

## CLAIMS

What is claimed is:

1. A computer-implemented method for automated status management in clinical trial systems, comprising:

- (a) maintaining a plurality of clinical trial entities in a database, each entity having an independent status lifecycle;
- (b) establishing dependency relationships between entities based on clinical trial business rules;
- (c) automatically computing entity status based on states of dependent entities using a hierarchical status computation algorithm;
- (d) validating status transitions across entity boundaries using cross-entity validation rules; and
- (e) synchronizing status changes across dependent entities in real-time using event-driven propagation.

2. The method of claim 1, wherein the hierarchical status computation algorithm comprises:

- (a) gathering current states of all dependent entities;

- (b) applying priority-based computation rules specific to clinical trial workflows; and
- (c) determining optimal status considering regulatory compliance requirements.

3. The method of claim 1, wherein cross-entity validation comprises:

- (a) constructing a real-time dependency graph of related entities;
- (b) validating proposed status transitions against dependency constraints; and
- (c) preventing transitions that would violate regulatory compliance rules.

4. The method of claim 1, wherein the clinical trial entities include studies, protocol versions, investigational sites, and study participants, and wherein each entity maintains status information including lifecycle state, regulatory approval status, and operational readiness.

5. The method of claim 1, wherein event-driven propagation comprises:

- (a) detecting status change events from any clinical trial entity;
- (b) identifying all dependent entities affected by the status change;
- (c) computing required status updates for dependent entities; and

(d) executing synchronized status updates across all affected entities.

6. The method of claim 2, wherein priority-based computation rules include:

(a) regulatory approval requirements taking highest priority;

(b) safety considerations taking second priority;

(c) operational readiness taking third priority; and

(d) administrative completeness taking lowest priority.

7. The method of claim 3, wherein the dependency graph comprises nodes representing clinical trial entities and edges representing dependency relationships, and wherein the graph is dynamically updated based on current entity states and configuration changes.

8. A computer system for automated status management in clinical trial workflows, comprising:

(a) a database storing a plurality of clinical trial entities, each having status information and dependency relationships;

(b) a hierarchical status computation engine configured to automatically determine entity status based on dependent entity states;

(c) a cross-entity validation framework configured to validate status transitions across entity boundaries;

(d) an event-driven synchronization module configured to propagate status changes across dependent entities in real-time; and

(e) a compliance rule engine configured to enforce regulatory requirements during status transitions.

9. The system of claim 8, wherein the hierarchical status computation engine comprises:

(a) a dependency resolver configured to identify all entities affecting status computation;

(b) a rule engine configured to apply clinical trial workflow-specific computation rules; and

(c) a status calculator configured to determine optimal status based on dependency analysis and regulatory requirements.

10. The system of claim 8, wherein the cross-entity validation framework comprises:

(a) a dependency graph builder configured to construct real-time dependency relationships;

(b) a constraint validator configured to verify proposed status transitions against business rules; and

(c) a regulatory compliance checker configured to ensure transitions comply with FDA and ICH guidelines.

11. The system of claim 8, wherein the event-driven synchronization module comprises:

(a) an event detector configured to identify status change events;

(b) an impact analyzer configured to determine affected dependent entities; and

(c) a synchronization orchestrator configured to coordinate status updates across multiple entities.

12. The system of claim 8, wherein the compliance rule engine comprises:

(a) a regulatory rule repository storing FDA and ICH compliance requirements;

(b) a business rule repository storing clinical trial workflow-specific rules; and

(c) a rule execution engine configured to evaluate proposed status transitions against stored rules.

13. A non-transitory computer-readable storage medium containing instructions that, when executed by a processor, cause the processor to perform a method for automated status management in clinical trial systems, the method comprising:

- (a) maintaining clinical trial entities with independent status lifecycles in a database;
- (b) establishing dependency relationships between entities based on clinical trial business rules;
- (c) automatically computing entity status using hierarchical status computation based on dependent entity states;
- (d) validating status transitions using cross-entity validation rules; and
- (e) synchronizing status changes across dependent entities using event-driven propagation.

14. The computer-readable storage medium of claim 13, wherein the instructions further cause the processor to:

- (a) construct dependency graphs representing relationships between clinical trial entities;
- (b) apply priority-based computation rules considering regulatory compliance;
- (c) prevent status transitions that would violate FDA or ICH guidelines; and

(d) maintain audit trails of all status changes for regulatory reporting.

15. The computer-readable storage medium of claim 13, wherein the hierarchical status computation includes multi-level analysis considering study-level status, protocol version status, site operational status, and regulatory approval status, with automated resolution of conflicting status indications through priority-based rules.