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Clinical trial data collection and analysis

This workflow automates the collection, validation, and analysis of clinical trial data for medical devices, ensuring regulatory compliance and accelerating evidence generation for market approval.

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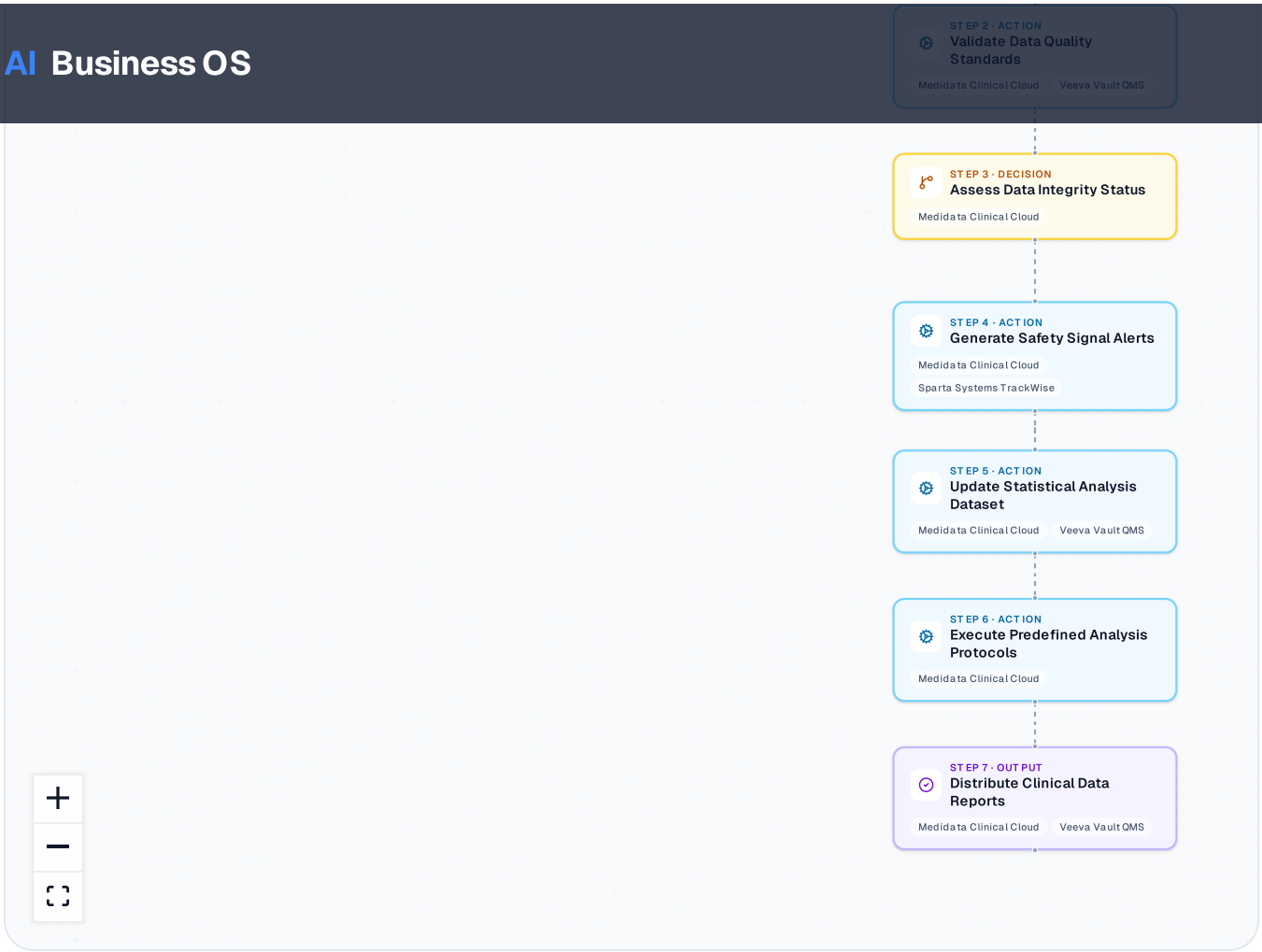
WORKFLOW TRIGGER

New patient data is submitted to the clinical trial database from a study site

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 Patient Data Submission

Clinical trial data is automatically captured when investigators submit patient case report forms through the electronic data capture system. The system validates data format and completeness upon receipt.

2

ACTION

Validate Data Quality Standards

Automated data validation checks are performed against predefined clinical protocol requirements and regulatory standards. Missing fields, out-of-range values, and protocol deviations are flagged for review.

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3

DECISION

Assess Data Integrity Status

The system determines if data passes validation criteria or requires correction. Critical errors trigger immediate alerts while minor issues are queued for batch resolution.

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4

ACTION

Generate Safety Signal Alerts

Real-time safety monitoring algorithms scan for adverse events and device malfunctions that require immediate reporting. Serious adverse events automatically trigger regulatory notification workflows.

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5

ACTION

Update Statistical Analysis Dataset

Validated data is automatically incorporated into the master clinical database and statistical analysis datasets. Data versioning and audit trails are maintained for regulatory inspection readiness.

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6

ACTION

Execute Predefined Analysis Protocols

Automated statistical analyses run according to the clinical trial's statistical analysis plan. Efficacy endpoints, safety profiles, and interim analysis reports are generated based on accumulated data.

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7

OUTPUT

Distribute Clinical Data Reports

Comprehensive clinical trial reports, safety summaries, and regulatory submission documents are automatically generated and distributed to stakeholders. Reports are formatted according to FDA and international regulatory requirements.

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Outputs

- Validated clinical trial database
- Automated safety surveillance reports
- Regulatory-ready clinical study reports
- Real-time trial monitoring dashboards

Key Metrics

- Data query resolution time
- Protocol deviation rate
- Time to safety report submission
- Clinical database lock timeline

Tools & Integrations

- Medidata Clinical Cloud
- Veeva Vault QMS
- Sparta Systems TrackWise

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