

# Rave SOP Management™

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## Life Sciences' Solution for SOP Management

Until more recently, life sciences companies faced difficult choices when adopting an SOP Management solution.

While quality/regulatory teams and other principal users at small-to-medium sized companies use inefficient paper/computer hybrid systems, larger companies maintain multiple legacy on-premise enterprise content management solutions — typically one for regulated content (like SOPs) and another for nonregulated content — which results in higher costs for software, services and validation.

*What do these solutions have in common?* They are dated and siloed, thus hindering system access, search and workflow. This disparate user experience, low adoption rate and increased compliance risk creates a clear need for a unified solution: one designed for end-users to manage SOPs and other regulated content, as well as nonregulated content, more efficiently.

Medidata offers a new standard when addressing these challenges: **Introducing SOP Management** — a 21 CFR, Part 11 compliant, validated, content integrity and collaboration platform for the modern digital workplace, and **the first end-to-end collaboration platform that actively maintains inspection readiness.**

SOP Management is a collaboration platform that empowers everyone to seamlessly manage SOPs and actively maintain compliance. Unified within the Medidata Clinical Cloud®, SOP Management allows users to create, store, view, edit, approve and jointly work on SOPs in a single application with cutting-edge UX capabilities. With live content integrity verification, life science companies can now use this fully-validated 21 CFR, Part 11 and Part 820-compliant system to ensure constant compliance.

## Key Features

- Audit trail and reporting
- Highly secure
- Compound document assembly (including templates, forms and watermarks)
- Electronic signatures
- Read & Acknowledge workflow
- Complete SOP lifecycle workflow
- Robust notifications on change requests, expiring documents, etc.
- Role-based workflow
- Content auto-naming
- Configurable folder structures
- Support audit readiness
- Import/bulk upload supporting migrations
- Rapid implementation
- Mobile enabled for content search and on-the-go access
- Deep integration with Box, the leading enterprise content management platform, allows you to search and manage both regulated and nonregulated content via one interface

## Why Medidata for SOP Management?

- Always Compliant

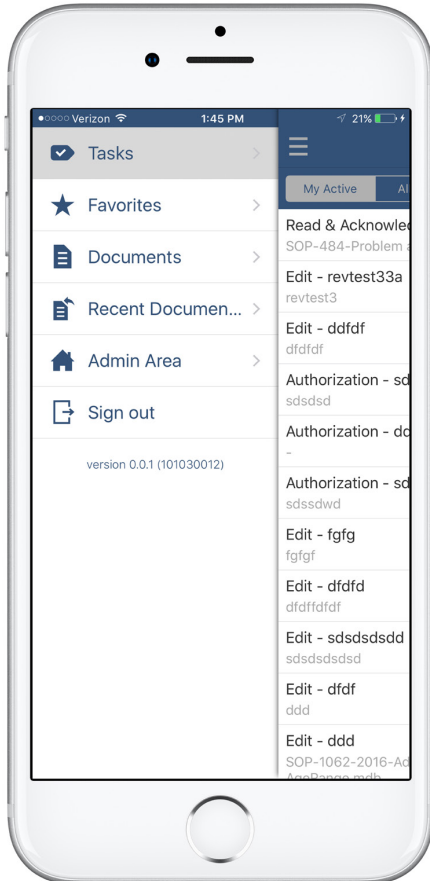
With first-of-its-kind, Live Content Verification technology, content integrity is verified every time content is read or written, providing an advanced compliance standard and actively ensuring inspection readiness.

- Incredible User Experience

Built with incredibly intuitive workflows and mobile functionality, now you can access, review and approve content from anywhere, anytime.

- Quick & Simple Implementation

One platform that can be implemented in weeks instead of months with minimal resources, leveraging Medidata's pre-built, pre-validated functionality and validated content migration.



## The Platform of Choice for Clinical Research

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords and excel sheets, you are now on a truly unified platform.

## About Medidata

Medidata is leading the digital transformation of life sciences, with the world's most-used platform for clinical development, commercial, and real-world data. Powered by artificial intelligence and delivered by the #1 ranked industry experts, Medidata helps pharmaceutical, biotech, medical device companies, and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata and its companies, Acorn AI and SHYFT, serve more than 1,200 customers and partners worldwide and empower more than 150,000 certified users every day to create hope for millions of patients. Discover the future of life sciences:

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