

Clinical Assessment Tools Used in Alzheimer's Disease Clinical Trials

This brochure was developed and funded by Biogen to provide a focused overview of tools historically used in Alzheimer's disease (AD) clinical trials. The information presented in this brochure is based on currently available literature and is not intended to act as a guide for decision making in clinical practice.

Aim of this Brochure

Clinical assessment tools used in Alzheimer's disease clinical trials may vary from trial to trial, and differ on several key aspects, making the direct comparison of results obtained across different clinical trials challenging^{1,2}.

This brochure provides a focused overview and comparison of 14 tools commonly used in AD clinical trials by highlighting the:

- Purpose of the tool
- Administration type
- Outcome scores
- Severity stage assessed
- Domains assessed

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Introduction

Overview of Alzheimer's disease

Alzheimer's disease (AD) is a progressive, chronic neurodegenerative disease. The clinical manifestation of AD is a continuum that starts without symptoms, develops into mild cognitive impairment (MCI) and advances to worsening dementia³. Though memory problems are the typical first sign of cognitive impairment, AD can affect a patient's cognitive abilities in a number of ways, as well as induce a change in their functional abilities, mood and behavior, quality of life, and dependence on their caregiver^{4,5}.

Categorizing a patient into symptomatic stages has aided in the diagnosis of AD³. These criteria – preclinical, MCI due to AD, and dementia due to AD – have been developed by the National Institute on Aging and Alzheimer's Association (NIA-AA) in 2011³. Defining AD in the context of observational and interventional research has shifted from a diagnosis based on the symptoms

and signs of disease, to a diagnosis based on pathological biomarker staging as reflected in the NIA-AA 2018 research framework⁶(Figure 1). Amyloid-beta (Aβ) biomarkers help determine whether or not an individual is in the Alzheimer's continuum, whilst pathologic tau biomarkers help determine if someone who is in the Alzheimer's continuum has AD. Cognitive symptoms are not specific for AD, and so are used to stage the severity of AD⁶.

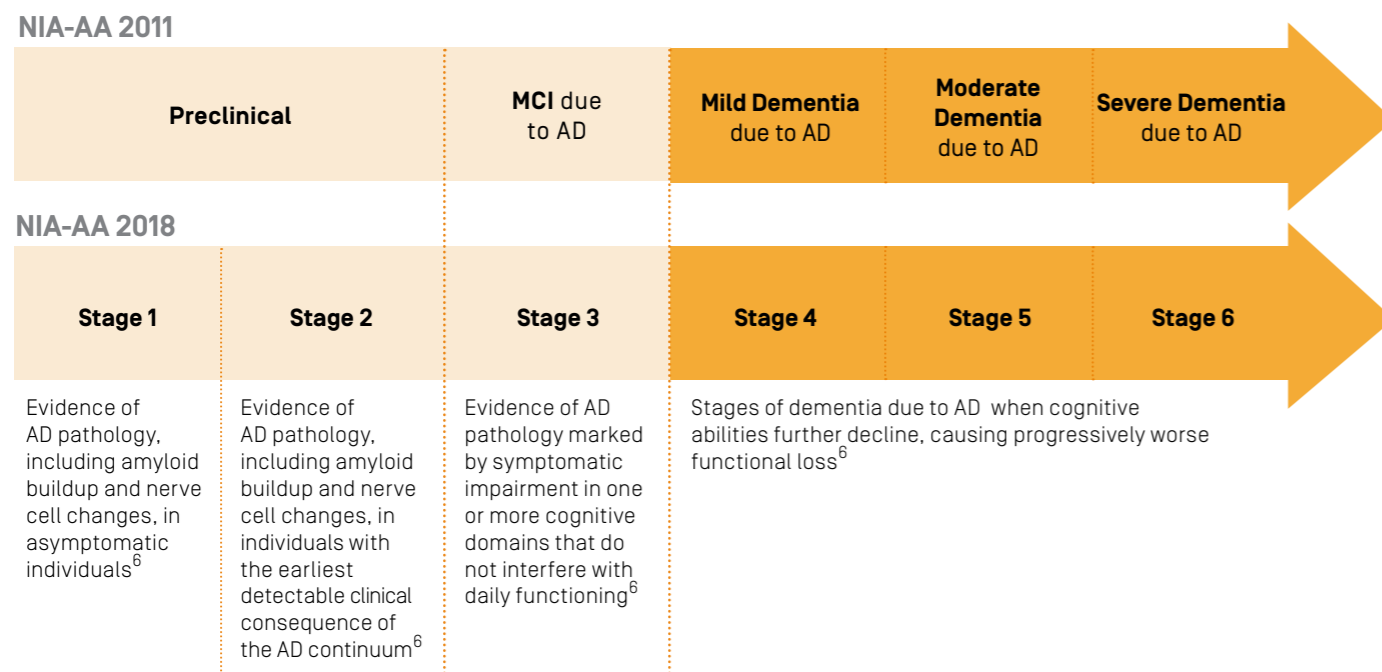
Clinical assessment tools used in Alzheimer's disease

