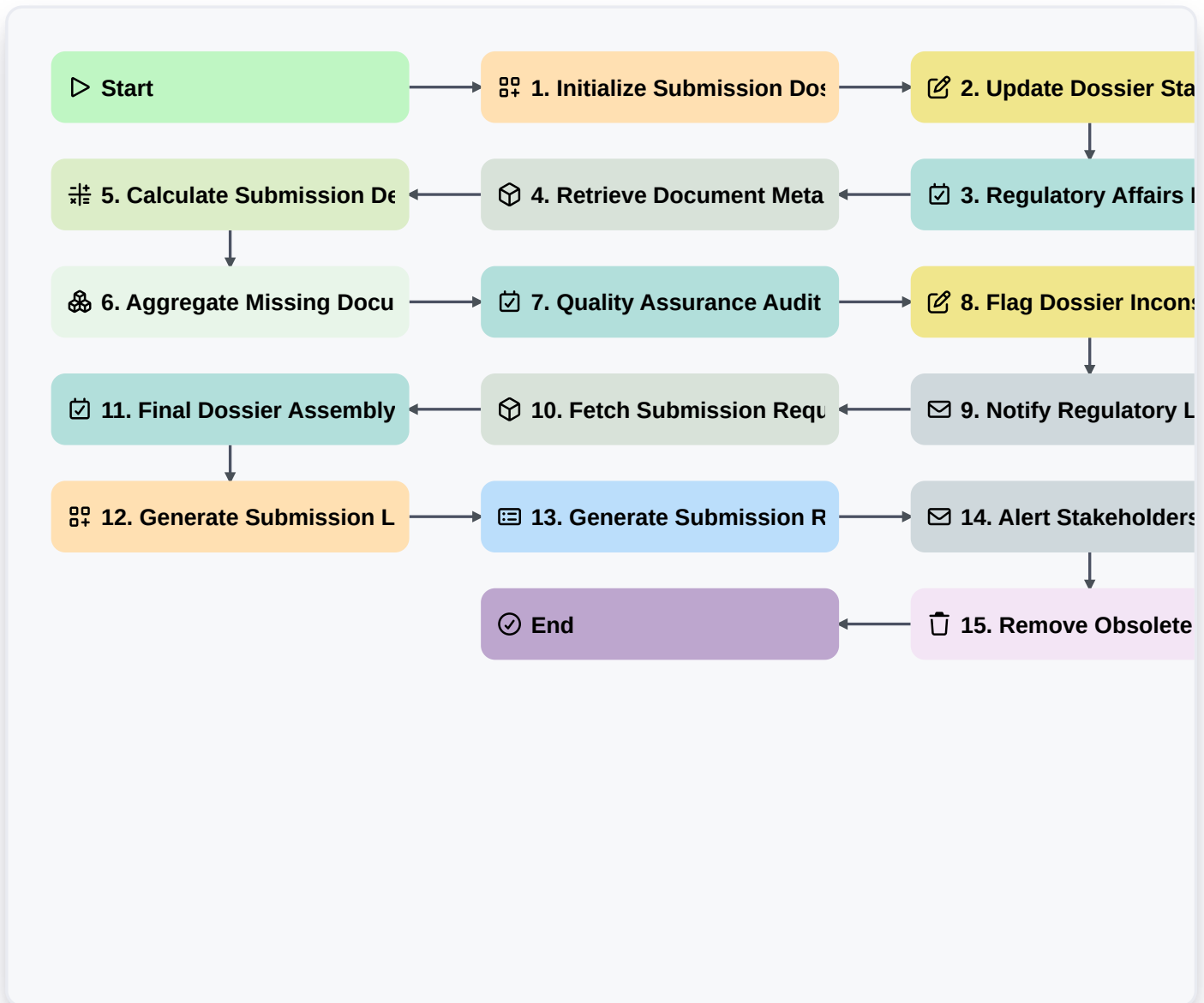


Regulatory Submission Dossier Management



▷ Start

Start of the Workflow/Process.

🗄️ 1. Initialize Submission Dossier

Create a new entry in the Dossier Data Model to start the submission lifecycle.

✍️ 2. Update Dossier Status

Update the status field of the Dossier entry (e.g., from 'Draft' to 'Review').

📋 3. Regulatory Affairs Review

Assign a task to the Regulatory Specialist to review the completeness of the dossier.

📦 4. Retrieve Document Metadata

Fetch all associated document entries (CMC, Clinical, Non-clinical) linked to the Dossier.

📅 5. Calculate Submission Deadline

Calculate the submission deadline based on the Dossier creation date plus a fixed regulatory lead time.

🔗 6. Aggregate Missing Document Count

Count the number of entries in the Document Model where the 'Status' field is not 'Finalized'.



📌 **7. Quality Assurance Audit**

Create a task for the QA team to verify the dossier against the checklist requirements.

✍️ **8. Flag Dossier Inconsistency**

Update the Dossier entry to set a 'Flagged' boolean to true if errors are found during review.

✉️ **9. Notify Regulatory Lead of Completion**

Send an automated email to the Regulatory Lead when the QA Audit task is marked as complete.

📦 **10. Fetch Submission Requirements**

Retrieve specific regulatory requirements from the Global Requirements Data Model based on the target region.

📌 **11. Final Dossier Assembly**

Create a task to compile all approved document entries into the final submission format.

📄 **12. Generate Submission Log**

Create a new entry in the Submission History model to record the final submission event.

📄 **13. Generate Submission Readiness Report**

Create a summary report showing the progress of all modules within the current dossier.

✉️ **14. Alert Stakeholders of Submission**

Send an email to the distribution list notifying them that the dossier has been officially submitted.

🗑️ **15. Remove Obsolete Drafts**

Delete temporary or superseded document entries from the data model after final assembly.

🏁 **End**

End of the Workflow/Process.