Recalla

# Validation Roadmap

A staged path from prototype framework to responsible evidence generation.

**Document status: Public resource / technical preview.** This document describes Recalla as a prototype-stage cognitive monitoring concept using voice-first cognitive biomarker signals. It does not present clinical validation or diagnostic claims.

## Overview

This roadmap describes how Recalla can responsibly move from a prototype-stage CARE Engine framework to expert-reviewed, evidence-generating validation work. It is not a claim that validation has already been completed.

## Stage 1: Internal Feasibility

- Create synthetic data pipeline and demo outputs.
- Review CARE Score interpretability and report language.
- Document limitations, failure modes, and unsafe claims to avoid.
- Perform internal usability checks with non-clinical synthetic scenarios.

## Stage 2: Expert Review

- Seek feedback from cognitive neurology, speech-language pathology, dementia-care, and digital biomarker experts.
- Review whether the clinical framing is responsible and understandable.
- Update feature dictionary, report language, and safety boundaries based on expert feedback.
- Do not list any advisor publicly without explicit permission.

## Stage 3: Benchmark Dataset Evaluation

- Identify public or licensed datasets with appropriate permissions.
- Define evaluation questions before running analysis.
- Report limitations and bias risks clearly.
- Avoid clinical claims from benchmark performance alone.

## Stage 4: Feasibility Pilot

- Plan a small 30-50 participant feasibility study if approved by relevant advisors/ethics pathways.
- Measure adherence, usability, signal stability, report usefulness, and participant experience.
- Collect qualitative feedback from caregivers or clinicians when appropriate.
- Keep outputs non-diagnostic and human-reviewed.

## Stage 5: Clinical Validation

- Develop formal study design with qualified clinical collaborators.
- Use appropriate ground truth or reference standards.
- Evaluate sensitivity, specificity, reliability, bias, calibration, and clinical utility only where applicable.
- Make claims only when supported by validated evidence and regulatory review.

## Evidence Matrix

| Evidence Type | Purpose | When to Publish |
|---|---|---|
| Synthetic demo | Show technical structure without patient data. | Now |
| Expert review notes | Show clinical responsibility and iteration. | After permission / de-identified summary |
| Benchmark report | Show performance exploration on approved datasets. | After dataset permission and careful limitations |
| Feasibility pilot report | Show usability and adherence evidence. | After ethics/privacy review and participant consent |
| Clinical validation paper | Support clinical claims if evidence allows. | Only after formal study completion |

## Success Metrics

- Check-in completion rate and longitudinal adherence.
- Report understandability for caregivers and clinicians.
- Signal stability across repeated check-ins.
- Safety of language and avoidance of diagnostic overreach.
- Expert acceptance of validation direction and risk boundaries.

## References and Background Sources

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4. Digital Medicine Society. Defining Digital Medicine. https://dimesociety.org/newsroom/blog/laying-the-foundation-defining-digital-medicine/
5. Alonso et al.. Definitions of digital biomarkers: a systematic mapping of the biomedical literature. https://pmc.ncbi.nlm.nih.gov/articles/PMC11015196/