Many assessment tools have been developed for AD care and research. These tools aid in diagnosing dementia, measuring changes in the disease course, decision making, monitoring impact of the disease on the caregiver, screening patients for inclusion/exclusion criteria of clinical trials, and to evaluate the potential efficacy of an intervention as clinical trial primary or secondary endpoints⁷⁻⁹.

Due to the complexity of the clinical continuum of AD, it is difficult to capture clinically meaningful changes in AD with a single assessment tool alone. Assessment tools may use distinct numerical scoring systems, assess the same, overlapping, or different stages of disease severity, or assess different domains or different aspects of a particular domain. When multiple clinical assessment tools are used together and considered alongside information obtained from fluid and/or imaging biomarkers, a more holistic understanding of the patient can be achieved^{6,7}.

This brochure facilitates comparison of some of the most common AD clinical assessment tools used in clinical trials by providing an overview of each tool's numerical scoring system, disease severity, and domains assessed.

Figure 1. Disease stages of AD classified by the NIA-AA 2011 and NIA-AA 2018 frameworks



Summary Infographic

This brochure facilitates comparison of AD clinical assessment tools commonly used in clinical trials. Some of these tools may be used in clinical practice. It is not an exhaustive list of every assessment tool available.

This infographic is a quick comparison across a selection of 14 assessment tools. The following pages include an expanded summary for each tool listed here.

	DISEASE STAGE						COGNITIVE DOMAIN					FUNCTIONAL DOMAIN		BEHAVIORAL DOMAIN	QUALITY OF LIFE	
	Preclinical			Dementia			Orientation	Attention and Working Memory	Memory	Visuospatial	Language	Executive Function	Basic-ADL	Instrumental-ADL	Neuropsychiatric Symptoms	
	S1	S2	S3	Mild AD	Moderate AD	Severe AD										
	NIA-AA 2011															
	NIA-AA 2018															
QDRS							✓	✓	✓		✓	✓	✓	✓	✓	
CDR-SB							✓	✓	✓		✓	✓	✓	✓		
MMSE							✓	✓	✓	✓	✓					
MoCA							✓	✓	✓	✓	✓	✓				
ADAS-Cog							✓	✓	✓	✓	✓					
A-IADL-Q													✓			
ADCS-ADL												✓	✓			
ADCS-ADL-MCI												✓	✓			
FAQ													✓			
NPI-Q															✓	
GDS															✓	
QOL-AD													✓		✓	✓
SF-36																✓
Zarit Burden Interview																✓

- Legend**
- Administered to Informant
 - Administered to Patient
 - Administered to both Patient and Informant

The orange arrows here indicate the Alzheimer's disease continuum; the green boxes on this diagram indicate the applicability of the test to the specific stage of dementia; please see further pages of the booklet for more detailed information.

QDRS^{10,11}

Purpose

To stage the severity of cognitive impairment via interview.

Disease Stage



Administered to **Patient* and Informant**

*Modified version for administration to patient



3-5 minutes

Higher Score = Greater Impairment / **30**

COGNITIVE DOMAIN

Orientation	<ul style="list-style-type: none"> Know and state the current date and place Keep track of time and place in everyday living
Attention & Working Memory	<ul style="list-style-type: none"> Sustain attention
Memory	<ul style="list-style-type: none"> Learn and recall new info during exam Learn and recall info in daily activities
Visuospatial	NOT ASSESSED
Language	<ul style="list-style-type: none"> Speak fluently, without pause or word finding Read and write as well as in the past
Executive Function	<ul style="list-style-type: none"> Solve problems and make decisions Demonstrate appropriate judgement

