



Industry's Role in Translating Research into Clinical Impact

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National Alzheimer's Project Act (NAPA)
Advisory Council on Alzheimer's Research, Care, and Services
May 8, 2023



Disclosure



- Amir A. Tahami is an employee of Eisai Inc.
- These slides present information on lecanemab, a product that has received approval from the US Food and Drug Administration (FDA) through the accelerated approval pathway, relying on surrogate endpoints. However, it's crucial to note that the ongoing approval for this indication is subject to verification of clinical benefit in a confirmatory trial.
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- The studies of lecanemab discussed within this slide deck are sponsored by Eisai Inc.

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An Overview

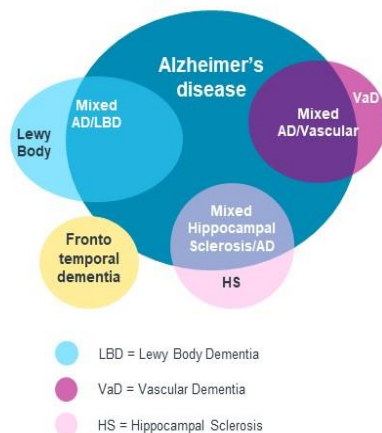
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A Chronic Progressive, Irreversible Neurodegenerative Disorder



Pathologies of Dementia^{2,3}



- AD is the cause of 60-80% of all dementia cases¹
- Other pathologies include Lewy body dementia, vascular dementia and hippocampal sclerosis²
- Dementia refers to a group of symptoms, including difficulties with memory, language and cognitive skills, that affect a person's ability to perform daily activities¹
- AD is the fifth largest global cause of death, resulting in approximately two million deaths each year⁴
- As prevalence increases, the number of deaths caused by AD and other dementias will also increase, with more deaths caused by dementia than cancer by 2040^{5,6}
- There is an unmet need for treatment that can impact the underlying pathophysiology of AD, in order to delay the progression of AD and improve the clinical outcome of the patient⁷

1. Alzheimer's Association, 2018 Alzheimer's Disease Facts and Figures. 2018;14(3):367-428. 2. Siemers E. The changing diagnostic criteria for AD, including early asymptomatic disease stages and their impact on clinical trial design. EPPIA Working Group. 2014. 3. Barker WW et al. Relative frequencies of Alzheimer disease, Lewy body, vascular and frontotemporal dementia, and hippocampal sclerosis in the state of Florida brain bank. Alzheimer Dis Assoc Disord 2002;16(4):203-12. 4. WHO. Global health estimates 2016 summary tables. World Health Organisation; 2018. 5. The Economist Intelligence Unit. Assessing the socioeconomic impact of Alzheimer's disease in western Europe and Canada. The Economist. 2017. 6. Etkind SN et al. How many people will need palliative care in 2040? Past trends, future projections and implications for services. BMC Med. 2017;15(1):102. 7. Cummings J, Fox N. Defining Disease Modifying Therapy for Alzheimer's Disease. J Prev Alzheimers Dis 2017;4(2):109-115.

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Global Socioeconomic Costs of Alzheimer's



Several different drivers contribute to AD costs, which often come from different budgets

Costs associated with caregiving can fall under many buckets, such as **opportunity costs, direct costs to the caregiver and cost of unpaid care**¹⁻⁴



In many markets, the direct medical costs associated with Alzheimer's and other dementias are **covered by national or regional healthcare systems and governments**⁵

Social care costs are often **funded from public funding**, e.g., tax, pension contributions or government grants, or can be **privately funded**⁵

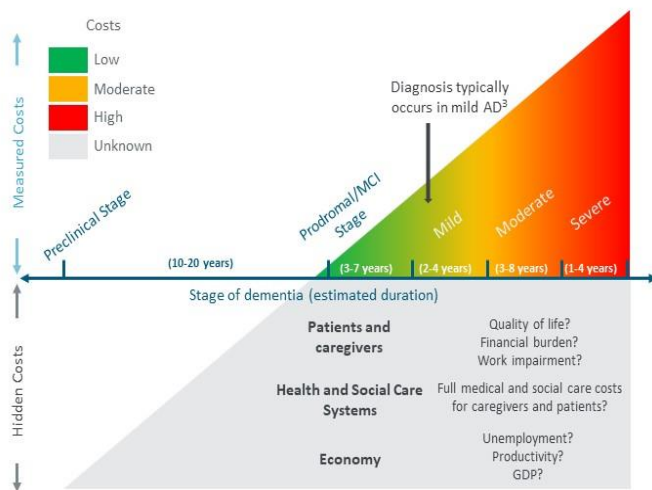
Institutionalization, e.g., nursing homes, are often required in later stages of AD, however depending on the market and situation, **financial responsibility can fall to patients and their family**⁷

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Increasing Burden of AD by Disease Severity



Measured and hidden societal costs associated with AD and other dementias^{1*}



El-Hayek YH et al. J Alzheimers Dis. 2019;70(2):323-341.

- Total costs relating to AD and other dementias include a combination of **direct, indirect, and intangible costs**¹
- Costs associated with AD have shown wide variation in estimation, for a number of reasons¹
- A large part of the costs associated to AD and other dementias are **"hidden"** and often **unaccounted for** or difficult to calculate¹
 - The average annual additional **cost of direct healthcare costs and lost productivity** in the years before diagnosis of AD or other dementias was higher than in matched controls
 - **Employment rates and income from employment** were lower in patients than in matched controls up to 10 years before diagnosis¹

