



Alzheimer's Disease
Unified Data Model (AD-UDM)
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Revision History

Version	Date	Description
1.0	14/03/2025	Initial finalized version of the AD Unified Data Model (AD-UDM).
1.1	21/03/2025	Added descriptive content for each section and clarified the overall scope, purpose, and objectives of the data model.
2.0	12/12/2025	Draft Version Data Dictionary based on the JSON Schema v20251017 , extracted on 12 December 2025 . Post-implementation update reflecting the data model as implemented in the application.
2.1	14/01/2026	Version including completed validation rules and reference lists.
2.2	28/01/2026	Finalized version 2.2 of the AD Unified Data Model (AD-UDM).

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1 Overview

This document describes the **Alzheimer's Disease Unified Data Model (AD-UDM)**, a structured and standardised framework for the representation, storage, and exchange of clinical data related to **Alzheimer's Disease (AD)**.

The **AD-UDM** is designed to support clinical data collection, research activities, and medical registries by providing a consistent and well-defined data structure that promotes interoperability across heterogeneous healthcare systems and data sources.

All fields and elements described in this version of the **AD-UDM** are based on the clinical, technical, and scientific information available at the time of publication. Ongoing feedback from clinical and scientific experts is expected and will be incorporated into future versions through a controlled versioning process.

The modular architecture of the **AD-UDM** enables progressive extension and refinement of the model without compromising backward compatibility or the integrity of existing data. This approach allows the model to evolve in parallel with advances in clinical practice and research, including the introduction of newly validated biomarkers, diagnostic criteria, and therapeutic strategies.

1.1 Alzheimer's Disease Unified Data Model (AD-UDM)

The **Alzheimer's Disease Unified Data Model (AD-UDM)** is designed using a **JSON-based data representation**, ensuring consistency, interoperability, scalability, and adaptability across multiple healthcare systems, research databases, and clinical registries.

The primary objectives of the **AD-UDM** are to:

- Enable **structured and standardised data collection** for clinical care, research, and registry use
- Support **longitudinal tracking** of disease progression, medical events, and treatment outcomes over time
- Ensure data privacy and regulatory compliance through the explicit identification, labelling, and controlled handling of **Personally Identifiable Information (PII)** fields within the data model
- Facilitate **secure integration and data exchange** with external medical registries and analytical platforms

1.2 What Is a Medical Record?

A medical record is a structured and comprehensive representation of a patient's health information, including identification details, medical history, diagnoses, treatments, and clinical test results. It serves as a core artefact for healthcare professionals, supporting clinical decision-making, longitudinal disease monitoring, and research activities.

In the context of **Alzheimer's Disease (AD)**, the medical record is particularly important for:

- Tracking **cognitive decline and disease progression** using standardised clinical and neuropsychological assessments
- Recording **biomarker evidence**, including findings from MRI, PET imaging, cerebrospinal fluid (CSF), and blood-based tests
- Documenting **treatments and clinical responses**, including disease-modifying therapies (DMTs), cognitive treatments, and non-pharmacological interventions

- Capturing **adverse events and safety signals** associated with treatments, such as Amyloid-Related Imaging Abnormalities (ARIA) or infusion-related reactions

1.3 Data Anonymization and PII Management

For data privacy and security, **Personally Identifiable Information (PII)** fields are explicitly identified within the data model **using a dedicated pii naming prefix**, enabling controlled handling and policy-based processing of identifiable data.

- PII fields are **excluded from data exchanges** with external medical registries
- Date of birth is **truncated to year and month** in the core medical record, while the full date of birth may be retained in PII-designated fields for local clinical use
- PII fields are retained only in scenarios where **patient records must be transferred between healthcare centres**, in accordance with applicable regulations

This approach supports compliance with data protection and privacy regulations while preserving data integrity for clinical care and research workflows.

1.4 Core Components of AD-UDM

The **Alzheimer's Disease Unified Data Model (AD-UDM)** is organised into a set of modular and clearly defined components, reflecting the longitudinal structure of a patient's medical record. Each component addresses a specific aspect of clinical data collection while remaining interoperable with the others.

1.4.1 Patient Profile

The Patient Profile section contains baseline and relatively stable patient information required for identification, stratification, and contextual interpretation of clinical data. It includes:

- **Identification**
Record identifiers, consent-related information, patient contact details, and care partner (informant) information, with Personally Identifiable Information (PII) fields explicitly identified within the data model
- **Demographics & Lifestyle**
Demographic characteristics, education and employment status and lifestyle factors such as physical activity, smoking, and alcohol use.
- **Medical History**
Relevant past medical history, comorbidities, family history, and other background information necessary for clinical and research interpretation.

1.4.2 Visits and Longitudinal Follow-up

The Visit component represents individual patient encounters and forms the backbone of longitudinal follow-up within the AD-UDM.

Each visit may include:

- **Cognitive Screening and Clinical Assessments**
Standardised cognitive and functional assessments (e.g. MMSE, MoCA)
- **Diagnosis and Disease Staging**
Diagnostic status, revisions over time, and disease staging.
- **Patient and Care Partner Clinical Outcomes**
Patient-reported and care partner-reported outcomes, including burden, dependency, and functional impact.
- **Additional Longitudinal Tracking**
Visit-level linkage to medical events, medical tests, and treatment changes occurring since the previous visit.

1.4.3 Medical Conditions and Events

This section captures clinically relevant medical conditions and events that may occur throughout the patient journey, independently of visits when required.

It includes structured subcategories for:

- Amyloid-Related Imaging Abnormalities (ARIA)
- Injection or Infusion Reactions
- Neurological and Neuropsychiatric Conditions
- Malignancies
- Infections or Infestations
- Other Significant Medical Events or Conditions

Each event supports structured documentation of timing, severity, outcomes, and, where applicable, links to treatment.

1.4.4 Medical Tests

The Medical Tests component supports structured capture of diagnostic and biomarker-related investigations. Test results are modelled independently of collection modality, allowing consistent analysis across settings.

Supported test categories include:

- MRI
- Biomarker PET Scan
- FDG PET Scan
- CT Scan
- Cerebrospinal Fluid (CSF)
- Buccal Swab
- Blood Tests

Test-specific metadata ensures appropriate linkage between results, test modality, and longitudinal context.

1.4.5 Treatments and Therapy Modifications

The Treatments component captures all therapeutic interventions relevant to Alzheimer's Disease management, including:

- AD-Specific Treatments
- Cognitive Treatments
- Other Treatments of Interest
- Non-Pharmacological Treatments

The **AD-UDM** supports comprehensive treatment tracking by recording start and end dates, dosing regimens and discontinuation reasons.

1.4.6 Reference Lists

The **Alzheimer's Disease Unified Data Model (AD-UDM)** leverages a set of centralised Reference Lists for selected domains where standardisation and cross-centre consistency are critical (e.g. ethnic origin, treatments, clinical outcome tests, ...). These Reference Lists are used to manage controlled vocabularies that are shared across forms and modules, while other value sets remain explicitly defined within the schema where appropriate.

For treatment-related reference lists, the **AD-UDM** adopts the **WHO Anatomical Therapeutic Chemical (ATC) Classification System, 2025 edition**, as the standard reference to ensure international consistency and interoperability.

2 How to Read This Document

This document describes the **AD-UDM** using a modular object-based structure, which mirrors the underlying JSON schema used for implementation. Each section represents an object or nested object, and fields are described using a consistent tabular format.

2.1 Document Structure

- Each table represents a data object and its fields.
- When a field references another object, it includes a link to that object's description.

Clicking on the object name will take you to its detailed definition.

To return to your previous position, press **ALT + Left Arrow** (Windows) or **Command + Left Arrow** (Mac) in most PDF readers.

2.2 Data Types and Field Structure

The data types listed in the Type column follow simplified JSON syntax, including:

- string
- integer
- number
- boolean
- object
- uuid
- array[object] : indicates a one-to-many relationship to a structured object
- array[uuid] : indicates a one-to-many relationship to external references via unique identifiers

2.3 Required Fields and Field Attributes

Within this document, required fields and field attributes are indicated at the object definition table level.

Each object definition table includes the following columns:

- **PII**
Indicates whether a field contains Personally Identifiable Information.
- **R (Required)**
Marks fields that are mandatory within the medical record.
- **MD (Minimum Dataset)**
Identifies fields that are recommended as they belong to the minimum dataset as defined by the schema.

- **Comments**

Provides general information and detailed field attributes, including data format, constraints (e.g. minimum or maximum values), enumerations (allowed values), and additional implementation notes.

All object definitions presented in this document are **automatically generated from the AD-UDM JSON Schema**, which serves as the **single source of truth** for field structure, constraints, and requirements

3 Medical Record Structure

The Medical Record represents **the top-level structured container** for all patient-related data within the **Alzheimer’s Disease Unified Data Model (AD-UDM)**. It provides a unified and standardised framework for capturing and organising clinical, demographic, diagnostic, and therapeutic information across the patient lifecycle.

The Medical Record supports systematic documentation of a patient’s medical background, diagnoses, healthcare encounters, medical events, diagnostic tests, and treatment history. Its longitudinal design enables consistent tracking of disease progression and clinical outcomes over time, which is particularly critical for chronic and progressive conditions such as Alzheimer’s Disease

All sections of the Medical Record align with the established **Alzheimer’s Disease Unified Data Model (AD-UDM)**., ensuring data integrity, consistency, and interoperability across systems and analytical platforms.

Section	Description	Type
schemaVersion	Version of the schema used to create this record	string
id	Patient’s globally unique identifier (UUID format)	string
localId	Patient’s local ID {DISEASE_CODE}-{CENTRE_ID}-{PATIENT_NUMBER}	string
diseaseCode	Disease code (‘ad’ in the context of Alzheimer’s Disease)	string
createdAt	Medical record creation timestamp (date-time format)	string
updatedAt	Medical record last modification timestamp (date-time format)	string
isActive	Indicates whether the medical record is active	boolean
isDeleted	Indicates whether the medical record has been logically deleted	boolean
patientProfile	Patient Profile section	array[object]
Visits	Visits section	array[object]
medicalEvents	Medical Events section	array[object]
medicalTests	Medical Tests section	array[object]
treatments	Treatments section	array[object]

Patient Identification

3.1 Patient Profile section

3.1.1 patientProfile

Field Name	Field Label	Type	PII	R	MD	Comments
identification	Identification	object		X		See object description
demographicsLifestyle	Demographics & Lifestyle	object				See object description
medicalHistory	Medical history	object				See object description
piiNotes	Notes	string	X			Any notes related to the patient

3.1.2 patientProfile.identification

Field Name	Field Label	Type	PII	R	MD	Comments
piiLastName	Last name	string	X	X		Patient's last name MaxLength=100
piiFirstName	First name	string	X	X		Patient's first name MaxLength=100
piiDob	Birth date	string	X	X		Patient's birth date Format: date
shortDob	Short birth date	string		X		Patient's short birth date (YYYY-MM) MinLength=7 MaxLength=7
piiNameAtBirth	Name at birth	string	X			Patient's name at birth MaxLength=100
sex	Sex at birth	string		X		Patient's sex at birth Allowed values: <ul style="list-style-type: none"> • Female: Female • Male: Male • Other: Other • NotSpecified: Not Specified
deathStatus	Death status	object		X		See object description

Field Name	Field Label	Type	PII	R	MD	Comments
piiDoctorInCharge	Doctor in charge	string	X			Doctor in charge Unique identifier (userId) of the clinician responsible for the patient. This value is selected from the list of active users in the application and references the internal user database Format: email
piiNhsNumber	NHS number	string	X			Patient NHS number (only applicable if the centre is in the UK) MinLength=10 MaxLength=10
piiHospitalCode	Hospital code	string	X			MaxLength=100
piiKeywords	Keywords	string	X			MaxLength=100
piiStudyCode	Study code	string	X			MaxLength=100
consent	Consent information	object		X		See object description
piiContactDetails	Contact details	object	X			See object description
carePartners	Care partners (informants)	array[object]				See object description

Validation Rules:

Patient uniqueness: a patient is uniquely identified by the combination of the following fields:

- piiLastName
- piiFirstName
- piiDob
- sex

3.1.3 patientProfile.identification.deathStatus

Field Name	Field Label	Type	PII	R	MD	Comments
isDeceased	Deceased?	boolean		X		Is the patient deceased?
date	Deceased date	string				Deceased Date Format: date
medicalEventId	Medical event ID	string				ID of the triggering medical event Format: uuid

Validation Rules:

- The death date cannot be earlier than the patient's date of birth
- The death date cannot be in the future
- If the patient is not deceased (isDeceased = false), the death date must not be populated
- If any medical event has an outcome of Death, the patient must be marked as deceased

3.1.4 patientProfile.identification.consent

Field Name	Field Label	Type	PII	R	MD	Comments
given	InRAD Consent and Registry Enrollment	string		X		Allowed values: • Yes • No
givenDate	Given date	string				Patient's consent given date Format: date
withdrawalDate	Withdrawal date	string				Patient's withdrawal date Format: date
piiWithdrawalReason	Withdrawal reason	string	X			Patient's withdrawal reason
consentForStudies	Interested in clinical trial participation?	string				Allowed values: • Unknown • Yes • No

Validation Rules:

- The consent given date cannot be earlier than the patient's date of birth
- The consent given date cannot be after the patient's date of death, if a death date is recorded
- The consent given date cannot be in the future
- The withdrawal date cannot be earlier than the consent given date
- If consent is given (given = Yes), withdrawal information must not be populated

3.1.5 patientProfile.identification.piiContactDetails

Field Name	Field Label	Type	PII	R	MD	Comments
piiStreet1	Street 1	string	X			Patient's address street Line 1 MaxLength=100
piiStreet2	Street 2	string	X			Patient's address street Line 2 MaxLength=100
piiCity	City	string	X			Patient's address city MaxLength=100
piiZipCode	Zip code	string	X			Patient's address zip code MaxLength=20
piiState	State	string	X			Patient's address state MaxLength=100
country	Country	string			X	Patient's address country - Must be an ISO 3166-1 Alpha-2 country code MinLength=2 MaxLength=2
piiHomePhone	Home phone	string	X			Patient's home phone MaxLength=50
piiWorkPhone	Work phone	string	X			Patient's work phone MaxLength=50
piiMobilePhone	Mobile phone	string	X			Patient's mobile phone MaxLength=50
piiEmail	Email	string	X			Patient's email address Format: email MaxLength=254
piiHealthInsurance	Health insurance	string	X			Patient's health insurance name MaxLength=100
piiHealthInsuranceReference	Health insurance reference	string	X			Patient's health insurance reference MaxLength=100

3.1.6 patientProfile.identification.carePartners

Field Name	Field Label	Type	PII	R	MD	Comments
piiLastName	Last name	string	X	X		Care partner's last name MaxLength=100
piiFirstName	First name	string	X	X		Care partner's first name MaxLength=100
piiDob	Birth date	string	X			Care partner's birth date Format: date
piiPhone	Phone number	string	X			Care partner's phone number MaxLength=50
piiEmail	Email	string	X			Care partner's email address Format: email MaxLength=254
relationship	Relationship	string				Care partner's relationship Allowed values: <ul style="list-style-type: none"> • Unknown • Spouse • Parent • Sibling • Child • Other
relationshipOther	Other relationship	string				Care partner's other relationship
livingWithPatient	Living with patient?	string		X		Care partner living with patient? Allowed values: <ul style="list-style-type: none"> • Unknown • Yes • No
consent	Consent details	object		X		See object description

3.1.7 patientProfile.identification.carePartners.consent

Field Name	Field Label	Type	PII	R	MD	Comments
given	Consent given?	string		X		Care partner's consent given? Allowed values: • Unknown • Yes • No
givenDate	Given date	string				Care partner's consent given date Format: date
withdrawalRequested	Withdrawal requested?	boolean				Care partner's withdrawal requested?
withdrawalDate	Withdrawal date	string				Care partner's withdrawal date Format: date
piiWithdrawalReason	Withdrawal reason	string	X			Care partner's withdrawal reason