FUNCTIONAL DOMAIN

Basic Activities of Daily Living**	<ul style="list-style-type: none"> Capable of personal hygiene Capable of dressing Contenance
Instrumental Activities of Daily Living**	<ul style="list-style-type: none"> Perform usual social and occupational functions Carry out household chores and use tools Interest in and able to carry out hobbies Manage everyday problems and finances

BEHAVIORAL DOMAIN

Neuro-psychiatric Symptoms	<ul style="list-style-type: none"> Change in personality or behavior Anxiety Symptoms of depression
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QUALITY OF LIFE

NOT ASSESSED

**Note: Not a complete list of ADLs assessed by the tool.

CDR-SB^{12,13}

Purpose

To stage the severity of cognitive impairment via interview.

Disease Stage



Administered to **Patient and Informant**



~90 minutes

Higher Score = Greater Impairment / **18**

COGNITIVE DOMAIN

Orientation	<ul style="list-style-type: none"> Know and state the current date and place Keep track of time and place in everyday living
Attention & Working Memory	<ul style="list-style-type: none"> Concentrate on everyday activities Manipulate information in one's head
Memory	<ul style="list-style-type: none"> Learn and recall new info during exam Learn and recall info in daily activities
Visuospatial	NOT ASSESSED
Language	<ul style="list-style-type: none"> Repeat sentences and phrases
Executive Function	<ul style="list-style-type: none"> Solve problems and make decisions Demonstrate appropriate judgement Plan and organize Think abstractly

FUNCTIONAL DOMAIN

Basic Activities of Daily Living*	<ul style="list-style-type: none"> Capable of personal hygiene Capable of dressing Capable of feeding Contenance
Instrumental Activities of Daily Living*	<ul style="list-style-type: none"> Perform usual social and occupational functions Carry out household chores and use tools Interest in and able to carry out hobbies Solve everyday problems and financial affairs

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

NOT ASSESSED

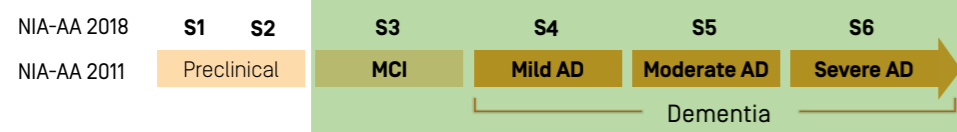
*Note: Not a complete list of ADLs assessed by the tool.

MMSE^{11,14-16}

Purpose

To screen the patient for cognitive impairment via interview.

Disease Stage



Administered to Patient only



5-10 minutes

Lower Score = Greater Impairment / 30

COGNITIVE DOMAIN

Orientation	<ul style="list-style-type: none"> Know and state the current date and place Keep track of time and place in everyday living
Attention & Working Memory	<ul style="list-style-type: none"> Follow examiner's instruction with focus Manipulate information in one's head
Memory	<ul style="list-style-type: none"> Learn and recall new info during exam
Visuospatial	<ul style="list-style-type: none"> Copy 2D geometric shapes
Language	<ul style="list-style-type: none"> Repeat sentences and phrases Name common objects Follow written and oral commands
Executive Function	NOT ASSESSED

FUNCTIONAL DOMAIN

NOT ASSESSED

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

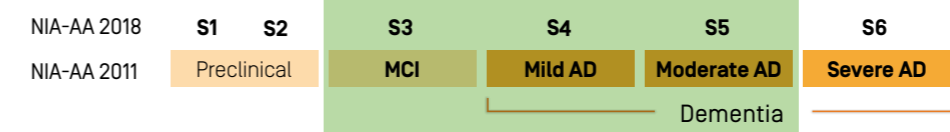
NOT ASSESSED

MoCA^{11,17,18}

Purpose

To screen the patient for cognitive impairment via interview.

Disease Stage



Administered to Patient only



10-12 minutes

Lower Score = Greater Impairment / 30

COGNITIVE DOMAIN

Orientation	<ul style="list-style-type: none"> Know and state the current date and place
Attention & Working Memory	<ul style="list-style-type: none"> Sustain attention Repeat series of digits Manipulate information in one's head
Memory	<ul style="list-style-type: none"> Learn and recall new info during exam
Visuospatial	<ul style="list-style-type: none"> Copy 3D geometric shapes Draw a clock without copying Copy a drawing of a cube
Language	<ul style="list-style-type: none"> Repeat sentences and phrases Name common objects Generate words from a specific category
Executive Function	<ul style="list-style-type: none"> Correct alternating numbers and letters Generate words starting with a specific letter Think abstractly Plan clock drawing

FUNCTIONAL DOMAIN

NOT ASSESSED

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

NOT ASSESSED

ADAS-Cog¹⁹⁻²¹

Purpose

To screen the patient for cognitive impairment via interview.

