

Clinical Validation Study

Research Protocol

- Study Design and Objectives
- Inclusion/Exclusion Criteria
- Sample Size Calculation

Validation Metrics

- Diagnostic Accuracy
- Sensitivity and Specificity
- Positive/Negative Predictive Value

Clinical Evaluation

- Expert Comparison Study
- Real Clinical Environment Testing
- Patient Safety Assessment

Regulatory Compliance

- IRB Approval
- FDA/CE Certification Preparation
- Clinical Trial Documentation