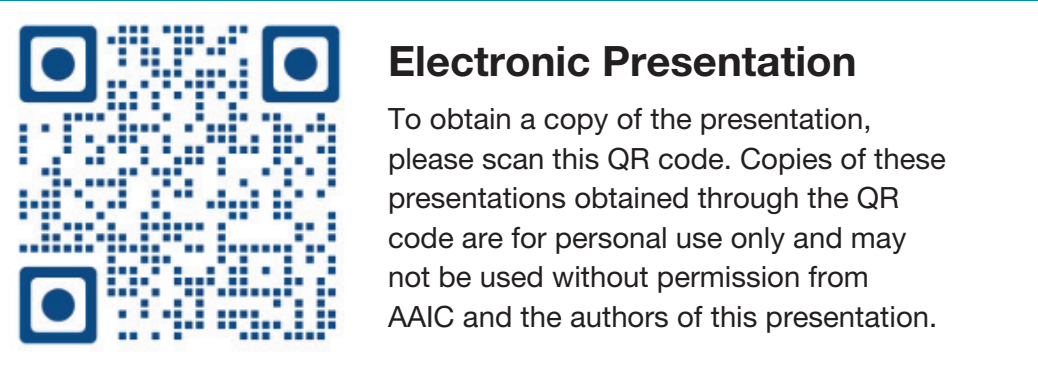


INITIATE-SC: A MULTICENTER REAL-WORLD STUDY OF SUBCUTANEOUS LECANEMAB INITIATION IN EARLY ALZHEIMER’S DISEASE

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Introduction

- In the US, lecanemab is indicated for the treatment of patients with MCI or mild dementia stage of AD.¹
- The initiation of treatment with lecanemab has been previously limited to IV infusions, while both IV and SC options have been approved for maintenance dosing after 18 months.¹
- The FDA is currently reviewing the supplemental Biologics License Application (sBLA) for a once-weekly 500 mg lecanemab administered by SC autoinjector (AI) as a starting dose for the treatment of early AD.²
- Clinical trials and real-world data have demonstrated the acceptability and utilization of SC administration during maintenance.^{3–7}
- INITIATE-SC is a prospective RWE study designed to characterize patient and care-partner experience, clinical implementation, and safety of 500 mg lecanemab SC AI weekly across diverse care settings in the US.
- This RWE study will help to:
 - Understand the real-world use, implementation, and experience with lecanemab SC AI across diverse populations and care settings.
 - Extend clinical study insights to broad, heterogeneous populations.
 - Capture variability in patient characteristics, provider practices, and health system workflows that cannot be fully represented in clinical studies alone.
 - Provide evidence on performance in everyday practice, helping to describe real-world patient selection and workflow approaches across different sites.

Methods

- **INITIATE-SC is a prospective, multicenter, observational, single-arm cohort study enrolling approximately 900 participants with early AD initiating SC AI lecanemab 500 mg across up to 25 US sites.**

Study Objectives and Design

- The INITIATE-SC study objectives are summarized in **Figure 1**.
- Participants from up to 25 sites will enroll into the study cohort at treatment initiation (index date is first SC AI dose) and be followed for up to 24 months, including the initiation period and maintenance phase (**Figure 2**).
- All treatment decisions, including dosing, monitoring, switching to/reinitiation of SC AI, and AE management, will follow routine care.
- A biomarker sub-study will evaluate longitudinal changes in AD-related biomarkers from treatment initiation to 24 months.

References: 1. LEQEMBI (lecanemab-irmb) prescribing information. Eisai Inc. <https://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf> (Accessed July 2026); 2. Press Release. Update on FDA Priority Review of LEQEMBI® IQLIK™ (lecanemab-irmb) Subcutaneous Injection as a Starting Dose for Early Alzheimer’s Disease. Eisai Inc. <https://www.eisai.com/news/2026/news202625.html> (Accessed July 2026); 3. Willis BA. Presented at the Alzheimer’s Association International Conference; Jul 16–20, 2023; Amsterdam, Netherlands; 4. Penner N, et al. Presented at the Alzheimer’s Association International Conference; Jul 27–31, 2025; Toronto, Canada; 5. Irizarry M, et al. Presented at the Alzheimer’s Association International Conference; Jul 27–31, 2025; Toronto, Canada; 6. Andreozzi E, et al. Presented at the Alzheimer’s Association International Conference; Jul 27–31, 2025; Toronto, Canada; 7. Turner RS, et al. Presented at the Alzheimer’s Association International Conference; Jul 27–31, 2025; Toronto, Canada.

