← Back to Pharmaceuticals PHARMACEUTICALS · WORKFLOW

Regulatory submission and compliance tracking

Automates regulatory submission preparation, filing, and compliance tracking throughout the approval process. Ensures timely submissions, monitors regulatory milestones, and maintains compliance documentation across multiple jurisdictions.

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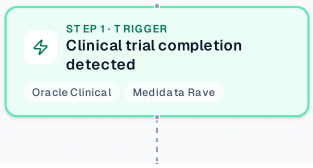
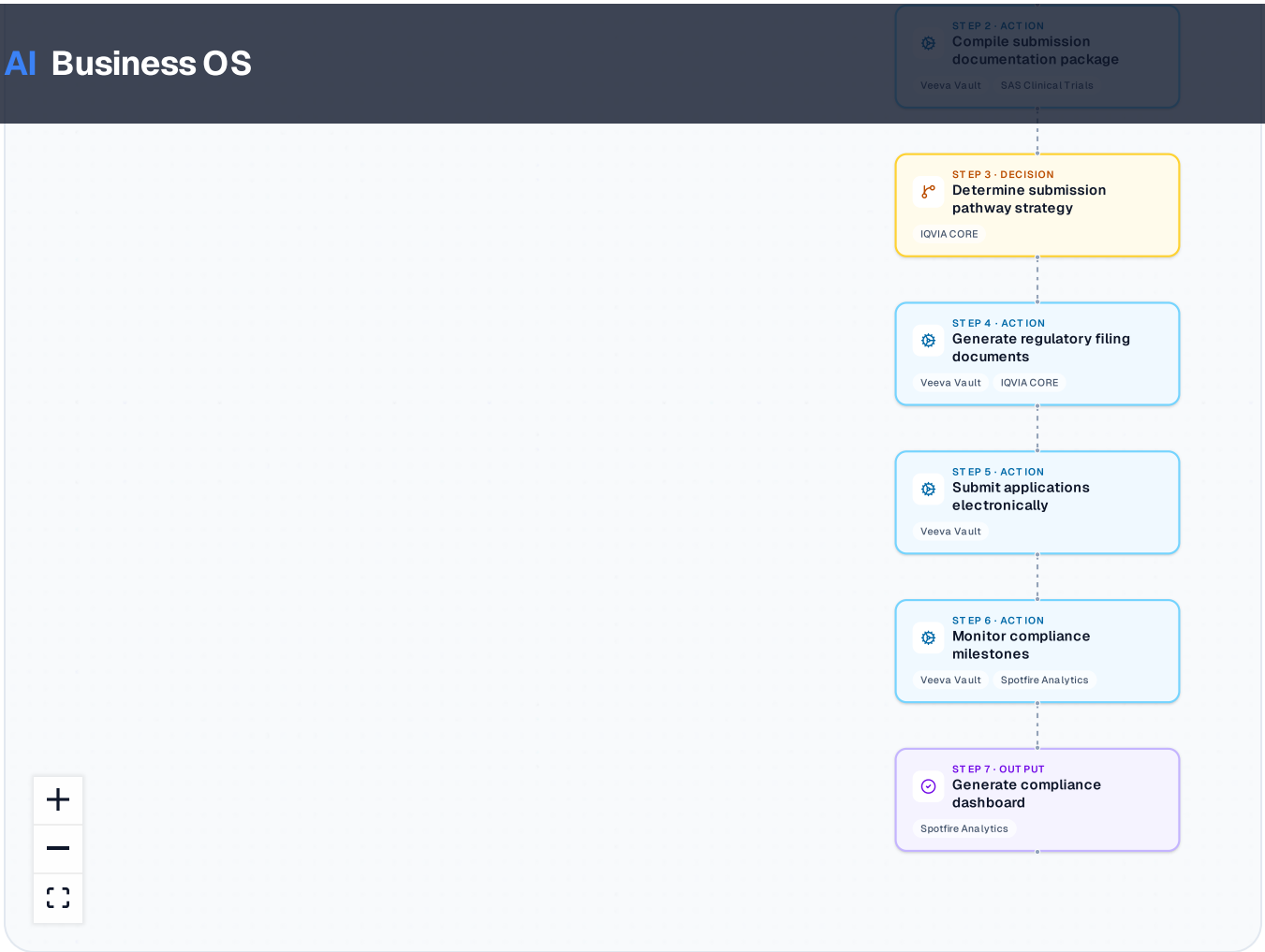
WORKFLOW TRIGGER
Clinical trial completion milestone reached in study management system

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

Clinical trial completion detected

System detects completion of Phase III clinical trial and triggers regulatory submission workflow. Initiates data compilation and regulatory document preparation process.

2

ACTION

Compile submission documentation package

Automatically aggregates clinical data, study reports, manufacturing information, and safety data into standardized regulatory submission formats. Validates data completeness and format compliance.

Veeva Vault SAS Clinical Trials

3

DECISION

Determine submission pathway strategy

AI system analyzes drug profile, indication, and regulatory history to determine optimal submission pathway (standard review, priority review, breakthrough therapy). Routes to appropriate regulatory preparation templates.

IQVIA CORE

4

ACTION

Generate regulatory filing documents

Creates jurisdiction-specific submission documents including CTD modules, regulatory forms, and supporting documentation. Formats documents according to FDA, EMA, or other regulatory authority requirements.

Veeva Vault IQVIA CORE

5

ACTION

Submit applications electronically

Transmits completed regulatory submissions through appropriate electronic gateways (eCTD, CDER, etc.). Tracks submission confirmations and assigns tracking numbers.

Veeva Vault

6

ACTION

Monitor compliance milestones

Continuously tracks regulatory review timelines, milestone dates, and agency communications. Generates alerts for required responses, additional data requests, and compliance deadlines.

Veeva Vault | Spotfire Analytics

7

OUTPUT

Generate compliance dashboard

Produces real-time regulatory status dashboard showing submission progress, upcoming deadlines, and compliance metrics. Provides executive reporting and regulatory team notifications.

Spotfire Analytics

Outputs

- Completed regulatory submission packages

- Real-time compliance tracking dashboard
- Automated regulatory milestone alerts

Key Metrics

- Submission timeline adherence rate
- Regulatory approval cycle time
- Compliance documentation completeness percentage

Tools & Integrations

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

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