Automation Solution - UNITYdx

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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
- Secure Communication, Complete Audit Trail and Tracking
- Highly Available Infrastructure – Secure, with Backup and Redundant Servers
- 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

- Safety Document Distribution with Digital Tracking

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

- Secure Transmission of Reports

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

- Reduce Human Effort and Probability of Error

  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

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

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

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

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

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

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

Implementation Strategies

- Regulatory Compliance: Prompt SUSAR communication; Inspection Findings
- Manual Process of SUSAR Reporting is prone to errors, inadequate documentation and lack of audit trails
- Automation enhances process efficiency, mitigates risks in ensuring compliance and saves time and effort
- Ensuring data security with robust measures to protect sensitive information related to SUSAR notifications
- Successful Implementation needs a partner with Safety, Validation and Quality Assurance Expertise
- Aim is to have a Robust, Efficient and Compliant Solution for SUSAR / Safety Document Communication

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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 full suite of Pharmacovigilance, Medical Affairs and Regulatory services.

- Clinical Safety Services
  - Case Processing, DSUR Authoring, Medical Monitoring, Medical Reviews, CSR Narratives Authoring, etc
- Post-marketed Pharmacovigilance Services
  - Case Processing, Aggregate Report Authoring, Risk Management Plan (RMP) & Risk Minimization, Global and Local Literature, etc
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