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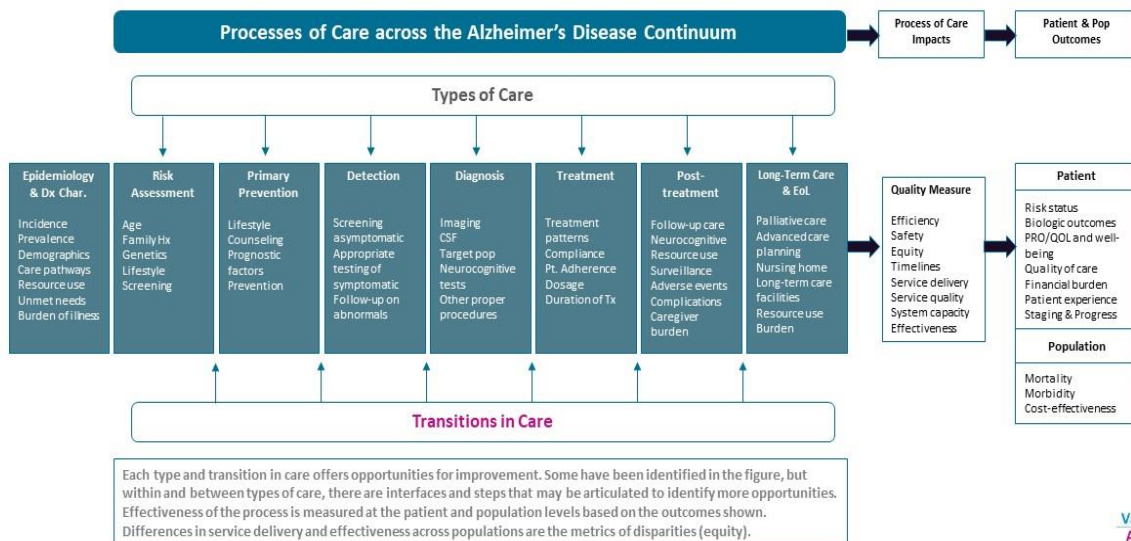
Clinical Care Pathway

As a tool to translate research into clinical impact



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Opportunities to Influence the Process of Care Across AD Continuum



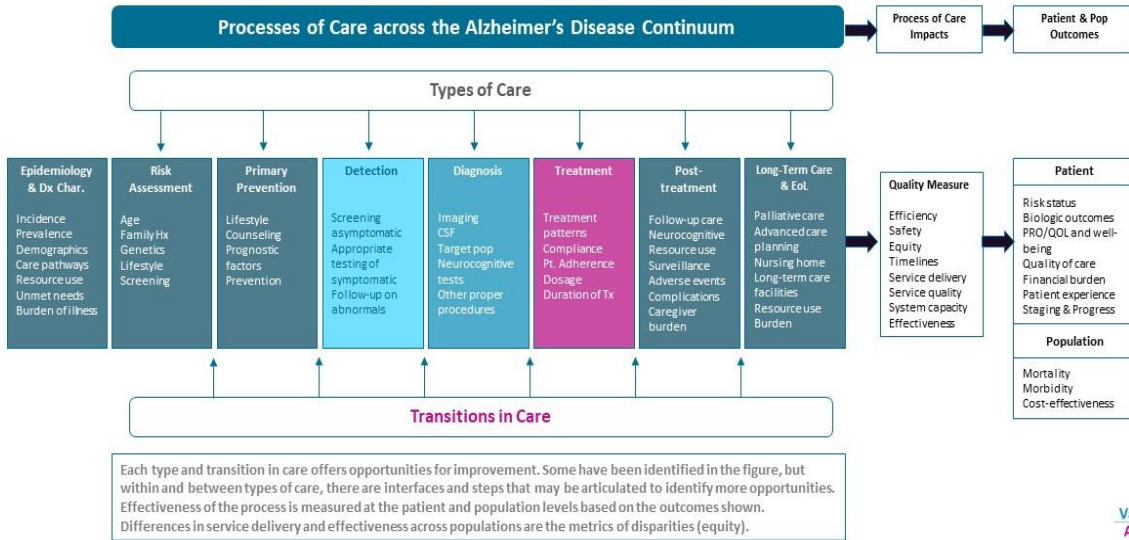
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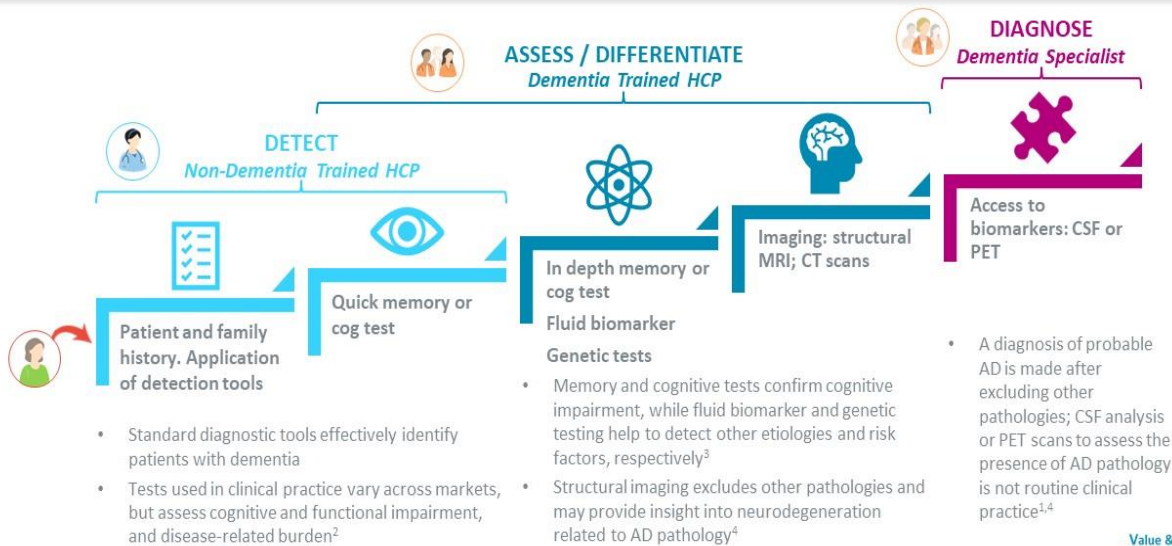