Validation Rules:

- The care partner consent given date cannot be in the future
- The care partner withdrawal date cannot be earlier than the care partner consent given date

3.1.8 patientProfile.demographicsLifestyle

Field Name	Field Label	Type	PII	R	MD	Comments
demographics	Demographics	object				See object description
lifestyle	Lifestyle	object				See object description

3.1.9 patientProfile.demographicsLifestyle.demographics

Field Name	Field Label	Type	PII	R	MD	Comments
isced2011EducationLevel	Education level	integer			X	Allowed values: <ul style="list-style-type: none"> • 0: Early childhood education • 1: Primary education • 2: Lower secondary education • 3: Upper secondary education • 4: Post-secondary non-tertiary education • 5: Short-cycle tertiary education • 6: Bachelor's or equivalent level • 7: Master's or equivalent level • 8: Doctoral or equivalent level • 9: Not elsewhere classified
educationLevelOther	Other education level	string				Patient's Education Level Other (If isced2011EducationLevel is 9 (Not elsewhere classified))
maritalStatus	Marital status	string				Patient's marital status Allowed values: <ul style="list-style-type: none"> • Married • Cohabiting • Separated • Divorced • Widowed • Single
linguisticAbility	Linguistic ability	string				Patient's linguistic ability Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • MonoLingual: Mono Lingual • Bilingual: Bilingual • MultiLingual: Multi-Lingual (3 or more)

Field Name	Field Label	Type	PII	R	MD	Comments
dominantHand	Dominant hand	string				Patient's dominant hand Allowed values: <ul style="list-style-type: none"> • Unknown • Right • Left • Ambidextrous
birthCity	Birth city	string				Patient's birth city MaxLength=100
birthCountry	Birth country	string				Patient's birth country (Must be an ISO 3166-1 Alpha-2 country code) MinLength=2 MaxLength=2
residenceAreaType	Residence area type	string				Patient's residence area type Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • City: City (> 50,000 inhabitants) • Town: Town (5,000 - 50,000 inhabitants) • Rural: Rural (< 5,000 inhabitants)
ethnicity	Ethnicity	string			X	Patient's ethnicity (Reference List: 'ethnicorigin')
ethnicityDetails	Ethnicity details	string				Patient's ethnicity other

patientProfile.demographicsLifestyle.lifestyle

Field Name	Field Label	Type	PII	R	MD	Comments
exerciseScale	Exercise scale	integer				Patient's exercise activity level Allowed values: <ul style="list-style-type: none"> • 1: 1 - Only for necessary chores • 2: 2 - Walking or other outdoor activities one or two times per week • 3: 3 - Walking or other outdoor activities several times per week • 4: 4 - Exercising one or two times per week to the point of perspiring and heavy breathing • 5: 5 - Exercising several times per week to the point of perspiring and heavy breathing • 6: 6 - Keep-fit heavy exercise or competitive sport several times per week
sleepHoursPerNight	Sleep hours per night	number				Average hours of sleep per night Minimum = 0 Maximum = 24 Multiple Of = 0.5
tobaccoUse	Tobacco use	object				See object description
alcoholUse	Alcohol Use	object				See object description
cannabisUse	Cannabis Use	object				See object description
otherRecreationalDrugUse	Other Recreational Drug Use	object				See object description

3.1.10 patientProfile.demographicsLifestyle.lifestyle.tobaccoUse

Field Name	Field Label	Type	PII	R	MD	Comments
status	Use status	string				Patient's tobacco use status Allowed values: <ul style="list-style-type: none"> • Never • Past • Current
cigarettesPerDay	Cigarettes / Day	integer				Number of cigarettes smoked per day
ageStarted	Age started	integer				Age when tobacco use started

Field Name	Field Label	Type	PII	R	MD	Comments
ageStopped	Age stopped	integer				Age when tobacco use stopped

Validation rules:

- If the tobacco use status is Never, the following fields must not be populated:
 - Cigarettes per day
 - Age started
- If the tobacco use status is not Past, the age stopped must be empty
- When both a start age and a stop age are provided, the stop age cannot be earlier than the start age
- The age started and age stopped cannot be greater than the patient's current age

3.1.11 patientProfile.demographicsLifestyle.lifestyle.alcoholUse

Field Name	Field Label	Type	PII	R	MD	Comments
status	Use status	string				Patient's alcohol use status Allowed values: • Never • Past • Current
consumption	Alcohol units	string				Patient's alcohol consumption level Allowed values: • Nil: Nil • LessThanSevenPerWeek: Less than 7 standard drinks per week • OnePerDayOrSevenPerWeek: 1 per day or 7 standard drinks per week • TwoPerDayOrFourteenPerWeek: 2 per day or 14 standard drinks per week • MoreThanFourteenPerWeek: More than 14 standard drinks per week
ageStarted	Age started	integer				Age when alcohol use started

Field Name	Field Label	Type	PII	R	MD	Comments
ageStopped	Age stopped	integer				Age when alcohol use stopped

Validation Rules:

- If the alcohol use status is Never, the following fields must not be populated:
 - Alcohol consumption
 - Age started
- If the alcohol use status is not Past, the age stopped must be empty
- When both a start age and a stop age are provided, the stop age cannot be earlier than the start age
- The age started and age stopped cannot be greater than the patient's current age

3.1.12 patientProfile.demographicsLifestyle.lifestyle.cannabisUse

Field Name	Field Label	Type	PII	R	MD	Comments
status	Use status	string				Patient's cannabis use status Allowed values: • Never • Past • Current
ageStarted	Age started	integer				Age when cannabis use started
ageStopped	Age stopped	integer				Age when cannabis use stopped

Validation Rules:

- If the cannabis use status is Never, the age started must not be populated
- If the cannabis use status is not Past, the age stopped must be empty
- When both a start age and a stop age are provided, the stop age cannot be earlier than the start age
- The age started and age stopped cannot be greater than the patient's current age

3.1.13 patientProfile.demographicsLifestyle.lifestyle.otherRecreationalDrugUse

Field Name	Field Label	Type	PII	R	MD	Comments
status	Use status	string				Patient's other recreational drug use status Allowed values: • Never • Past • Current
ageStarted	Age started	integer				Age when other recreational drug use started
ageStopped	Age stopped	integer				Age when other recreational drug use stopped

Validation Rules:

- If the other recreational drug use status is Never, the age started must not be populated
- If the other recreational drug use status is not Past, the age stopped must be empty
- When both a start age and a stop age are provided, the stop age cannot be earlier than the start age
- The age started and age stopped cannot be greater than the patient's current age

3.1.14 patientProfile.medicalHistory

Field Name	Field Label	Type	PII	R	MD	Comments
entryDate	Entry date	string			X	Entry date (in the clinic) Format: date
referredFrom	Referral institution	string				
referredBy	Referral speciality	string				
piiDoctorName	Doctor name	string	X			
patientConditions	Patient Medical Conditions & Events History	object				See object description

Field Name	Field Label	Type	PII	R	MD	Comments
1stDegDementiaHistory	Has anyone in the patient's first-degree family been diagnosed with dementia?	string			X	First Degree Family Dementia History? Allowed values: • Unknown • Yes • No
1stDegFamilyDementiaHistory	First degree family dementia history	array[object]				See object description
piiNotes	Notes	string	X			Any notes related to the record

Validation Rules:

- If at least one first-degree family dementia history record exists, the first-degree dementia history status must be set to Yes (1stDegDementiaHistory)

3.1.15 patientProfile.medicalHistory.patientConditions

Field Name	Field Label	Type	PII	R	MD	Comments
hasHistory	Does the patient have a history of medical conditions or events?	string			X	Allowed values: • Unknown • Yes • No
neurologicalStatus	Neurological/neurodegenerative condition(s), including traumatic brain injury	string				History of neurological/neurodegenerative condition(s), including traumatic brain injury? Allowed values: • Yes • No
cerebrovascularStatus	Cerebrovascular disorders	string				History of cerebrovascular disorders? Allowed values: • Yes • No
cardiovascularStatus	Other cardiovascular disorders	string				History of other cardiovascular disorders? Allowed values: • Yes • No

Field Name	Field Label	Type	PII	R	MD	Comments
psychiatricStatus	Psychiatric disorders	string				History of psychiatric disorders? Allowed values: • Yes • No
bloodStatus	Blood/lymphatic disease (i.e clotting disorders)	string				History of blood/lymphatic disease (i.e clotting disorders)? Allowed values: • Yes • No
malignancyStatus	Malignancy	string				History of malignancy? Allowed values: • Yes • No
metabolicStatus	Metabolic Conditions (e.g. diabetes)	string				History of Metabolic Conditions (e.g. Diabetes) Allowed values: • Yes • No
immuneStatus	Immune/autoimmune conditions	string				History of immune/autoimmune conditions? Allowed values: • Yes • No
infectionStatus	Severe infections or infestations	string				History of severe infections or infestations? Allowed values: • Yes • No
otherConditionsStatus	Other conditions	string				History of other conditions? Allowed values: • Yes • No

Validation Rules:

- If the medical history status is not Yes (hasHistory), all condition-specific fields must be empty

- If the medical history status is Yes (hasHistory), all condition-specific fields must be completed
- If the medical history status is Yes (hasHistory), at least one condition must be marked as Yes

3.1.16 patientProfile.medicalHistory.1stDegFamilyDementiaHistory

Field Name	Field Label	Type	PII	R	MD	Comments
relationship	Relationship	string		X		Patient's first degree family relationship Allowed values: <ul style="list-style-type: none"> • Unknown • Father • Mother • Brother • Sister • Son • Daughter
piiLastName	Last name	string	X			Family member's last name MaxLength=100
piiFirstName	First name	string	X			Family member's first name MaxLength=100
piiDob	Date of birth	string	X			Family member's date of birth Format: date
dementiaDiseases	Dementia Diseases	array[object]		X		See object description

3.1.17 patientProfile.medicalHistory.1stDegFamilyDementiaHistory.dementiaDiseases

Field Name	Field Label	Type	PII	R	MD	Comments
dementiaDisease	Dementia disease	string				Dementia disease code (MedDRA) OR Allowed values: <ul style="list-style-type: none"> • AdMimics: AD mimics (e.g. LATE, PART, AGD) • AlcoholRelatedDementia: Alcohol related Dementia • AlzheimersDisease: Alzheimer's Disease • CorticobasalDegeneration: Corticobasal Degeneration (CBD) • Downsyndrome: Down's Syndrome • FrontotemporalDementia: Frontotemporal Dementia (FTD) • HuntingtonsDisease: Huntington's Disease • LewyBodyDementia: Lewy Body Dementia (LBD) • MajorDepression: Major Depression • NormalPressureHydrocephalus: Normal Pressure Hydrocephalus (NPH) • ParkinsonsDisease: Parkinson's Disease • PrionAssociatedDementia: Prion Associated Dementia • ProgressiveSupranuclearPalsy: Progressive Supranuclear Palsy (PSP) • VascularDementia: Vascular Dementia (VaD)
onsetAge	Age at onset	integer				Age at onset
outcome	Disease outcome	string				Dementia disease outcome Allowed values: <ul style="list-style-type: none"> • Unknown • Ongoing • Death
ageAtDeath	Age at death	integer				Age at death

Validation Rules:

- The age at death must only be provided when the outcome is Death
- When both an onset age and an age at death are provided, the age at death must not be earlier than the age at onset

3.2 Visits section

3.2.1 Visits

Field Name	Field Label	Type	PII	R	MD	Comments
id	Visit ID	string		X		Format: uuid
visitDate	Visit Date	string		X		Format: date
piiExaminedBy	Examined by	string	X			Format: email
basic	Basic	object				See object description
diagnosis	Diagnosis	object				See object description
medicalEvents	Medical Conditions & Events	object				See object description
treatments	Treatments	object				See object description
medicalTests	MRI & Medical Tests	object				See object description
clinicalOutcomes	Clinical Outcome	object				See object description
carePartnerOutcome	Patient/CP Outcome	object				See object description
piiNotes	Notes	string	X			

Validation Rules:

- The visit date cannot be earlier than the patient's date of birth
- The visit date cannot be in the future

3.2.2 visits.basic

Field Name	Field Label	Type	PII	R	MD	Comments
visitStatus	Visit Status	object				See object description
cognitiveScreeningTest	Cognitive Screening Test	object				See object description
clinicalStage	Clinical Stage	object				See object description
milestoneEvents	Milestone Events	object				See object description
clinicalTrials	Clinical Trial Participation	object				See object description
vitalSigns	Vital Signs	object				See object description
impactMetrics	Since Last Visit	object				See object description

3.2.3 visits.basic.visitStatus

Field Name	Field Label	Type	PII	R	MD	Comments
isFirstVisit	First visit	boolean				
isAdministrative	Administrative	boolean				
isRoutineScheduled	Routine scheduled/Follow-up	boolean				
isUnscheduledOrAcuteEvent	Unscheduled / Acute event	boolean				
isPhone	Phone	boolean				
isRemote	Remote	boolean				
retrospective	Retrospective	boolean				
other	Other visit status	string				

3.2.4 visits.basic.cognitiveScreeningTest

Field Name	Field Label	Type	PII	R	MD	Comments
hasCognitiveScreeningTest	Has the patient undergone any MMSE and/or MoCA tests?	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Yes • No
tests	Tests	array[object]				See object description

Validation Rules:

- If one or more cognitive screening tests are recorded, the cognitive screening test indicator must be set to Yes (hasCognitiveScreeningTest)

3.2.5 visits.basic.cognitiveScreeningTest.tests

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test type	string		X		
testDate	Test date	string		X		Format: date
version	Version	string				
versionOther	Version other	string				
score	Score	number				
maxScore	Max score	number				

Validation Rules:

- If the test version is not “Other”, the “other version” field must be empty

3.2.6 visits.basic.clinicalStage

Field Name	Field Label	Type	PII	R	MD	Comments
hasClinicalStageChanges	Has the patient's clinical stage been assessed?	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Assessed: Assessed • NotAssessed: Not Assessed
stage	Clinical stage at this visit	string				Allowed values: <ul style="list-style-type: none"> • NotYetAssigned: Not yet assigned • Stage0-AsymptomaticDeterministicGene: Stage 0 - Asymptomatic, deterministic gene • Stage1-AsymptomaticBiomarkerEvidence: Stage 1 - Asymptomatic, biomarker evidence only • Stage2-TransitionalDecline: Stage 2 - Transitional decline (subjective cognitive decline) • Stage3-MildCognitiveImpairment: Stage 3 - Cognitive impairment with early functional impact (MCI) • Stage4-MildDementia: Stage 4 - Dementia with mild functional impairment • Stage5-ModerateDementia: Stage 5 - Dementia with moderate functional impairment • Stage6-SevereDementia: Stage 6 - Dementia with severe functional impairment

Validation Rules:

- If the clinical stage is not assessed, the stage field must be empty
- If the clinical stage is assessed, the stage field must be completed

3.2.7 visits.basic.milestoneEvents

Field Name	Field Label	Type	PII	R	MD	Comments
hasMilestoneChanges	Has the patient's living, driving, and employment status been assessed?	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Assessed: Assessed • NotAssessed: Not Assessed
livingStatus	Living status	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • OwnHome: Own Home (owned or rented) • IntermediateAccommodation: Intermediate Accommodation (not dementia specific) • DementiaSpecificResidentialAccommodation: Dementia Specific Residential Accommodation • LongTermInstitutionalCare: Long Term Institutional Care (Nursing Home/Hospice) • Other: Other
livingStatusOther	Other living status	string				
livingArrangement	Living arrangement	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • LivesAlone: Lives alone • LivesWithPartner: Lives with spouse or partner • LivesWithFamily: Lives with family • Other: Other
drivingStatus	Driving status	string				Allowed values: <ul style="list-style-type: none"> • ActivelyDriving: Actively Driving • NoLongerDriving: No Longer Driving • NeverDrove: Never Drove
noLongerDrivingReason	Reason for no longer driving	string				Allowed values: <ul style="list-style-type: none"> • DueToAlzheimer: Due to Alzheimer's • Other: Other
noLongerDrivingReasonOther	Other reason for no longer driving	string				

