

Documentation Standards (Documentation Standards)

Required Documents

- Model Card: Model characteristics, performance, limitations
- Data Card: Training data source, characteristics, bias
- Technical Documentation: Architecture, hyperparameters
- Clinical Documentation: Usage guidelines, contraindications

Audit Trail

- All model versions and change history
- Training data lineage (Data Lineage)
- User access logs
- Prediction results and feedback records

Document Templates

- Version Release Notes: Change summary
- Validation Reports: Detailed validation results
- Risk Assessment: Risk analysis and mitigation plan

- User Manual: User guide