

The CLEAR Team Protocol: A Randomized Controlled Trial of a Streamlined Approach to Amyloid-Targeting Therapy Screening



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We anticipate that blood-based biomarker pre-screening combined with telehealth digital literacy assessment and education will reduce time to determination of eligibility for amyloid targeting therapies

BACKGROUND

- Amyloid Targeting Therapy (ATT) eligibility process for individuals with Alzheimer's Disease (AD) **spans 2–4 months** (i.e., APOE genetic testing, MRI brain, amyloid PET) – making it inefficient for timely care
 - ~ **80%-95%** of individuals evaluated will be **found ineligible** for ATT
- The **Cognitive and Laboratory Evaluation for Amyloid-Related Therapy (CLEAR) Telehealth-mediated (Team) Protocol** streamlines early identification, cognitive evaluation, and eligibility determination for ATT candidates
 - Developed using the **Reach, Efficacy, Adoption, Implementation, Maintenance (RE-AIM)** framework.

OBJECTIVES

- Describe the CLEAR Team Protocol
- Evaluate preliminary data on the effectiveness of the CLEAR Team Protocol:
 - Efficiency of determining eligibility for ATTs
 - Healthcare resource utilization

PARTICIPANTS

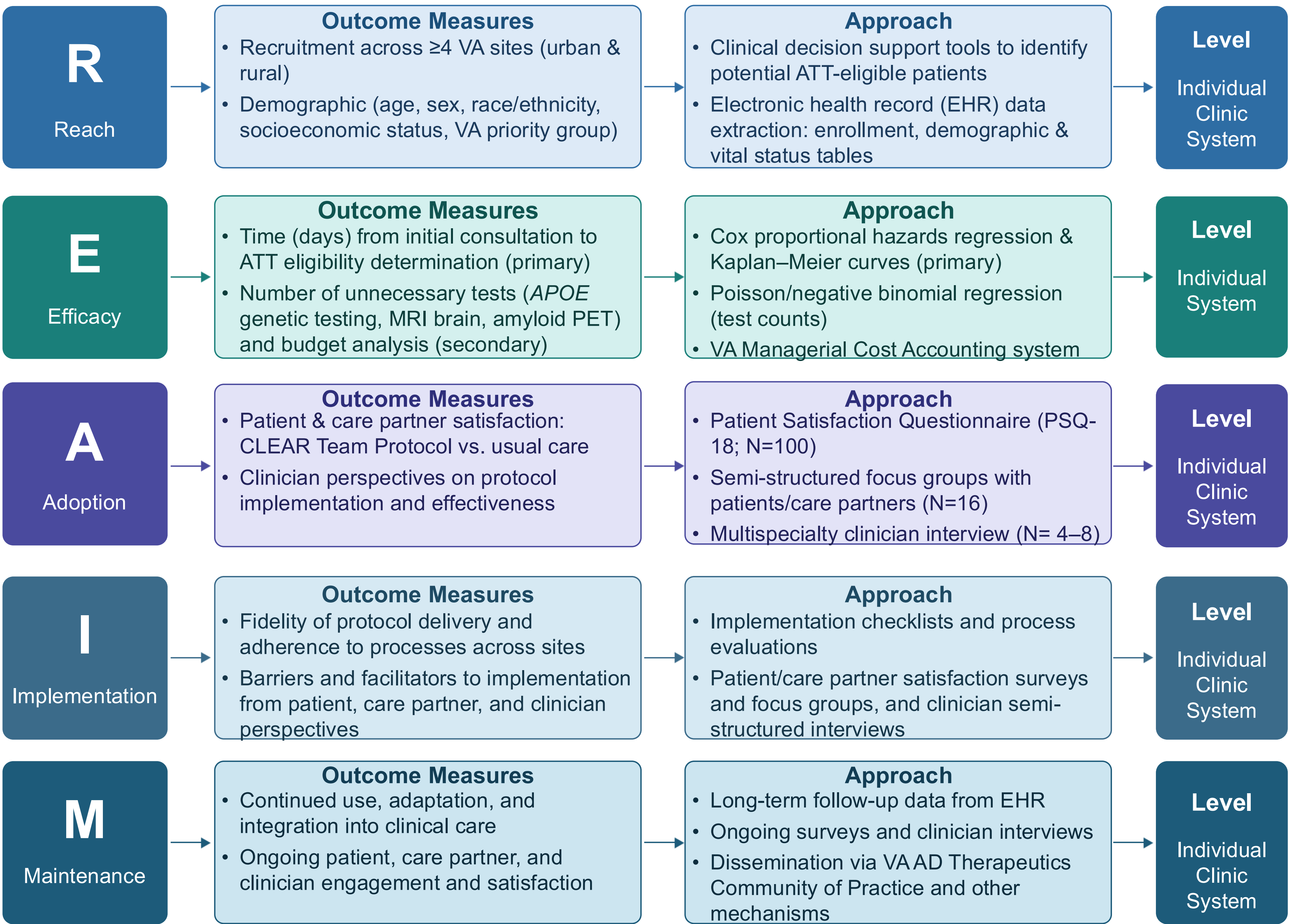
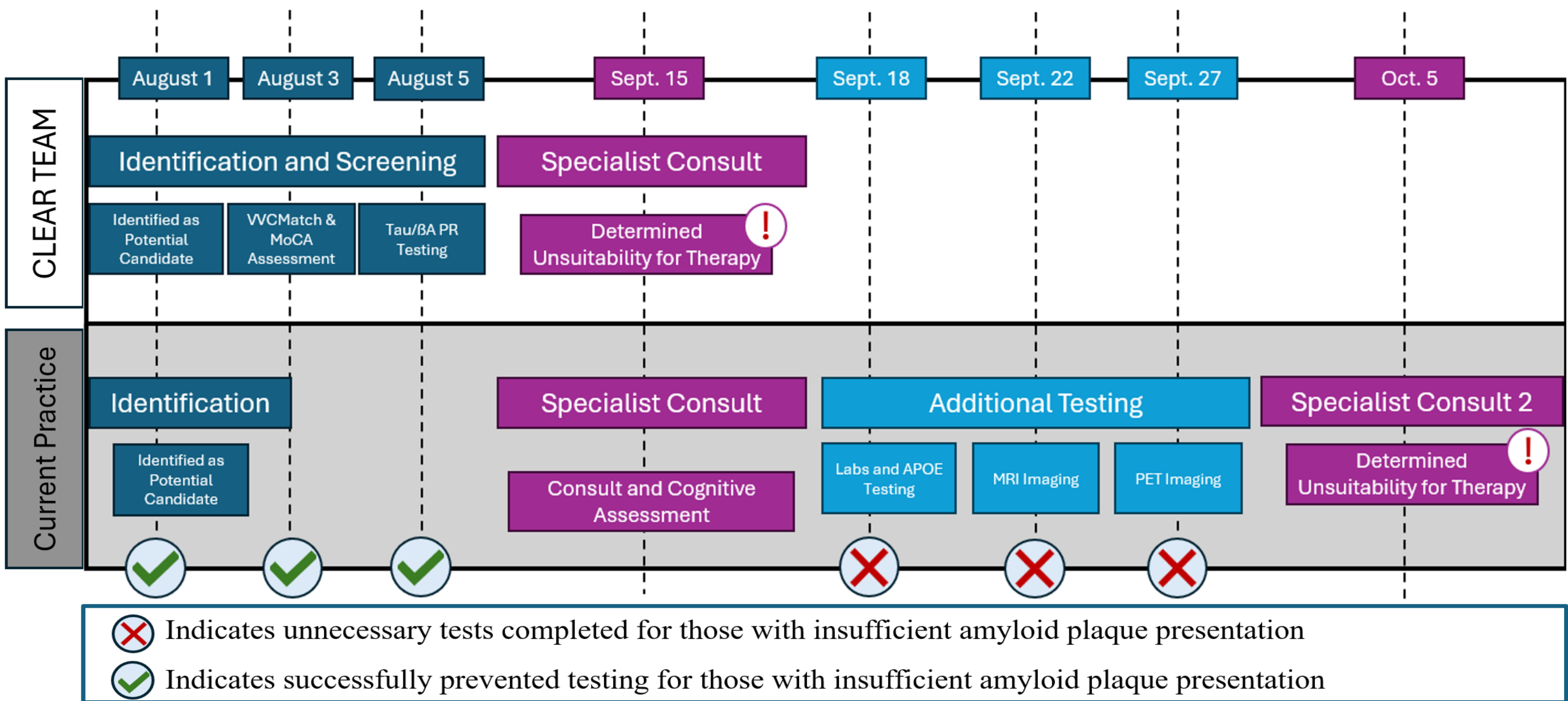
- Veterans ≥ 60 years old with a suspected diagnoses of mild cognitive impairment or mild dementia due to AD who are potentially eligible for ATTs based on chart review

