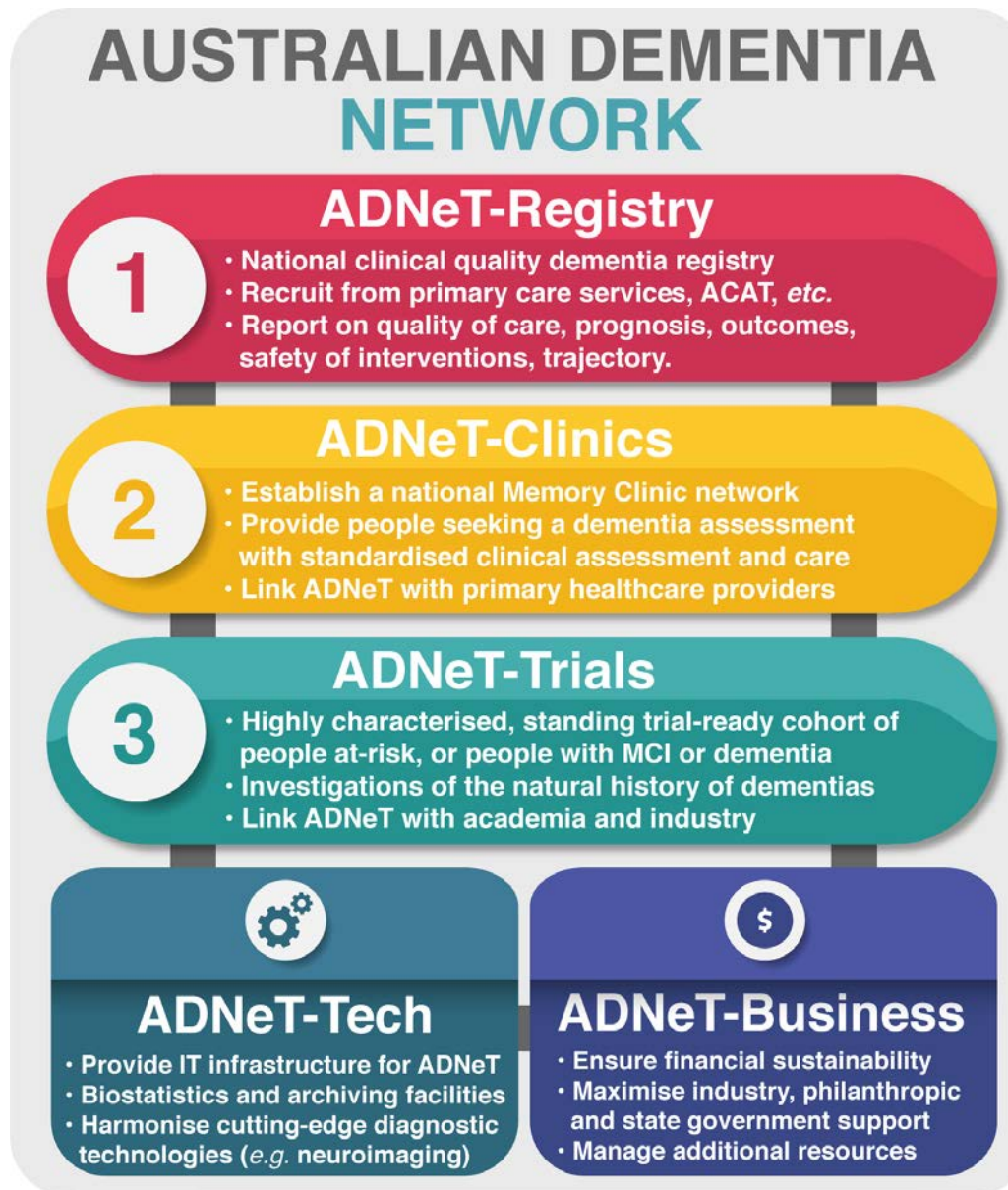


Australian Government  
NHMRC National Institute for Dementia Research



Three initiatives

Two support packages

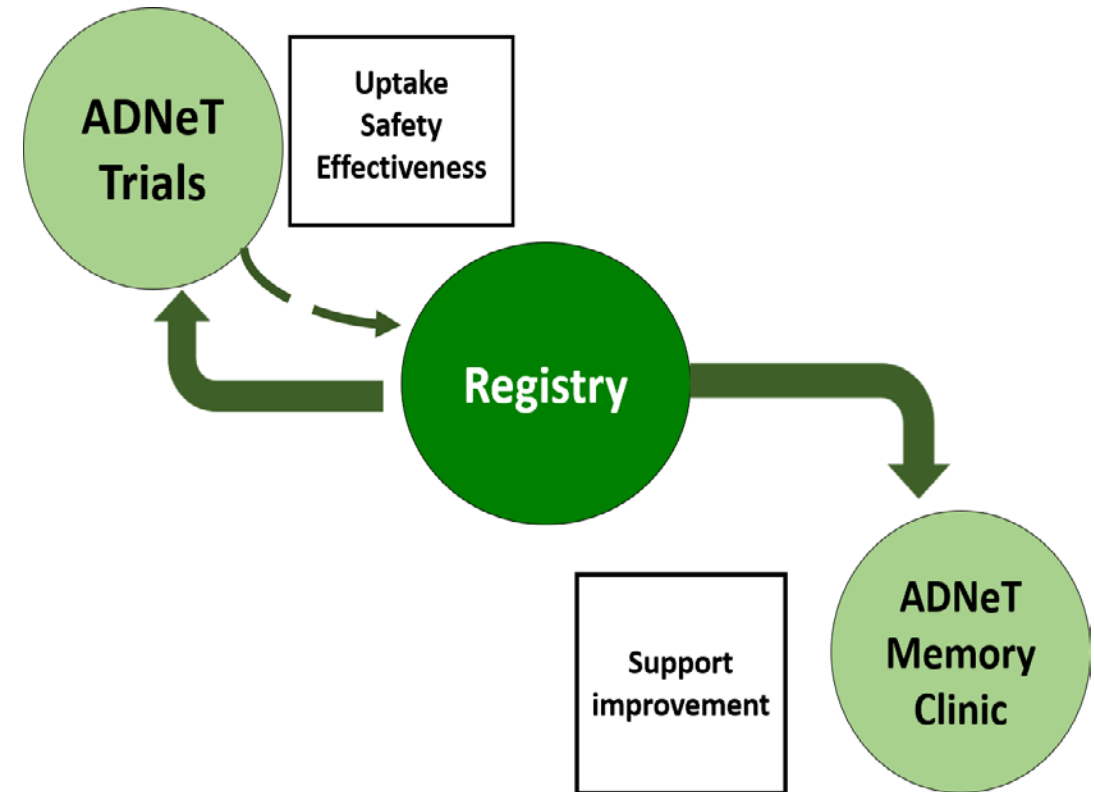


# ADNeT in brief

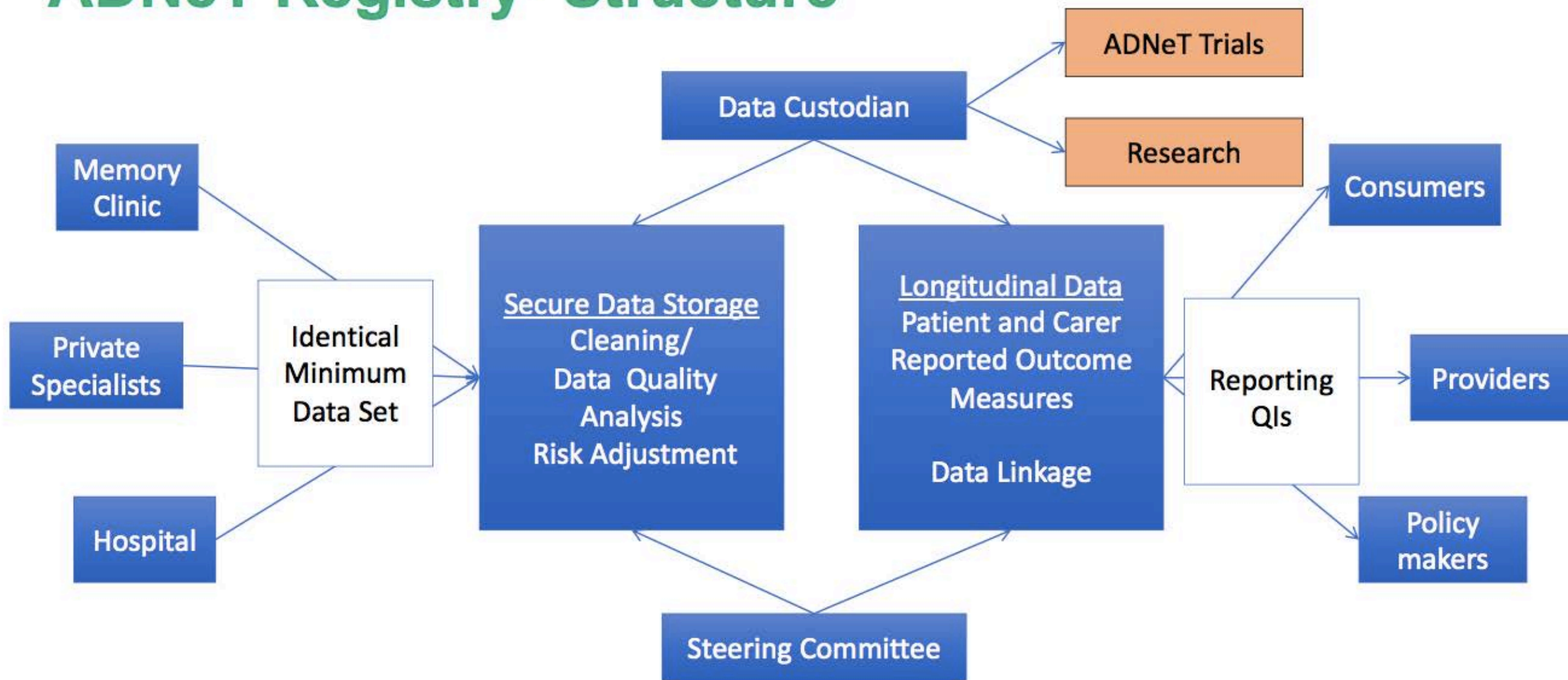
- Clinical Quality Registry (CQR) for newly diagnosed dementia or mild cognitive impairment
- Memory Clinics – expand, standardize and support
- Clinical Trial sites – expand and support
- Longitudinal (n=2,000) and Trial ready (n=500) cohorts – *blood, MRI, cognition, amyloid and tau PET, +/-CSF every 2 years*

# ADNeT Registry

- Collect data to benchmark standard of clinical care
- Highlight variations in the processes and outcomes of care
- Feedback this data to clinicians, healthcare providers and consumers
- Connect persons interested in research to ADNeT trials
- Assess uptake and impact of new therapies



# ADNeT Registry- Structure



# ADNeT Clinics

- Establish a collaborative network of Memory Clinics
