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 ≥ 90%

- Specificity ≥ 85%

- AUC ≥ 0.90

- Subgroup performance evaluation (age, gender, race)