

M142

PRACTICAL FACTORS INFLUENCING THE USE OF CONFIRMATORY BLOOD-BASED BIOMARKERS IN ALZHEIMER’S CARE

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Electronic Presentation

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Introduction

- Blood-based biomarkers (BBMs) are reshaping AD diagnostic pathways by enabling earlier, more accessible amyloid confirmation.¹
- Alzheimer’s Association Clinical Practice Guidelines (CPGs) recommend BBM tests as triage tools and alternatives to amyloid PET/CSF testing when performance thresholds are met.²
- Real-world implementation remains heterogeneous, with limited characterization of drivers across settings.³
- An aim of this prospective, multi-site implementation science study was to explore barriers and facilitators of confirmatory BBM use in routine clinical practice and assess variation across settings.

Methods

- Semi-structured interviews and focus groups were conducted with clinicians and support personnel across 3 clinical settings (rural private, academic, and private neurology) to capture clinical, operational, and logistical perspectives on BBM implementation.
- Qualitative analysis was conducted using the Consolidated Framework for Implementation Research (CFIR v2) as a guiding structure to identify themes related to implementation barriers, facilitators, workflow integration, and operational processes.⁴
- Confirmatory BBMs were defined as high-performing tests meeting CEOi criteria for identifying amyloid pathology without the need for follow-up testing, with results interpreted within the clinical context (per CPGs).^{2,5}

Results

Study Population

- A total of 13 participants across rural (n=5), academic (n=5), and private neurology clinic (n=3) settings completed 1:1 interviews, and a subset participated in 2 focus groups (September–November 2025).
- Participants included clinicians (n=10) and clinical support personnel (n=3).

BBM Implementation Themes

- Across settings, convergence indicated that BBM implementation was primarily constrained by operational and system-level factors rather than clinical confidence in BBM testing (**Figure 1**).

Implementation Drivers

- Workflow design was a dominant driver of BBM implementation (**Figure 2**), while system-level factors, such as financial navigation, reimbursement limitations, and regulatory gaps were identified as key barriers.

Clinical Setting Variation

- Successful BBM implementation was associated with integrated clinical workflows, structured follow-up, and standardized testing and interpretation. Implementation varied by site due to differences in infrastructure, access, and system complexity (**Figure 3**).

Priorities for Scalable Implementation

- Key requirements for scalable implementation of confirmatory BBMs are summarized in **Figure 4**.