Abbreviations: AD, Alzheimer’s disease; AE, adverse event; AI, autoinjector; ARIA, amyloid-related imaging abnormalities; ARIA-E, ARIA-edema/effusion; ARIA-H, ARIA-hemosiderin/microhemorrhage; EHR, electronic health record; FDA, US Food and Drug Administration; HCP, healthcare professional; IV, intravenous; MCI, mild cognitive impairment; MRI, magnetic resonance imaging; RE-AIM, Reach, Effectiveness, Adoption, Implementation, Maintenance; RWE, real-world evidence; sBLA, supplemental Biologics License Application; SC, subcutaneous; US, United States.

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Methods

Study Population

- **Cohort A:** approximately 800 *de novo* lecanemab participants who are starting treatment with lecanemab SC AI.
- **Cohort B:** up to 100 participants who initiate anti-amyloid treatment with IV administration and subsequently transition to SC AI within 6 months.
- Care partners of participants will have the option to enroll in this study.
- Key inclusion and exclusion criteria are summarized in **Figure 3**.

Figure 1. Study Objectives

Primary Objective	• To assess participant’s overall experience (acceptability, reported feasibility, satisfaction, quality of life, and confidence) during lecanemab SC AI treatment
Secondary Objectives	• To assess real-world treatment patterns associated with SC AI treatment • To assess care partner’s overall experience (acceptability, reported feasibility, satisfaction, quality of life, and confidence) during lecanemab SC AI treatment • To characterize real-world site workflows supporting SC AI administration, describing enablers and barriers • To assess participant’s disease stage in routine clinical practice based on clinician judgment and site-specific cognitive assessments • To characterize ARIA-E and ARIA-H events (incidence, timing, severity, resolution) captured through routine care after lecanemab 500 mg SC AI treatment • To characterize injection-site reactions reported during routine clinical care after lecanemab SC AI treatment
Exploratory Objectives	• To evaluate biomarker changes over time during lecanemab SC AI treatment • Cohort B: to assess the duration of IV treatment before transition and describe the reasons for transitioning to SC AI, as reported by the clinician, in participants who initiate anti-amyloid IV treatment and then transition to SC AI treatment

