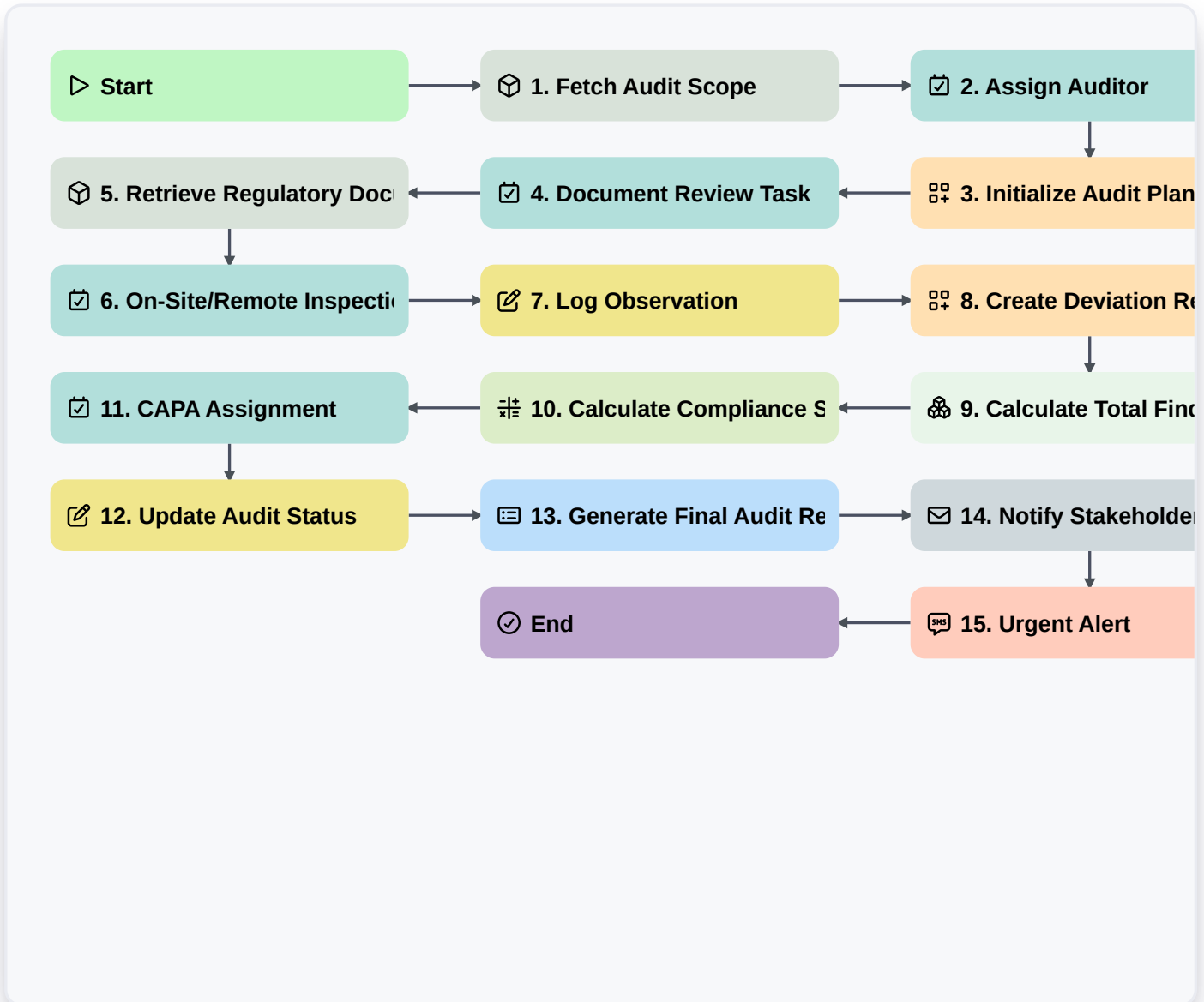


Good Clinical Practice (GCP) Compliance Audit



Start

Start of the Workflow/Process.

1. Fetch Audit Scope

Retrieve the specific clinical study details and site information from the Study Data Model to define the audit boundaries.

2. Assign Auditor

Create a task for the Lead Auditor to review the scope and formally assign an auditing team.

3. Initialize Audit Plan

Create a new entry in the Audit Plan Data Model containing the audit date, methodology, and checklist requirements.

4. Document Review Task

Create a task for the auditor to review essential regulatory documents (e.g., Investigator Brochure, Protocol).

5. Retrieve Regulatory Documents

Fetch all relevant regulatory documents from the Document Management Data Model for the selected study.

6. On-Site/Remote Inspection

Create a task for the active inspection phase where the auditor verifies source data against the CRF.



7. Log Observation

Update the Audit Finding entry with specific details, severity (Major/Minor/Critical), and evidence descriptions.

8. Create Deviation Record

Create a new entry in the Deviation Tracking model whenever a non-compliance issue is identified during the audit.

9. Calculate Total Findings Count

Aggregate all entries in the Audit Findings model to provide a total count of Major and Minor deviations found.

10. Calculate Compliance Score

Execute a formula to calculate the overall compliance percentage based on the ratio of passed vs. failed audit checkpoints.

11. CAPA Assignment

Create a task for the Study Manager to initiate Corrective and Preventive Actions (CAPA) for all critical findings.

12. Update Audit Status

Update the main Audit Entry status to 'Closed' once all findings have been addressed and signed off.

13. Generate Final Audit Report

Create a comprehensive PDF/Report summarizing the scope, findings, and compliance score for regulatory submission.

14. Notify Stakeholders

Send an email to the Clinical Operations Director and Sponsor with the final Audit Report attached.

15. Urgent Alert

Send an SMS to the Quality Assurance Lead if a 'Critical' level finding is recorded during the audit.

End

End of the Workflow/Process.