Results

Figure 1. Agreement Across Key BBM Implementation Themes

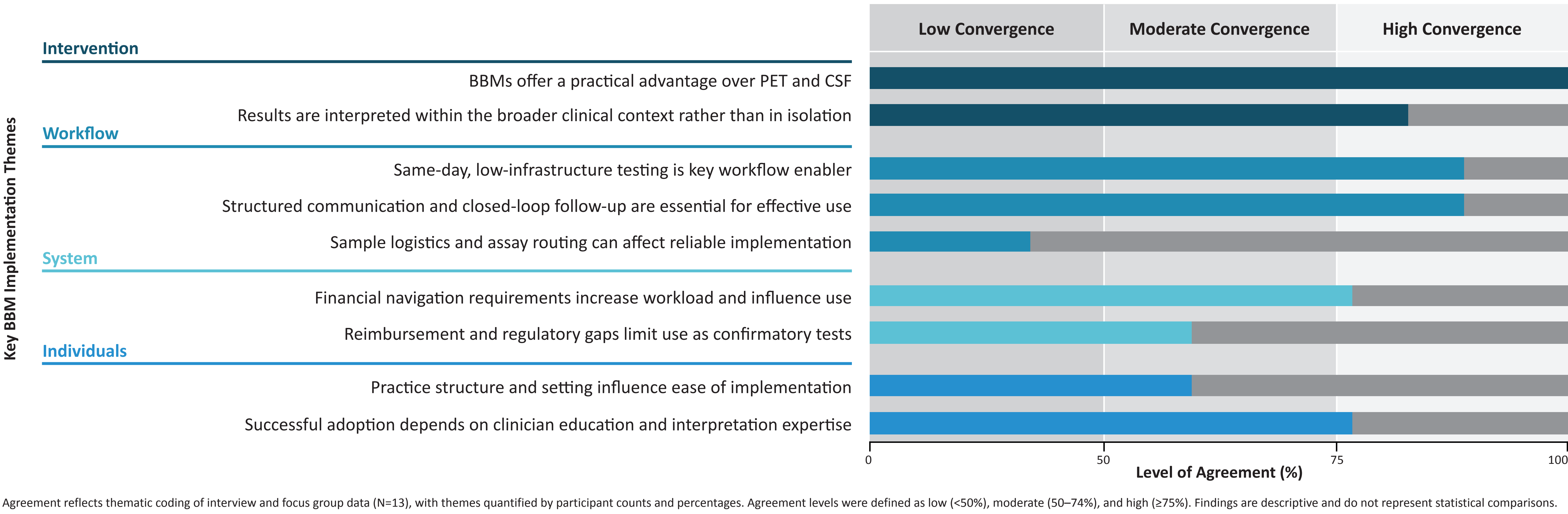


