Recalla

Responsible Use & Safety Brief

Clinical safety boundaries and responsible-use principles for Recalla.

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.

Purpose

This brief defines how Recalla should be described, reviewed, and used during its prototype and validation-readiness stage. It is intended for advisors, pilot partners, reviewers, and early collaborators.

Intended Direction

- Support longitudinal cognitive monitoring through short voice check-ins.
- Provide structured trend summaries for caregiver and clinician review.
- Help identify when a human review or follow-up conversation may be useful.
- Create a responsible validation pathway before any clinical claims are made.

Not Intended For

- Diagnosis of dementia, Alzheimer's disease, mild cognitive impairment, or any medical condition.
- Emergency assessment, crisis response, or urgent clinical triage.
- Replacing physician evaluation, cognitive screening, neuropsychological testing, or clinical judgement.
- Making medication, treatment, insurance, employment, or eligibility decisions.
- Processing real patient data without ethics, privacy, consent, and data-protection review.

Language Rules

Avoid Saying	Use Instead
Detects dementia	Supports longitudinal cognitive monitoring
Diagnoses Alzheimer's	Not intended for diagnosis
Clinically validated	Validation pathway planned / validation in progress only when true
Predicts cognitive decline	Tracks change from baseline in repeated check-ins
Better than screening tests	Complements formal assessment with between-visit context

HIPAA compliant / FDA ready	Designed with privacy and responsible-use principles

Data and Consent Principles

- Explain clearly what information is collected and why.
- Obtain explicit consent before collecting voice or transcript data.
- Allow users to understand whether data is shared with caregivers or clinicians.
- Use synthetic or de-identified data for public demonstrations.
- Avoid public display of real voice recordings, transcripts, or medical history.

Human Review Principle

Any meaningful change signal should be treated as a prompt for human review, not as a clinical conclusion. The appropriate response may be a caregiver conversation, clinician review, or formal assessment depending on context.

Prototype Disclaimer

Recalla is a prototype-stage concept. It is not a diagnostic medical device. Any real-world healthcare deployment would require appropriate clinical validation, privacy review, ethics review, regulatory review, and qualified healthcare oversight.

References and Background Sources

1. FDA-NIH Biomarker Working Group. BEST Resource: Harmonizing Biomarker Terminology. https://www.fda.gov/media/99221/download
2. Digital Medicine Society. Defining Digital Medicine. https://dimesociety.org/newsroom/blog/laying-the-foundation-defining-digital-medicine/
3. Alonso et al.. Definitions of digital biomarkers: a systematic mapping of the biomedical literature. https://pmc.ncbi.nlm.nih.gov/articles/PMC11015196/