- Develop a common dataset
- Establish an electronic database
- Link electronic database to ADNeT CQR and Trials
- Facilitate new Memory Clinics
- Provide training and professional development
- Develop computerized assessment options and new intervention tools



# ADNeT Trials

Speed the development of effective therapies by:

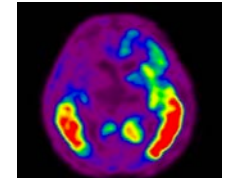
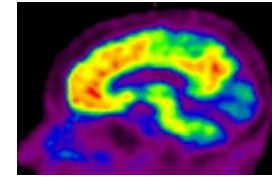
- Enabling faster trials
- Support existing and new trials sites
- Supporting Trials Network (Dementia Trials Australia)
- Liaise with Pharma

| Progress to date                      |   |
|---------------------------------------|---|
| Online Trial Ready database           | ADNeT website volunteer screening portal, collaboration with Step Up for Dementia Research (on-line volunteer trial matching service),<br>ClinTrial Refer App.  |
| TRC                                   | <ul style="list-style-type: none"> <li>• ADNeT Trials Screening operating in Melbourne</li> <li>• MK6240 and NAV4694 production sites in all major cities</li> <li>• Including subjects from AIBL and other longitudinal studies</li> <li>• 310 added since Jan 2019 (95 MCI/early AD). 50 into trials.</li> </ul>  |
| Trial delivery sites across Australia | 9 initial trial sites across Australia <ul style="list-style-type: none"> <li>• VIC – Austin Health; Alfred/Caulfield; Royal Melbourne</li> <li>• NSW – Macquarie/KARA/Hornsby/Sydney University Brain and Mind Centre; Prince of Wales/NeuRA</li> <li>• TAS – University of Tasmania/Royal Hobart Hospital</li> <li>• SA – SAHMRI/Flinders/TQEH/Royal Adelaide Hospital</li> <li>• WA – Fremantle/Hollywood Hospital/Edith Cowan University</li> <li>• QLD – Princess Alexandra/HIRF/Royal Brisbane</li> </ul> |
| Trials Network                        | <ul style="list-style-type: none"> <li>• Partnership with AC4R, Neuroscience Trials Australia and Australian Clinical Trials Alliance</li> <li>• National ethics resource</li> </ul>  |