Opportunities to Influence the Process of Care Across AD Continuum



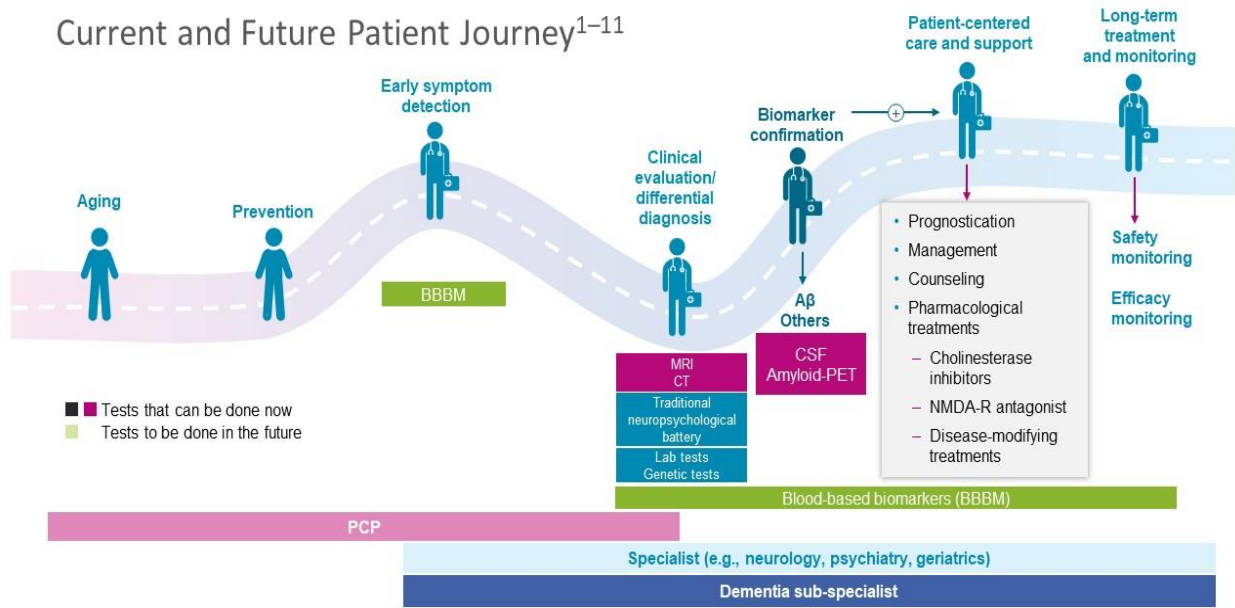
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The Current Diagnostic Pathway is complex but can effectively identify patients with AD dementia by excluding other causes¹



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Current and Future Patient Journey¹⁻¹¹



A β , amyloid beta; AD, Alzheimer's disease; CSF, cerebrospinal fluid; CT, computerized tomography; MRI, magnetic resonance imaging; NMDA-R, N-methyl-D-aspartate receptor; PCP, primary care physician; PET, positron emission tomography
 1. Hlavka JP, et al. *Rand Health Q*. 2019;8(3):2. 2. Fowler NR, et al. *J Am Geriatr Soc*. 2012;60(6):1037-43. 3. Wong-Lin K, et al. *BMC Med*. 2020;18(1):398. 4. Budeller MM, et al. *J Appl Lab Med*. 2020; 5(1): 194-208; 5. Hampel H, et al. *Nat Rev Neurol*. 2018;14:639-652. 6. Cummings J, et al. *Alzheimers Dement (NY)*. 2021;7:e12179. 7. Parsons C, et al. *BMC Palliat Care*. 2019;18(1):6. 8. Hampel H, et al. *Nat Aging*. 2022;2:692-703; 9. Kourtis LC, et al. *NPJ Digit Med*. 2019;2:9. 10. Au R, et al. *Adv Geriatr Med Res*. 2019;1:e190003. 11. Mattke S, et al. Available at: <https://cesr.usc.edu/sites/default/files/Implications%20of%20Alzheimer%27s%20Treatment%20for%20Organization%20and%20Payment%20of%20Medica%20Practices%20in%20the%20United%20States%202020%29.pdf>. Accessed 20 April 2023

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Triggers for Change



- Earlier and more accurate diagnosis** of AD is now possible
- Timely diagnosis will allow patients to access **new treatment options**
- Emerging therapies necessitate **clinical staging and biomarker confirmation** of AD diagnosis
- General neurologists need to **prepare for a shift in practice** so that patients will benefit from advances in AD care
- Neurologists will encounter new questions and challenges with respect to **selection of patients** for new treatments, new paradigms for monitoring treatment, and revised treatment expectations

AD, Alzheimer's disease

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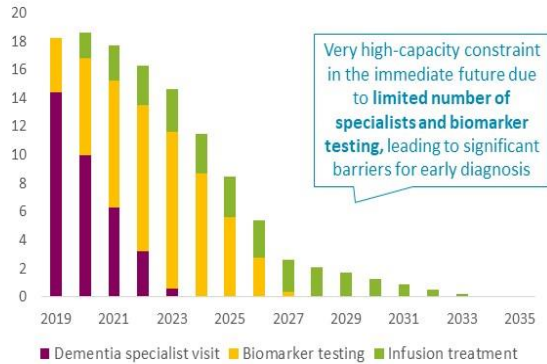
System Constraint in Addressing AD Patients' Needs

AD care statistics for US Health System

- US population: **63.4M**
- Estimated active dementia cases: **1.1M**
- Number of neurologists: **17,408**
- Number of geriatricians: **7,560**
- Number of geriatric psychiatrists: **1,953**
- Specialists per 1,000 people: -

Large gap between officially diagnosed AD patients (340k) and prevalence estimates

Projected Wait Times for AD Diagnosis and Treatment (average time delay in months)



Source: Liu JI. et al. Assessing the Preparedness of the U.S. Health Care System Infrastructure for an Alzheimer's Treatment. Santa Monica, CA: RAND Corporation, 2017. https://www.rand.org/pubs/research_reports/RR2272.html

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Capacity & Education Constraints Emerge During Likely Diagnostic & Treatment protocol for DMTs



Current landscape – likely to change following DMT availability

Diagnostic constraint	Diagnostic constraint	Treatment constraint	Monitoring constraint
Neurologist	PET Scan	IV Infusion	MRI
<p>Many neurologists already have extensive waiting lists, prior to DMT launch</p> <p>DMTs likely to increase demand further, with initial wait times projected to extend more than a year in broad-label scenarios</p>	<p>Limited market for A-beta PET currently, but estimated annual spare U.S. capacity of ~250K Amyloid PET scans¹</p> <p>Certification of machines and HCP training likely to be additional constraints</p>	<p>Research suggests limited excess U.S. infusion capacity (estimated ~2.7M – 4.0M infusions, or 100K-150K bi-weekly infused patients)</p> <p>Prior analogues (e.g., RA) do suggest demand-driven build-out of capacity is likely</p>	<p>Estimated annual spare U.S. capacity of ~22M MRIs, though regional capacity issues possible</p> <p>Limited knowledge of ARIA among radiologists may present education needs for follow-up testing capacity</p>