Field Name	Field Label	Type	PII	R	MD	Comments
employmentStatus	Employment status	string				Allowed values: <ul style="list-style-type: none"> • EmployedPartTime: Employed (Part-time) • EmployedFullTime: Employed (Full-time) • Retired: Retired • Student: Student • Unemployed: Unemployed • Homemaker: Home-maker • Other: Other
employmentChangeReason	Reason for employment status change	string				Allowed values: <ul style="list-style-type: none"> • DueToAlzheimer: Due to Alzheimer's • Other: Other
employmentChangeReasonOther	Other reason for employment status change	string				
needsProfessionalHelp	Needs professional help	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Yes • No

Validation Rules:

- If milestone changes are not assessed, all milestone-related fields must be empty
- If milestone changes are assessed, the following fields must be completed:
 - Living status
 - Driving status
 - Employment status
- “Other” detail fields must only be populated when the corresponding value is Other:
 - Living status other
 - No longer driving reason other
 - Employment change reason other
- Living arrangement and professional help information must only be provided when the living status is Own home or Intermediate accommodation
- If the driving status is not “No longer driving”, the reason for no longer driving must be empty
- If employment status is not provided, the employment change reason must be empty

3.2.8 visits.basic.clinicalTrials

Field Name	Field Label	Type	PII	R	MD	Comments
currentOrPastParticipation	Current or past participation in clinical trials?	string			X	Allowed values: <ul style="list-style-type: none"> Past: Past participation in clinical trials Current: Current participation in clinical trials No: No participation

3.2.9 visits.basic.vitalSigns

Field Name	Field Label	Type	PII	R	MD	Comments
heightCentimeters	Height (cm)	number			X	Minimum = 0 Multiple Of = 0.1
heightFeet	Height (ft)	integer			X	
heightInches	Height (in)	integer				
heightUnit		string				Allowed values: <ul style="list-style-type: none"> Centimeters: cm FeetAndInches: feet/inches
weightKilograms	Weight (kg)	number			X	Minimum = 0 Multiple Of = 0.1
weightPounds	Weight (lb)	integer			X	
weightOunces	Weight (oz)	integer				
weightUnit		string				Allowed values: <ul style="list-style-type: none"> Kilograms: kg PoundsAndOunces: lb/oz
bloodPressureSystolic	Blood Pressure Systolic	integer				
bloodPressureDiastolic	Blood Pressure Diastolic	integer				
heartRate	Pulse	integer				

Validation Rules:

- If height is recorded in feet and inches, the height in centimeters must be empty
- If height is recorded in centimeters, the height in feet and inches must be empty
- If weight is recorded in pounds and ounces, the weight in kilograms must be empty
- If weight is recorded in kilograms, the weight in pounds and ounces must be empty

3.2.10 visits.basic.impactMetrics

Field Name	Field Label	Type	PII	R	MD	Comments
nbDaysMissedWork		number				Minimum = 0 Multiple Of = 0.1
nbDaysRehabilitation		number				Minimum = 0 Multiple Of = 0.1
nbDaysHospital		number				Minimum = 0 Multiple Of = 0.1
nbAmbulatoryVisits		integer				

3.2.11 visits.diagnosis

Field Name	Field Label	Type	PII	R	MD	Comments
status	Status	string		X		Allowed values: <ul style="list-style-type: none"> • NotYetAssigned: Not Yet Assigned • WorkingDiagnosis: Working Diagnosis • ConfirmedDiagnosis: Confirmed Diagnosis
diagnosisDate	Diagnosis date	string				Format: date
serviceOfDiagnosis	Service of diagnosis	string				Allowed values: <ul style="list-style-type: none"> • PrimaryCare: Primary Care • Neurology: Neurology • Psychiatry: Psychiatry • CareOfTheElderly/GeriatricMedicine: Care of the Elderly / Geriatric Medicine • Other: Other
otherServiceOfDiagnosis	Other service of diagnosis	string				
alzheimersDisease	Alzheimer's disease	boolean				
certainty	Certainty	string			X	Allowed values: <ul style="list-style-type: none"> • PossibleAD: Possible AD • ProbableAD: Probable AD • DefiniteAD: Definite AD

Field Name	Field Label	Type	PII	R	MD	Comments
diseaseStage	Stage at diagnosis	string				<p>Allowed values:</p> <ul style="list-style-type: none"> • Stage0-AsymptomaticDeterministicGene: Stage 0 - Asymptomatic, deterministic gene • Stage1-AsymptomaticBiomarkerEvidence: Stage 1 - Asymptomatic, biomarker evidence only • Stage2-TransitionalDecline: Stage 2 - Transitional decline (subjective cognitive decline) • Stage3-MildCognitiveImpairment: Stage 3 - Cognitive impairment with early functional impact (MCI) • Stage4-MildDementia: Stage 4 - Dementia with mild functional impairment • Stage5-ModerateDementia: Stage 5 - Dementia with moderate functional impairment • Stage6-SevereDementia: Stage 6 - Dementia with severe functional impairment
hasOtherDementiasDegenerativeDiseases	Other dementias/degenerative diseases	boolean				
otherDementiasDegenerativeDiseases	Other dementias/degenerative diseases	array				

Field Name	Field Label	Type	PII	R	MD	Comments
otherDementiasDegenerativeDiseases	Dementia disease	string				Dementia disease code (MedDRA) OR Allowed values: <ul style="list-style-type: none"> • AdMimics: AD mimics (e.g. LATE, PART, AGD) • AlcoholRelatedDementia: Alcohol related Dementia • CorticobasalDegeneration: Corticobasal Degeneration (CBD) • Downsyndrome: Down's Syndrome • FrontotemporalDementia: Frontotemporal Dementia (FTD) • HuntingtonsDisease: Huntington's Disease • LewyBodyDementia: Lewy Body Dementia (LBD) • MajorDepression: Major Depression • NormalPressureHydrocephalus: Normal Pressure Hydrocephalus (NPH) • ParkinsonsDisease: Parkinson's Disease • PrionAssociatedDementia: Prion Associated Dementia • ProgressiveSupranuclearPalsy: Progressive Supranuclear Palsy (PSP) • VascularDementia: Vascular Dementia (VaD)
clinicalPresentation	Clinical Presentation	object				See object description
imageEvidenceSummary	Image Evidence Summary	object				See object description
biomarkers	Biomarkers	object				See object description
genetics	Genetics	object				See object description

Validation Rules:

- The diagnosis date cannot be earlier than the patient's date of birth
- The diagnosis date cannot be in the future
- The diagnosis date cannot be after the patient's date of death, if a death date is recorded
- The diagnosis date cannot be after the visit date
- The "other service of diagnosis" field must only be populated when the service of diagnosis is Other
- If the diagnosis status is Not yet assigned, all diagnosis-related selections and dates must be cleared
- If the diagnosis status is Working diagnosis or Confirmed diagnosis, the diagnosis date and service of diagnosis must be provided

- Alzheimer’s disease details (certainty and disease stage) must only be provided when Alzheimer’s disease is selected
- If other dementias are not selected, the list of other dementias must be empty
- If other dementias are selected, at least one dementia type must be specified

3.2.12 visits.diagnosis.clinicalPresentation

Field Name	Field Label	Type	PII	R	MD	Comments
symptomsOnset	Symptoms onset	string				Format: date
predominantSymptomSyndrome	Predominant Symptom/Syndrome (First two years)	string			X	Allowed values: <ul style="list-style-type: none"> • NoSpecificSymptomSyndrome: No specific symptom/syndrome • AmnesticSyndrome: Amnestic Syndrome (Typical Presentation of AD) • PosteriorCorticalSyndrome: Posterior Cortical Syndrome (PCS) • FrontalSyndrome: Frontal Syndrome (Behavioural/dysexecutive) • PrimaryProgressiveAphasia: Primary progressive aphasia • OtherAtypicalPresentations: Other Atypical Presentations
otherPredominantSymptomSyndrome	Other predominant symptom/syndrome	string				

Validation Rules:

- The “other predominant symptom syndrome” field must only be populated when the predominant symptom syndrome is “Other atypical presentations”
- If no predominant symptom syndrome is selected, the “other predominant symptom syndrome” field must be empty

3.2.13 visits.diagnosis.imageEvidenceSummary

Field Name	Field Label	Type	PII	R	MD	Comments
atrophyHypometabolismStatus	Atrophy/Hypometabolism	string			X	Allowed values: <ul style="list-style-type: none"> • NotDone: Not Done • Positive: Positive • Negative: Negative • Indeterminate: Indeterminate
otherImagingFindings	Other imaging findings	object			X	See object description

3.2.14 visits.diagnosis.imageEvidenceSummary.otherImagingFindings

Field Name	Field Label	Type	PII	R	MD	Comments
cerebralVascularLesions	Cerebral vascular lesions (infarcts or others)	boolean				
cerebralAmyloidAngiopathy	Cerebral amyloid angiopathy	boolean				
postTraumatic	Post-traumatic	boolean				
other	Other	boolean				
otherFindings	Other findings	string				

Validation Rules:

- If Other is not selected, the other imaging findings field must be empty

3.2.15 visits.diagnosis.biomarkers

Field Name	Field Label	Type	PII	R	MD	Comments
amyloidStatus	Amyloid status	string			X	Allowed values: <ul style="list-style-type: none"> • NotDone: Not Done • Positive: Positive • Negative: Negative • Indeterminate: Indeterminate
amyloidStatusConfirmedBy	Amyloid status confirmed by	string				Allowed values: <ul style="list-style-type: none"> • BiomarkerPETScan: Biomarker PET Scan • BloodTest: Blood Test • CSF: CSF
tauStatus	Tau status	string			X	Allowed values: <ul style="list-style-type: none"> • NotDone: Not Done • Positive: Positive • Negative: Negative • Indeterminate: Indeterminate
tauStatusConfirmedBy	Tau status confirmed by	string				Allowed values: <ul style="list-style-type: none"> • BiomarkerPETScan: Biomarker PET Scan • BloodTest: Blood Test • CSF: CSF

Validation Rules:

- The amyloid status confirmation method may only be provided when an amyloid status is recorded and is not “Not done”
- The tau status confirmation method may only be provided when a tau status is recorded and is not “Not done”

3.2.16 visits.diagnosis.genetics

Field Name	Field Label	Type	PII	R	MD	Comments
apoe	APOE	string			X	Allowed values: <ul style="list-style-type: none"> • NotDone: Not Done • Unknown: Unknown • E2E2: E2, E2 • E2E3: E2, E3 • E2E4: E2, E4 • E3E3: E3, E3 • E3E4: E3, E4 • E4E4: E4, E4 • Other: Other
otherApoe	Other APOE	string				
appStatus	APP	string			X	Allowed values: <ul style="list-style-type: none"> • NotDone: Not Done • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)
psen1Status	PSEN1	string			X	Allowed values: <ul style="list-style-type: none"> • NotDone: Not Done • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)
psen2Status	PSEN2	string			X	Allowed values: <ul style="list-style-type: none"> • NotDone: Not Done • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)
otherGenes	Other genes	array[object]				See object description

Validation Rules:

- The other APOE field must only be populated when APOE is set to “Other”

3.2.17 visits.diagnosis.genetics.otherGenes

Field Name	Field Label	Type	PII	R	MD	Comments
geneName	Gene name	string		X		
qualitativeResult	Qualitative result	string		X		Allowed values: <ul style="list-style-type: none"> • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)

3.2.18 visits.medicalEvents

Field Name	Field Label	Type	PII	R	MD	Comments
hasMedicalEvents	Since Last Visit - Has the patient experienced any medical conditions & events?	string			X	Allowed values: <ul style="list-style-type: none"> • Unknown • Yes • No
ariaDetected	ARIA?	string				Allowed values: <ul style="list-style-type: none"> • Yes • No
injectionInfusionReactionDetected	Significant Injection or Infusion Reactions?	string				Allowed values: <ul style="list-style-type: none"> • Yes • No
malignancyDetected	Malignancies?	string				Allowed values: <ul style="list-style-type: none"> • Yes • No
infectionInfestationsDetected	Significant Infections or Infestations?	string				Allowed values: <ul style="list-style-type: none"> • Yes • No

Field Name	Field Label	Type	PII	R	MD	Comments
neurologicalConditionDetected	Significant Neurological Conditions?	string				Allowed values: • Yes • No
otherMedicalEventDetected	Significant Medical Events/Conditions?	string				Allowed values: • Yes • No
medicalEventChanges	Have there been any changes in ongoing medical conditions & events?	string				Allowed values: • Unknown • Yes • No

Validation Rules:

- If medical events are not reported, all medical event detection fields must be empty
- If medical events are reported, at least one medical event type must be marked as detected

3.2.19 visits.treatments

Field Name	Field Label	Type	PII	R	MD	Comments
adSpecificTreatmentChanges	Has there been a change to AD-Specific treatments?	string				Allowed values: • Unknown • Yes • No

3.2.20 visits.medicalTests

Field Name	Field Label	Type	PII	R	MD	Comments
mriScanPerformed	Has the patient undergone an MRI scan?	string			X	Allowed values: • Unknown • Yes • No

3.2.21 visits.clinicalOutcomes

Field Name	Field Label	Type	PII	R	MD	Comments
cognitiveFunctionalOutcomes	Cognitive Functional Outcomes	array[object]				See object description
functionalOutcomes	Functional Outcomes	array[object]				See object description
otherOutcomes	Other Outcomes	array[object]				See object description

Validation Rules:

- When both a score and a maximum score are provided, the score must not exceed the maximum score

3.2.22 visits.clinicalOutcomes.cognitiveFunctionalOutcomes

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test type	string		X		
testDate	Test date	string		X		Format: date
version	Version	string				
versionOther	Version other	string				
score	Score	number				
maxScore	Max score	number				

3.2.23 visits.clinicalOutcomes.functionalOutcomes

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test type	string		X		
testDate	Test date	string		X		Format: date
version	Version	string				
versionOther	Version other	string				
score	Score	number				
maxScore	Max score	number				

3.2.24 visits.clinicalOutcomes.otherOutcomes

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test type	string		X		
testDate	Test date	string		X		Format: date
version	Version	string				
versionOther	Version other	string				
score	Score	number				
maxScore	Max score	number				

3.2.25 visits.carePartnerOutcome

Field Name	Field Label	Type	PII	R	MD	Comments
outcomes	Outcomes	array[object]				See object description
otherOutcomes	Other Outcomes	array[object]				See object description

Validation Rules:

- When both a score and a maximum score are provided, the score must not exceed the maximum score

3.2.26 visits.carePartnerOutcome.outcomes

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test type	string		X		
testDate	Test date	string		X		Format: date
version	Version	string				
versionOther	Version other	string				
score	Score	number				
maxScore	Max score	number				

3.2.27 visits.carePartnerOutcome.otherOutcomes

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test type	string		X		

Field Name	Field Label	Type	PII	R	MD	Comments
testDate	Test date	string		X		Format: date
version	Version	string				
versionOther	Version other	string				
score	Score	number				
maxScore	Max score	number				

3.3 Medical Conditions & Events section

3.3.1 medicalEvents

Field Name	Field Label	Type	PII	R	MD	Comments
id	Medical Event ID	string		X		Format: uuid
eventType	Event Type	string		X		Allowed values: <ul style="list-style-type: none"> • ARIA: ARIA • InjectionOrInfusionReactions: Injection or Infusion Reactions • NeurologicalNeuropsychiatricConditions: Neurological/Neuropsychiatric Conditions • Malignancies: Malignancies • InfectionsOrInfestations: Infections or Infestations • OtherSignificantMedicalEventsCondition: Other Significant Medical Events/Condition
startDate	Medical Event Start Date	string		X		Medical Event Start Date Format: date
seriousAdverseEvent	Serious Adverse Event (SAE)	object				See object description
outcome	Outcome	object		X		See object description
drugRelated	Drug Related	object				See object description
piiNotes	Notes	string	X			Any notes related to the medical event
classificationMedDRACodes	MedDRA classification	array[string]		X		MedDRA Classification (Must be a valid MedDRA code)
details		object		X		Structure depends on eventType. See event-specific object description: <ul style="list-style-type: none"> • ARIA • Injection or Infusion Reactions

