Enterprise Architecture Compliance Checklist (Life Sciences)

# 1. General Information

• Project/Initiative Name: Global Clinical Trial Platform  
• Project ID: CT-2025-01  
• Reviewer: EA Governance Lead  
• Date of Review: 2025-09-02  
• Version: 1.0

# 2. Checklist Categories

## A. Business Alignment

[x] Supports Clinical Development strategy  
[x] Engages Regulatory Affairs and Clinical Operations stakeholders  
[ ] Business case approved by Portfolio Committee

## B. Application Architecture

[x] Application integrates with Electronic Data Capture (EDC) system  
[x] Reuses standard APIs for safety reporting  
[ ] Legacy decommission plan defined

## C. Data Architecture

[x] Clinical trial data stored according to CDISC standards  
[x] Data retention aligned with GxP requirements  
[ ] Data anonymization plan for patient data

## D. Technology Architecture

[x] Hosted in validated GxP-compliant cloud  
[x] Disaster recovery plan documented  
[ ] Performance benchmarks validated

## E. Security Architecture

[x] HIPAA and GDPR requirements covered  
[x] Role-based access control implemented  
[ ] Annual penetration test scheduled

## F. Governance & Compliance

[x] Aligns with EA Principles (AP-01 Data Integrity, AP-02 Patient-Centric)  
[ ] Exceptions approved by QA  
[ ] Governance plan post go-live documented

# 3. Summary

• Total Checks: 18  
• Checks Passed: 13  
• Checks Failed: 5  
• Exceptions Granted: 2

# 4. Sign-off

• Reviewed By: Chief Architect  
• Date: 2025-09-02  
• Approval: Pending