1. Based on 398 centers, only 75% of those centers having capacity (30%), 8hr operating hours, open 250 days per year, 1.5 scans per hour
Source: Eisai research, expert interviews

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Disease Impact



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Managing the Impact and Challenges of Advanced AD



Cognitive functioning



Cognitive decline becomes more pronounced as the disease progresses, with patients developing behavioural changes and eventual unawareness of surroundings^{1,2}

Activities of daily living



As patients reach later stages of AD, they are capable of performing only a **limited range of ADLs**; they may struggle with simple tasks such as toileting or bathing, and they cannot perform tasks such as cooking, cleaning or writing³

Quality of life



As AD progresses, the **applicability of QoL domains changes**; enjoyment of daily activities is no longer relevant^{4,5} and patients HRQoL is predicted based on the extent of their functional impairments⁶

Caregiver burden



As patients progress, more caregiver time is required⁷ and the **psychological stressors and demands placed on the caregiver change**⁸; increases in cognitive and functional impairment and the rate of these negatively affect caregiver well-being⁹

Although the symptoms of AD worsen over time, the rate of disease progression is variable between patients and dependent on many factors¹

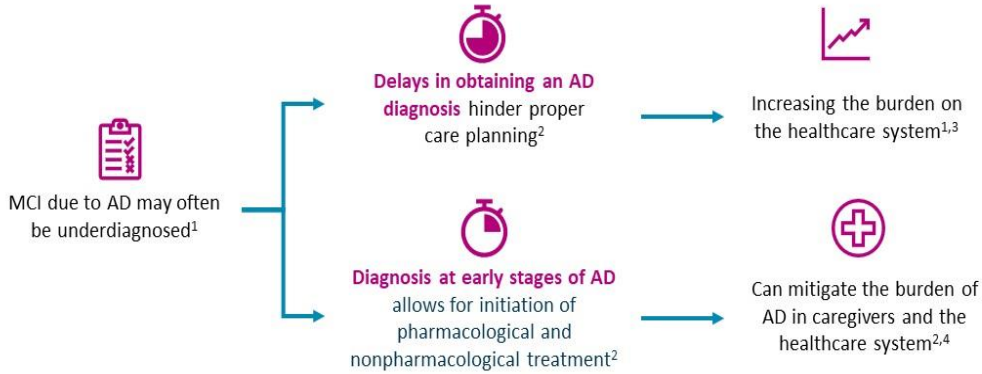
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Early MCI Diagnosis: Reducing Care Costs and Planning for the Future



If 88% of individuals who develop AD are diagnosed in the MCI phase, a cumulative total of ~\$7 trillion* could be saved in medical and long-term care costs† for the US population. †5

*These savings include \$2.3 trillion in Medicare savings, \$2.3 trillion in Medicaid savings and \$1.4 trillion in other savings (i.e. out-of-pocket expenses and private insurance). †Cumulative costs are in 2017 dollars and calculated using (a) an annual 3% discount rate to account for the anticipated value of the money over time and (b) a medical growth rate — the anticipated real growth rate of medical expenditures above and beyond inflation — of 3.1%. ‡Includes those alive in 2018, with early detection measures were assumed to begin in 2020.
 AD=Alzheimer's disease, MCI=mild cognitive impairment.
 1. Alzheimer's Association. 2022 Alzheimer's disease facts and figures. *Alzheimer's Dement.* 2022;18:1-122. 2. Dubois B, et al. *J Alzheimer's Dis.* 2015;49:617-631. 3. Kirson NY, et al. *BMC Geriatr.* 2016;16:138. 4. Gettsos D, et al. *Alzheimer's Dement.* 2012;8(1):22-30. 5. Alzheimer's Association. 2018 Alzheimer's disease facts and figures. *Alzheimer's Dement.* 2018;14:367-426.

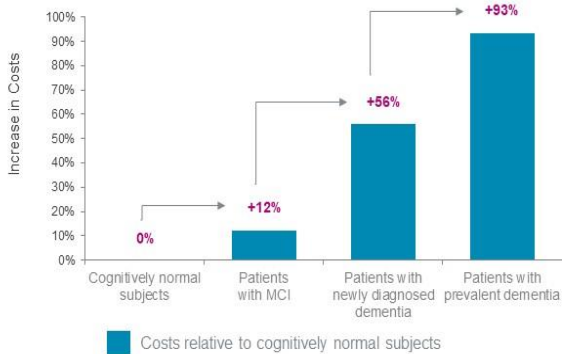
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Early Diagnosis Necessary to Realize the Value of Treatments Slowing Cognitive and Functional Decline



Mean Annual Medical Costs Along the Spectrum of Cognitive Impairment^{1,2}

(relative to cognitively normal subjects, based on unadjusted per-patient per-year cost in 2010)



- Societal and healthcare costs per patient differ significantly between mild, moderate and severe AD groups (including caregiver productivity, length of hospitalization, etc.)^{1,2}
- Next generation treatments target the underlying pathology of the disease and aim to slow cognitive and functional decline³
- A treatment that keeps patients in the early stages of the disease for longer, before significant cognitive and functional decline, can provide value to healthcare systems⁴⁻⁷
 - Value is realized by delaying institutionalization of care (including, caregiver productivity, length of hospitalization, etc.)
- The value of such a treatment can only be realized if diagnosis and initiation of treatment is made early in the AD continuum, at the MCI due to AD or mild AD stages

1- Alzheimer's Association, 2020 Alzheimer's disease facts and figures. *Alzheimer's Dement.* 2020. 16: 391-460. 2- Leisboron CL et al. Direct medical costs and source of cost differences across the spectrum of cognitive decline: a population-based study. *Alzheimer's Dement.* 2015;11(8):917-932. 3- van Dyck CH. Anti-Amyloid-β Monoclonal Antibodies for Alzheimer's Disease: Pitfalls and Promise. *Biol Psychiatry.* 2018;83(4):311-319. 4- Brookmeyer R et al. Forecasting the prevalence of preclinical and clinical Alzheimer's disease in the United States. *Alzheimer's Dement.* 2018;14(2):121-129. 5- Lewis et al. The Trajectory of Dementia in the UK - Making a difference. Report for Alzheimer's Research UK by CHE Consulting. 2014. 6- Banerjee et al. Clinical and cost effectiveness of services for early diagnosis and intervention in dementia. *International journal of geriatric psychiatry.* 2009; 24: 748-754. 7- Knapp et al. Scenarios of dementia care: What are the impacts on cost and quality of life? The London School of Economics and Political Science. 2014.

