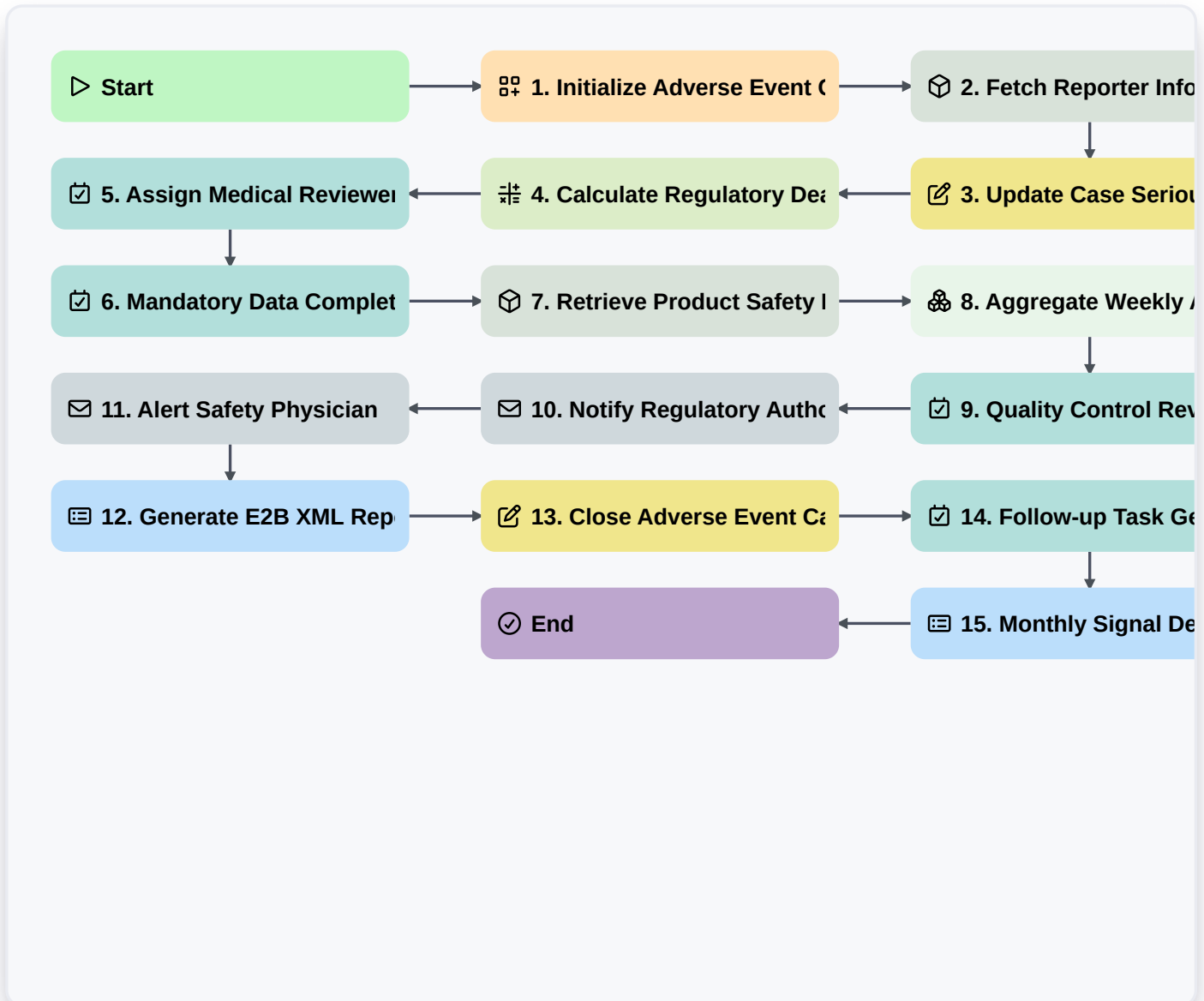


Pharmacovigilance And Adverse Event Reporting



Start

Start of the Workflow/Process.

1. Initialize Adverse Event Case

Create a new entry in the Adverse Event Data Model to capture initial intake details.

2. Fetch Reporter Information

Retrieve existing contact details from the Reporter Data Model using the provided identifier.

3. Update Case Seriousness

Update the current Case entry with updated seriousness criteria based on medical assessment.

4. Calculate Regulatory Deadline

Calculate the submission deadline by adding 7 or 15 days to the 'Date of Receipt' based on seriousness.

5. Assign Medical Reviewer

Create a task for a Medical Doctor to perform a causality assessment of the event.



📌 **6. Mandatory Data Completeness Check**

Verify presence of 4 minimum criteria: Patient, Reporter, Event, and Product.

📦 **7. Retrieve Product Safety Profile**

Get existing safety data from the Product Data Model to check for known signals.

🔗 **8. Aggregate Weekly AE Volume**

Sum the total number of new Adverse Event entries created in the last 7 days for trend analysis.

📌 **9. Quality Control Review**

Create a task for the QA specialist to verify the accuracy of the coded MedDRA terms.

✉️ **10. Notify Regulatory Authorities**

Send an automated email to the relevant Health Authority (e.g., FDA/EMA) with the case summary.

✉️ **11. Alert Safety Physician**

Send an urgent email alert to the Safety Physician if a 'Serious' event is identified.

📄 **12. Generate E2B XML Report**

Create a standardized regulatory-compliant report formatted for electronic submission.

✍️ **13. Close Adverse Event Case**

Update the status of the Case entry to 'Closed' and timestamp the closure date.

📌 **14. Follow-up Task Generation**

Create a follow-up task if the initial case entry is missing critical clinical information.

📄 **15. Monthly Signal Detection Report**

Create a monthly summary report aggregating all processed cases for the Safety Management Committee.

🏁 **End**

End of the Workflow/Process.