## ADNeT PET tracer production.

- NAV4694 for  $A\beta$  imaging
- MK6240 for tau imaging



>90% coverage of the  
Australian population

PERTH

Sir Charles Gardner  
Hospital

ADELAIDE

MELBOURNE

Austin Health

SAHMRI

SYDNEY

Liverpool Hospital

BRISBANE

Royal Brisbane  
Hospital

FDA approved tracers will be  
obtained from Cyclotek Ltd.

# ADNeT Trial Screening

Melbourne site receiving 300 MCI/early AD referrals per year from specialists and growing.

Initial phone and on-site screening identifies 100 for scans/year

NAV4694 amyloid and MK6240 tau PET, MRI and detailed cognitive assessment.

Into a trial, trial ready cohort or longitudinal study cohort.

Program ready to run in Perth and will be functioning in Sydney, Brisbane and Adelaide by early 2020.

## ADNeT Trials Screening Referral Form

### Information and Referrals

Email: ADNeTscreening@florey.edu.au

Phone: 03 9389 2938

Fax: 03 9387 5061

### Referring Specialist

Name: \_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

### Eligibility Guide

- Probable MCI or mild AD
- Aged 50 to 85
- Availability of a reliable study partner/informant
- Formal education of  $\geq 7$  years
- Fluent in English
- MMSE score  $\geq 20$
- Capable of tolerating neuropsychological assessment
- No serious unstable comorbid conditions

### Prior Investigations

Please tick if previously completed:

- MRI in last 6 months
- FDG PET in last 12 months
- Consultant letter attached

### Amyloid PET Disclosure

Amyloid PET result to be disclosed by:

- ADNET trials screening staff
- Referring clinician

### Further Investigations

Please arrange an expedited brain SPECT and FDG PET if amyloid or tau imaging are negative

- Yes

Please provide patient details or affix label

UR: \_\_\_\_\_ Date of birth: \_\_\_\_\_

Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Address: \_\_\_\_\_

Preferred contact (if different): \_\_\_\_\_



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Protocol, multisite ethics application and payments under preparation.

Screening sites (one per state for commercial trials but multiple academic) will screen, neuropsych, scan (may use multiple PET and MRI sites), feedback and refer (with initial referrer) then invoice ADNeT at academic or commercial rate.

## PROTOCOL

### **The Australian Dementia Network (ADNeT): Screening for trials and longitudinal research on trials ready cohort (TRC)**

Protocol Number (Mandatory field): ADNET-TRIALS1

Version: # 1

Date: 01/10/2019

Author/s:

Dr Joanne Robertson

Sponsor/s:

This is an investigator-initiated study supported by NHMRC funding

#### CONFIDENTIAL

This document is confidential and the property of Austin Health. No part of it may be transmitted, reproduced, published, or used without prior written authorisation from the institution.

#### Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

## STUDY SYNOPSIS

Proposed sites for  
Ethics application.

More can be added!

