

From measurement to clinical benefit.

Three questions. Three types of evidence. No automatic shortcuts.

Validated for what?

START WITH THE INTENDED USE [1]

Specify the population, setting and decision. Evidence for diagnosis does not automatically support screening, prognosis or treatment monitoring.

01 MEASUREMENT

Analytical validation

Can we trust the measurement?

Establish that the method measures its target reliably, with error acceptable for its intended use. For laboratory assays, assess accuracy and bias, precision, selectivity, quantification limits, range and stability. [2]

Before measuring: check sample collection, processing and storage. Handling effects can mimic biological differences. [2]

Precision does not guarantee accuracy.

02 INTERPRETATION

Clinical validation

Can we trust the clinical meaning?

Test the claimed relationship with disease or a clinical outcome in the intended population. [6] For diagnosis, use a suitable reference standard, representative participants and independent data, with thresholds fixed before evaluation.

Report performance: sensitivity, specificity and their uncertainty, not only group differences. [3]

Group differences do not prove individual accuracy.

03 PATIENT BENEFIT

Clinical utility

Does using it benefit patients?

Compare care using the test with usual care or an alternative pathway. Assess patient-relevant benefits and harms, including missed cases, unnecessary follow-up and delays. [4]

In practice: the tool must also be usable by the intended people in the intended setting. [5]

Changing decisions does not prove benefit.

Evidence at one level does not establish the next. Requirements depend on the intended use.

What this means in neuroscience

ILLUSTRATIVE IMPLICATIONS

PET: correlation is not agreement.

A simplified method that always doubles a reference value can correlate perfectly without being interchangeable. Likewise, shortening one scan does not test repeatability across separate scans.

Blood, PET and digital: test added value.

An association with PET or p-tau does not establish that a digital score can replace those measures or improve care. It may offer complementary information. A digital cognitive assessment is not automatically a biomarker. [3,4,5]

BEFORE SAYING "VALIDATED", ASK

For which use, in whom, and with what evidence?

SELECTED SOURCES / CLICK TO READ

1 FDA - Context of use

3 FDA - Diagnostic test evaluation (2007)

5 FDA - Digital health technologies (2023)

2 FDA - Biomarker assay validation (2026)

4 NCI - Clinical utility

6 Goldsack et al. - V3 framework (2020)