Figure 2. BBM Implementation: Pathway Facilitators and Barriers

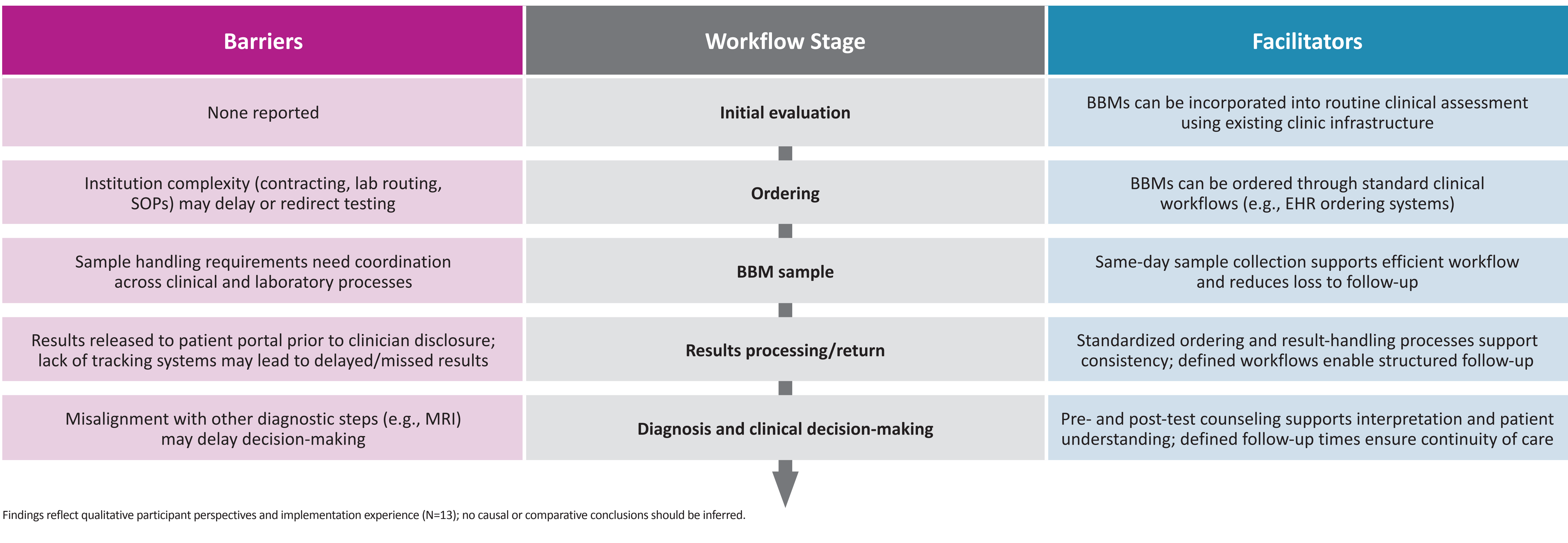


Figure 3. Variation in BBM