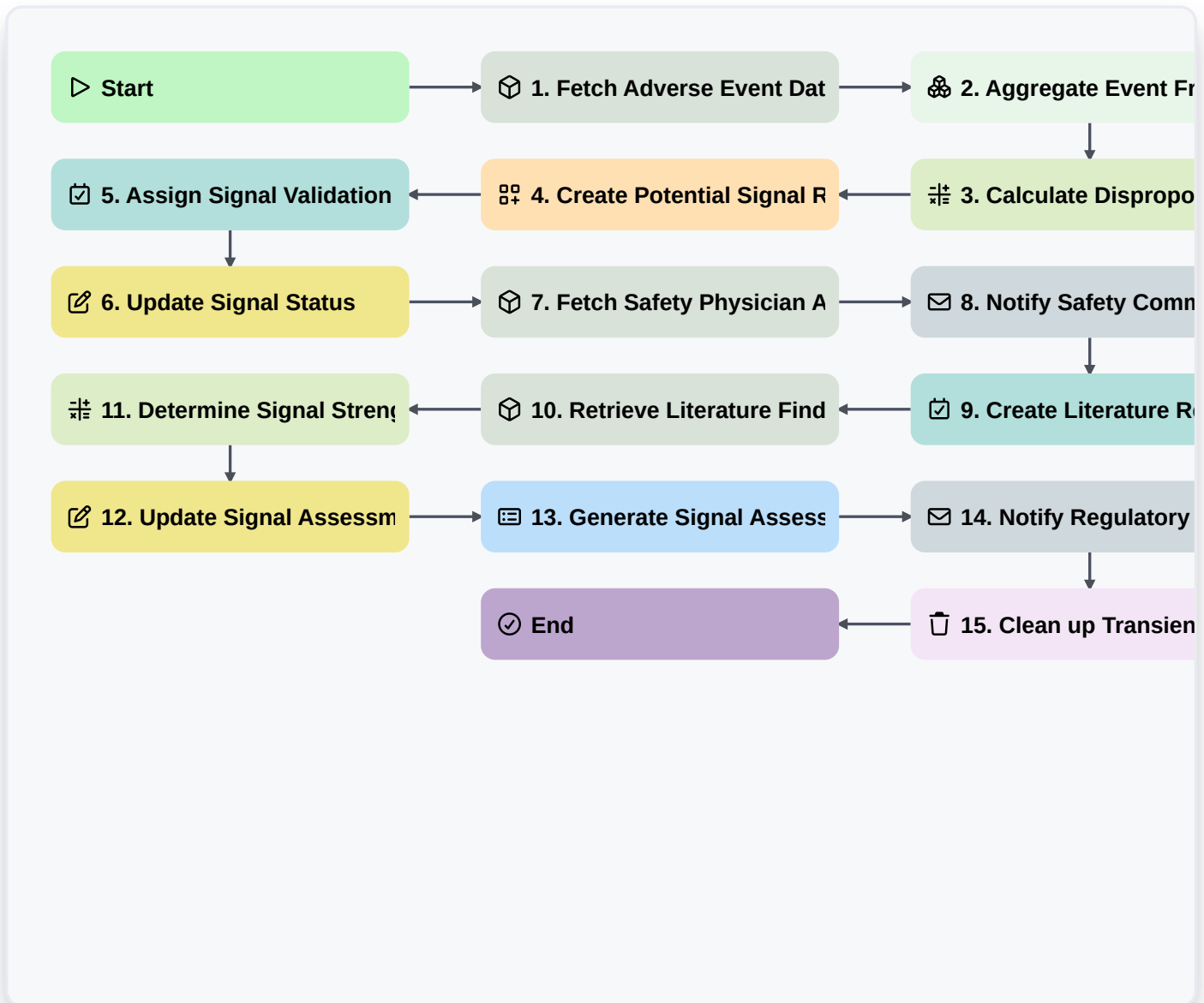


Drug Safety Signal Detection Process



Start

Start of the Workflow/Process.

1. Fetch Adverse Event Data

Retrieve all recent adverse event entries from the Pharmacovigilance Data Model for screening.

2. Aggregate Event Frequency

Calculate the total count and frequency of specific MedDRA terms across the retrieved dataset.

3. Calculate Disproportionality Index

Execute R-value or PRR (Proportional Reporting Ratio) calculations to identify statistical signals.

4. Create Potential Signal Record

Generate a new entry in the 'Signal Detection Log' for any case that exceeds the statistical threshold.

5. Assign Signal Validation Task

Create a task for a Drug Safety Physician to review the identified signal for clinical relevance.

6. Update Signal Status

Update the 'Signal Detection Log' entry to 'Under Review' once the validation task is assigned.



7. Fetch Safety Physician Assigned

Retrieve contact information and availability for the assigned Safety Physician from the User Data Model.

8. Notify Safety Committee

Send an email notification to the Safety Management Team regarding a newly detected potential signal.

9. Create Literature Review Task

Create a task for the Medical Writing team to perform a targeted literature search on the signal.

10. Retrieve Literature Findings

Pull data entries from the 'Literature Review' data model to assess evidence strength.

11. Determine Signal Strength Score

Calculate a weighted score based on literature evidence, clinical importance, and statistical significance.

12. Update Signal Assessment

Update the 'Signal Detection Log' with the final assessment decision (e.g., Validated, Non-Signal, or Follow-up Required).

13. Generate Signal Assessment Report

Create a formal PDF/Document report summarizing the signal detection process, data, and conclusion.

14. Notify Regulatory Affairs

Send an email to the Regulatory Affairs department if the signal is validated and requires potential labeling changes.

15. Clean up Transient Screening Data

Delete temporary screening calculation entries from the system to maintain data hygiene after process completion.

End

End of the Workflow/Process.