Disease Stage



Administered to **Patient only**

~45 minutes

Higher Score = Greater AD Severity

/85 Max Score for ADAS-Cog13

/90 Max Score for ADAS-Cog14*

*14-item version includes Maze task

COGNITIVE DOMAIN

Orientation • Know and state the current date and place

Attention & Working Memory • Sustain attention
 • Follow examiner's instruction with focus

Memory • Learn and recall new info during exam

Visuospatial • Copy geometric shapes

Language • Name common objects
 • Speak fluently, without pause or word finding
 • Follow written and oral commands

Executive Function • Assessed via Maze task in ADAS-Cog14

FUNCTIONAL DOMAIN

NOT ASSESSED

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

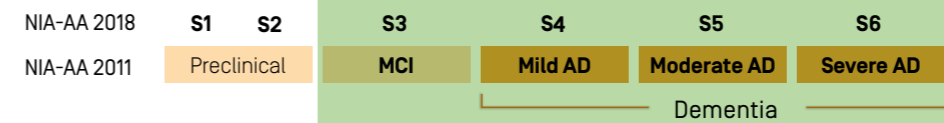
NOT ASSESSED

A-IADL-Q²²⁻²⁶

Purpose

To assess the performance of instrumental activities of daily living by the patient via questionnaire.

Disease Stage



Administered to **Informant only**

20-25 minutes

Lower Score = Poorer Functional Performance

/20-80 Max Score for 70-item*

*Scored using item response theory (IRT)

COGNITIVE DOMAIN

NOT ASSESSED

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

NOT ASSESSED

FUNCTIONAL DOMAIN

Basic Activities of Daily Living NOT ASSESSED

Instrumental Activities of Daily Living**

- Perform usual social and occupational functions
- Carry out household chores and use tools
- Interest in and able to carry out hobbies
- Solve everyday problems and financial affairs
- Transportation

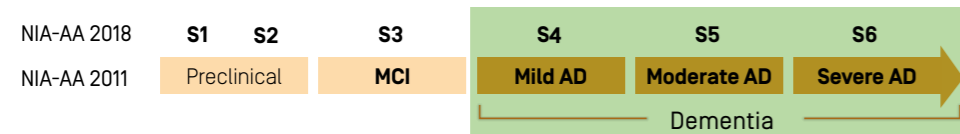
**Note: Not a complete list of ADLs assessed by the tool.

ADCS-ADL^{9,27}

Purpose

To assess the performance of basic and instrumental activities of daily living by the patient via questionnaire.

Disease Stage



Administered to Informant only
 ~20 minutes

Lower Score = Poorer Functional Performance /78

COGNITIVE DOMAIN

NOT ASSESSED

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

NOT ASSESSED

FUNCTIONAL DOMAIN

- Basic Activities of Daily Living***
 - Capable of personal hygiene
 - Capable of dressing
 - Capable of feeding
 - Contenance
- Instrumental Activities of Daily Living***
 - Perform usual social and occupational functions
 - Carry out household chores and use tools
 - Interest in and ability to carry out hobbies

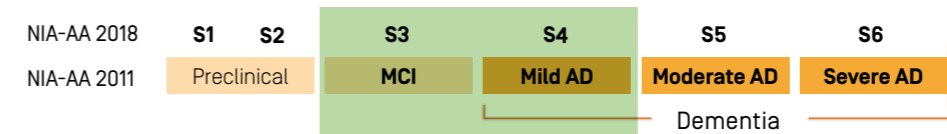
*Note: Not a complete list of ADLs assessed by the tool.

ADCS-ADL-MCI²⁸

Purpose

To assess the performance of basic and instrumental activities of daily living by the patient via questionnaire.