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Costs Associated with Alzheimer's Disease Progression



Highest Impact from MCI to Mild AD

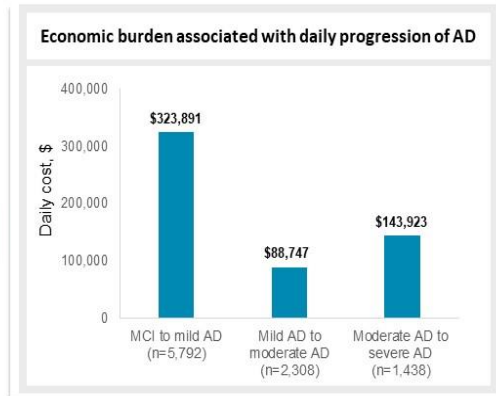
Objective

- To estimate the economic burden of daily transitions* to later stages of AD in the US

Results

Number of daily transitions and annual burden estimates per patient

	Number of patients per day	Annual transition costs per patient
MCI due to AD ¹ to mild AD	5,792	\$20,410
Mild AD ² to moderate AD	2,308	\$14,035
Moderate ³ AD to severe AD	1,438	\$36,519



Timely intervention may slow AD progression and mitigate the economic and health burden of AD in the US

*Used a funnel-based approach by deriving prevalence of all-cause MCI and AD dementia clinical syndrome among the US population aged ≥50 years from previously published studies and applying annual transition probabilities from the National Alzheimer's Coordinating Center to the amyloid-positive case estimates, which were pulled from the Amyloid Biomarker Study. ¹Approximately 6.9 million individuals were estimated to have MCI due to AD with a 30.7% annual probability of transitioning to mild AD in 2021. ²Approximately 2.5 million individuals were estimated to have mild AD with a 33.6% annual probability of transitioning to moderate AD in 2021. ³Approximately 1.7 million individuals were estimated to have moderate AD with a 30.2% annual probability of transitioning to severe AD in 2021.
 AD=Alzheimer's disease; MCI=mild cognitive impairment.
 Razavi M, et al. Poster presented at the 15th Clinical Trials on Alzheimer's Disease (CTAD); November 29-December 2, 2022.

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Benefits of Early Diagnosis of AD



- Implementation of coordinated care plans
- Better management of symptoms
- Patient safety improvements
- Potential cost savings: social and informal care
- Quality of life – postponement of institutionalization

AD, Alzheimer's disease
 1. Dubois B, et al. J Alzheimers Dis 2016;49(3):617-631

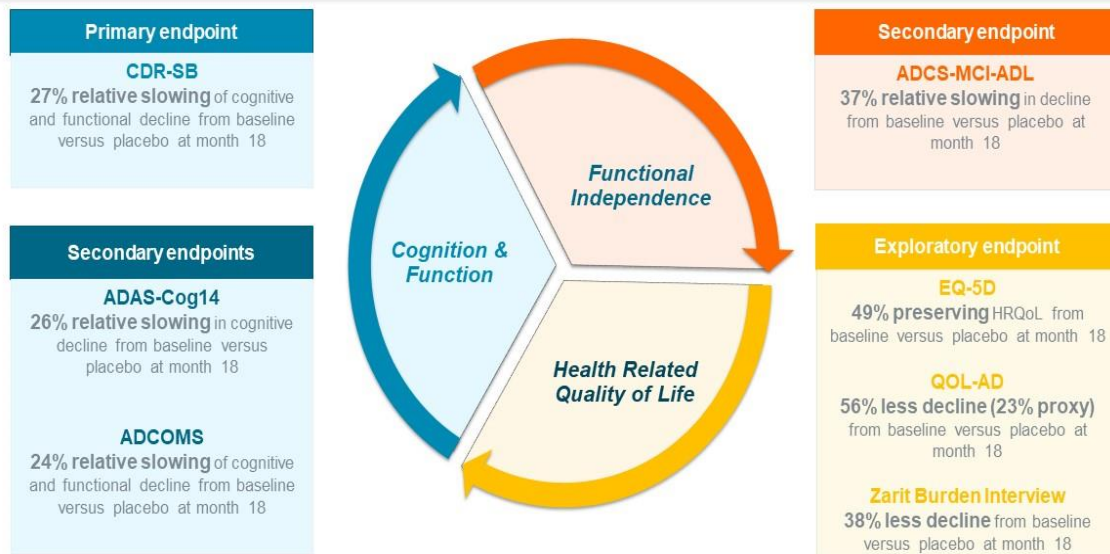
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Impact of Intervention Clarity AD Trial



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Lecanemab Impact on Different Dimensions of AD



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Most Common Adverse Events



Adverse Events Of Special Interest (Pooled preferred terms [PTs])	Placebo (n=897) %	Lecanemab (n=898) %
Infusion-related reaction	7.4	26.4
ARIA-E	1.7	12.6
ARIA-H (pooled PTs)	9.0	17.3
Isolated ARIA-H (pooled PTs)	7.8	8.9

Other Adverse Events >5%	Placebo (n=897) %	Lecanemab (n=898) %
Headache	8.1	11.1
Fall	9.6	10.4
Urinary tract infection	9.1	8.7
COVID-19	6.7	7.1
Back pain	5.8	6.7
Arthralgia	6.9	5.9
Dizziness	5.1	5.5
Diarrhea	6.5	5.3
Anxiety	4.2	5.0

- There were no significant trends in mean changes over time or shifts from baseline for any of the laboratory, ECG or vital sign parameters and no notable differences between groups

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182 | ARIA-E, amyloid related imaging abnormalities - edema; ARIA-H, ARIA-H, ARIA with hemosiderin deposits; COVID-19, coronavirus disease of 2019 ECG, electrocardiogram.

