

ABSTRACTABSTRACT

A computer-implemented system for automated multi-level status management in clinical trial workflows addresses the technical challenges of coordinating status across multiple interdependent entities including studies, protocol versions, investigational sites, and participants. The system comprises a hierarchical status computation engine that automatically determines entity status based on dependent entity states using priority-based computation rules specific to clinical trial workflows. A cross-entity validation framework constructs real-time dependency graphs and validates proposed status transitions against regulatory compliance rules to prevent violations of FDA and ICH guidelines. An event-driven synchronization module propagates status changes across dependent entities in real-time, maintaining data integrity and regulatory compliance. The system reduces operational overhead, eliminates status inconsistencies, and ensures regulatory compliance through automated workflow orchestration. The invention provides technical advantages including enhanced data integrity through cross-entity validation, improved performance via event-driven architecture, and scalability supporting large-scale multi-site clinical trials while maintaining strict regulatory compliance requirements.

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