UNITY™ dx

ACCELERATING OUTCOMES

Blog:

Automation Solution – UNITY™ dx

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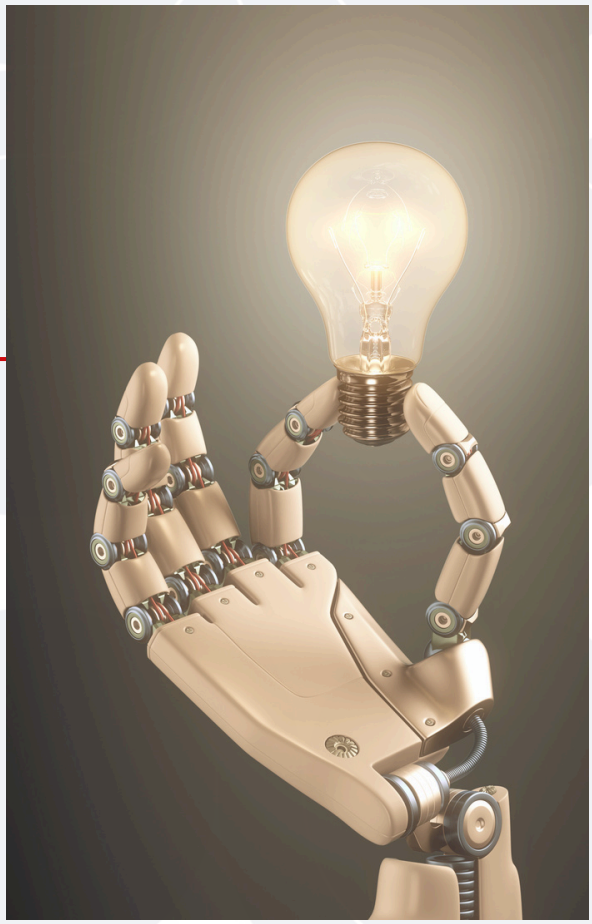
Essential Automation Solution Components



TECHNOLOGY

- Digital Monitoring of Safety Communications with site
- Tracking of Delivery Receipts and Acknowledgement Compliance
- Custom Configurations for Site Reminders and Email templates
- Complete Logical Separation of Sponsor (Customer) data
- Secure login using Multi-Factor Authentication
- Pre-Validated as per GAMP-5 guidelines
- Permission-based Access Control for Software Features, Read-only access
- 21CFR Part11 compliant Audit Trail Maintenance

SOLUTION DRIVERS

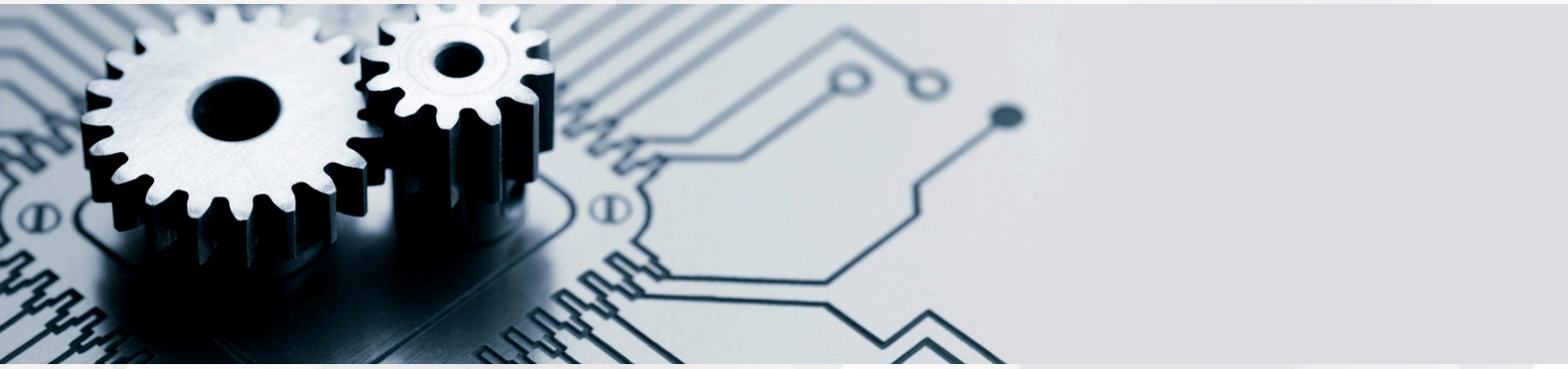
High Volume Communication that requires Tracking