|                          |   |
|--------------------------|---|
| Title:                   | The Australian Dementia Network (ADNeT): Screening for trials and longitudinal research on trials ready cohort (TRC)  |
| Short Title:             | ADNeT – Screens and Trials Ready Cohort   |
| Design:                  | Phase I, multiple site, open label  |
| Study Centres:           | <ul style="list-style-type: none"> <li>• Austin Health</li> <li>• Edith Cowan University</li> <li>• Macquarie University</li> <li>• Melbourne Health</li> <li>• Monash University</li> <li>• Newcastle University</li> <li>• QIMR Berghofer Medical Research Institute</li> <li>• St Vincent's Health</li> <li>• South Australian Health and Medical Research Institute</li> <li>• The Florey Institute of Neuroscience and Mental Health</li> <li>• The University of Melbourne</li> <li>• University of New South Wales</li> <li>• University of Sydney</li> <li>• University of Tasmania</li> </ul> <ul style="list-style-type: none"> <li>• Alfred</li> <li>• RBH</li> </ul>  |
| Hospital:                | Austin Health   |
| Principal Investigator:  | Prof. Christopher Rowe  |
| Associate Investigators: | Prof. Colin Masters, Prof. Ralph Martins, Prof Michael Breakspear, Prof. Perminder Sachdev  |
| Primary Objective:       | 1. To establish a trials ready cohort for interventions for Alzheimer's disease (AD) and other neurodegenerative diseases causing dementia  |
| Secondary Objectives     | <ol style="list-style-type: none"> <li>1. To compare quantified global and regional A<math>\beta</math>-amyloid (A<math>\beta</math>) burden as assessed with [18F]-NAV4694 and global and regional tau burden as assessed with [18F]-MK6240 in the same participants</li> <li>2. To assess quantified A<math>\beta</math> and tau burden in cerebrospinal fluid (CSF) in a subset of the same participants</li> <li>3. To develop and validate blood-based biomarkers</li> <li>4. To investigate genetic risk factors</li> <li>5. To assess the degree of tau accumulation, A<math>\beta</math> accumulation, atrophy, cognition, medical and lifestyle factors to identify modifiable factors that may delay</li> </ol> |

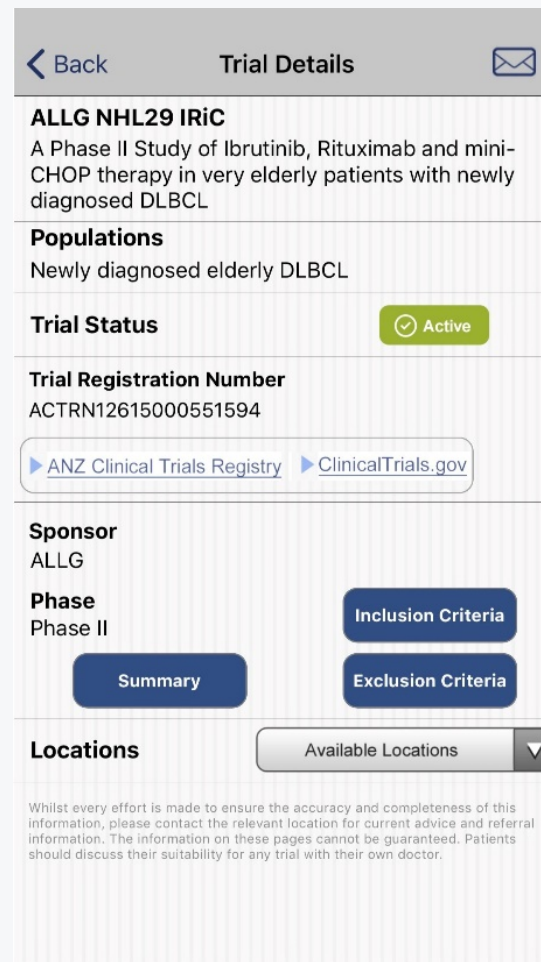
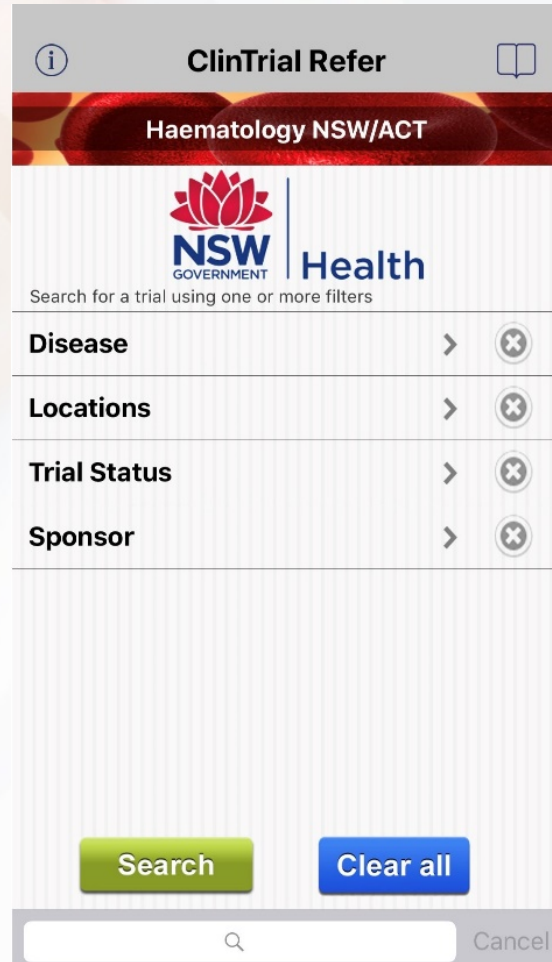
Coming to AUSTRALIA