Implementation Across Clinical Settings

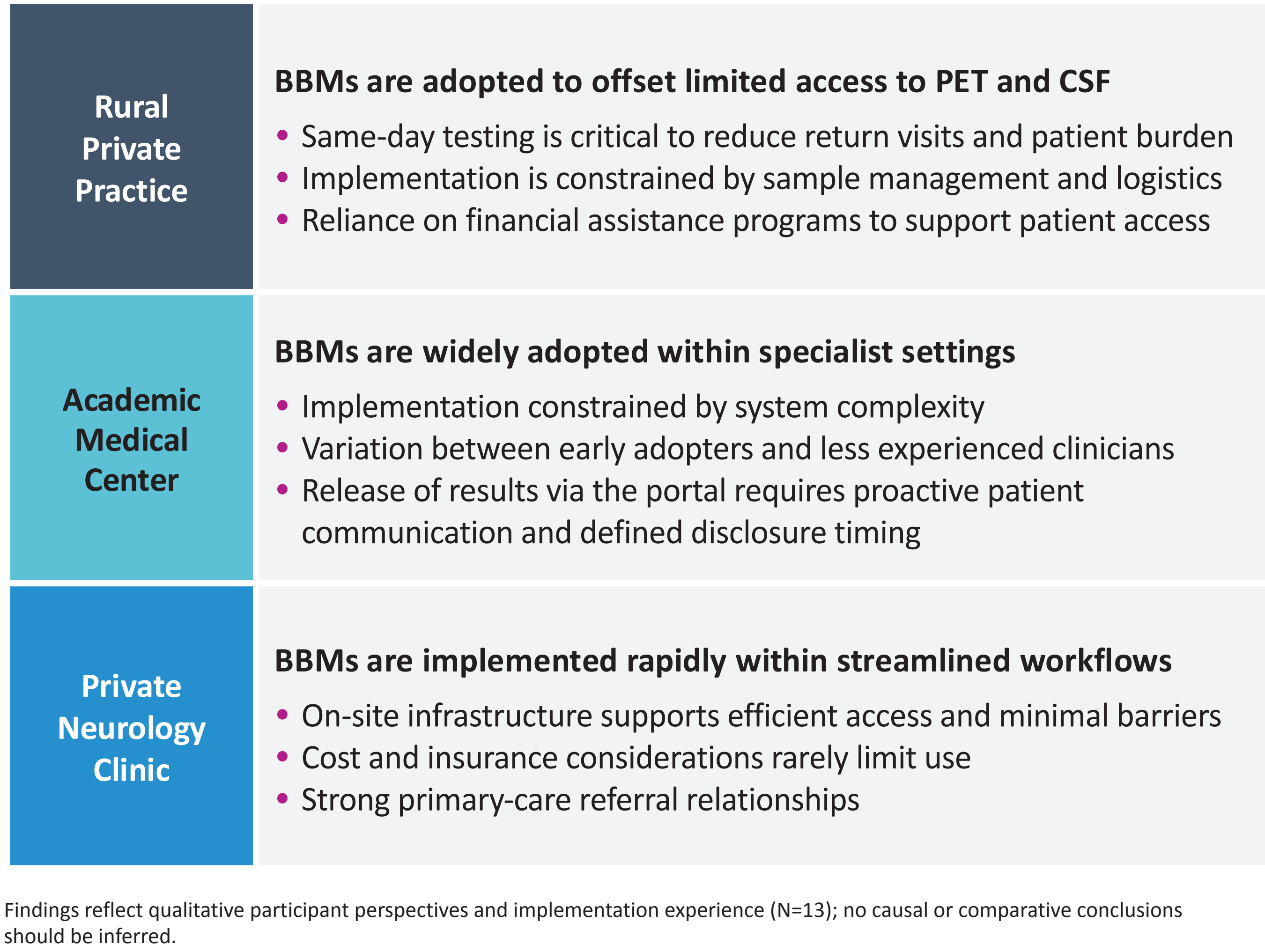
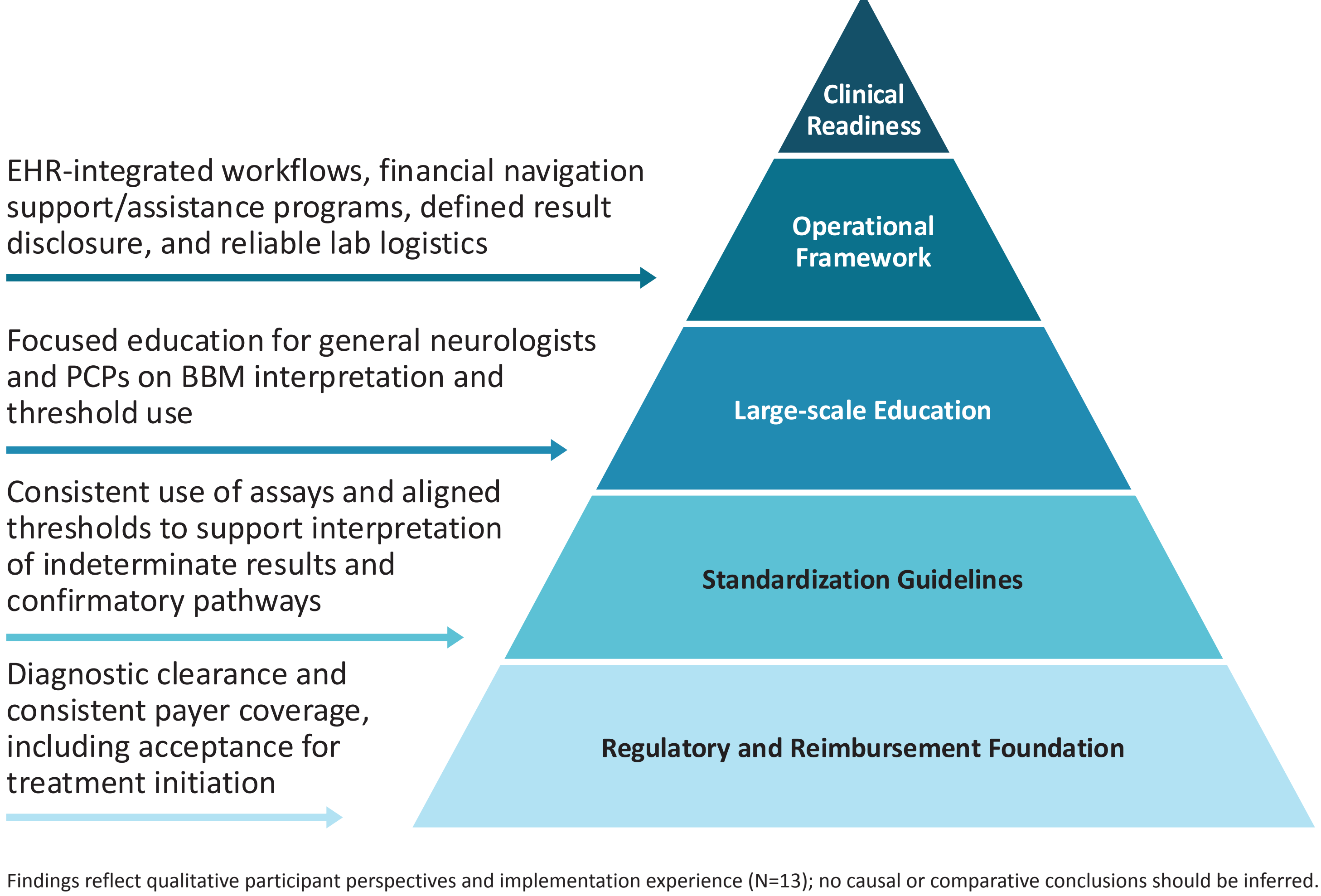