Field Name	Field Label	Type	PII	R	MD	Comments
						<ul style="list-style-type: none"> • Neurological/Neuropsychiatric Conditions • Malignancies • Infections or Infestations • Other Significant Medical Events/Condition

Validation Rules :

- The medical event start date cannot be earlier than the patient's date of birth
- The medical event start date cannot be in the future

3.3.2 medicalEvents.seriousAdverseEvent

Field Name	Field Label	Type	PII	R	MD	Comments
isSeriousAdverseEvent	Yes	Array[string]				Allowed values: <ul style="list-style-type: none"> • ResultsInDeath: Results in death • IsLifeThreatening: Is life-threatening • PermanentSeriousDisabilityIncapacity: Permanent/serious disability incapacity • RequiresProlongsHospitalisation: Requires/prolongs hospitalisation • CongenitalAnomalyBirthDefect: Congenital anomaly/birth defect • OtherMedicallyImportantCondition: Other medically important condition

Validation Rules:

- If the medical event is not classified as a serious adverse event, the serious adverse event type list must be empty

3.3.3 medicalEvents.outcome

Field Name	Field Label	Type	PII	R	MD	Comments
status	Outcome Status	string		X		Allowed values: <ul style="list-style-type: none"> • Unknown • Ongoing • Recovery • Death
endDate	Medical Event End Date	string				Format: date

Validation Rules:

- If the outcome status is Unknown or Ongoing, the end date must be empty
- When an end date is provided (for Recovery or Death outcomes), the end date:
 - cannot be earlier than the patient’s date of birth
 - cannot be in the future
 - cannot be earlier than the medical event start date
- If the medical event is classified as a serious adverse event resulting in death, the outcome status must be Death
- If the medical event outcome is Death, the patient must be marked as deceased

3.3.4 medicalEvents.drugRelated

Field Name	Field Label	Type	PII	R	MD	Comments
relationship	Drug relationship	string		X		Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • NotRelated: Not related • Related: Related
treatmentId	Treatment	string				Format: uuid

Validation Rules:

- If the relationship is Unknown or Not related, the treatment reference must be empty
- If the relationship is Related, the referenced treatment must exist in the patient’s treatment list
- If the relationship is Related, the referenced treatment must be a pharmacological treatment (non-pharmacological treatments are not allowed)

3.3.5 medicalEvents.details (ARIA)

Field Name	Field Label	Type	PII	R	MD	Comments
severityLevel	Severity	string		X		Allowed values: <ul style="list-style-type: none"> • Mild: Mild • Moderate: Moderate • Severe: Severe • LifeThreatening: Life-threatening
mriPerformed	Was an MRI performed?	string		X		Allowed values: <ul style="list-style-type: none"> • Unknown • Yes • No
isAria	ARIA	boolean				
isAriaE	ARIA-E	boolean				
isAriaH	ARIA-H	boolean				
isMicrohaemorrhage	Microhaemorrhage	boolean				ARIA-H Microhaemorrhage
isSuperficialSiderosis	Superficial Siderosis	boolean				ARIA-H Superficial Siderosis
ichGreaterThan1cm	Intracranial haemorrhage (ICH) greater than 1 cm	boolean				
presenceOfSymptoms	Presence of symptoms	string		X		Allowed values: <ul style="list-style-type: none"> • Symptomatic • Asymptomatic
symptomHeadache	Headache	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Yes • No
symptomDizziness	Dizziness	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Yes • No
symptomNausea	Nausea	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Yes • No

Field Name	Field Label	Type	PII	R	MD	Comments
symptomSeizure	Seizure	string				Allowed values: • Unknown • Yes • No
symptomConfusion	Confusion	string				Allowed values: • Unknown • Yes • No
symptomsDetailMedDRACodes	Other symptoms	array[string]				Symptoms list (Must be valid MedDRA codes)
treated	Treatment for this event	string				Allowed values: • Unknown: Unknown • NotTreated: Not treated • Ambulatory: Ambulatory • Hospitalized: Hospitalized

Validation Rules:

- If MRI was not performed or is unknown:
 - ARIA must be reported as present
 - ARIA-E and ARIA-H must not be reported
- If MRI was performed:
 - ARIA must not be reported
 - At least one of ARIA-E or ARIA-H must be selected
- ARIA-H subtypes (microhaemorrhage, superficial siderosis) may only be recorded when ARIA-H is present
- If MRI was not performed or is unknown, ARIA-H subtypes must not be populated
- ICH greater than 1 cm may only be recorded when an MRI was performed
- If MRI was not performed or is unknown, the ICH > 1 cm field must be empty
- If the ARIA event is symptomatic, all standard symptom questions must be answered
- If the ARIA event is asymptomatic, all symptom fields and symptom detail codes must be empty
- Symptom detail (MedDRA) codes may only be provided when the event is symptomatic
- If the event is asymptomatic, symptom detail codes must not be provided

3.3.6 medicalEvents.details (Injection or Infusion Reactions)

Field Name	Field Label	Type	PII	R	MD	Comments
severityLevel	Severity	string		X		Allowed values: <ul style="list-style-type: none"> • Mild: Mild • Moderate: Moderate • Severe: Severe • LifeThreatening: Life-threatening
treated	Treatment for this event	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • NotTreated: Not treated • Ambulatory: Ambulatory • Hospitalized: Hospitalized

3.3.7 medicalEvents.details (Neurological/Neuropsychiatric Conditions)

Field Name	Field Label	Type	PII	R	MD	Comments
severityLevel	Severity	string		X		Allowed values: <ul style="list-style-type: none"> • Mild: Mild • Moderate: Moderate • Severe: Severe • LifeThreatening: Life-threatening
treated	Treatment for this event	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • NotTreated: Not treated • Ambulatory: Ambulatory • Hospitalized: Hospitalized

3.3.8 medicalEvents.details (Malignancies)

Field Name	Field Label	Type	PII	R	MD	Comments
severityLevel	Severity	string		X		Allowed values: <ul style="list-style-type: none"> • Mild: Mild • Moderate: Moderate • Severe: Severe • LifeThreatening: Life-threatening
treatmentModality	Treatment Modality	object				See object description
stage	Stage at diagnosis	string		X		Allowed values: <ul style="list-style-type: none"> • Unknown • I • II • III • IV
primarySite	Site of primary cancer	string				
histologicalDiagnosis	Histological diagnosis	string				

3.3.9 medicalEvents.details.treatmentModality (Malignancies)

Field Name	Field Label	Type	PII	R	MD	Comments
unknown	Unknown	boolean				
notTreated	Not treated	boolean				
chemotherapy	Chemotherapy	boolean				
radiotherapy	Radiotherapy	boolean				
surgery	Surgery	boolean				
other	Other	boolean				
otherDetails	Other details	string				

Validation Rules:

- Treatment modality cannot be both “Unknown” and “Not treated” at the same time
- Treatment modality details may only be provided when “Other” is selected
- If “Other” is not selected, the other treatment details field must be empty
- If treatment modality is Unknown:
 - All other treatment modality options must be unselected

- The other treatment details field must be empty
- If treatment modality is Not treated:
 - All other treatment modality options must be unselected
 - The other treatment details field must be empty

3.3.10 medicalEvents.details (Infections or Infestations)

Field Name	Field Label	Type	PII	R	MD	Comments
severityLevel	Severity	string		X		Allowed values: <ul style="list-style-type: none"> • Mild: Mild • Moderate: Moderate • Severe: Severe • LifeThreatening: Life-threatening
treated	Treatment for this event	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • NotTreated: Not treated • Ambulatory: Ambulatory • Hospitalized: Hospitalized

3.3.11 medicalEvents.details (Other Significant Medical Events/Condition)

Field Name	Field Label	Type	PII	R	MD	Comments
severityLevel	Severity	string		X		Allowed values: <ul style="list-style-type: none"> • Mild: Mild • Moderate: Moderate • Severe: Severe • LifeThreatening: Life-threatening
treated	Treatment for this event	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • NotTreated: Not treated • Ambulatory: Ambulatory • Hospitalized: Hospitalized

3.4 Medical Tests section (MRI)

3.4.1 medicalTests

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test Type	string		X		Allowed values: • MRI
id	Medical Test ID	string		X		Format: uuid
examDate	Exam Date	string		X		Format: date
examPurpose	Purpose	string		X		Allowed values: • Diagnosis: Diagnosis • TreatmentBaseline: Treatment Baseline • ARIAAssessment: ARIA Assessment • ClinicalFollowUp: Clinical Follow-up • Other: Other
examPurposeOther	Other purpose	string				
machine	MRI Machine	string				
fieldStrength	Field Strength	string				Allowed values: • Unknown: Unknown • T1_5: 1.5T • T3: 3T • Other: Other
fieldStrengthOther	Field Strength Other	string				
contrastUsed	Contrast Used	string				Allowed values: • Unknown • Yes • No
contrastType	Contrast Type	string				
t1Sequence	T1	boolean				
t1Dimension	T1 Dimension	string				Allowed values: • Unknown • 2D • 3D
t2Sequence	T2	boolean				
t2Dimension	T2 Dimension	string				Allowed values: • Unknown • 2D • 3D

Field Name	Field Label	Type	PII	R	MD	Comments
flairSequence	FLAIR	boolean				
flairDimension	FLAIR Dimension	string				Allowed values: • Unknown • 2D • 3D
t2sSequence	T2*	boolean				
t2sDimension	T2* Dimension	string				Allowed values: • Unknown • 2D • 3D
swiSequence	SWI	boolean				
swiDimension	SWI Dimension	string				Allowed values: • Unknown • 2D • 3D
dwiSequence	DWI	boolean				
dwiDimension	DWI Dimension	string				Allowed values: • Unknown • 2D • 3D
otherSequence	Other	boolean				
otherSequenceName	Other Sequence Name	string				
otherSequenceDimension	Other Sequence Dimension	string				Allowed values: • Unknown • 2D • 3D
structuralAssessments	Structural Assessments	object				See object description
cerebralVascularAssessments	Cerebral Vascular Assessments	object				See object description
ariaDetection	ARIA/ICH Detection	object				See object description
piiNotes	Notes	string	X			Any notes related to the medical test

Validation Rules:

- A medical test exam date cannot be earlier than the patient's date of birth.
- A medical test exam date cannot be in the future

- The “other exam purpose” field must only be populated when the selected exam purpose is “Other”
- The field strength “other” field must only be populated when field strength is “Other”
- If contrast was not used, the contrast type field must be empty
- A sequence dimension must only be provided when the corresponding sequence is selected
- If a sequence checkbox is not selected, its associated dimension field must be empty
- Other sequence fields must only be populated when an “other sequence” is selected

3.4.2 medicalTests.structuralAssessments

Field Name	Field Label	Type	PII	R	MD	Comments
hasStructuralAssessments	Structural Assessments	boolean				
globalCorticalAtrophy	Global Cortical Atrophy (GCA)	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Mild Atrophy • 2: Moderate Atrophy • 3: Severe (End-Stage) Atrophy: 'Knife Blade' Atrophy
medialTemporalLobeAtrophyLeft	Medial Temporal Lobe Atrophy (Scheltens) - Left	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Only Widening of the Choroid Fissure • 2: Also Widening of the Temporal Horn of the Lateral Ventricle • 3: Moderate Loss of Hippocampal Volume (decrease in height) • 4: Severe Volume (Loss of Hippocampus)
medialTemporalLobeAtrophyRight	Medial Temporal Lobe Atrophy (Scheltens) - Right	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Only Widening of the Choroid Fissure • 2: Also Widening of the Temporal Horn of the Lateral Ventricle • 3: Moderate Loss of Hippocampal Volume (decrease in height) • 4: Severe Volume (Loss of Hippocampus)

Field Name	Field Label	Type	PII	R	MD	Comments
parietalLobeAtrophyLeft	Parietal Lobe Atrophy (Koedam) - Left	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Mild Widening of the Sulci Without Evident Loss of the Gyri • 2: Substantial Widening of the Sulci and Volume Loss of the Gyri • 3: Severe (End-Stage Atrophy)
parietalLobeAtrophyRight	Parietal Lobe Atrophy (Koedam) - Right	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Mild Widening of the Sulci Without Evident Loss of the Gyri • 2: Substantial Widening of the Sulci and Volume Loss of the Gyri • 3: Severe (End-Stage Atrophy)
hasNeurodegenerativeDiseaseSpecificAtrophyMarkers	Neurodegenerative Disease-Specific Atrophy Markers	boolean				
signOfPossibleMSA	Sign of possible MSA	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Yes: Yes • No: No • NotAvailable: Not Available
msaMarkers	MSA Markers	object				See object description
presenceOfPSPAtrophy	Presence of PSP atrophy	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Yes: Yes • No: No • NotAvailable: Not Available

Validation Rules:

- Structural assessment scores must only be populated when structural assessments are present (hasStructuralAssessments)
- Disease-specific atrophy marker fields must only be populated when neurodegenerative disease-specific markers are present (hasNeurodegenerativeDiseaseSpecificAtrophyMarkers)
- MSA-specific marker must only be selected when possible MSA is indicated (signOfPossibleMSA)

- FTD-like atrophy laterality must only be selected when FTD-like atrophy is present (presenceOfFTDLikeAtrophy)

3.4.3 medicalTests.structuralAssessments.ftdAtrophyRegions

Field Name	Field Label	Type	PII	R	MD	Comments
frontal	Frontal	object				See object description
temporal	Temporal	object				See object description

3.4.4 medicalTests.structuralAssessments.ftdAtrophyRegions.frontal

Field Name	Field Label	Type	PII	R	MD	Comments
left	Left	boolean				
right	Right	boolean				
asymmetric	Asymmetric	boolean				

3.4.5 medicalTests.structuralAssessments.ftdAtrophyRegions.temporal

Field Name	Field Label	Type	PII	R	MD	Comments
left	Left	boolean				
right	Right	boolean				
asymmetric	Asymmetric	boolean				

3.4.6 medicalTests.cerebralVascularAssessments

Field Name	Field Label	Type	PII	R	MD	Comments
hasCerebralVascularAssessments	Cerebral Vascular Assessments	boolean				
presenceOfAnyStrategicInfarcts	Presence of Any Strategic Infarcts	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Yes: Yes • No: No • NotAvailable: Not Available

Field Name	Field Label	Type	PII	R	MD	Comments
presenceOfMacrohaemorrhage	Presence of Macrohaemorrhage	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Yes: Yes • No: No • NotAvailable: Not Available
numberOfMacrohaemorrhages	Number of Macrohaemorrhages	integer				Minimum = 0
presenceOfMicrohaemorrhage	Presence of Microhaemorrhage	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Yes: Yes • No: No • NotAvailable: Not Available
numberOfMicrohaemorrhages	Number of microhaemorrhages	object				See object description
presenceOfSuperficialSiderosis	Presence of Superficial Siderosis	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Yes: Yes • No: No • NotAvailable: Not Available
numberOfSuperficialSiderosis	Number of Superficial Siderosis	integer				Minimum = 0
enlargedPerivascularSpace	Enlarged Perivascular Space (EPVS)	object				See object description
presenceOfLacunes	Presence of Lacunes	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Yes: Yes • No: No • NotAvailable: Not Available
numberOfLacunes	Number of Lacunes	object				See object description
whiteMatterLesions	White Matter Lesions	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Lesions • 1: Focal Lesions • 2: Beginning Confluence of Lesions • 3: Diffuse Involvement of the Entire Region

