

Clinical Validation Requirements (Clinical Validation Requirements)



Validation Protocol

- Independent test dataset (minimum 100-500 cases)
- Multi-center Validation
- Expert evaluation (Gold Standard)
- Prospective vs Retrospective study



Re-validation Criteria

- On model architecture change
- Training data distribution change > 10%
- Addition of new disease or subtype
- Performance variation > 5%



Performance Metrics

- Sensitivity \geq 90%
- Specificity \geq 85%

- AUC ≥ 0.90
- Subgroup performance evaluation (age, gender, race)