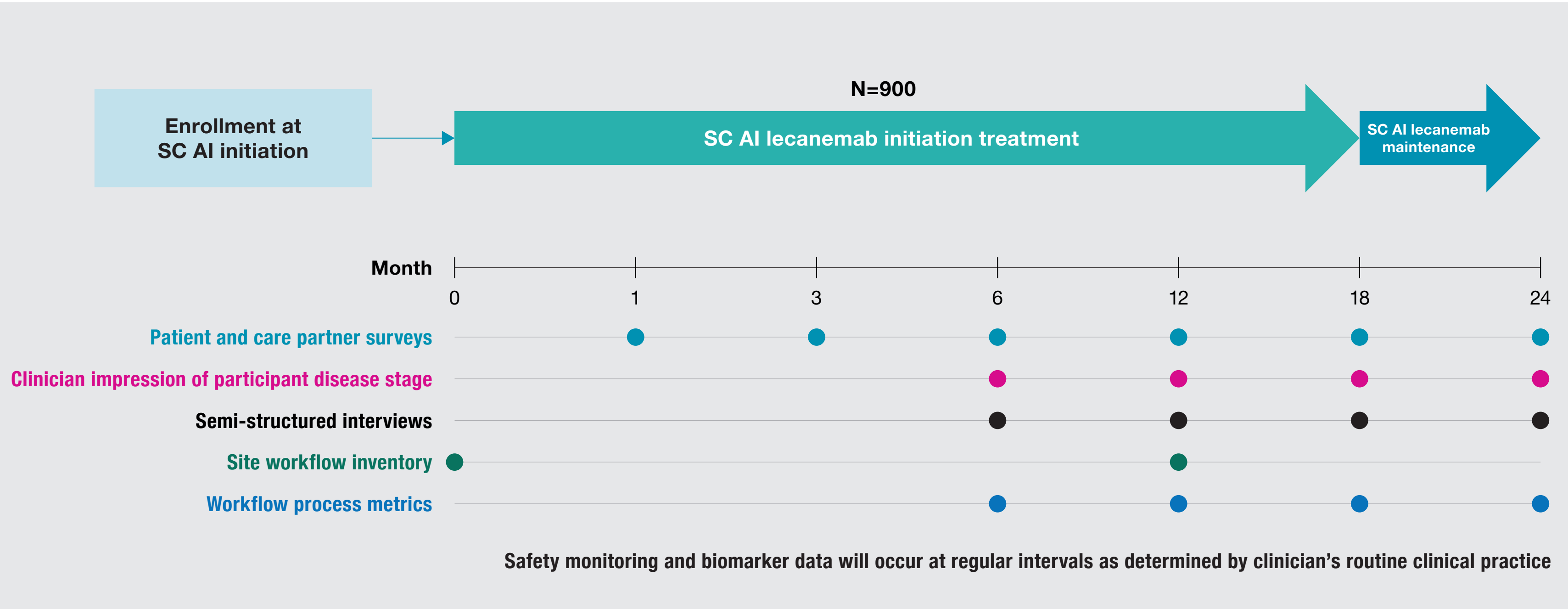
Figure 3. Inclusion and Exclusion Criteria for Participants and Care Partners

	Inclusion Criteria	Exclusion Criteria
Participants	• Participants in either cohort are eligible for treatment with lecanemab per the approved indication as determined by the treating clinician • Participants in either cohort are prescribed lecanemab SC AI for initiation by the treating physician either for the first time (Cohort A) or after transitioning from previously prescribed IV anti-amyloid treatment (Cohort B) as part of routine clinical care • Participants in either cohort are able and willing to provide informed consent for all aspects of the study on or shortly after the index date of the first dose of lecanemab SC AI	• Participants in either cohort are taking part in an interventional clinical study • Participants are not eligible for treatment with lecanemab as per approved label
Care Partners	• Care partners in either cohort, if present, are able and willing to provide written informed consent for all aspects of the study	• There are no exclusion criteria for care partners

Conclusions

- INITIATE-SC will characterize real-world adherence, persistence, patient and care-partner experience, and safety with SC AI lecanemab.
- Findings from the INITIATE-SC study may inform site workflows and implementation strategies to support scalable, high-quality SC AI care delivery across diverse clinical settings.

Figure 2. Study Design



Study Assessments

- Study assessment timing is summarized in **Figure 2**.
- **Patient and care partner surveys** to assess perceived treatment management, satisfaction, and overall experience, e.g., RE-AIM Framework.
- **Clinician impression of participant disease stage**, a single-item measure that uses a 3-item response scale: participant has improved, participant is stable, participant has progressed (in cognitive decline/AD).
 - Routine **cognitive and functional assessments** will be captured from the EHR. These assessments are not prespecified and will differ both in the assessment and cadence by site.
- Prospectively defined **workflow process metrics** to quantitatively assess workflow performance, including MRI scheduling, missed/delayed doses, and deviations from scheduled procedures.

Safety Monitoring, Biomarkers, and Additional Analyses

- **Safety monitoring**, including AEs (e.g., injection-related reactions) and ARIA reporting, at regular intervals as determined by clinician’s routine clinical practice.
- **Biomarker data** derived exclusively from routine clinical testing performed as part of site routine care and documented in the EHR.
- **Semi-structured interviews** with key site personnel, including investigators and study coordinators, to assess feasibility, acceptability, barriers and facilitators to implementation, and adherence to protocol-defined workflows.
- **Site workflow inventory**, developed in collaboration with site investigators to systematically document key SC AI-related workflows.
- Analyses stratified by age, sex, and region will be included.