Field Name	Field Label	Type	PII	R	MD	Comments
basalGangliaLesions	Basal Ganglia Lesions	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Lesions • 1: 1 Focal Lesion (?5 mm) • 2: >1 Focal lesion • 3: Confluent Lesions
t2Hyperintensities	T2 Hyperintensities	object				See object description

Validation Rules:

- Cerebral vascular assessment fields must only be populated when cerebral vascular assessments are present (hasCerebralVascularAssessments)
- Macrohaemorrhage count must only be provided when macrohaemorrhage is present (presenceOfMacrohaemorrhage)
- Superficial siderosis count must only be provided when superficial siderosis is present (presenceOfSuperficialSiderosis)
- Microhaemorrhage details must only be populated when microhaemorrhages are present (presenceOfMicrohaemorrhage)
- Lacune counts must only be populated when lacunes are present (presenceOfLacunes)

3.4.7 medicalTests.cerebralVascularAssessments.numberOfMicrohaemorrhages

Field Name	Field Label	Type	PII	R	MD	Comments
total	Total	integer				Minimum = 0
hasCorticalRegions	Cortical	boolean				
corticalRegions	Cortical Regions	integer				Minimum = 0
hasDeepRegions	Deep	boolean				
deepRegions	Deep Regions	integer				Minimum = 0
hasInfratentorialRegions	Infratentorial	boolean				
infratentorialRegions	Infratentorial Regions	integer				Minimum = 0

Validation Rules:

- Regional microhaemorrhage counts must only be provided when the corresponding region is selected

3.4.8 medicalTests.cerebralVascularAssessments.enlargedPerivascularSpace

Field Name	Field Label	Type	PII	R	MD	Comments
basalGanglia	Basal Ganglia	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • 0=no EPVS: 0=no EPVS • 1=1-10 EPVS: 1=1-10 EPVS • 2=11-20 EPVS: 2=11-20 EPVS • 3=21-40 EPVS: 3=21-40 EPVS • 4=>40 EPVS: 4=>40 EPVS
centrumSemiovale	Centrum Semiovale	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • 0=no EPVS: 0=no EPVS • 1=1-10 EPVS: 1=1-10 EPVS • 2=11-20 EPVS: 2=11-20 EPVS • 3=21-40 EPVS: 3=21-40 EPVS • 4=>40 EPVS: 4=>40 EPVS
midbrain	Midbrain	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • 0=No EPVS visible: 0=No EPVS visible • 1=EPVS visible: 1=EPVS visible

3.4.9 medicalTests.cerebralVascularAssessments.numberOfLacunes

Field Name	Field Label	Type	PII	R	MD	Comments
whiteMatter	White Matter	integer				Minimum = 0
basalGanglia	Basal Ganglia	integer				Minimum = 0
brainstem	Brainstem	integer				Minimum = 0

3.4.10 medicalTests.cerebralVascularAssessments.t2Hyperintensities

Field Name	Field Label	Type	PII	R	MD	Comments
numberOfT2HyperintenseLesions	Number of T2 Hyperintense Lesions	integer				Minimum = 0

Field Name	Field Label	Type	PII	R	MD	Comments
volumeOfT2Hyperintensities	Volume of T2 Hyperintensities	number				Minimum = 0
volumeUnit	Volume Unit	string				Allowed values: <ul style="list-style-type: none"> • mm3: mm3 • mL: mL
presenceOfT2HyperintensityWithMultispotPattern	Presence of T2 Hyperintensity with a multispot pattern	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Yes: Yes • No: No • NotAvailable: Not Available

3.4.11 medicalTests.ariaDetection

Field Name	Field Label	Type	PII	R	MD	Comments
hasAriaIchDetection	ARIA/ICH detection performed?	boolean				
ariaDetected	ARIA Detected?	string				Allowed values: <ul style="list-style-type: none"> • Detected: Detected • NotDetected: Not Detected
ariaType	ARIA Type	string				Allowed values: <ul style="list-style-type: none"> • ARIA-H: ARIA-H • ARIA-E: ARIA-E • ARIAMixed: ARIA Mixed
ichGreaterThan1cm	Intracranial haemorrhage (ICH) greater than 1 cm?	string				Allowed values: <ul style="list-style-type: none"> • Detected: Detected • NotDetected: Not Detected
ariaHDetails	ARIA-H Details	object				See object description
ariaEDetails	ARIA-E Details	object				See object description
brainRegionsAffected	Brain Regions Affected	object				See object description

Validation Rules:

- ARIA detection fields must only be populated when ARIA/ICH detection is enabled (hasAriaIchDetection)
- ARIA type must only be provided when ARIA is detected (ariaDetected)
- ARIA-H detail fields must only be populated for ARIA-H (ariaType)

- ARIA-E detail fields must only be populated for ARIA-E (ariaType)
- Brain region affected selections must only be populated when an ARIA type is specified
- If ariaType is empty or unset, all brain region flags must not be selected (must be empty/false)

3.4.12 medicalTests.ariaDetection.ariaHDetails

Field Name	Field Label	Type	PII	R	MD	Comments
nbMicroHaemorrhage	Number of new microhaemorrhages	integer				Minimum = 0
newMicroHaemorrhageSeverity	New Microhaemorrhage Severity	integer				Allowed values: <ul style="list-style-type: none"> • -1: Unknown • 0: No new • 1: Mild - Less than 5 new • 2: Moderate - 5 to 9 • 3: Severe - 10 or more new
nbSuperficialSiderosis	Number of new Superficial Siderosis	integer				Minimum = 0
newSuperficialSiderosisSeverity	New Superficial Siderosis Severity	integer				Allowed values: <ul style="list-style-type: none"> • -1: Unknown • 0: No new area • 1: Mild - 1 new area • 2: Moderate - 2 new areas • 3: Severe - More than 2 new areas

3.4.13 medicalTests.ariaDetection.ariaEDetails

Field Name	Field Label	Type	PII	R	MD	Comments
edemaSeverity	Edema Imaging Severity	integer				Allowed values: <ul style="list-style-type: none"> • -1: Unknown • 0: No ARIA-E • 1: Mild (< 5 cm, Monofocal) • 2: Mild+ (< 5 cm, Multifocal) • 3: Moderate (5-10 cm, Monofocal) • 4: Moderate+ (5-10 cm, Multifocal) • 5: Severe (> 10 cm, Monofocal or Multifocal)

3.4.14 medicalTests.ariaDetection.brainRegionsAffected

Field Name	Field Label	Type	PII	R	MD	Comments
frontalLobeLeft	Frontal Lobe Left	boolean				
frontalLobeRight	Frontal Lobe Right	boolean				
parietalLobeLeft	Parietal Lobe Left	boolean				
parietalLobeRight	Parietal Lobe Right	boolean				
occipitalLobeLeft	Occipital Lobe Left	boolean				
occipitalLobeRight	Occipital Lobe Right	boolean				
temporalLobeLeft	Temporal Lobe Left	boolean				
temporalLobeRight	Temporal Lobe Right	boolean				
cerebellumRegion	Cerebellum Region	boolean				
otherRegions	Other Regions	boolean				

3.5 Medical Tests section (Biomarker PET Scan)

3.5.1 medicalTests

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test Type	string		X		Allowed values: • BiomarkerPETScan
id	Medical Test ID	string		X		Format: uuid
examDate	Exam Date	string		X		Format: date
examPurpose	Purpose	string				Allowed values: • ClinicalFollowUp: Clinical Follow-up • Diagnosis: Diagnosis • Other: Other
examPurposeOther	Other purpose	string				
machine	Machine Type	string				
amyloidImaging	Amyloid Imaging	object				See object description
taulmaging	Tau Imaging	object				See object description
otherBiomarkerImaging	Other Biomarker Imaging	object				See object description
piiNotes	Notes	string	X			Any notes related to the medical test

Validation Rules:

- A medical test exam date cannot be earlier than the patient’s date of birth.
- A medical test exam date cannot be in the future
- The “other exam purpose” field must only be populated when the selected exam purpose is “Other”

3.5.2 medicalTests.amyloidImaging

Field Name	Field Label	Type	PII	R	MD	Comments
hasAmyloidImaging	Amyloid Imaging	boolean				
tracerUsed	Tracer Used	string				Allowed values: <ul style="list-style-type: none"> • Florbetapir • Flutemetamol • Florbetaben • Other
tracerUsedOther	Other Tracer	string				
qualitativeResult	Qualitative Result	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Positive • Negative • Uncertain
brainRegionsAffected	Brain Regions Affected	object				See object description
wholeBrainValue	Whole Brain Value	number				Minimum = 0
wholeBrainUnit	Whole Brain Unit	string				Allowed values: <ul style="list-style-type: none"> • Centiloid • SUVr

Validation Rules:

- Amyloid imaging fields must only be populated when amyloid imaging is present (hasAmyloidImaging)
- The other tracer field must only be populated when tracer is “Other” (tracerUsed)

3.5.3 medicalTests.amyloidImaging.brainRegionsAffected

Field Name	Field Label	Type	PII	R	MD	Comments
temporalLobeLeft	Left Temporal Lobe	boolean				
temporalLobeRight	Right Temporal Lobe	boolean				
parietalLobeLeft	Left Parietal Lobe	boolean				
parietalLobeRight	Right Parietal Lobe	boolean				
frontalLobeLeft	Left Frontal Lobe	boolean				
frontalLobeRight	Right Frontal Lobe	boolean				
occipitalLobeLeft	Left Occipital Lobe	boolean				
occipitalLobeRight	Right Occipital Lobe	boolean				

3.5.4 medicalTests.tauImaging

Field Name	Field Label	Type	PII	R	MD	Comments
hasTauImaging	Tau Imaging	boolean				
tracerUsed	Tracer Used	string				Allowed values: • Tauvid • Other
tracerUsedOther	Other Tracer	string				
qualitativeResult	Qualitative Result	string				Allowed values: • Unknown • Positive • Negative • Uncertain
brainRegionsAffected	Brain Regions Affected	object				See object description
wholeBrainValue	Whole Brain Value	number				Minimum = 0
wholeBrainUnit	Whole Brain Unit	string				Allowed values: • CenTauR • SUVr

Validation Rules:

- Tau imaging fields must only be populated when tau imaging is present (hasTauImaging)

- The other tracer field must only be populated when tracer is “Other” (tracerUsed)

3.5.5 medicalTests.tauImaging.brainRegionsAffected

Field Name	Field Label	Type	PII	R	MD	Comments
temporalLobeLeft	Left Temporal Lobe	boolean				
temporalLobeRight	Right Temporal Lobe	boolean				
parietalLobeLeft	Left Parietal Lobe	boolean				
parietalLobeRight	Right Parietal Lobe	boolean				
frontalLobeLeft	Left Frontal Lobe	boolean				
frontalLobeRight	Right Frontal Lobe	boolean				
occipitalLobeLeft	Left Occipital Lobe	boolean				
occipitalLobeRight	Right Occipital Lobe	boolean				

3.5.6 medicalTests.otherBiomarkerImaging

Field Name	Field Label	Type	PII	R	MD	Comments
hasOtherBiomarkerImaging	Other Biomarker Imaging	boolean				
biomarkerName	Biomarker Name	string				
tracerUsed	Tracer Used	string				
qualitativeResult	Qualitative Result	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Positive • Negative • Uncertain
brainRegionsAffected	Brain Regions Affected	object				See object description
wholeBrainSuvr	Whole Brain	number				Minimum = 0

Validation Rules:

- Other biomarker imaging fields must only be populated when other biomarker imaging is present (hasOtherBiomarkerImaging)

3.5.7 medicalTests.otherBiomarkerImaging.brainRegionsAffected

Field Name	Field Label	Type	PII	R	MD	Comments
temporalLobeLeft	Left Temporal Lobe	boolean				
temporalLobeRight	Right Temporal Lobe	boolean				
parietalLobeLeft	Left Parietal Lobe	boolean				
parietalLobeRight	Right Parietal Lobe	boolean				
frontalLobeLeft	Left Frontal Lobe	boolean				
frontalLobeRight	Right Frontal Lobe	boolean				
occipitalLobeLeft	Left Occipital Lobe	boolean				
occipitalLobeRight	Right Occipital Lobe	boolean				

3.6 Medical Tests section (FDG PET Scan)

3.6.1 medicalTests

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test Type	string		X		Allowed values: • FDGPETScan
id	Medical Test ID	string		X		Format: uuid
examDate	Exam Date	string		X		Format: date
examPurpose	Purpose	string				Allowed values: • ClinicalFollowUp: Clinical Follow-up • Diagnosis: Diagnosis • Other: Other
examPurposeOther	Other purpose	string				
machine	Machine Type	string				
hypometabolism	Hypometabolism	object		X		See object description
piiNotes	Notes	string	X			Any notes related to the medical test

Validation Rules:

- A medical test exam date cannot be earlier than the patient’s date of birth.
- A medical test exam date cannot be in the future
- The “other exam purpose” field must only be populated when the selected exam purpose is “Other”

3.6.2 medicalTests.hypometabolism

Field Name	Field Label	Type	PII	R	MD	Comments
qualitativeResult	Qualitative Result	string		X		Allowed values: <ul style="list-style-type: none"> • Unknown • Positive • Negative • Uncertain
brainRegionsAffected	Brain Regions Affected	object				See object description
wholeBrainSuvr	Whole Brain	number				Minimum = 0

3.6.3 medicalTests.hypometabolism.brainRegionsAffected

Field Name	Field Label	Type	PII	R	MD	Comments
leftTemporalLobe	Left Temporal Lobe	boolean				
rightTemporalLobe	Right Temporal Lobe	boolean				
leftParietalLobe	Left Parietal Lobe	boolean				
rightParietalLobe	Right Parietal Lobe	boolean				
leftFrontalLobe	Left Frontal Lobe	boolean				
rightFrontalLobe	Right Frontal Lobe	boolean				
leftOccipitalLobe	Left Occipital Lobe	boolean				
rightOccipitalLobe	Right Occipital Lobe	boolean				

3.7 Medical Tests section (CT Scan)

3.7.1 medicalTests

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test Type	string		X		Allowed values: <ul style="list-style-type: none"> • CTScan

Field Name	Field Label	Type	PII	R	MD	Comments
id	Medical Test ID	string		X		Format: uuid
examDate	Exam Date	string		X		Format: date
examPurpose	Purpose	string				Allowed values: <ul style="list-style-type: none"> • ClinicalFollowUp: Clinical Follow-up • Diagnosis: Diagnosis • Other: Other
examPurposeOther	Other purpose	string				
machine	Machine Type	string				CT Scan Machine
contrastUsed	Contrast Used	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Yes • No
contrastType	Contrast Type	string				
structuralAssessments	Structural Assessments	object				See object description
cerebralVascularAssessments	Cerebral Vascular Assessments	object				See object description
piiNotes	Notes	string	X			Any notes related to the medical test

Validation Rules:

- A medical test exam date cannot be earlier than the patient’s date of birth.
- A medical test exam date cannot be in the future
- The “other exam purpose” field must only be populated when the selected exam purpose is “Other”
- The contrast type field must only be populated when contrast was used (contrastUsed)

3.7.2 medicalTests.structuralAssessments

Field Name	Field Label	Type	PII	R	MD	Comments
hasStructuralAssessments	Structural Assessments	boolean				
globalCorticalAtrophy	Global Cortical Atrophy (GCA)	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Mild Atrophy • 2: Moderate Atrophy • 3: Severe (End-Stage) Atrophy: 'Knife Blade' Atrophy

