

Clinical Validation Requirements

Clinical validation is the process of demonstrating the **safety and effectiveness of medical AI in a real clinical environment**

Analytical Validation

Verify that the algorithm works accurately as intended

Clinical Validation

Evaluate whether it provides meaningful results in actual clinical settings

Validation Design Considerations

Study Design: Prospective vs. Retrospective

Sample Size: Sufficient data to ensure statistical power

Control Group: Compare with existing standard of care or clinical judgment

Endpoints: Sensitivity, Specificity, AUC, Clinical Outcomes

Subgroup Analysis: Evaluate demographic diversity

Performance Metrics

Sensitivity, Specificity, PPV, NPV, AUC

Clinical Impact

Diagnostic accuracy, treatment outcomes, patient safety

Bias Assessment

Performance consistency across race, gender, and age

Real-World Evidence

- Performance data in actual clinical settings
- Post-market surveillance data
- Registry studies

- Electronic Health Record (EHR) analysis

 **Key Point:** Clinical validation must go beyond simple algorithm accuracy to demonstrate improvement in patient outcomes within actual clinical workflows