## Clinical Study Protocol

|                                      |  |  |  |
|--------------------------------------|--|--|--|
| <b>Study Protocol Number:</b>        | BAN2401-G000-301   |  |  |
| <b>Study Protocol Title:</b>         | A Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study With an Open-Label Extension Phase to Confirm Safety and Efficacy of BAN2401 in Subjects With Early Alzheimer's Disease |  |  |
| <b>Sponsor:</b>                      | Eisai Inc.<br>100 Tice Boulevard<br>Woodcliff Lake,<br>New Jersey 07677<br>US  | Eisai Ltd.<br>European Knowledge<br>Centre<br>Mosquito Way<br>Hatfield, Hertfordshire<br>AL10 9SN UK | Eisai Co., Ltd.<br>4-6-10 Koishikawa<br>Bunkyo-Ku,<br>Tokyo 112 8088<br>JP |
| <b>Investigational Product Name:</b> | BAN2401  |  |  |
| <b>Indication:</b>                   | Alzheimer's disease  |  |  |
| <b>Phase:</b>                        | 3  |  |  |

# ClinTrial Refer App Features





# ClinTrial Refer App

Trial Data and Locations:

Eligibility

Trial Summary

Available Locations

Other Details

HD21 for Advanced Stages (BEACON)  
NCT02661503

Phase 3 **Open**

HD21 for Advanced Stages Treatment Optimization Trial in the First-line Treatment of Advanced Stage Hodgkin Lymphoma; Comparison of 6 Cycles of Escalated BEACOPP With 6 Cycles of BrECADD

- Eligibility >
- Trial Summary >
- Available Locations >
- Other Details >

### Eligibility

**Minimum Age**  
18 years old

**Maximum Age**  
60 years old

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**Inclusion Criteria**

- Histologically proven classical Hodgkin lymphoma - First diagnosis, no previous treatment, 18 to 60 years of age - Stage IIB with large mediastinal mass and/or extranodal lesions, stage III or IV

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**Exclusion Criteria**

- Composite lymphoma or nodular lymphocyte-predominant Hodgkin lymphoma
- Previous malignancy (exceptions: basaloma, carcinoma in situ of the cervix uteri, completely resected melanoma TNMpT1) - Prior chemotherapy or radiotherapy

### Available Locations

- Concord Repatriation General Hospital (Haematology)**  
Recruiting
- Gosford Hospital (Haematology)**  
Recruiting
- Monash Health (Haematology)**  
Recruiting
- Prince of Wales Hospital (Haematology)**  
Recruiting
- Princess Alexandra Hospital (Haematology)**  
Recruiting
- Royal Adelaide Hospital (Haematology)**  
Recruiting
- Royal Hobart Hospital**

# Version 2 Integrated Solution

Single database, but same philosophy:

- Free to download, quick, easy to use
- Targeted features to suit the needs of different networks.
- Data remains from source - trial units – key to currency and accuracy
- Now Live