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Clarity AD: A Diverse Clinical Trial Population Baseline Comorbidities and Comedications



Characteristic	Combined Total N=1795	United States N=948
Comorbidities		
Hypertension, n (%)	993 (55.3%)	612 (64.6%)
Hyperlipidemia, n (%)	1085 (60.4%)	674 (71.1%)
Ischemic Heart Disease, n (%)	291 (16.2%)	189 (19.9%)
Diabetes, n (%)	271 (15.1%)	180 (19.0%)
Obesity, n (%)	298 (16.6%)	229 (24.2%)
At least 2 comorbidities above, n (%)	917 (51.1%)	604 (63.7%)
At least 3 comorbidities above, n (%)	441 (24.6%)	319 (33.6%)
At least 4 comorbidities above, n (%)	139 (7.7%)	111 (11.7%)
At least 5 comorbidities above, n (%)	25 (1.4%)	22 (2.3%)
Comedications		
Anticoagulants	80 (4.5%)	54 (5.7%)

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Value and Clinical Meaningfulness

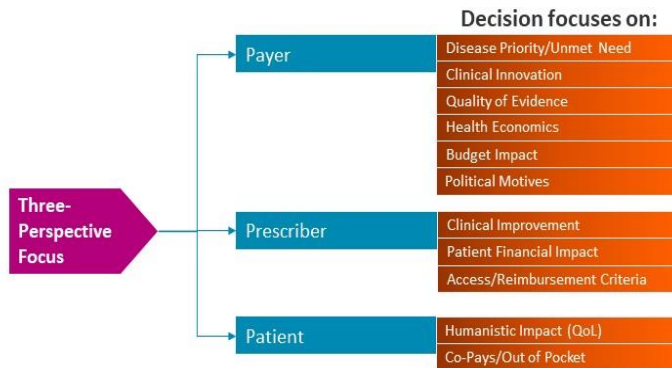


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Recognizing Stakeholders Perspectives



Multiple decision makers, each with different value perceptions, influence patient access and product success



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Clinical Meaningfulness Framework



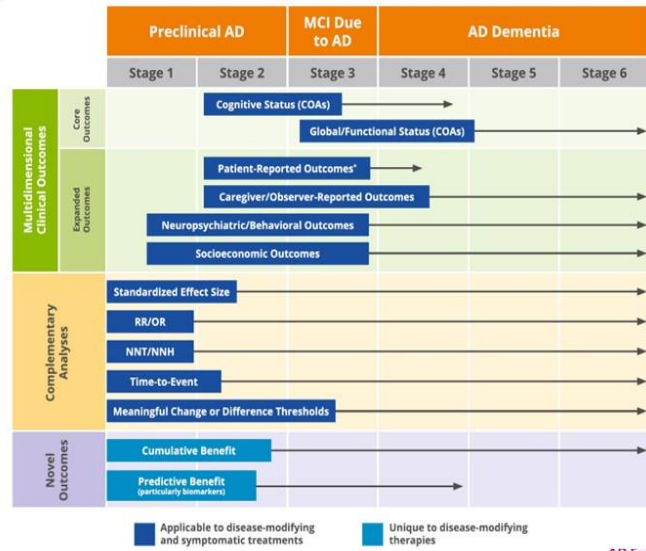
Umbrella Framework of Meaningful Benefits in AD

'Meaningful Benefits' is a recently proposed framework which aims to comprehensively cover the benefits offered by DMTs in AD

Covers multiple outcomes beyond cognition and functioning

Includes complementary analyses beyond time-to-event/survival analyses

Includes novel outcomes that are unique to DMTs



Assunção SS et al. Meaningful benefits: a framework to assess disease-modifying therapies in preclinical and early Alzheimer's disease. *Alzheimers Res Ther*. 2022; 14: 54.



In Early AD, A 25% Slowing of Progression on CDR-SB Considered Meaningful by Patients, Families, Care Partners, and Clinicians



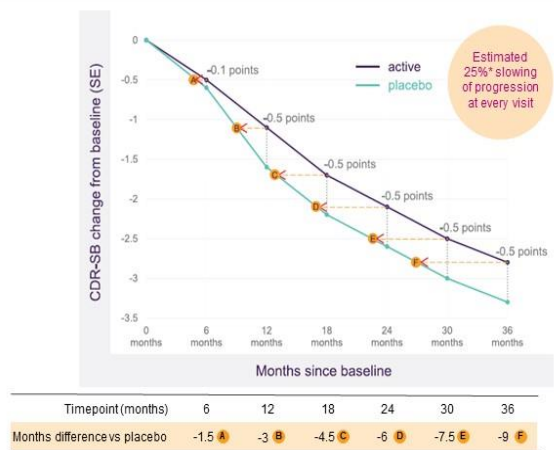
Objective

- To consider how cognitive and functional measures can help identify clinically meaningful slowing of disease progression within RCTs

Insights from the Alzheimer's Association workgroup:

- A patient with a **25% slowing of progression** on CDR-SB* over a given timepoint **gains additional time in milder disease stages**
- A 0.5 reduction in CDR-SB[†] score within a single domain would represent a noticeable loss of independence, function, and ability to those with early-stage AD

Time savings between CDR-SB change in score at a specific timepoint



*25% reduction in progression is frequently cited as an appropriate benchmark for clinical meaningfulness. [†]CDR-SB is the total of scores from each of 6 CDR domains, with each domain graded on this scale: 0, 0.5, 1, 2, 3. AD=Alzheimer's disease; CDR-SB=Clinical Dementia Rating-Sum of Boxes; RCT=randomized controlled trial; SE=standard error. Petersen RC, et al. *Alzheimers Dement*. 2023. doi:10.1002/alz.12959.



