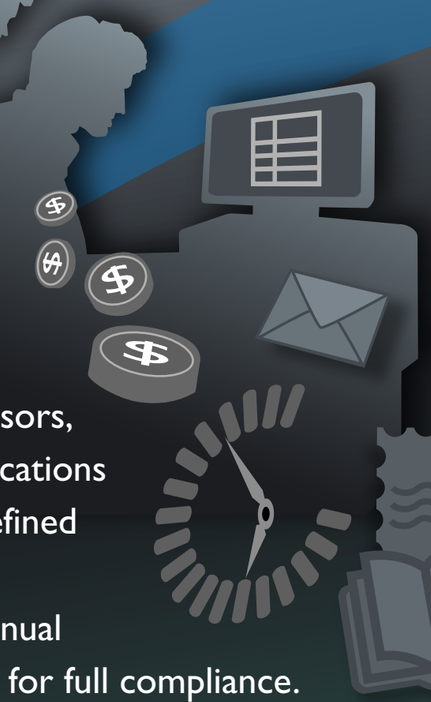
Why Automated Safety Report Notification Makes Sense

To reduce the risk for both patients and clinical trial sponsors, pharmaceutical companies must send written safety notifications to investigators and other stakeholders within a tightly defined time frame after first becoming aware of a Suspected Unexpected Serious Adverse Reaction (SUSAR). Yet a manual approach is costly and labor-intensive, with no assurances for full compliance.



Challenges of a Manual Process

- Distributing safety reports within regulated timeframes
- Costly and labor-intensive manual processes & distribution methods
- Complying with country-specific requirements
- Tracking acknowledgement receipts
- Providing documentation for the Trial Master File

1. Select relevant investigators and other stakeholders
2. Prepare and collate reports & cover letters
3. Securely distribute
4. Maintain management reports
5. Track acknowledgement receipts
6. Generate required documentation

Automation Is the Key

A solution such as agNotify™ is *specifically designed* to automate the electronic distribution of clinical safety reports to investigators, IRBs/IECs and other stakeholders.

- Supports differing regulatory obligations
- Automatically generates distribution lists
- Automates the secure distribution of cross-study safety reports & cover letters based on user-configurable templates
- Gives investigators easy access to their safety reports
- Automates the tracking of acknowledgement receipts
- Generates detailed transaction history reports
- Integrates with leading Safety and Clinical systems
- Cloud-based solution eliminates the burden of basic IT tasks

Benefits of agNotify™

- Easy to set up
- Saves significant costs
- Reduces administrative burden of highly qualified employees
- Ensures compliance for receipt and read verification

LEARN MORE

Topic Webinar: SUSAR Reporting: Taking the Pain Out of Regulatory Compliance

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