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Adverse event reporting and pharmacovigilance

This workflow automatically processes adverse event reports from multiple sources, performs safety signal detection, and generates regulatory submissions to ensure compliance with pharmacovigilance requirements.

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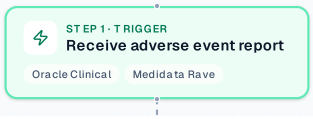
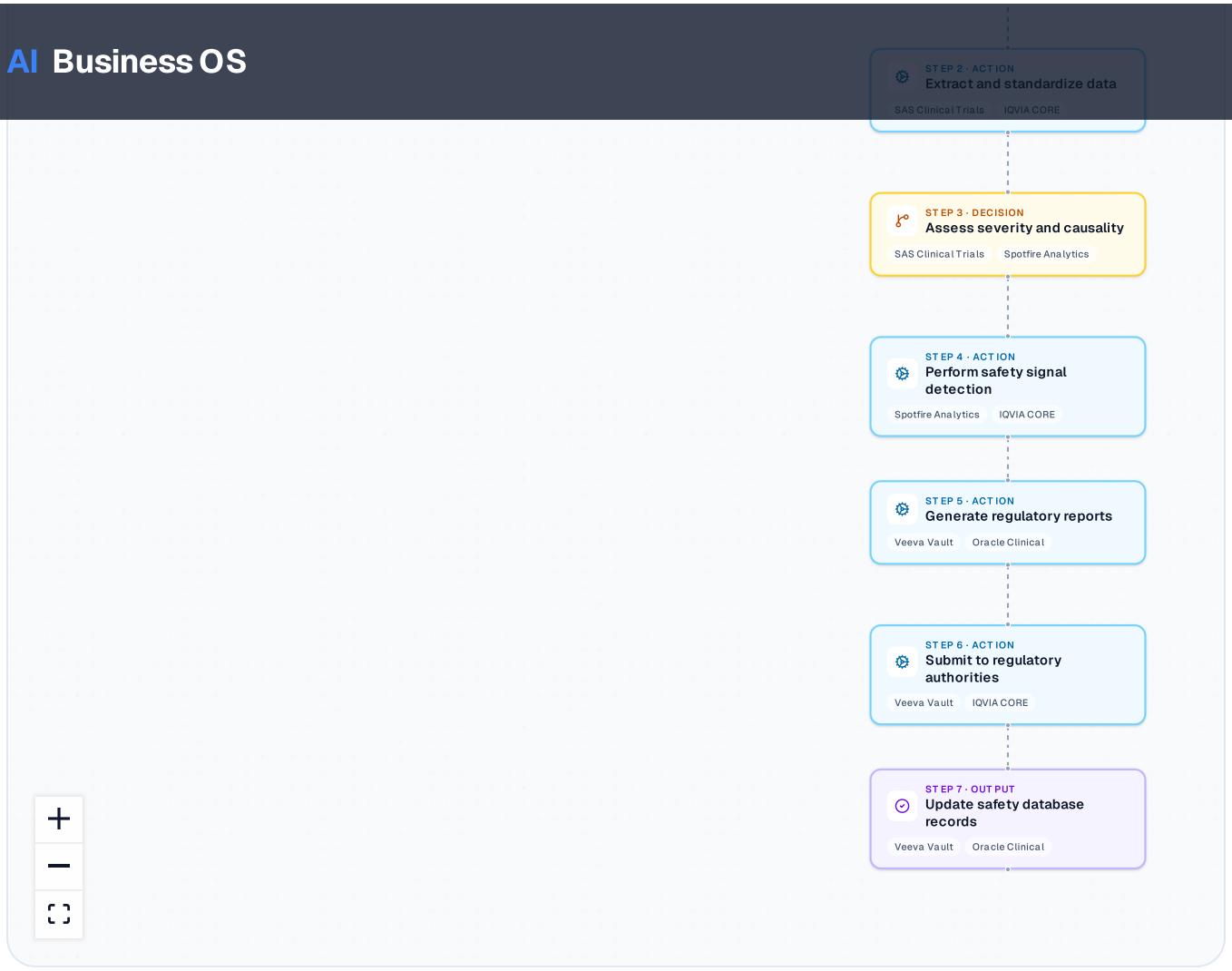
WORKFLOW TRIGGER

Adverse event report is submitted through patient portal, healthcare provider, or clinical trial system.

Visual Flow

Each node represents an automated step. Connections show how data and decisions move through the workflow.





Step-by-Step Breakdown

Detailed explanation of each automated stage in the workflow.

1

TRIGGER

Receive adverse event report

System detects incoming adverse event report from various sources including patient portals, healthcare providers, or clinical trial platforms.

Initial data validation and standardization occurs.

Oracle Clinical | Medidata Rave

2

ACTION

Extract and standardize data

AI system extracts relevant medical information, patient demographics, and drug details using NLP. Data is mapped to MedDRA coding standards for regulatory compliance.

SAS Clinical Trials | IQVIA CORE

3

DECISION

Assess severity and causality

Algorithm evaluates the adverse event severity, determines causality relationship to study drug, and classifies urgency level. Routes serious adverse events for expedited processing.

SAS Clinical Trials | Spotfire Analytics

4

ACTION

Perform safety signal detection

Statistical analysis compares event against historical safety database to identify potential new safety signals. Machine learning models flag unusual patterns or emerging risks.

Spotfire Analytics | IQVIA CORE

5

ACTION

Generate regulatory reports

System automatically creates required regulatory submissions including CIOMS forms, periodic safety reports, and expedited reports. Documents are formatted per regional requirements.

Veeva Vault | Oracle Clinical

6

ACTION

Submit to regulatory authorities

Automated submission of safety reports to FDA, EMA, and other global regulatory bodies within required timelines. Confirmation receipts are tracked and stored.

Veeva Vault | IQVIA CORE

7

OUTPUT

Update safety database records

All processed adverse event data, analysis results, and regulatory submissions are permanently stored in the pharmacovigilance database. Audit trails and compliance documentation are maintained.

Veeva Vault | Oracle Clinical

Outputs

- Regulatory compliance reports submitted to authorities

- Updated pharmacovigilance safety database
- Safety signal alerts and risk assessments

Key Metrics

- Adverse event processing time
- Regulatory submission compliance rate
- Safety signal detection accuracy

Tools & Integrations

- Veeva Vault
- Oracle Clinical
- Medidata Rave
- SAS Clinical Trials
- IQVIA CORE
- Spotfire Analytics

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