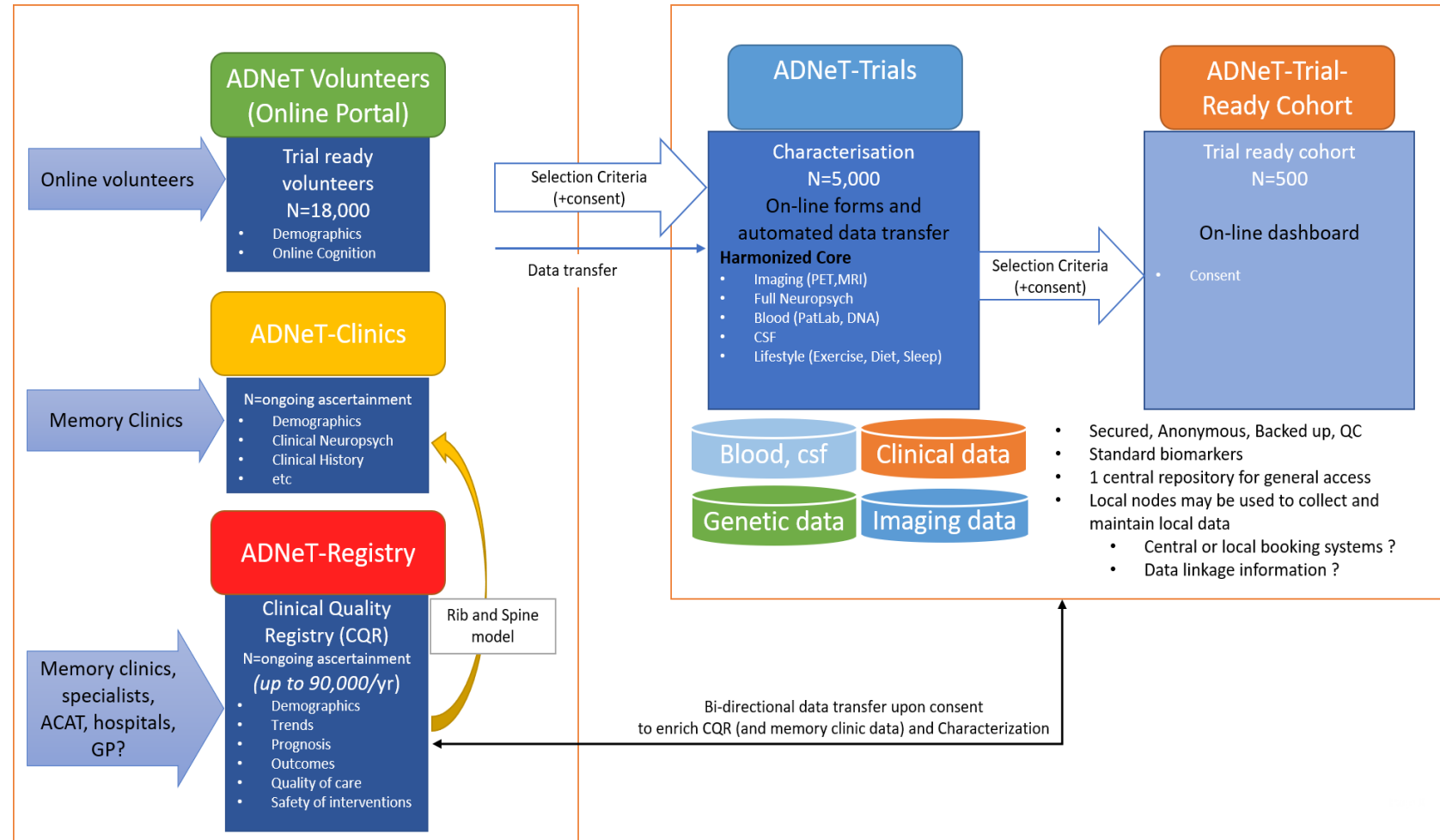
The **Hon Greg Hunt MP, Minister for Health**, launched version 2.0 at the **Australian Clinical Trials Alliance (ACTA) International Conference, 3 October 2019.**





# ADNeT Technology (CSIRO, Monash University, Newcastle University, QIMR)

- Provide IT infrastructure for ADNeT Registry, Clinics and Trials.
- Develop and harmonise innovative diagnostic technologies (imaging and fluid biomarkers).



# ADNeT Business

To establish sustainable income sources to ensure viability beyond current funding and to connect with organisations supporting clinical trials.

**Investment : over 5 years is expected to be > \$40 M:**

- \$18 million from NHMRC NIDR
- \$2 million from The Wicking Trust and Yulgilbar Foundation
- \$10 million from industry (\$2 million to date)
- \$10 million in matching funds, in-kind support and further philanthropic donations

Milestones for 2019

- Establish ADNeT commercial entity
- Establish Industry Advisory Board and Precompetitive Funding

# ADNeT Precompetitive Consortium

Seeking pharma support for trials screening and trial ready cohort.

Existing programs have been through individual contracts with Astra Zeneca, Biogen and Abbvie.

National role out is needed to meet requirements and this needs additional funding.

# ADNeT Precompetitive Consortium

## Call for Interest

If interested please forward contact details of relevant persons from your company to Larry Ward, ADNeT Head of Business Development, at [Larry.ward@mentalhealthcrc.com](mailto:Larry.ward@mentalhealthcrc.com).



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