Automation in Routine Use for Data Collection and Processing for Scalable Faster RWE Generation

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Abstract

Introduction
Rapid and effective data collection and analysis for RWE generation has never been more important. Data collected at scale with near-real time ingestion including transparent audit trails will increasingly require automations that reliably process and make data available for analysis quickly.

Safety data are collected internationally across heterogenous settings at scale. We describe the impact on routine processes of two Robotic Process Automations (RPAs) and insights for furthering zero-touch processing capability.

Methods:
A duplicate check assistant (DCA), utilizes a list of safety case ids (input spreadsheet) to be checked for duplicates. DCA automatically logs into the safety database, navigates menu and selection items to open each case, extracts relevant data elements, searches the database for potentially duplicate cases using pre-defined sequences, captures resulting information into the input spreadsheet, and attaches the spreadsheet to the respective case in the safety database. A second data quality reviewer (DQR) extracts relevant field contents from the database into the input spreadsheet and field discrepancies are highlighted based on pre-defined rules.

Results:
For a week in March 2020, DCA executed on 1510 cases, reducing human effort from 3 mins to 1 min 42 secs per case; DQR on 458 cases from 38 mins 27 secs to 28 mins 25 secs per case. Both automations executed without error or human intervention. Since routine use, the automations have resulted in estimated savings of 1202.3 person-hours.

Conclusions:
Routine production-use automation for safety data has provided tangible benefits through fast and consistent workflow execution with minimal manual intervention. Implementing automations requires close examination of existing workflows and extensive end-user involvement in requirements development and testing. Understanding how to minimize human intervention while fulfilling business goals is critical. Expanding rule-based automation while incorporating AI and ML capabilities will provide even further benefits for Safety and RWD collection.

Background

Ever increasing individual case safety report (ICSR) volumes require supplementing human efforts [1, 2]. Automation techniques to ensure that data contained within the safety database is free of duplicates, subject to minimal manual review, provide a transparent audit trail, while maintaining a high degree of quality and compliance focus are utilized to deliver immediate workflow enhancements.

Method

Definition: Two existing processes were examined. User requirements were developed for each automation.

Development: Two process automations were developed using commercially available automation software.

Testing: System and capacity testing were performed.

Pilot Release: After satisfying user requirements and successfully passing all test cases, both automations were released into a limited scale pilot.

Production Release: After successfully completing the pilot, both automations were released to production in March 2020.

Enhancement: After initial release, both automations were enhanced in an improvement cycle.

Results – Duplicate Check Assistant (DCA) Automation

Figure 1. DCA Automation Workflow

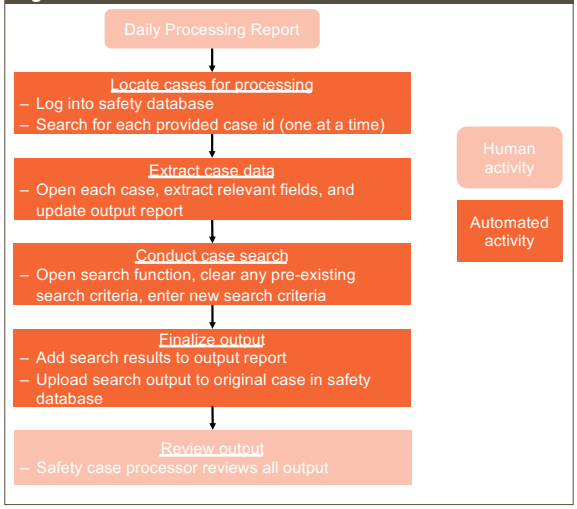

Table 1. DCA Automation Results, Single Week in March 2020

Cases Processed	1,510
Time Saved per Case	78 seconds
Total Time Savings	~32 hours

Table 2. DCA Automation Results, March to September 2020

Cases Processed	152,343
Time Saved per Case	78 seconds
Total Time Savings	~3,300 hours

Results – Data Quality Reviewer (DQR) Automation

Figure 2. DQR Automation Workflow

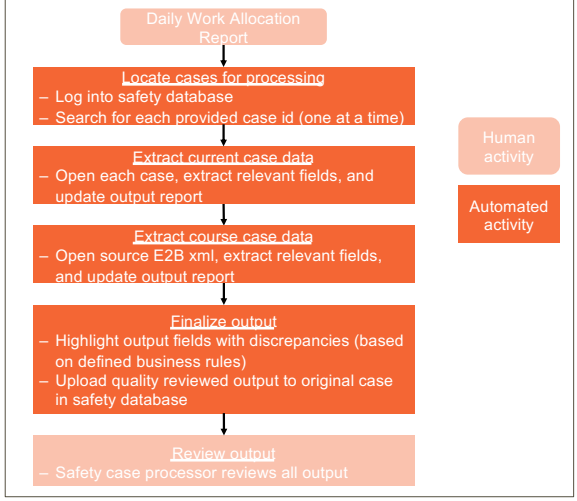

Table 3. DQR Automation Results, Single Week in March 2020

Cases Processed	458
Time Saved per Case	602 seconds
Total Time Savings	~76 hours

Table 4. DQR Automation Results, March to September 2020

Cases Processed	30,702
Time Saved per Case	602 seconds
Total Time Savings	~5,134 hours

Conclusions

Two key lessons learned in implementing automations is to initially perform a close examination of existing workflows and include extensive end-user involvement in requirements development and testing.

The automation examples presented here highlight the efficiency benefits to a Safety organization. The production use of automation for safety data has provided tangible benefits through fast and consistent workflow execution with minimal manual intervention.

References

[1] Lewis, D.J. and McCallum, J.F., 2020. Utilizing advanced technologies to augment pharmacovigilance systems: Challenges and opportunities. *Therapeutic innovation & regulatory science*, *54*(4), pp.888-899.

[2] Bate, A. and Hobbiger, S.F.. Artificial Intelligence, Real-World Automation and the Safety of Medicines. *Drug Safety*, In Press.

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