



No Need for End of Study CDs: Medidata Introduces NEW Rave Digital EOS Media Delivery

December 13, 2018

Sponsors, CROs, and Sites Retain and Easily Access End Of Study Media Necessary to Meet Regulatory Requirements

- Reduces Regulatory Burden through Automatic Event Triggers from Rave EDC to Edge RCM
- Edge RCM Automates and Simplifies Access to EOS Documents
- Eliminates Need to Distribute and Use CDs for Clinical Trial End of Study Media

NEW YORK--(BUSINESS WIRE)--Dec. 13, 2018-- To ease and unify Rave End of Study (EOS) document management, Medidata (NASDAQ:MDSO) today introduced a new, automated function of Edge Regulatory Content Management (RCM). Triggered automatically from Rave EDC, the new [Edge RCM feature](#) organizes, distributes and retains EOS documents to maintain regulatory compliance and inspection readiness.

Today, the majority of EOS media is distributed on CDs. By combining Rave EDC and Edge RCM, the EOS process becomes automated and unified on the Medidata Cloud. This combination:

- Simplifies the EOS document delivery method
- Improves audit compliance by providing full electronic signatures for content delivery
- Preserves media in accordance with regulatory requirements

"It is not a question of whether a site will be audited, but when. Scrambling to gather the requisite documents at the close of a study is a manual, logistical nightmare and compliance risk. By unifying Rave EDC and RCM, we are digitizing the full study management process to enable sites to streamline EOS document management and support regulatory requirements," said Perry Steinberg, vice president, product management, Medidata.

The new Edge RCM content library will streamline stakeholder access to approved and accurate documents from Rave EDC. The features include:

- Single sign-on for data managers, CRAs and support staff
- Controlled access for sponsors/CROs and sites to study data
- Automated ingestion of EOS media into Edge RCM using a scheduled process
- Migration notifications to study monitors, sponsors/CROs and site users

About Medidata

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