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Regulatory submission preparation

Automatically compiles, validates, and formats regulatory submission packages for drug approval applications by aggregating data from laboratory systems and ensuring compliance standards are met.

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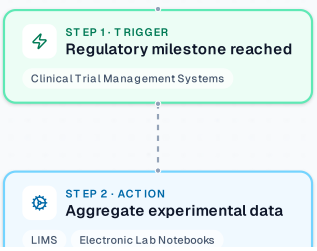
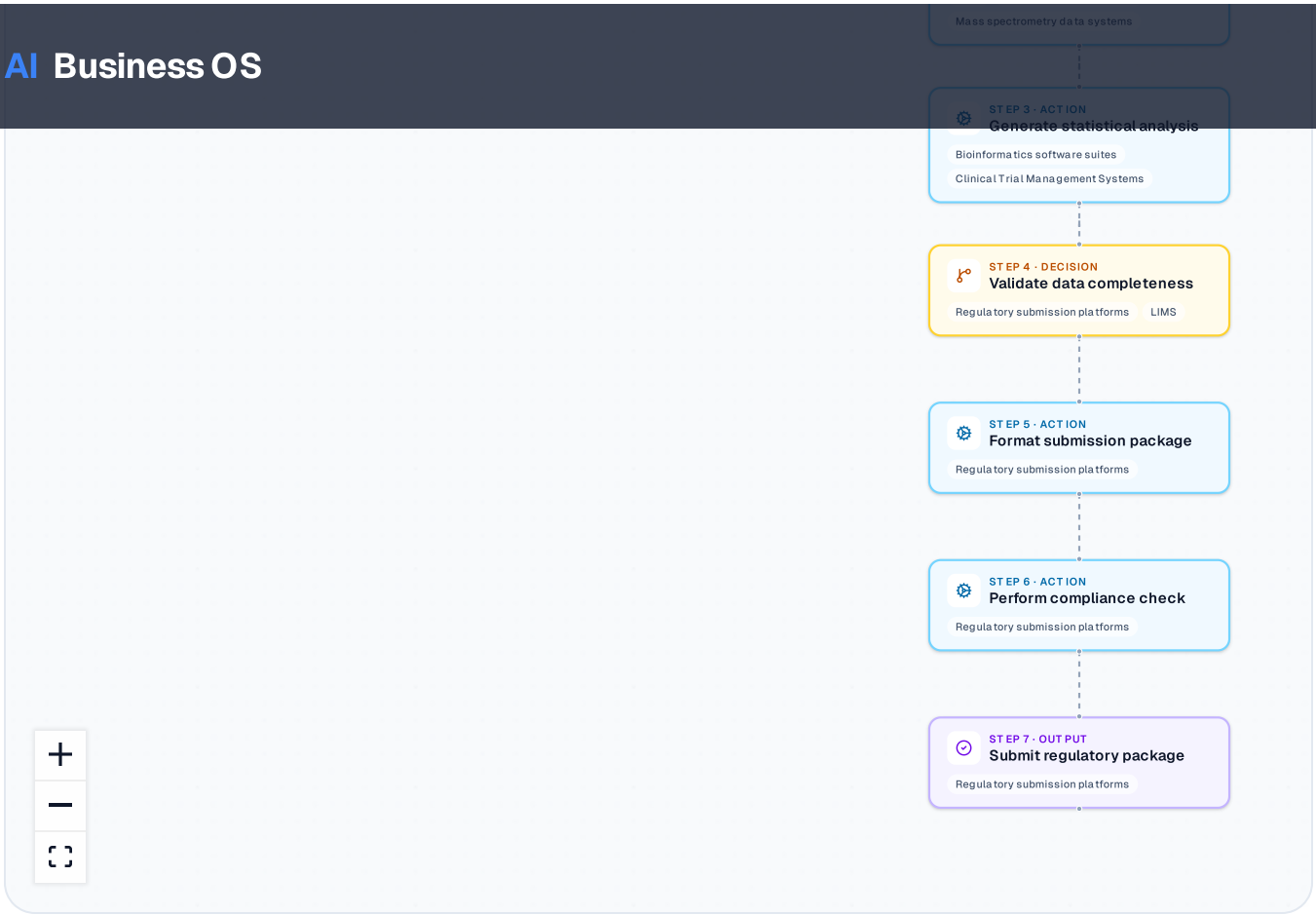
WORKFLOW TRIGGER
Clinical trial reaches predefined milestone or regulatory deadline approaches

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

Regulatory milestone reached

System detects that a clinical trial has reached a key milestone or regulatory submission deadline is approaching. Automatically initiates the submission preparation workflow.

Clinical Trial Management Systems

2

ACTION

Aggregate experimental data

Pulls all relevant experimental data, protocols, and analytical results from laboratory systems. Consolidates data from multiple sources into a structured format.

LIMS | Electronic Lab Notebooks | Mass spectrometry data systems

3

ACTION

Generate statistical analysis

Performs automated statistical analysis on clinical and preclinical data using bioinformatics tools. Creates required efficacy and safety reports.

Bioinformatics software suites | Clinical Trial Management Systems

4

DECISION

Validate data completeness

Checks if all required data elements, documents, and analyses are complete according to regulatory guidelines. Routes to remediation if gaps are found.

Regulatory submission platforms | LIMS

5

ACTION

Format submission package

Automatically formats all documents and data according to regulatory agency requirements (FDA, EMA, etc.). Creates standardized submission structure and electronic common technical document (eCTD).

Regulatory submission platforms

6

ACTION

Perform compliance check

Runs automated compliance validation against current regulatory guidelines and standards. Flags any potential issues for human review.

Regulatory submission platforms

7

OUTPUT

Submit regulatory package

Generates final submission package ready for regulatory agency review. Creates audit trail and notification to stakeholders.

Regulatory submission platforms

Outputs

- Validated regulatory submission package
- Compliance audit report
- Submission tracking dashboard

Key Metrics

- Submission preparation time reduction
- Data completeness percentage
- First-time approval rate

Tools & Integrations

- Clinical Trial Management Systems
- LIMS
- Electronic Lab Notebooks
- Mass spectrometry data systems
- Bioinformatics software suites
- Regulatory submission platforms

AI Business OS