Field Name	Field Label	Type	PII	R	MD	Comments
medialTemporalLobeAtrophyLeft	Medial Temporal Lobe Atrophy (Scheltens) - Left	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Only Widening of the Choroid Fissure • 2: Also Widening of the Temporal Horn of the Lateral Ventricle • 3: Moderate Loss of Hippocampal Volume (decrease in height) • 4: Severe Volume (Loss of Hippocampus)
medialTemporalLobeAtrophyRight	Medial Temporal Lobe Atrophy (Scheltens) - Right	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Only Widening of the Choroid Fissure • 2: Also Widening of the Temporal Horn of the Lateral Ventricle • 3: Moderate Loss of Hippocampal Volume (decrease in height) • 4: Severe Volume (Loss of Hippocampus)
parietalLobeAtrophyLeft	Parietal Lobe Atrophy (Koedam) - Left	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Mild Widening of the Sulci Without Evident Loss of the Gyri • 2: Substantial Widening of the Sulci and Volume Loss of the Gyri • 3: Severe (End-Stage Atrophy)
parietalLobeAtrophyRight	Parietal Lobe Atrophy (Koedam) - Right	integer				Allowed values: <ul style="list-style-type: none"> • 0: No Atrophy • 1: Mild Widening of the Sulci Without Evident Loss of the Gyri • 2: Substantial Widening of the Sulci and Volume Loss of the Gyri • 3: Severe (End-Stage Atrophy)

Validation Rules:

- Structural assessment scores must only be populated when structural assessments are present (hasStructuralAssessments)

3.7.3 medicalTests.cerebralVascularAssessments

Field Name	Field Label	Type	PII	R	MD	Comments
hasCerebralVascularAssessments	Cerebral Vascular Assessments	boolean				
presenceOfAnyStrategicInfarcts	Presence of Any Strategic Infarcts	string				Allowed values: <ul style="list-style-type: none"> Unknown: Unknown Yes: Yes No: No NotAvailable: Not Available
presenceOfMicrohaemorrhage	Presence of Microhaemorrhage	string				Allowed values: <ul style="list-style-type: none"> Unknown: Unknown Yes: Yes No: No NotAvailable: Not Available
presenceOfLacunes	Presence of Lacunes	string				Allowed values: <ul style="list-style-type: none"> Unknown: Unknown Yes: Yes No: No NotAvailable: Not Available
numberOfLacunes	Number of Lacunes	object				See object description
whiteMatterLesions	White Matter Lesions	integer				Allowed values: <ul style="list-style-type: none"> 0: No Lesions 1: Focal Lesions 2: Beginning Confluence of Lesions 3: Diffuse Involvement of the Entire Region
basalGangliaLesions	Basal Ganglia Lesions	integer				Allowed values: <ul style="list-style-type: none"> 0: No Lesions 1: 1 Focal Lesion (=5 mm) 2: >1 Focal lesion 3: Confluent Lesions

Validation Rules:

- Cerebral vascular assessment fields must only be populated when cerebral vascular assessments are present (hasCerebralVascularAssessments)

- Lacune counts must only be populated when lacunes are present (presenceOfLacunes)

3.7.4 medicalTests.cerebralVascularAssessments.numberOfLacunes

Field Name	Field Label	Type	PII	R	MD	Comments
whiteMatter	White Matter	integer				Minimum = 0
basalGanglia	Basal Ganglia	integer				Minimum = 0
brainstem	Brainstem	integer				Minimum = 0

3.8 Medical Tests section (CSF)

3.8.1 medicalTests

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test Type	string		X		Allowed values: • CSF
id	Medical Test ID	string		X		Format: uuid
examDate	Exam Date	string		X		Format: date
examPurpose	Purpose	string				Allowed values: • ClinicalFollowUp: Clinical Follow-up • Diagnosis: Diagnosis • Other: Other
examPurposeOther	Other purpose	string				
biosampleStorage	Biosample Storage	string				Allowed values: • Unknown: Unknown • Yes: Yes • No: No
storageDate	Storage Date	string				Format: date
storageLocation	Storage Location	string				
amyloidMeasurements	Amyloid Measurements	object				See object description
tauMeasurements	tauMeasurements	object				See object description
otherMarkers	Other Markers	object				See object description
piiNotes	Notes	string	X			Any notes related to the medical test

Validation Rules:

- A medical test exam date cannot be earlier than the patient’s date of birth.
- A medical test exam date cannot be in the future
- The “other exam purpose” field must only be populated when the selected exam purpose is “Other”
- CSF biosample storage details must only be populated when biosample storage is confirmed (biosampleStorage)

3.8.2 medicalTests.amyloidMeasurements

Field Name	Field Label	Type	PII	R	MD	Comments
hasAmyloidMeasurements	Amyloid Measurements	boolean				
assayMethod	Assay Method	string				Allowed values: <ul style="list-style-type: none"> • Unknown • ELISA • IP MS • SIMOA • Other
assayMethodOther	Other Assay Method	string				
provider	Provider	string				
qualitativeResult	Qualitative Result	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Positive • Negative • Uncertain
ab42Concentration	Amyloid Aβ42 Concentration	number				Multiple Of = 0.1
ab42ConcentrationUnit	Unit	string				
ab40Concentration	Amyloid Aβ40 Concentration	number				Multiple Of = 0.1
ab40ConcentrationUnit	Unit	string				
ab42Ab40Ratio	Aβ42/Aβ40 Ratio	number				Multiple Of = 0.01
totalTauAb42Ratio	Total Tau/Aβ42 Ratio	number				Multiple Of = 0.01
pTau181Ab42Ratio	p-Tau181/Aβ42 Ratio	number				Multiple Of = 0.01
pTau217Ab42Ratio	p-Tau217/Aβ42 Ratio	number				Multiple Of = 0.01

Validation Rules:

- Amyloid measurement fields must only be populated when amyloid measurements are present (hasAmyloidMeasurements)

- The assay method “other” field must only be populated when assay method is “Other” (assayMethod)

Ratios must only be provided when their required input concentrations are present and compatible:

- **Aβ42 / Aβ40 ratio**
Must be empty unless both Aβ42 and Aβ40 concentrations are present
Requires matching concentration units
When present, the ratio must equal ab42Concentration / ab40Concentration
- **Total Tau / Aβ42 ratio**
Must be empty unless both Total Tau and Aβ42 concentrations are present
Requires matching concentration units
When present, the ratio must equal totalTauConcentration / ab42Concentration
- **p-Tau181 / Aβ42 ratio**
Must be empty unless both p-Tau181 and Aβ42 concentrations are present
Requires matching concentration units.
When present, the ratio must equal pTau181Concentration / ab42Concentration
- **p-Tau217 / Aβ42 ratio**
Must be empty unless both p-Tau217 and Aβ42 concentrations are present
Requires matching concentration units
When present, the ratio must equal pTau217Concentration / ab42Concentration

3.8.3 medicalTests.tauMeasurements

Field Name	Field Label	Type	PII	R	MD	Comments
hasTauMeasurements	Tau Measurements	boolean				
assayMethod	Assay Method	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • ELISA: ELISA • IP MS: IP MS • SIMOA: SIMOA • Other: Other
assayMethodOther	Other Assay Method	string				
provider	Provider	string				
qualitativeResult	Qualitative Result	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Positive

Field Name	Field Label	Type	PII	R	MD	Comments
						<ul style="list-style-type: none"> Negative Uncertain
totalTauConcentration	Total Tau Concentration	number				Multiple Of = 0.1
totalTauConcentrationUnit	Unit	string				
pTau181Concentration	p-Tau 181 Concentration	number				Multiple Of = 0.1
pTau181ConcentrationUnit	Unit	string				
pTau205Concentration	p-Tau 205 Concentration	number				Multiple Of = 0.1
pTau205ConcentrationUnit	Unit	string				
pTau217Concentration	p-Tau 217 Concentration	number				Multiple Of = 0.1
pTau217ConcentrationUnit	Unit	string				
pTau231Concentration	p-Tau 231 Concentration	number				Multiple Of = 0.1
pTau231ConcentrationUnit	Unit	string				
mtbrTau243Concentration	MTBR-Tau 243 Concentration	number				Multiple Of = 0.1
mtbrTau243ConcentrationUnit	Unit	string				

Validation Rules:

- Tau measurement fields must only be populated when tau measurements are present (hasTauMeasurements)
- The assay method “other” field must only be populated when assay method is “Other” (assayMethod)

3.8.4 medicalTests.otherMarkers

Field Name	Field Label	Type	PII	R	MD	Comments
hasOtherMarkers	Other Markers	boolean				
assayMethod	Assay Method	string				Allowed values: <ul style="list-style-type: none"> Unknown: Unknown ELISA: ELISA IP MS: IP MS SIMOA: SIMOA Other: Other
assayMethodOther	Other Assay Method	string				
provider	Provider	string				

Field Name	Field Label	Type	PII	R	MD	Comments
neurofilamentLightChainConcentration	Neurofilament Light Chain (NfL) Concentration	number				Multiple Of = 0.1
neurofilamentLightChainConcentrationUnit	Unit	string				
glialFibrillaryAcidicProteinConcentration	Glial Fibrillary Acidic Protein (GFAP) Concentration	number				Multiple Of = 0.1
glialFibrillaryAcidicProteinConcentrationUnit	Unit	string				
alphaSynucleinConcentration	a-Synuclein Concentration	number				Multiple Of = 0.1
alphaSynucleinConcentrationUnit	Unit	string				

Validation Rules:

- Other CSF marker fields must only be populated when other markers are present (hasOtherMarkers)
- The assay method “other” field must only be populated when assay method is “Other” (assayMethod)

3.9 Medical Tests section (Buccal Swab)

3.9.1 medicalTests

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test Type	string		X		Allowed values: • BuccalSwab
id	Medical Test ID	string		X		Format: uuid
examDate	Exam Date	string		X		Format: date
examPurpose	Purpose	string				Allowed values: • ClinicalFollowUp: Clinical Follow-up • Diagnosis: Diagnosis • Other: Other
examPurposeOther	Other purpose	string				
biosampleStorage	Biosample Storage	string				Allowed values: • Unknown: Unknown • Yes: Yes • No: No
storageDate	Storage Date	string				Format: date
storageLocation	Storage Location	string				
genotyping	Genotyping	object				See object description

Field Name	Field Label	Type	PII	R	MD	Comments
piiNotes	Notes	string	X			Any notes related to the medical test

Validation Rules:

- A medical test exam date cannot be earlier than the patient’s date of birth.
- A medical test exam date cannot be in the future
- The “other exam purpose” field must only be populated when the selected exam purpose is “Other”

3.9.2 medicalTests.genotyping

Field Name	Field Label	Type	PII	R	MD	Comments
hasGenotyping	Genotyping	boolean				
assayMethod	Assay Method	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • ELISA: ELISA • IP MS: IP MS • SIMOA: SIMOA • Other: Other
assayMethodOther	Other Assay Method	string				
provider	Provider	string				
apoeGenotype	APOE Genotype	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • E2, E2: E2, E2 • E2, E3: E2, E3 • E2, E4: E2, E4 • E3, E3: E3, E3 • E3, E4: E3, E4 • E4, E4: E4, E4 • Other: Other
apoeGenotypeOther	Other APOE Genotype	string				

Field Name	Field Label	Type	PII	R	MD	Comments
amyloidPrecursorProtein	Amyloid Precursor Protein (APP)	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)
presenilin1	Presenilin 1 (PSEN1)	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)
presenilin2	Presenilin 2 (PSEN2)	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)
otherGenes	Other Genes	array[object]				See object description

Validation Rules:

- Genotyping fields must only be populated when genotyping is present (hasGenotyping)
- The APOE genotype “other” field must only be populated when APOE genotype is “Other” (apoeGenotype)
- The assay method “other” field must only be populated when assay method is “Other” (assayMethod)

3.9.3 medicalTests.genotyping.otherGenes

Field Name	Field Label	Type	PII	R	MD	Comments
geneName	Gene Name	string		X		Min Length = 1
qualitativeResult	Qualitative Result	string		X		Allowed values: <ul style="list-style-type: none"> • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)

3.10 Medical Tests section (Blood Test)

3.10.1 medicalTests

Field Name	Field Label	Type	PII	R	MD	Comments
testType	Test Type	string		X		Allowed values: • BloodTest
id	Medical Test ID	string		X		Format: uuid
examDate	Exam Date	string		X		Format: date
examPurpose	Purpose	string				Allowed values: • ClinicalFollowUp: Clinical Follow-up • Diagnosis: Diagnosis • Other: Other
examPurposeOther	Other purpose	string				
biosampleStorage	Biosample Storage	string				Allowed values: • Unknown: Unknown • Yes: Yes • No: No
storageDate	Storage Date	string				Format: date
storageLocation	Storage Location	string				
amyloidMeasurements	Amyloid Measurements	object				See object description
tauMeasurements	Tau Measurements	object				See object description
otherMarkers	Other Markers	object				See object description
genotyping	Genotyping	object				See object description
piiNotes	Notes	string	X			Any notes related to the medical test

Validation Rules:

- A medical test exam date cannot be earlier than the patient’s date of birth.
- A medical test exam date cannot be in the future
- The “other exam purpose” field must only be populated when the selected exam purpose is “Other”
- Blood biosample storage details must only be populated when biosample storage is confirmed (biosampleStorage)

Blood test biomarker measurements - consistency rules

Blood biomarker measurement sections follow the same validation patterns as CSF, including:

- **Master flag gating**
Biomarker fields must only be populated when the corresponding has* flag is true.
- **Assay method “Other” gating**
The “other assay method” field must only be populated when the assay method is "Other".
- **Calculated ratio integrity (where applicable)**
Ratios must only be provided when the required input concentrations are present.
Input concentrations must use matching units.
When present, ratios must equal the corresponding calculated values.

3.10.2 medicalTests.amyloidMeasurements

Field Name	Field Label	Type	PII	R	MD	Comments
hasAmyloidMeasurements	Amyloid Measurements	boolean				
assayMethod	Assay Method	string				Allowed values: <ul style="list-style-type: none"> • Unknown • ELISA • IP MS • SIMOA • Other
assayMethodOther	Other Assay Method	string				
provider	Provider	string				
qualitativeResult	Qualitative Result	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Positive • Negative • Uncertain
ab42Concentration	Amyloid A β 42 Concentration	number				Multiple Of = 0.1
ab42ConcentrationUnit	Unit	string				
ab40Concentration	Amyloid A β 40 Concentration	number				Multiple Of = 0.1
ab40ConcentrationUnit	Unit	string				
ab42Ab40Ratio	A β 42/A β 40 Ratio	number				Multiple Of = 0.01
totalTauAb42Ratio	Total Tau/A β 42 Ratio	number				Multiple Of = 0.01
pTau181Ab42Ratio	p-Tau181/A β 42 Ratio	number				Multiple Of = 0.01
pTau217Ab42Ratio	p-Tau217/A β 42 Ratio	number				Multiple Of = 0.01

3.10.3 medicalTests.tauMeasurements

Field Name	Field Label	Type	PII	R	MD	Comments
hasTauMeasurements	Tau Measurements	boolean				
assayMethod	Assay Method	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • ELISA: ELISA • IP MS: IP MS • SIMOA: SIMOA • Other: Other
assayMethodOther	Other Assay Method	string				
provider	Provider	string				
qualitativeResult	Qualitative Result	string				Allowed values: <ul style="list-style-type: none"> • Unknown • Positive • Negative • Uncertain
totalTauConcentration	Total Tau Concentration	number				Multiple Of = 0.1
totalTauConcentrationUnit	Unit	string				
pTau181Concentration	p-Tau 181 Concentration	number				Multiple Of = 0.1
pTau181ConcentrationUnit	Unit	string				
pTau205Concentration	p-Tau 205 Concentration	number				Multiple Of = 0.1
pTau205ConcentrationUnit	Unit	string				
pTau217Concentration	p-Tau 217 Concentration	number				Multiple Of = 0.1
pTau217ConcentrationUnit	Unit	string				
pTau231Concentration	p-Tau 231 Concentration	number				Multiple Of = 0.1
pTau231ConcentrationUnit	Unit	string				
mtbrTau243Concentration	MTBR-Tau 243 Concentration	number				Multiple Of = 0.1
mtbrTau243ConcentrationUnit	Unit	string				

3.10.4 medicalTests.otherMarkers

Field Name	Field Label	Type	PII	R	MD	Comments
hasOtherMarkers	Other Markers	boolean				

