FACT SHEET

rSDV by Octalsoft

Remote Source Data Verification

rSDV

- Reduction in on-site monitoring time & cost
- Verification of source data, anytime, anywhere
- Speedy detection and fast resolution of source verification queries
- Email triggers for critical action items

To know more, email us at
info@octalsoft.com
inquiry@octalsoft.com

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+91 (760) 098-3010

Schedule a **Demo** with our Product Specialist today!

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REMOTE SOURCE DATA VERIFICATION BENEFITS

Flexible Deployment & Integration Options

- Octalsoft's rSDV is available as a standalone application and also as an integrated single sign-on module with Octalsoft's EDC
- Standalone rSDV can be integrated through API with:
  - Third party EDC systems
  - Octalsoft or Third party eTMF for integrating eISF module
  - Clinical site based Electronic Health Record (EHR) systems for integrativng electronic source records, if required

Source Data Verification Workflow

- Configurable document review workflow
- Online collaborative comment mechanism to address any questions during the review process, such as
  - Add comments (CRA)
  - Respond to comments (CRC)
  - Re-open or close comments, as applicable (CRA)
  - Mark document as verified (CRA)
  - Approve documents for deletion (CRA)
  - Delete verified document (CRA)
- Bulk verification of documents (CRA)
- Bulk response to comments (CRA & CRC)

> It has been a game-changer for clinical studies by simplifying and automating our document verification process. The accuracy and efficiency of Octalsoft's rSDV solution have exceeded our expectations, allowing us to improve productivity and reduce manual errors. I highly recommend Octalsoft's rSDV solution to any company looking for a reliable and advanced solution for document verification
>
> **Arun Janardhanan**
> Senior Project Manager | Octalsoft

Purpose-Built Electronic File Sharing System

- Clinical site users control the upload & deletion of source documents
- Upload PDFs/images into the standardized subject specific and visit specific folders
- Configure the eISF TOC as per client specifications
- Upload eISF documents into the standardized study specific folders
- Predefined & unique file nomenclature for easy identification and search
- Multi-upload functionality

Personal Data Protection

- GDPR & HIPAA compliant
- Permission-based controls to limit source document visibility and functional capabilities
- Source document deletion from application as well as database to prevent uncontrolled access post study closure
- Sensitive data shared over a secured online portal

Reports & Dashboard

- Real-time dashboards and interactive reports to track activities, check statuses and manage workflows such as
  - Document Status Report > All Sites & Site Specific
    - Document Uploaded
    - Verification Ongoing
    - Verification Completed
    - Document Deleted
  - Document Comment Status Report
    - Open
    - Re-open
    - Responded
    - Closed
  - Recent Uploads with hyperlink

OUR UNIQUE CUSTOMER SUPPORT STRUCTURE

Detailed User Manuals/Guides

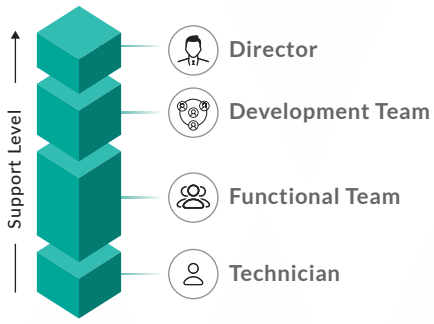
One Stop-Hassle Free Support

- Detailed user guides & training sheets for every product module
- Guided video tutorial sessions to address user queries
- Exhaustive FAQ sheets per product module

24 X 7 Help Desk Support

Our Specialists are Always Available to Resolve Your Queries

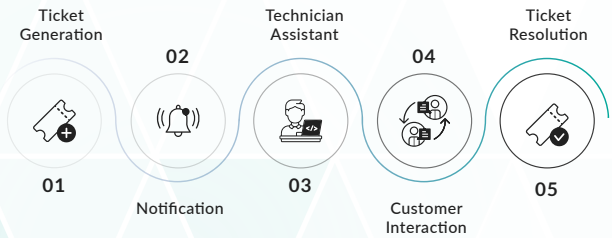
1. Customized screen for every user
2. Integrated online & offline support
3. Comprehensive repository of common queries
4. Module embedded chatbot



Embedded Agile Ticketing Feedback System

Your Query is Our Priority

Issue based (bug, enhancement, data rectification & others) ticket resolution system to address urgent queries on priority



AI Powered Module Specific Chatbot

Personalized Just for You!

1. Specific phone key number allocation to every client
2. Local & international support
3. Integrated online & offline support

Meet **Emily,**

Clinical Research Coordinator

She works at a large clinical research organization. With over 5 years of experience in clinical research, Emily is responsible for coordinating and managing clinical trials across various therapeutic areas. Her key responsibilities include ensuring adherence to protocols, regulatory compliance,include protocols, regulatory compliance, and accurate and timely data collection and reporting.

However, Emily faces several challenges in managing clinical trials, such as coordinating with multiple study sites, ensuring timely data collection and reporting, and conducting source data verification (SDV) to ensure the accuracy of clinical trial data.

As a result, Emily has adopted an Octalsoft rSDV. Our solution provided Emily with real-time access to study data and enabled remote monitoring of data quality and accuracy, eliminating the need for onsite visits by CRAs.

With our rSDV solution, Emily has been able to manage clinical trials more efficiently and effectively. She can now remotely monitor data quality, conduct SDV with greater accuracy, and ensure timely and accurate data collection and reporting.

WHY CONSIDER OUR eCLINICAL SOLUTION?

Single Unified Mobile-Enabled Platform

End-to-end physically & logically secured cloud solution that effortlessly manages data collection, IP supplies, randomization, study compliance, and documents

Regulatory Compliant

Compliant with all current & highest regulatory guidelines:

GDPR | FDA 21 CFR Part 11 | EU COMPLIANT Annex 11 | GAMP 5 | cdisc | HIPAA COMPLIANT | GxP | ICH GCP

Patient Centric

Integrated ePRO & eConsent enables you to conduct patient-centric virtual trials to access diverse population all over the world for smarter and faster trials

Audit Ready Database

End-to-end physically & logically secured cloud solution that effortlessly manages data collection, IP supplies, randomization, study compliance, and documents

Global Mega Trials in Multiple Languages

Experience conducting global trials for all types of studies and trial phases with US FDA Submission | EMA Submission | DCGI Submission

Fast Study Startup

Shortest build times with over 90% of studies deployed within 2-4 weeks. Easy-to-use trial builder allows quicker configuration of eCRFs

Configurable, Customizable, Cost Effective & Easy to Use

The platform can easily integrate with your existing system and can also get designed as per your requirements for increased flexibility, mobility and scalability

Unparalleled Global Customer Support

End-to-end physically & logically secured cloud solution that effortlessly manages data collection, IP supplies, randomization, study compliance, and documents

Our Values

For 15+ years, we've mastered the art of Simplifying Technology so that greater discoveries can happen sooner. As a leading eClinical Solution provider, we've always invested in the right expertise, experts, and technology that keeps us, and you at the forefront of science and medicine. As a trusted tech partner for some of the world's leading clinical trial initiatives, our values of innovation, reliability, and client satisfaction guide everything we do.

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