Lifetime Health Outcomes of Lecanemab in Patients with Early AD (i.e., MCI due to AD and mild AD dementia): A Patient-Level Simulation



Target Population

Adults with the diagnosis of MCI due to AD and mild AD dementia (Early AD) and confirmed evidence of Aβ+ pathology similar to the CLARITY AD trial population

The AD Archimedes condition-event (ACE)

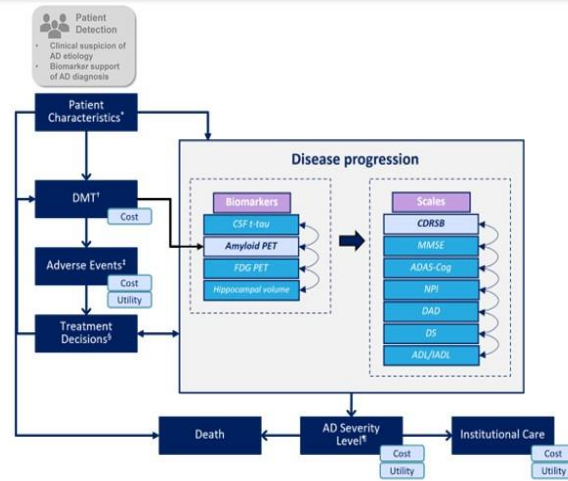
A Patient-level simulation model capturing AD pathophysiology, progression and management, incl. effects of disease modification and early intervention

Data sources

Data sources for base-case and scenario analyses included LEC Phase 2b trial (Study 201), ADNI data, and published literature

Outcomes

1. Total life years and quality-adjusted life years (QALY)
2. Societal costs of care
3. Value-based pricing (incl. scenarios and sensitivities)



ADNI data was used to predict Alzheimer's disease natural history and identify relationships based on patient's characteristics, biomarkers, and assessment scales.

ADNI: Alzheimer's Disease Neuroimaging Initiative

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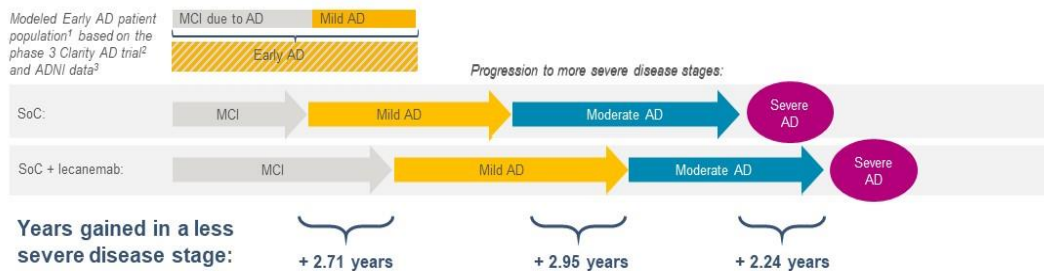
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Lecanemab Delay in Clinical Decline and Disease Progression



Simulated mean time advancing to mild, moderate, and severe Alzheimer's disease was longer for patients in the lecanemab-treated group than for patients in the standard of care group



The results from the modeling demonstrate the potential clinical value of lecanemab for patients with early AD and how it can slow the rate of disease progression, delay progression to AD dementia with several years and reduce the need for institutionalized care

1. Tahami Monfared AA et al. *Neurother*. 2023 Apr 2. doi: 10.1007/s40120-023-00473-w.
 2. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med*. 2023;388(1):9-21.
 3. ADNI [Alzheimer's Disease Neuroimaging Initiative] study

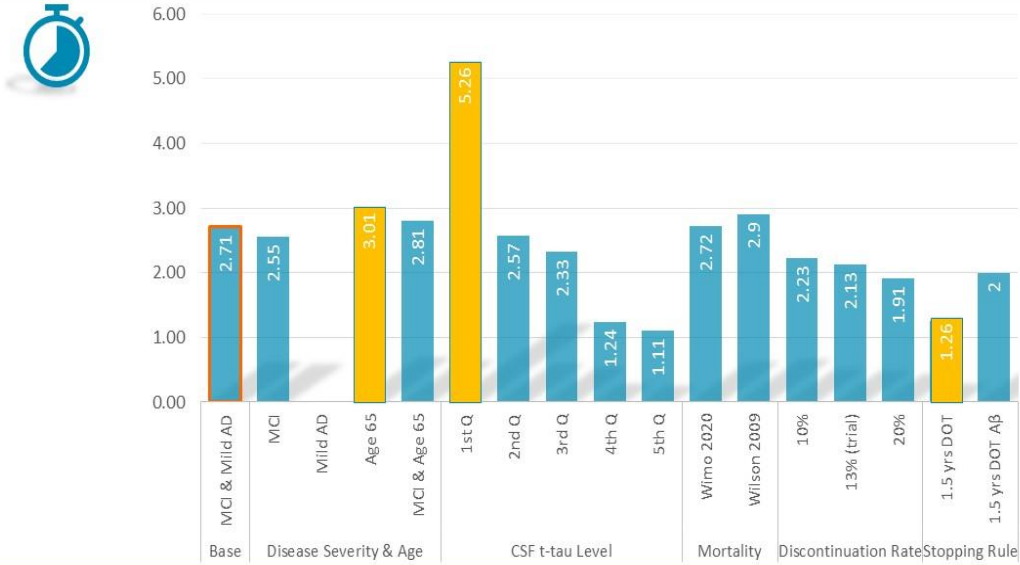
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Scenario Analyses - Time to *Mild AD Dementia*



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The Industry Role



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Industry's Role in Translating Research into Clinical Impact



1 Drug Discovery and Development

6 Access and Distribution

2 Clinical Trials

7 Medical Education and Awareness

3 Regulatory Approval

8 Collaboration with Researchers

4 Manufacturing and Quality Control

9 Post-Marketing Studies

5 Pharmacovigilance

10 Patient Support Programs

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Previous Failures Have Not Discouraged the Industry



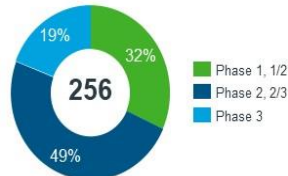
The cost of AD drug development is high, and failures are common (US \$42.5 B as of 1995)[†]