Field Name	Field Label	Type	PII	R	MD	Comments
assayMethod	Assay Method	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • ELISA: ELISA • IP MS: IP MS • SIMOA: SIMOA • Other: Other
assayMethodOther	Other Assay Method	string				
provider	Provider	string				
neurofilamentLightChainConcentration	Neurofilament Light Chain (NFL) Concentration	number				Multiple Of = 0.1
neurofilamentLightChainConcentrationUnit	Unit	string				
glialFibrillaryAcidicProteinConcentration	Glial Fibrillary Acidic Protein (GFAP) Concentration	number				Multiple Of = 0.1
glialFibrillaryAcidicProteinConcentrationUnit	Unit	string				
alphaSynucleinConcentration	a-Synuclein Concentration	number				Multiple Of = 0.1
alphaSynucleinConcentrationUnit	Unit	string				

3.10.5 medicalTests.genotyping

Field Name	Field Label	Type	PII	R	MD	Comments
hasGenotyping	Genotyping	boolean				
assayMethod	Assay Method	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • ELISA: ELISA • IP MS: IP MS • SIMOA: SIMOA • Other: Other
assayMethodOther	Other Assay Method	string				
provider	Provider	string				

Field Name	Field Label	Type	PII	R	MD	Comments
apoeGenotype	APOE Genotype	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • E2, E2: E2, E2 • E2, E3: E2, E3 • E2, E4: E2, E4 • E3, E3: E3, E3 • E3, E4: E3, E4 • E4, E4: E4, E4 • Other: Other
apoeGenotypeOther	Other APOE Genotype	string				
amyloidPrecursorProtein	Amyloid Precursor Protein (APP)	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)
presenilin1	Presenilin 1 (PSEN1)	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)
presenilin2	Presenilin 2 (PSEN2)	string				Allowed values: <ul style="list-style-type: none"> • Unknown: Unknown • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)
otherGenes	Other Genes	array[object]				See object description

Validation Rules:

- Genotyping fields must only be populated when genotyping is present (hasGenotyping)

- The APOE genotype “other” field must only be populated when APOE genotype is “Other” (apoeGenotype)
- The assay method “other” field must only be populated when assay method is “Other” (assayMethod)

3.10.6 medicalTests.genotyping.otherGenes

Field Name	Field Label	Type	PII	R	MD	Comments
geneName	Gene Name	string		X		
qualitativeResult	Qualitative Result	string		X		Allowed values: <ul style="list-style-type: none"> • Positive: Positive • Negative: Negative • VariantOfUnknownSignificance: Variant of Unknown Significance (VUS)

3.11 Treatments section (AD Specific Treatments)

3.11.1 Treatments

Field Name	Field Label	Type	PII	R	MD	Comments
id	Treatment ID	string		X		Format: uuid
treatmentType	Treatment type	string		X		Allowed values: <ul style="list-style-type: none"> • ADSpecificTreatments
atcCode	ATC code	string		X		ATC Code for treatment
treatmentName	Treatment name	string		X		
administrationDetails	Administration Details	array[object]		X		See object description
discontinuationReason	Reason for discontinuation	string				Allowed values: <ul style="list-style-type: none"> • TreatmentCourseCompleted: Treatment course completed • TreatmentTargetAchieved: Treatment target achieved • ProgressionOfDisease: Progression of disease • LackOfEfficacy: Lack of efficacy • MedicalEventRelatedToTreatment: Medical condition & event related to treatment • MedicalEventUnrelatedToTreatment: Medical condition & event unrelated to treatment

Field Name	Field Label	Type	PII	R	MD	Comments
						<ul style="list-style-type: none"> • NonAdherence: Non-adherence • Convenience: Convenience • Contraindication: Contraindication • Economic/FinancialReason: Economic/Financial reason • Other: Other
discontinuationReasonOther	Other discontinuation reason	string				Treatment discontinuation reason other
discontinuationInitiator	Discontinuation Initiator	object				See object description
piiNotes	Notes	string	X			

Validation Rules:

- If the most recent treatment administration period has no end date, the discontinuation reason must be empty
- If the most recent treatment administration period has an end date, a discontinuation reason must be provided
- The “other discontinuation reason” field must only be populated when the discontinuation reason is “Other”

3.11.2 treatments.administrationDetails

How to record AD-specific treatment courses

This section supports **single-dose administrations** as well as **multi-period courses** that include **titration steps** and **interruptions** (e.g., ARIA-related holds). Model each period as a row with a start/end date and dose. For titrations, **add a new period when dose changes**; the **end date of the prior period** is the **day before** the next period starts. For interruptions, insert a period with **dose = 0** for the hold and resume with the next period when treatment restarts. Keep periods **chronological and non-overlapping**.

Field Name	Field Label	Type	PII	R	MD	Comments
startDate	Start date	string		X		Treatment Start Date Format: date
endDate	End date	string				Treatment End Date Format: date
dosage	Dosage	object				See object description

Validation Rules:

- Treatment administration periods must be chronologically ordered
- Each treatment period must start after the previous period has ended
- An end date is required for all treatment periods except the most recent one

- When an end date is provided, it cannot be earlier than the start date
- Treatment administration cannot start before the patient's date of birth
- Treatment administration periods must not overlap
- For single-dose treatments, the start date and end date must be the same.

3.11.3 treatments.administrationDetails.dosage

Field Name	Field Label	Type	PII	R	MD	Comments
dose	Dose	number				Dosage value Minimum = 0
unit	Unit	string				Allowed values: <ul style="list-style-type: none"> • Other • g • LSU • mcg • mg • mg/kg • mL • mmol • MU • tablet • TU • U

Field Name	Field Label	Type	PII	R	MD	Comments
period	Period	string				Allowed values: <ul style="list-style-type: none"> • Other • 2 / Week • / Week • 2 / Day • 3 / Week • / 3 Hours • / 2 Hours • 3 / Day • / 3 Days • / 2 Days • / Hour • / Day • / 4 Hours • 4 / Day • / Month • / 3 Months • / 4 Weeks • / 5 Weeks • / 6 Weeks • / 7 Weeks • / 8 Weeks • Single Dose • Daily for 5 days • Daily for 3 days • / 2 Weeks • / 6 Months • 5 Day Course • 5 Day Course (Week 1 and Week 5)

Field Name	Field Label	Type	PII	R	MD	Comments
route	Route	string				Allowed values: <ul style="list-style-type: none"> • IM • Implant • Inhalation • Instillation • Intravesical • IV • Nasal • Oral • Parenteral • Rectal • SC • Sublingual • Transdermal • Urethral • Vaginal • Other

3.11.4 treatments.discontinuationInitiator

Field Name	Field Label	Type	PII	R	MD	Comments
patient	Patient	boolean				Patient initiated discontinuation
carePartnerOrFamily	Care partner/family	boolean				Care partner or family initiated discontinuation
doctorOrClinicalTeam	Doctor/clinical team	boolean				Doctor or clinical team initiated discontinuation
other	Other	boolean				Other initiated discontinuation
otherDetails	Other Details	string				Other initiated discontinuation details

Validation Rules:

- If the most recent treatment administration period has no end date, no discontinuation initiator must be provided
- The “other initiator” details field must only be populated when “Other” is selected as the discontinuation initiator

3.12 Treatments section (Cognitive Treatments)

3.12.1 treatments

Field Name	Field Label	Type	PII	R	MD	Comments
id	Treatment ID	string		X		Format: uuid
treatmentType	Treatment type	string		X		Allowed values: • CognitiveTreatments
atcCode	ATC code	string		X		ATC Code for treatment. Non-ATC treatments use the format: {TREATMENT_TYPE}-{REGION}-{NAME}. Example: 'COGNITIVE-DE-Ginkgo Biloba Food supplement'
treatmentName	Treatment name	string		X		
administrationDetails	Administration Details	array[object]		X		See object description
discontinuationReason	Reason for discontinuation	string				Allowed values: • TreatmentCourseCompleted: Treatment course completed • TreatmentTargetAchieved: Treatment target achieved • ProgressionOfDisease: Progression of disease • LackOfEfficacy: Lack of efficacy • MedicalEventRelatedToTreatment: Medical condition & event related to treatment • MedicalEventUnrelatedToTreatment: Medical condition & event unrelated to treatment • NonAdherence: Non-adherence • Convenience: Convenience • Contraindication: Contraindication • Economic/FinancialReason: Economic/Financial reason • Other: Other
discontinuationReasonOther	Other discontinuation reason	string				Treatment discontinuation reason other
piiNotes	Notes	string	X			

Validation Rules:

- The “other discontinuation reason” field must only be populated when the discontinuation reason is “Other”

3.12.2 treatments.administrationDetails

Field Name	Field Label	Type	PII	R	MD	Comments
startDate	Start date	string		X		Treatment Start Date Format: date
endDate	End date	string				Treatment End Date Format: date
dosage	Dosage	object				See object description

Validation Rules:

- Treatment administration cannot start before the patient's date of birth
- When an end date is provided, it cannot be earlier than the start date
- For single-dose treatments, the start date and end date must be the same
- If a treatment-level discontinuation reason is provided, the corresponding treatment administration period must have an end date

3.12.3 treatments.administrationDetails.dosage

Field Name	Field Label	Type	PII	R	MD	Comments
dose	Dose	number				Dosage value Minimum = 0
unit	Unit	string				Allowed values: <ul style="list-style-type: none"> • Other • g • LSU • mcg • mg • mg/kg • mL • mmol • MU • tablet • TU • U

Field Name	Field Label	Type	PII	R	MD	Comments
period	Period	string				Allowed values: <ul style="list-style-type: none"> • Other • 2 / Week • / Week • 2 / Day • 3 / Week • / 3 Hours • / 2 Hours • 3 / Day • / 3 Days • / 2 Days • / Hour • / Day • / 4 Hours • 4 / Day • / Month • / 3 Months • / 4 Weeks • / 5 Weeks • / 6 Weeks • / 7 Weeks • / 8 Weeks • Single Dose • Daily for 5 days • Daily for 3 days • / 2 Weeks • / 6 Months • 5 Day Course • 5 Day Course (Week 1 and Week 5)

Field Name	Field Label	Type	PII	R	MD	Comments
route	Route	string				Allowed values: <ul style="list-style-type: none"> • IM • Implant • Inhalation • Instillation • Intravesical • IV • Nasal • Oral • Parenteral • Rectal • SC • Sublingual • Transdermal • Urethral • Vaginal • Other

3.13 Treatments section (Other Treatments of Interest)

3.13.1 treatments

Field Name	Field Label	Type	PII	R	MD	Comments
id	Treatment ID	string		X		Format: uuid
treatmentType	Treatment type	string		X		Allowed values: <ul style="list-style-type: none"> • OtherTreatmentsOfInterest
atcCode	ATC code	string		X		ATC Code for treatment.
treatmentName	Treatment name	string		X		
administrationDetails	Administration Details	array[object]		X		See object description
discontinuationReason	Reason for discontinuation	string				Allowed values: <ul style="list-style-type: none"> • TreatmentCourseCompleted: Treatment course completed • TreatmentTargetAchieved: Treatment target achieved • ProgressionOfDisease: Progression of disease • LackOfEfficacy: Lack of efficacy

Field Name	Field Label	Type	PII	R	MD	Comments
						<ul style="list-style-type: none"> • MedicalEventRelatedToTreatment: Medical condition & event related to treatment • MedicalEventUnrelatedToTreatment: Medical condition & event unrelated to treatment • NonAdherence: Non-adherence • Convenience: Convenience • Contraindication: Contraindication • Economic/FinancialReason: Economic/Financial reason • Other: Other
discontinuationReasonOther	Other discontinuation reason	string				Treatment discontinuation reason other
piiNotes	Notes	string	X			

Validation Rules:

- The “other discontinuation reason” field must only be populated when the discontinuation reason is “Other”

3.13.2 treatments.administrationDetails

Field Name	Field Label	Type	PII	R	MD	Comments
startDate	Start date	string		X		Treatment Start Date Format: date
endDate	End date	string				Treatment End Date Format: date
dosage	Dosage	object				See object description

Validation Rules:

- Treatment administration cannot start before the patient’s date of birth
- When an end date is provided, it cannot be earlier than the start date
- For single-dose treatments, the start date and end date must be the same
- If a treatment-level discontinuation reason is provided, the corresponding treatment administration period must have an end date

3.13.3 treatments.administrationDetails.dosage

Field Name	Field Label	Type	PII	R	MD	Comments
dose	Dose	number				Dosage value Minimum = 0
unit	Unit	string				Allowed values: <ul style="list-style-type: none"> • Other • g • LSU • mcg • mg • mg/kg • mL • mmol • MU • tablet • TU • U

Field Name	Field Label	Type	PII	R	MD	Comments
period	Period	string				Allowed values: <ul style="list-style-type: none"> • Other • 2 / Week • / Week • 2 / Day • 3 / Week • / 3 Hours • / 2 Hours • 3 / Day • / 3 Days • / 2 Days • / Hour • / Day • / 4 Hours • 4 / Day • / Month • / 3 Months • / 4 Weeks • / 5 Weeks • / 6 Weeks • / 7 Weeks • / 8 Weeks • Single Dose • Daily for 5 days • Daily for 3 days • / 2 Weeks • / 6 Months • 5 Day Course • 5 Day Course (Week 1 and Week 5)

Field Name	Field Label	Type	PII	R	MD	Comments
route	Route	string				Allowed values: <ul style="list-style-type: none"> • IM • Implant • Inhalation • Instillation • Intravesical • IV • Nasal • Oral • Parenteral • Rectal • SC • Sublingual • Transdermal • Urethral • Vaginal • Other
Field Name	Field Label	Type	PII	R	MD	Comments

Field Name	Field Label	Type	PII	R	MD	Comments
discontinuationReason	Reason for discontinuation	string				Allowed values: <ul style="list-style-type: none"> • TreatmentCourseCompleted: Treatment course completed • TreatmentTargetAchieved: Treatment target achieved • ProgressionOfDisease: Progression of disease • LackOfEfficacy: Lack of efficacy • MedicalEventRelatedToTreatment: Medical condition & event related to treatment • MedicalEventUnrelatedToTreatment: Medical condition & event unrelated to treatment • NonAdherence: Non-adherence • Convenience: Convenience • Contraindication: Contraindication • Economic/FinancialReason: Economic/Financial reason • Other: Other
discontinuationReasonOther	Other discontinuation reason	string				Treatment discontinuation reason other

3.14 Treatments section (Non-Pharmacological Treatments)

3.14.1 treatments

Field Name	Field Label	Type	PII	R	MD	Comments
id	Treatment ID	string		X		Format: uuid
treatmentType	Treatment type	string		X		Allowed values: <ul style="list-style-type: none"> • NonPharmacologicalTreatments
atcCode	ATC code	string		X		ATC Code for treatment.
treatmentName	Treatment name	string		X		
administrationDetails	Administration Details	array[object]		X		See object description
piiNotes	Notes	string	X			

3.14.2 treatments.administrationDetails

Field Name	Field Label	Type	PII	R	MD	Comments
startDate	Start date	string		X		Treatment Start Date Format: date
endDate	End date	string				Treatment End Date Format: date
duration	Frequency and Duration	object				See object description

Validation Rules:

- Treatment administration cannot start before the patient’s date of birth
- When an end date is provided, it cannot be earlier than the start date

3.14.3 treatments.administrationDetails.duration

Field Name	Field Label	Type	PII	R	MD	Comments
amount	Amount	number				Duration of treatment Minimum = 0
unit	Unit	string				Allowed values: <ul style="list-style-type: none"> • minute • hour • day
frequency	Frequency	string				Allowed values: <ul style="list-style-type: none"> • day • week • month