METHODS

- Randomized to intervention or control
 - Intervention (CLEAR Team Protocol):**
 - Pre-consultation **blood-based biomarkers** collected (phosphorylated tau 217 (pTau-217) and beta amyloid 42/40 ratio)
 - Telehealth digital literacy assessment (**VVCMATCH**) to determine appropriateness, and provide education as needed
 - Control:** Clinician-determined usual care

OUTCOME MEASURES

- Primary:** Time to ATT eligibility determination
- Secondary:**
 - Healthcare utilization (i.e., APOE genetic tests, brain MRIs, and amyloid PET scans)
 - Healthcare costs
 - Telehealth utilization
 - Patient, care partner, and clinician satisfaction



PRELIMINARY RESULTS

- As of 06/24/2026, 19 participants enrolled (11 control group, 8 intervention group); target N=100 (50 per group).
- N=10 participants** (Control: N=6; CLEAR Team: N=4) reached ATT eligibility determination
- Time to ATT eligibility determination**
 - Control:** mean 64 days (range 55–157)
 - CLEAR Team:** mean 6 days (range 0–21)
- Testing Utilization:**
 - Control:** 4/6 APOE, 3/6 MRI, 1/6 PET
 - CLEAR Team:** 1/4 APOE, 0/4 MRI, 2/4 PET

PLANNED STATISTICAL ANALYSIS

- Primary outcome:** Kaplan-Meier survival curves and Cox proportional hazards models
- Secondary outcomes:** Poisson or negative binomial regression
- Continuous outcomes:** Linear regression or appropriate nonparametric methods

SATISFACTION WITH CARE

- Patient/care partner satisfaction**
 - Self-reported satisfaction surveys
 - Focus groups
- Clinician satisfaction**
 - Semi-structured interviews
- Goal:** To gather in-depth insights into patient, care partner, and clinician experiences, perspectives, and challenges with the CLEAR Team Protocol in clinical practice

CONCLUSIONS

- The CLEAR Team Protocol improves efficiency in ATT clinical screening and eligibility determination by identifying ineligible patients earlier, streamlining diagnostic workflows, and supporting the use of telehealth.
- Preliminary result suggest that the CLEAR Team Protocol **reduced the time to ATT eligibility determination, and reduced healthcare utilization**
- If effective, this approach may accelerate treatment eligibility determination while reducing unnecessary testing and improving care efficiency

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