Disease Stage



Administered to Informant only
 Not specified

Lower Score = Poorer Functional Performance /53

COGNITIVE DOMAIN

NOT ASSESSED

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

NOT ASSESSED

FUNCTIONAL DOMAIN

- Basic Activities of Daily Living**
 - Capable of dressing
- Instrumental Activities of Daily Living***
 - Perform usual social and occupational functions
 - Carry out household chores and use tools
 - Interest in and able to carry out hobbies
 - Shopping and meal preparation
 - Manage appointments

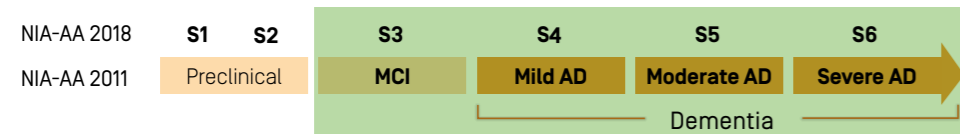
*Note: Not a complete list of ADLs assessed by the tool.

FAQ²⁹

Purpose

To assess the performance of instrumental activities of daily living by the patient via questionnaire.

Disease Stage



Administered to Informant only



Not specified

Higher Score = Poorer Functional Performance /30

COGNITIVE DOMAIN

NOT ASSESSED

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

NOT ASSESSED

FUNCTIONAL DOMAIN

Basic Activities of Daily Living NOT ASSESSED

Instrumental Activities of Daily Living*

- Perform usual social and occupational functions
- Interest in and ability to carry out hobbies
- Transportation
- Shopping and meal preparation
- Manage appointments and medications

*Note: Not a complete list of ADLs assessed by the tool.

NPI-Q³⁰⁻³¹

Purpose

To assess the frequency and severity of neuropsychiatric symptoms, and degree of caregiver distress via questionnaire.



Administered to Informant only



< 5 minutes

Higher Score = Greater Neuropsychiatric Disturbances or Caregiver Distress

/36 Max Score for Symptom Severity

/60 Max Score for Caregiver Distress

COGNITIVE DOMAIN

NOT ASSESSED

FUNCTIONAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

NOT ASSESSED


BEHAVIORAL DOMAIN


Neuro-psychiatric Symptoms

- Aberrant motor behavior
- Apathy
- Agitation or aggression
- Anxiety
- Delusions
- Depression or dysphoria
- Disinhibition
- Elation or euphoria
- Hallucinations
- Irritability or lability
- Change in appetite or sleep

GDS^{11,32}

Purpose
To screen for depression via questionnaire.

 Administered to **Patient only**

 5-10 minutes

Higher Score = Greater Severity of Depressive Symptoms

/30 Max Score for Long Form

/15 Max Score for Short Form

COGNITIVE DOMAIN

NOT ASSESSED

FUNCTIONAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

NOT ASSESSED


BEHAVIORAL DOMAIN


Neuro-psychiatric Symptoms

- Symptoms of depression in the elderly

QOL-AD³³

Purpose
To assess the global quality of life in an Alzheimer's disease patient via interview.

 Administered to **Patient and Informant**

 ~10 minutes

Lower Score = Poorer Quality of Life

/52

COGNITIVE DOMAIN

NOT ASSESSED

FUNCTIONAL DOMAIN

Basic Activities of Daily Living

NOT ASSESSED

Instrumental Activities of Daily Living

- Perform usual social or occupational functions
- Carry out household chores
- Interest in and ability to carry out activities

BEHAVIORAL DOMAIN

Neuro-psychiatric Symptoms

- Mood state

QUALITY OF LIFE

- Physical health
- Energy
- Finances and living situation
- Memory

SF-36^{34,35}

Purpose

To assess the health-related quality of life of the patient or informant via interview.



Administered to **Patient and Informant**



<10 minutes

Lower Score = Poorer Quality of Life **/100**

COGNITIVE DOMAIN

NOT ASSESSED

FUNCTIONAL DOMAIN

NOT ASSESSED

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

- Physical health
- Mental health
- Energy

Zarit Burden Interview³⁶⁻³⁸

Purpose

To assess caregiver burden via interview.



Administered to **Informant only**



-5 minutes

Higher Score = Greater Burden

/88 Max Score for 22-item

COGNITIVE DOMAIN

NOT ASSESSED

FUNCTIONAL DOMAIN

NOT ASSESSED

BEHAVIORAL DOMAIN

NOT ASSESSED

QUALITY OF LIFE

- Caregiver's physical health
- Caregiver's mental health
- Caregiver's finances
- Caregiver's social life
- Relationship between caregiver and impaired person

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