

## 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