Figure 4. Key Requirements for Scalable Implementation of Confirmatory BBMs



Conclusions

- Confirmatory BBMs were clinically acceptable and operationally adaptable across diverse practice settings in this prospective, multi-site study.
- Implementation was constrained by operational and system-level factors, including workflow capacity, financial navigation, reimbursement limitations, and regulatory gaps, rather than clinical uncertainty in BBM testing.
- Same-day testing with defined follow-up emerged as a key workflow enabler, particularly in settings with limited access to PET and CSF.
- Scalable implementation will require improved education and standardization, including clinician training and consistent assay platforms and interpretation frameworks.
- Findings indicate that successful BBM implementation depends on coordinated system, operational, and clinical readiness, rather than increased test availability alone.
- Observed variability may not capture the range of clinical workflows, highlighting the need for broader representation to strengthen generalizability.

References: 1. Palmqvist S, et al. *Alzheimers Dement*. 2025;21:e70535. 2. Schöhl M, et al. *Lancet Healthy Longev*. 2024;5:100630. 3. Prufert Q, et al. *Alzheimers Dement*. 2025;21:e70891. 4. Damschroder LJ, et al. *Implement Sci*. 2022;17:75. 5. Schindler SE, et al. *Nat Rev Neurol*. 2024;20:426–439. **Abbreviations:** AD, Alzheimer’s disease; BBM, blood-based biomarker; CFIR, Consolidated Framework for Implementation Research; CSF, cerebrospinal fluid; EHR, electronic health record; MRI, magnetic resonance imaging; PCP, primary care physician; PET, positron emission tomography; SOP, standard operating procedure. **Acknowledgments:** The study was conducted by Premier Inc., funded by Eisai Inc. and Biogen. Medical writing support was provided by Panacea85, funded by Eisai Inc. and Biogen. **Disclosures:** Kimberly Petro is an employee of Eisai Inc. JEG reports NIH research support and consulting relationships with Beckmann Coulter, Biogen, BMS, CervoMed, Cognition Therapeutics, Cognivue, Eisai, Eli Lilly, GE Healthcare, Genentech, Lobe, and Roche. LZ receives consulting fees from Novartis and Eisai. ABA is a principal investigator for Eisai Inc., Eli Lilly, Bristol Myers Squibb, Cassava, and Novo Nordisk. MNS has stock/stock options in Alzheon and Lighthouse Pharmaceuticals, is on the Board of Directors for CervoMed, and receives consulting/speaker fees from AbbVie, Alzinova, Anavex, Cognito Therapeutics, Eisai, GSK, NeuroTherapia, Otsuka, Recall Therapeutics, and Signant. RSD receives speaker/consulting fees from Eli Lilly and Amgen; serves as a principal investigator for Abbvie, Alnylam, Ariobio, Biogen, Biohaven, Eisai, Eli Lilly, ONO pharma, and Vima. DG serves as editor of Alzheimer’s Disease Research and Treatment; membership on data safety monitoring boards for Elan and Janssen; participation as an investigator in trials sponsored by Eli Lilly and Avid; and NIH research support (P50 AG05131 [PI] and U01 AG10483 [co-investigator]). SM serves on the board of directors of Sensio Systems and scientific advisory boards of Alzpath, BMS, and Boston Millennia Partners; receives consulting fees from Biogen, C2N, Eisai, Genentech, Novartis, Novo Nordisk, and Roche-Genentech; and is principal investigator on research contracts between USC and Biogen, Eisai, C2N, and Roche-Genentech. MMM receives research funding from NIH/NIA, the Department of Defense, the Alzheimer’s Association, and the Davos Alzheimer’s Consortium; serves as Senior Editor for Alzheimer’s Research and Therapy and Alzheimer’s & Dementia; and receives consulting/advisory fees from Althira, Biogen, Cognito Therapeutics, Eisai, LabCorp, Eli Lilly, Merck, Neurogen Biomarking, Novo Nordisk, Roche, and Siemens Healthineers. NJG is an employee of Premier Applied Sciences, Premier Inc., which received funding from Eisai Inc. for the study. CA, FF, and DRJ are employees of Eisai Inc.