Highly Available Infrastructure – Secure, with Backup and Redundant Servers

Secure Communication, Complete Audit Trail and Tracking

Configurable, Regulatory Compliant

SERVICE



- Simplified sync with Safety Systems via E2B R3 XML upload, EDI connection
- Automated assessment of Regulatory, Site and EC/IRB reporting timelines via Reporting Rules
- Detailed Compliance Reports with case-level and site-level as well as aggregated data presentation
- Custom Templates for Site Notifications and Reminders
- Cross-Reporting for multi-country trials
- Retrospective Reporting for New Sites joining a study
- Trial, Contact, Site and Product Masters for rapid integration with Safety and Clinical Databases

Benefits of Automation in Safety Document Distribution

Safety Document* Distribution Solution for Clinical Sites

* 7/15-day SUSARs, DSURs, USRs

Safety Document Distribution with Digital Tracking

Secure Transmission of Reports

Reduce Human Effort and Probability of Error

ENHANCED COMPLIANCE TRACKING

User-friendly dashboard with study/ site/ product-specific filters for data and reports

SECURE TRANSMISSION

21 CFR Part 11 compliant, Sign-in via secure access code received on verified email

GREATER PROCESS EFFICIENCY

Automatic tracking and reminders, Cross-reporting, Retrospective reporting. Can be integrated with a CTMS for real-time updates

About UNITYdx™

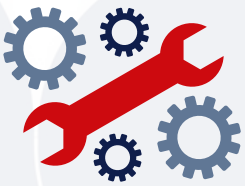
Soterius offers its in-house tool SUSAR Notification , UNITYdx, which automates the sending and tracking of SUSARs to the Clinical Trial Sites. System integration and standardization allow UNITYdx to work with any standard safety database. Multi-channel communication hub ensures prompt, compliant, efficient, and secure communication between Clinical Trial sites, Safety Teams (CROs and Sponsors), and Clinical teams.

Challenges in Manual Process of SUSAR Notification

Lack of regulatory-compliant audit trails

Excel-based tracking prone to data integrity issues

Super busy Sites and Investigators do not respond



Maintenance of contact information on Excel prone to error

Multiple emails for 1 SUSAR in case of multiple studies at a Site.

Institutional policies block email delivery notifications

Implementation Strategies

Transition, Integrations and Training

ASSESSMENT #01

Evaluation of existing manual processes and identifying bottlenecks, inefficiencies, and key areas requiring automation

REQUIREMENT MAPPING #02

Prepare a plan outlining milestones and resources needed for the transition and map the requirements to the automation software's feature list

SELECTION #03

Select the appropriate software to meet the requirements considering factors such as scalability, integration, and user-friendliness

CUSTOMIZATION AND INTEGRATION #04

Identify required configurations and customization, if any, for the software to ensure that it integrates into existing workflows

IMPLEMENTATION AND SUPPORT #05

Integrate the software into the existing workflow, considering rapid roll-back to existing workflow if required, and provide necessary support for the team

MONITORING AND OPTIMIZATION #06

Regular assessment of software performance, feedback, issue resolution, and optimization to maximize efficiency and effectiveness over time

Key Takeaways

01 Regulatory Compliance: Prompt SUSAR communication; Inspection Findings

02 Manual Process of SUSAR Reporting is prone to errors, inadequate documentation and lack of audit trails

03 Automation enhances process efficiency, mitigates risks in ensuring compliance and saves time and effort

04 Ensuring data security with robust measures to protect sensitive information related to SUSAR notifications

05 Successful Implementation needs a partner with Safety, Validation and Quality Assurance Expertise

06 Aim is to have a Robust, Efficient and Compliant Solution for SUSAR / Safety Document Communication

About Author

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12+ Years of Pharmacovigilance Experience
Pharma and Clinical Research professional
Managed PV Teams across ICSR and SAE Processing, Literature Management, EV Systems, Regulatory Reporting
Current focus on Client Engagement, Product Development, Validation and Deployment

Our Services

Soterius offers end-to-end Pharmacovigilance, Medical Affairs and Regulatory services.

- Clinical Safety Services
- Post-marketed Pharmacovigilance Services
- Innovation & Technology
- Medical Affairs and Medical Writing

About Soterius™

Soterius is a strong team of pharma professionals who design customized, innovative, and cost-efficient processes for clinical safety, pharmacovigilance, and medical affairs. Our deep industry knowledge and up to date insights let us combine agile, people powered intelligence in pioneering customer centric solutions. Our innovative technology solutions include engagement tools and communications platforms to create a unified and compliant medical access facility. With a strong global presence, we provide comprehensive clinical and post marketed safety services, that include aggregate report writing, signal detection and management, global literature surveillance, risk management, case processing and regulatory reporting.

We use state-of-the-art technologies to solve complex safety operations problems, be it case processing, intake, site reporting for clinical trials, or literature search and management. We have one of the most accurate solutions for case intake and case processing using AI.

We support companies from the initial development stage of a drug/vaccine to the approval and ultimate marketing of the therapy, supporting ongoing operations and regulatory commitments globally.

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