Number of Alzheimer's Active Clinical Trials



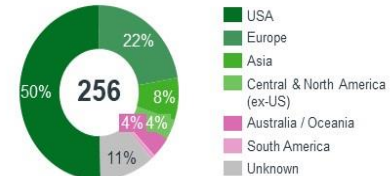
- Due to high unmet need and the raising disease burden, the **clinical research on Alzheimer's Disease is extensive**, despite numerous failures in the previous years
- Potential AD drugs constitute the majority of the pipeline, with behavioural therapies, devices and diagnostic agents also high on the agenda

Number of Clinical Trials By Development Phase



- With approximately 80% of active clinical trials in Phase 1 or 2, the majority of investigative therapies for Alzheimer's Disease remain in **early development**
- However, numerous assets in Phase 3 clinical development promise the **introduction of disease-modifying therapies** in the next 3-5 years

Number of Clinical Trials By Geographic Split



- Disease-modifying drugs offer ambitious prospects towards the "holy grail" of AD research – slowing disease progression and curing the disease altogether
- The predominance of Alzheimer's clinical trials are **concentrated in the US**, followed by Europe and Asia

IQVIA. EFPIA Pipeline Innovation Review. Pipeline Overview, August 2022. https://www.efpia.eu/media/676661/iqvia_efpia_pipeline-review_final-report_public-final.pdf
[†] Cummings J et al. The costs of developing treatments for Alzheimer's disease: A retrospective exploration Alzheimers Dement. 2022 Mar;18(3):469-477.

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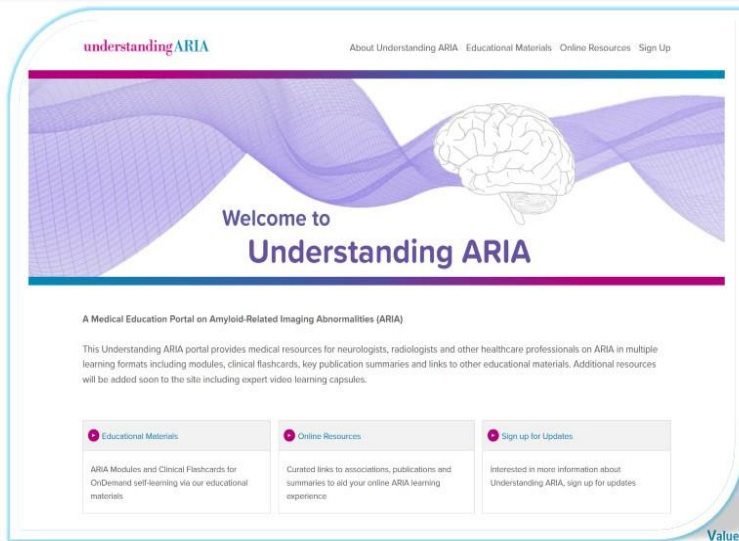


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- 2 Self-guided educational materials: infographics
- 3 Self-guided educational materials: Expert video learning capsules
- 4 ARIA online resources: overview of key ARIA articles
- 5 ARIA MRI Cased-Based Learning Sessions
- 6 Live webinars



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Self-Guided Educational Materials Tailored to Multiple Stakeholders

Slide Decks



Understanding Amyloid-Related Imaging Abnormalities (ARIA)
For the Neurologist

Understanding Amyloid-Related Imaging Abnormalities (ARIA)
For the Radiologist

Understanding Amyloid-Related Imaging Abnormalities (ARIA)
For the Primary Care Physician

Sub-topics

Introducing ARIA	Pathophysiology
Deeper focus on ARIA	Clinical manifestations of ARIA
Diagnosis of ARIA	Management of ARIA

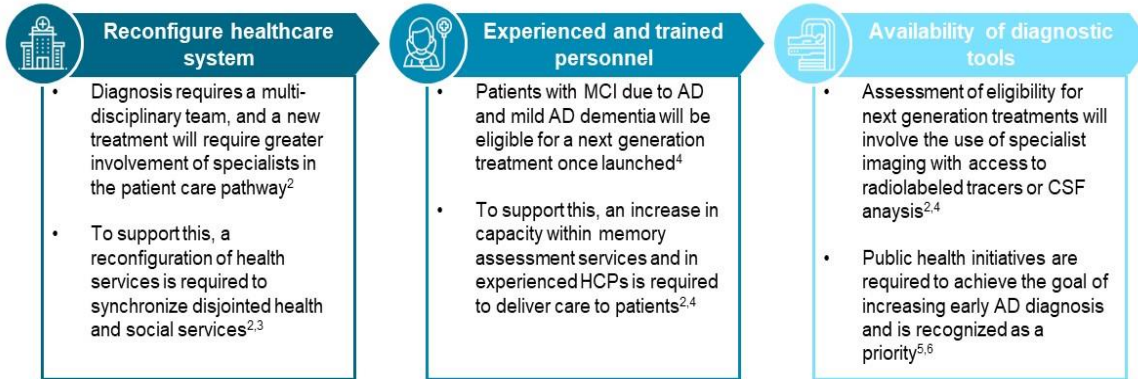
Available on www.understandingARIA.com

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Public / Private Collaboration Needed to Support Provision of Care



Research predicts significant waiting lists if a new treatment became available for MCI due to AD patients in 2020, if access required biomarker confirmation.^{1,4} Many of these patients would develop AD dementia while waiting for access to treatment^{1,4}



In recognition of the challenges facing AD diagnosis, the WHO and several national healthcare organizations have implemented policy initiatives to improve AD diagnosis and care⁷

1- Alzheimer's Association, 2020 Alzheimer's disease facts and figures. 2- Alzheimer's Research UK. Thinking Differently. Preparing today to implement future dementia treatments. 2018. 3-The Economist. Assessing the socioeconomic impact of AD in western Europe and Canada, 2017. 4- Liu J. et al. Assessing the Preparedness of the U.S. Health Care System Infrastructure for an Alzheimer's Treatment. RAND Corporation, 2017. 5- Alzheimer's Association. A public health approach to Alzheimer's and other dementias. 2016. 6- Donegan K et al. Trends in diagnosis and treatment for people with dementia in the UK from 2005 to 2015. The Lancet. Public Health. 2017. 7- World Health Organization (WHO). Global action plan on the public health response to dementia. 2017-2025.

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Thank You

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