4 Reference Lists

4.1 Countries

List name: ad.referencelist.country.csv

Key	Value
AF	Afghanistan
AX	Åland Islands
AL	Albania
DZ	Algeria
AS	American Samoa
AD	Andorra
AO	Angola
AI	Anguilla
AQ	Antarctica
AG	Antigua and Barbuda
AR	Argentina
AM	Armenia
AW	Aruba
AU	Australia
AT	Austria
AZ	Azerbaijan
BS	Bahamas
BH	Bahrain
BD	Bangladesh
BB	Barbados
BY	Belarus
BE	Belgium
BZ	Belize
BJ	Benin
BM	Bermuda
BT	Bhutan
BO	Bolivia, Plurinational State of
BQ	Bonaire, Sint Eustatius and Saba
BA	Bosnia and Herzegovina
BW	Botswana
BV	Bouvet Island
BR	Brazil

Key	Value
IO	British Indian Ocean Territory
BN	Brunei Darussalam
BG	Bulgaria
BF	Burkina Faso
BI	Burundi
CV	Cabo Verde
KH	Cambodia
CM	Cameroon
CA	Canada
KY	Cayman Islands
CF	Central African Republic
TD	Chad
CL	Chile
CN	China
CX	Christmas Island
CC	Cocos (Keeling) Islands
CO	Colombia
KM	Comoros
CG	Congo
CD	Congo, Democratic Republic of the
CK	Cook Islands
CR	Costa Rica
CI	Côte d'Ivoire
HR	Croatia
CU	Cuba
CW	Curaçao
CY	Cyprus
CZ	Czechia
DK	Denmark
DJ	Djibouti
DM	Dominica
DO	Dominican Republic

Key	Value
EC	Ecuador
EG	Egypt
SV	El Salvador
GQ	Equatorial Guinea
ER	Eritrea
EE	Estonia
SZ	Eswatini
ET	Ethiopia
FK	Falkland Islands (Malvinas)
FO	Faroe Islands
FJ	Fiji
FI	Finland
FR	France
GF	French Guiana
PF	French Polynesia
TF	French Southern Territories
GA	Gabon
GM	Gambia
GE	Georgia
DE	Germany
GH	Ghana
GI	Gibraltar
GR	Greece
GL	Greenland
GD	Grenada
GP	Guadeloupe
GU	Guam
GT	Guatemala
GG	Guernsey
GN	Guinea
GW	Guinea-Bissau
GY	Guyana

Key	Value
HT	Haiti
HM	Heard Island and McDonald Islands
VA	Holy See
HN	Honduras
HK	Hong Kong
HU	Hungary
IS	Iceland
IN	India
ID	Indonesia
IR	Iran, Islamic Republic of
IQ	Iraq
IE	Ireland
IM	Isle of Man
IL	Israel
IT	Italy
JM	Jamaica
JP	Japan
JE	Jersey
JO	Jordan
KZ	Kazakhstan
KE	Kenya
KI	Kiribati
KP	Korea, Democratic People's Republic of
KR	Korea, Republic of
KW	Kuwait
KG	Kyrgyzstan
LA	Lao People's Democratic Republic
LV	Latvia
LB	Lebanon
LS	Lesotho
LR	Liberia
LY	Libya

Key	Value
LI	Liechtenstein
LT	Lithuania
LU	Luxembourg
MO	Macao
MG	Madagascar
MW	Malawi
MY	Malaysia
MV	Maldives
ML	Mali
MT	Malta
MH	Marshall Islands
MQ	Martinique
MR	Mauritania
MU	Mauritius
YT	Mayotte
MX	Mexico
FM	Micronesia, Federated States of
MD	Moldova, Republic of
MC	Monaco
MN	Mongolia
ME	Montenegro
MS	Montserrat
MA	Morocco
MZ	Mozambique
MM	Myanmar
NA	Namibia
NR	Nauru
NP	Nepal
NL	Netherlands, Kingdom of the
NC	New Caledonia
NZ	New Zealand
NI	Nicaragua

Key	Value
NE	Niger
NG	Nigeria
NU	Niue
NF	Norfolk Island
MK	North Macedonia
MP	Northern Mariana Islands
NO	Norway
OM	Oman
PK	Pakistan
PW	Palau
PS	Palestine, State of
PA	Panama
PG	Papua New Guinea
PY	Paraguay
PE	Peru
PH	Philippines
PN	Pitcairn
PL	Poland
PT	Portugal
PR	Puerto Rico
QA	Qatar
RE	Réunion
RO	Romania
RU	Russian Federation
RW	Rwanda
BL	Saint Barthélemy
SH	Saint Helena, Ascension and Tristan da Cunha
KN	Saint Kitts and Nevis
LC	Saint Lucia
MF	Saint Martin (French part)
PM	Saint Pierre and Miquelon
VC	Saint Vincent and the Grenadines

Key	Value
WS	Samoa
SM	San Marino
ST	Sao Tome and Principe
SA	Saudi Arabia
SN	Senegal
RS	Serbia
SC	Seychelles
SL	Sierra Leone
SG	Singapore
SX	Sint Maarten (Dutch part)
SK	Slovakia
SI	Slovenia
SB	Solomon Islands
SO	Somalia
ZA	South Africa
GS	South Georgia and the South Sandwich Islands
SS	South Sudan
ES	Spain
LK	Sri Lanka
SD	Sudan
SR	Suriname
SJ	Svalbard and Jan Mayen
SE	Sweden
CH	Switzerland
SY	Syrian Arab Republic
TW	Taiwan, Province of China
TJ	Tajikistan
TZ	Tanzania, United Republic of
TH	Thailand
TL	Timor-Leste
TG	Togo
TK	Tokelau

Key	Value
TO	Tonga
TT	Trinidad and Tobago
TN	Tunisia
TR	Türkiye
TM	Turkmenistan
TC	Turks and Caicos Islands
TV	Tuvalu
UG	Uganda
UA	Ukraine
AE	United Arab Emirates
GB	United Kingdom of Great Britain and Northern Ireland
US	United States of America
UM	United States Minor Outlying Islands
UY	Uruguay
UZ	Uzbekistan
VU	Vanuatu
VE	Venezuela, Bolivarian Republic of
VN	Viet Nam
VG	Virgin Islands (British)
VI	Virgin Islands (U.S.)
WF	Wallis and Futuna
EH	Western Sahara
YE	Yemen
ZM	Zambia
ZW	Zimbabwe

4.2 Cognitive Tests

List Name: `ad.outcomelist.cognitivescreening.csv`

Name	Description	Version	MaxScore
MMSE	Mini-Mental State Examination	MMSE-1	30
MMSE	Mini-Mental State Examination	MMSE-2	30
MMSE	Mini-Mental State Examination	MMSE-2:SV	30

Name	Description	Version	MaxScore
MMSE	Mini-Mental State Examination	MMSE-2:EV	30
MMSE	Mini-Mental State Examination	SMMSE	30
MMSE	Mini-Mental State Examination	Other	30
MoCA	Montreal Cognitive Assessment	MoCA 8.1	30
MoCA	Montreal Cognitive Assessment	MoCA 8.2	30
MoCA	Montreal Cognitive Assessment	MoCA 8.3	30
MoCA	Montreal Cognitive Assessment	Other	30

4.3 Cognitive Functional Tests

List Name: ad.outcomelist.cognitivefunctional.csv

Name	Description	Version	MaxScore
CDR-SB	Clinical Dementia Rating - Sum of Boxes		18

4.4 Functional Tests

List Name: ad.outcomelist.functional.csv

Name	Description	Version	MaxScore
FAQ	Functional Activities Questionnaire		30
A-IADL-Q	Amsterdam Instrumental Activities of Daily Living	Short	30
A-IADL-Q	Amsterdam Instrumental Activities of Daily Living Questionnaire	Long	70

4.5 Patient/CP Outcomes Tests

List Name: ad.outcomelist.patientorcarepartner.csv

Name	Description	Version	MaxScore
RUD Lite	Resource Utilization in Dementia - Lite Version		30

Name	Description	Version	MaxScore
Dependency Scale	Zhu 2018		15
ZBI	Zarit Burden Interview	Interview	88
ZBI	Zarit Burden Interview	Short	48
ZBI	Zarit Burden Interview	Screen	16
NPI-Q	Neuropsychiatric Inventory - Questionnaire		144

4.6 Ethnic Origins

List Name: ad.referencelist.ethnicorigin.csv

Key	Value
Not provided	Not provided
Mixed race	Mixed race
White/Caucasian	White/Caucasian
Black/African	Black/African
Middle East/North Africa	Middle East/North Africa
East Asian	East Asian
South Asian	South Asian
Indigenous	Indigenous

4.7 Institutions

List Name: ad.referencelist.institutions.csv

Key	Value
Unknown	Unknown
Primary Care	Primary Care
Memory Clinic	Memory Clinic
Secondary Care Hospital	Secondary Care Hospital
Tertiary Neuroscience Centre	Tertiary Neuroscience Centre
Direct from Patient	Direct from Patient

4.8 Laboratory Tests Units

List Name: ad.referencelist.labunits.csv

Key	Value
g/dL	g/dL
U/L	U/L
g/L	g/L
pg/mL	pg/mL
umol/L	umol/L
mmol/L	mmol/L
10e9/L	10e9/L
10e12/L	10e12/L
nmol/L	nmol/L
pmol/L	pmol/L
L/L	L/L
%	%
Other/Unknown	Other/Unknown

4.9 Specialities

List Name: ad.referencelist.specialities.csv

Key	Value
General Practitioner	General Practitioner
Geriatrician	Geriatrician
Immunologist	Immunologist
Neurologist	Neurologist
Neuropsychologist	Neuropsychologist
Ophthalmologist	Ophthalmologist
Physical Therapist	Physical Therapist
Psychiatrist	Psychiatrist
Psychologist	Psychologist
Radiologist	Radiologist

4.10 Treatments

4.10.1 AD Specific Treatments

AtcCode	Name	Dose	Unit	Period	Route
N06DX05	Donanemab (Kisunla)		mg	/ 4 Weeks	IV
N06DX05	Donanemab Trial		mg	/ 4 Weeks	IV
N06DX04	Lecanemab (Leqembi)		mg	/ 2 Weeks	IV
N06DX04	Lecanemab Trial		mg	/ 2 Weeks	IV
N06DX03	Aducanumab (Aduhelm)		mg	/ 4 Weeks	IV
N06DX03	Aducanumab Trial		mg	/ 4 Weeks	IV
A10BJ06	Semaglutide Trial				
AD-Trontinemab	Trontinemab Trial				IV
AD-ClinicalTrialNotListed	Clinical Trial Treatment (not listed)				

4.10.2 Cognitive Treatments

A global reference list of cognitive treatments is maintained and applies to all centres.

Where applicable, this global list is **extended with country-specific reference entries**, as defined below. These country-specific entries are made available **in addition to the global list**, based on the country associated with the centre.

Centres only see and use the entries relevant to their country configuration.

4.10.2.1 Global List

List Name: `ad.treatmentlist.cognitive.csv`

AtcCode	Name	Dose	Unit	Period	Route
N06DA	Anticholinesterases				
N06DA01	tacrine		g		Oral
N06DA02	donepezil		mg		Oral
N06DA03	rivastigmine		mg		Oral
N06DA03	rivastigmine		mg		Transdermal
N06DA04	galantamine		mg		Oral
N06DA05	ipidacrine				

AtcCode	Name	Dose	Unit	Period	Route
N06DA52	donepezil and memantine				
N06DA53	donepezil, memantine and Ginkgo folium				
N06DX01	memantine		mg		Oral
COGNITIVE-Ginkgo Biloba Food supplement	Ginkgo biloba (food supplement)			/ Day	Oral
N06DX02	Ginkgo folium		g		Oral
COGNITIVE-Souvenaid	Souvenaid	125	mL	/ Day	Oral
COGNITIVE-ClinicalTrialNotListed	Clinical Trial Treatment (not listed)				

4.10.2.2 Belgium

List Name: ad.treatmentlist.cognitive.be.csv

AtcCode	Name	Dose	Unit	Period	Route
COGNITIVE-BE-Tavoforce	Tavoforce			/ Day	Oral
COGNITIVE-BE-Tavonin	Tavonin			/ Day	Oral

4.10.2.3 Brazil

List Name: ad.treatmentlist.cognitive.br.csv

AtcCode	Name	Dose	Unit	Period	Route
COGNITIVE-BR-Ginkoba	Ginkoba			/ Day	Oral
COGNITIVE-BR-Bioginkgo	Bioginkgo			/ Day	Oral
COGNITIVE-BR-Tebonin	Tebonin			/ Day	Oral

4.10.2.4 Switzerland

List Name: ad.treatmentlist.cognitive.ch.csv

AtcCode	Name	Dose	Unit	Period	Route
COGNITIVE-CH-Symfona	Symfona			/ Day	Oral
COGNITIVE-CH-Tebokan	Tebokan			/ Day	Oral
COGNITIVE-CH-Tebofortin	Tebofortin			/ Day	Oral
COGNITIVE-CH-Rezirkane	Rezirkane			/ Day	Oral

AtcCode	Name	Dose	Unit	Period	Route
COGNITIVE-CH-Ginkgo Mepha	Ginkgo Mepha			/ Day	Oral

4.10.2.5 Czech Republic

List Name: ad.treatmentlist.cognitive.cz.csv

AtcCode	Name	Dose	Unit	Period	Route
COGNITIVE-CZ-Tebokan	Tebokan			/ Day	Oral
COGNITIVE-CZ-Gingio	Gingio			/ Day	Oral
COGNITIVE-CZ-Tanakan	Tanakan			/ Day	Oral
COGNITIVE-CZ-Tebofortan	Tebofortan			/ Day	Oral

4.10.2.6 Germany

List Name: ad.treatmentlist.cognitive.de.csv

AtcCode	Name	Dose	Unit	Period	Route
COGNITIVE-DE-Tebonin	Tebonin				
COGNITIVE-DE-Gingium	Gingium				
COGNITIVE-DE-Ginkobil	Ginkobil				
COGNITIVE-DE-Ginkgo ADGC	Ginkgo ADGC				
COGNITIVE-DE-Ginkgobeta	Ginkgobeta				

4.10.2.7 Spain

List Name: ad.treatmentlist.cognitive.es.csv

AtcCode	Name	Dose	Unit	Period	Route
COGNITIVE-ES-Tanakene	Tanakene			/ Day	Oral
COGNITIVE-ES-Tebofortan	Tebofortan			/ Day	Oral
COGNITIVE-ES-Tavonin	Tavonin			/ Day	Oral

4.10.2.8 Turkey

List Name: ad.treatmentlist.cognitive.tr.csv

AtcCode	Name	Dose	Unit	Period	Route
COGNITIVE-TR-Tebokan	Tebokan				
COGNITIVE-TR-Gingus intens	Gingus intens				

4.10.3 Other Treatments of Interest

The reference list for Other Treatments of Interest is not reproduced in this document due to the very large number of entries. This list is based on the **standard ATC classification (WHO ATC, 2025 version)** and should be considered the authoritative reference for all substances falling under this category.

4.10.4 Non Pharmacological Treatments

List Name: ad.treatmentlist.nonpharma.csv

AtcCode	Name	Dose	Unit	Period	Route
NONPHARMA-Art Therapy	Art Therapy				
NONPHARMA-Cognitive rehabilitation	Cognitive rehabilitation				
NONPHARMA-Cognitive Stimulation Therapy (CST)	Cognitive Stimulation Therapy (CST)				
NONPHARMA-Mindfulness and Relaxation Techniques	Mindfulness and Relaxation Techniques				
NONPHARMA-Music Therapy	Music Therapy				
NONPHARMA-Neuropsychological Training	Neuropsychological Training				
NONPHARMA-Occupational Therapy	Occupational Therapy				
NONPHARMA-Physiotherapy	Physiotherapy				
NONPHARMA-Psychotherapy	Psychotherapy				
NONPHARMA-Reality Orientation Therapy	Reality Orientation Therapy				
NONPHARMA-Reminiscence Therapy	Reminiscence Therapy				
NONPHARMA-Speech Therapy	Speech Therapy				