Implementing an automated SAE Reporting tool using a Clinical Database

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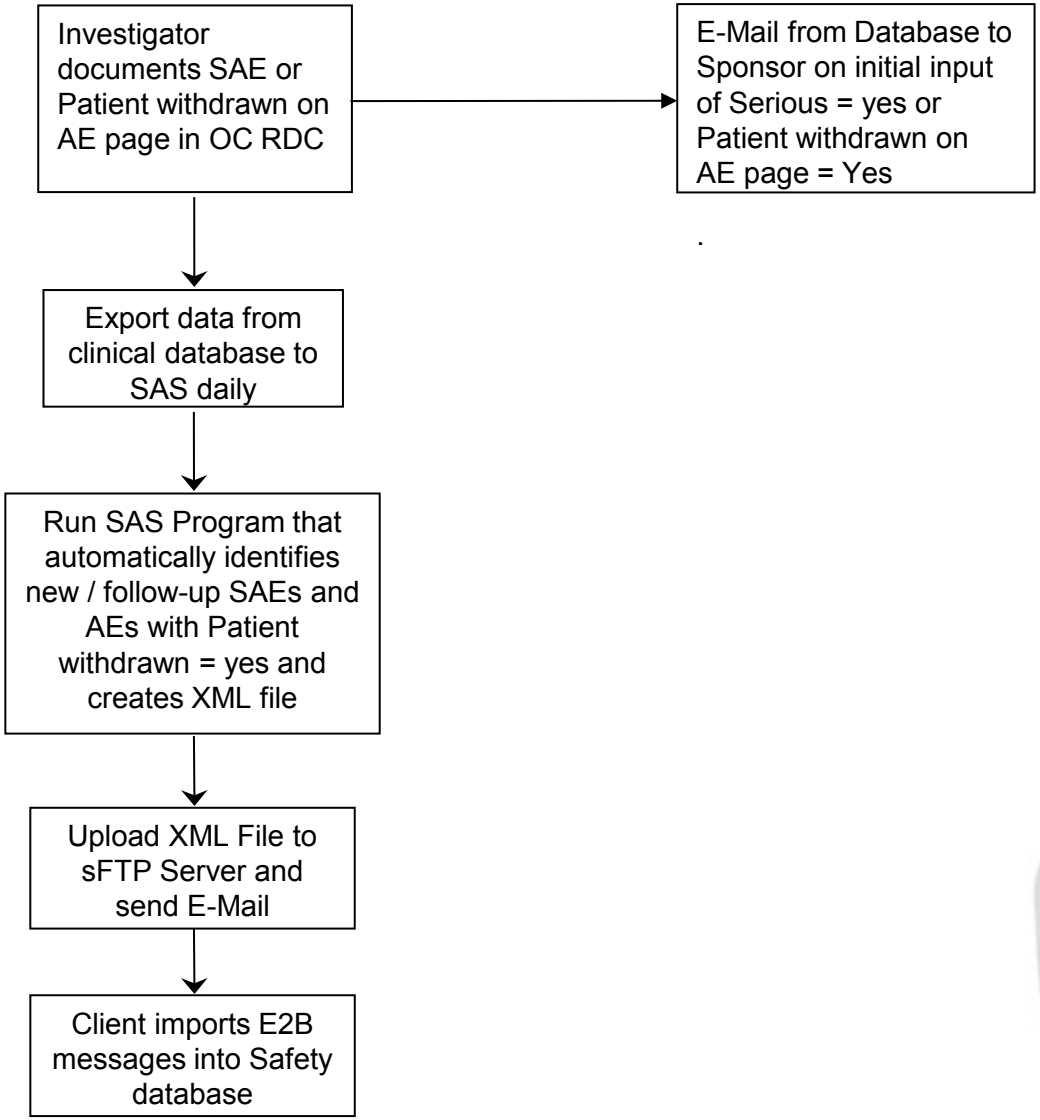
Agenda

- Overview
- Implementation
- Points to consider
- Validation & Documentation
- Examples
- References

Overview


Investigator documents SAE or Patient withdrawn on AE page in OC RDC
E-Mail from Database to Sponsor on initial input of Serious = yes or Patient withdrawn on AE page = Yes
Export data from clinical database to SAS daily
Run SAS Program that automatically identifies new / follow-up SAEs and AEs with Patient withdrawn = yes and creates XML file
Upload XML File to sFTP Server and send E-Mail
Client imports E2B messages into Safety database

Points to consider

- Clear Definition of Requirements
  - When should updates be sent, etc.
- PV personnel has less knowledge / experience with clinical databases
- Requirements of E2B vs. Protocol vs. Standard
- Additional Information to be collected
  - SAE information
  - Investigator Information (contact details)
  - Medically confirmation
- Additional Information to be derived
  - Message number
  - Safetyreport ID

Points to consider

- Clear IDs from DB for AEs, CMs, MHs, etc.
- Signatures of various departments and the customer needed
  - i.e. goes out for cross functional and client review
- Train monitors, DCs, etc.
- Database/CRF changes could effect the system
- Not only SAE are of interest for SAE, also AEs leading to withdrawal, medically important Aes
- E2B version updates (project was based on R2, current standard is R3)
- Restriction of PV/safety database to import E2B messages

Validation & Documentation

- GAMP 5 documentation required
  - GAMP Good Practice Guide: Calibration Management
  - GAMP Good Practice Guide: Validation of Process Control Systems (Neue Version für 2009 geplant)
  - GAMP Good Practice Guide: Validation of Legacy Systems
  - GAMP Good Practice Guide: A Risk-Based Approach to Compliant Electronic Records and Signatures
  - GAMP Good Practice Guide: Validation of Laboratory Computerized Systems
  - GAMP Good Practice Guide: IT Infrastructure Control and Compliance
  - GAMP Good Practice Guide: Global Information Systems Control and Compliance
  - GAMP Good Practice Guide: Testing of GxP Systems
  - GAMP Good Practice Guide: Electronic Data Archiving

Validation & Documentation

- According to Accovion SOPs
  - System Registration
  - Validation Plan
  - User Requirements
    - → Requirements should be clearly explained here
  - Risk Analysis
  - Design Specifications
  - IT-Testing
    - → Testing of single tools / programs
  - Installation Qualification
  - Admin Manual
  - Traceability Matrix

Validation & Documentation

- According to Accovion SOPs
  - User Acceptance Test
    - → Test of whole system with test data and upload of E2B files into safety database
    - → Test data generated for a one week test
  - User manual
  - 21 CFR Part 11
  - Business Continuity Plan
  - System Release

Examples E2B (R2)

- Example files as reported to the agency:
  - http://www2.bfarm.de/uaw/
- Results from UAT
  - message_1_1.xml

References

- FDA guidances E2B(R3):
  http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm274966.htm

- EMA guidances E2B(R3):
  http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002767.pdf

  http://eudravigilance.ema.europa.eu/human/docs/guid%C2%AFP%C2%AFTechnical%20Documentation%C2%AFEMEA-H-20665-04-en-Final_Revision_2.pdf

- ICH E2B (R2 & R3)
  R3: http://www.ich.org/products/electronic-standards.html
  R2:
  http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM149932.pdf

Questions?

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