

Automation of ESDCAQ V-TMF Filing

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Use Case Highlights

COVID-19 caused travel and site access restrictions and Trial Managers unable to visit investigator sites in person. COVID-19 caused a huge influx of completed ESDCAQ* to evaluate if Electronic Medical Record systems are compliant and can be accessed remotely to perform remote Source Data Verification. Completed ESDCAQ questionnaires must be filed in the Trial Master File. V-TMF filing is a manual and time-consuming process executed by a centralized team of TMF analysts. ESDCAQ filing backlog jeopardizing JJ Clinical Operations.

Problem Statement

JJCO and TMF teams process ESDCAQ questionnaires (ESDCAQ) to determine and record whether hospital information systems are qualified for on-site clinical study monitoring and permitted for remote electronic Source Data Verification (eSDV). Each completed questionnaire needs to be manually uploaded into the V-TMF content management system. Once COVID-19 impacted the ability to perform in-person site visits due to travel and hospital restrictions, the need for remote study monitoring significantly increased. Accordingly, dozens of new ESDCAQ requests were raised and submitted for filing in V-TMF. The TMF team became overwhelmed after which it was decided to fast track the ESDCAQ BOT development. The ESDCAQ BOT automates the filing of ESDCAQ questionnaires into V-TMF in accordance with a set of business process rules and leveraging existing QA review workflows in V-TMF.

Solution Used

The ESDCAQ virtual worker presents a new way to perform document filing in V-TMF in compliance with healthcare regulation. It enables faster ESDCAQ processing outside regular business hours and enabled JJCO to react very quickly on the Covid-19 pandemic and alleviate impact onto Clinical Operations.

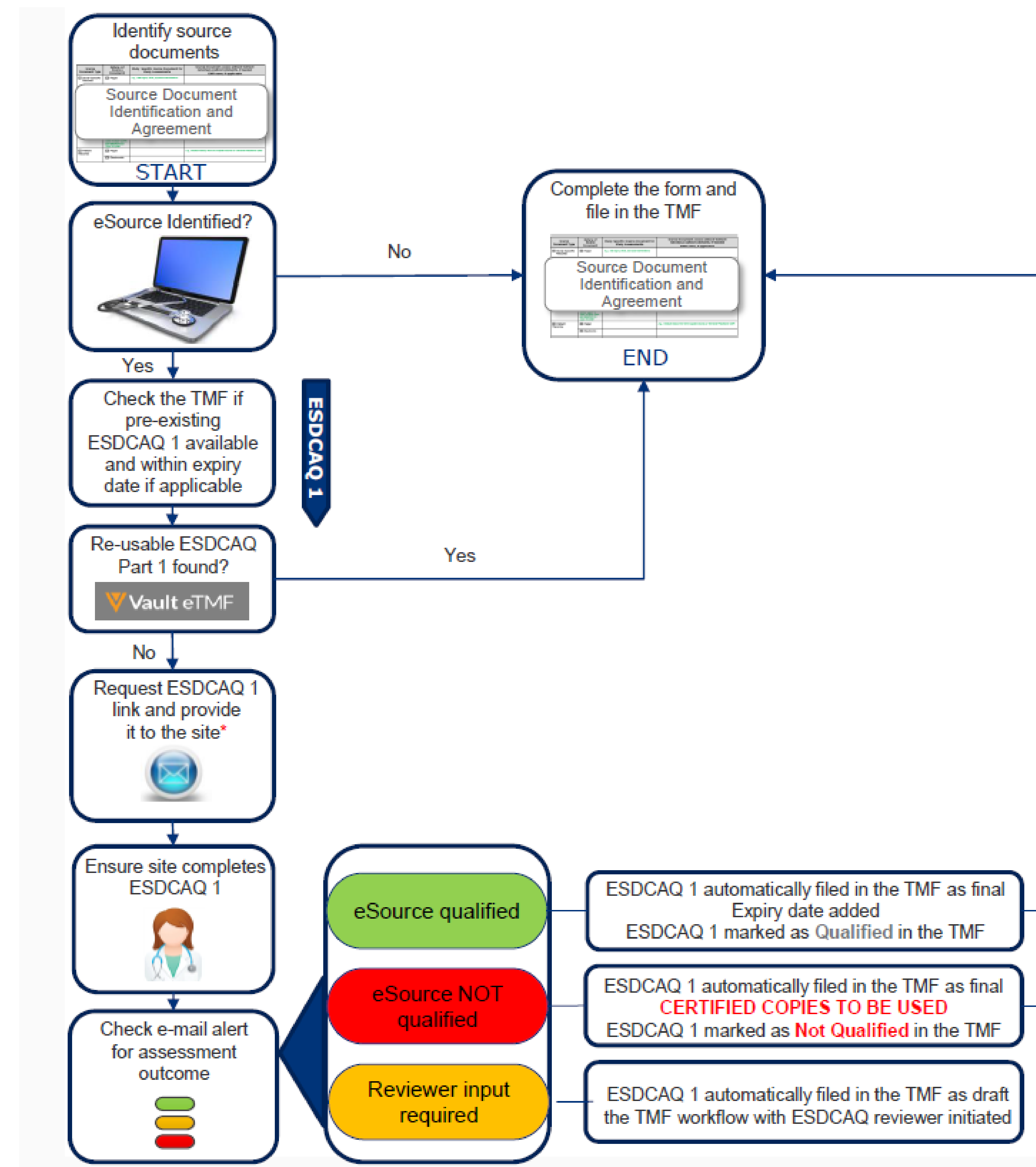


Figure 1: Scope of automation

Results – Impact

Experience: the ESDCAQ automation Bot ensures that ESDCAQ questionnaires are appropriately filed in follow up of earlier filed documents and uses document versioning to replace updated questionnaires. The Bot also flags when filing requests are out of standard business process to ensure that old or redundant ESDCAQ documents are accounted for. For shared documents the Bot ensures that secondary parties are notified about the most current version and asked to link up to the latest versions in a timely manner. Workload for CIT-TMF team decreased for uploading ESDCAQ documents

Effectiveness: The ESDCAQ virtual worker has reduced ESDCAQ filing timelines and removed any bottlenecks or potential backlog in ESDCAQ filing process. The automation has also eliminated a lot of manual routine work and enabled TMF team to spend their valuable time on business value added activities. Increased compliance by flagging up versioned ESDCAQ's in TMF to secondary trial managers. Enabled expedition of remote study monitoring capabilities in JJCO.

Efficiency: Significant cost avoidance. Increases efficiency, allowing resources to focus on value-added activities.

Key Innovations in Delivery

To date this automation is the fastest automation delivered in the organization to meet the clinical organization's COVID-19 urgency. Maximized flexibility using easily configurable process decision matrixes, email templates and environment variables. Enablement of non-continuous processing and deferred inflight process inputs from secondary study managers. Use of Veeva Application Program Interfaces instead of classic User Interface spying methods, learnings leveraged with other RPA efforts.

Conclusions/Next Steps

The ESDCAQ Automation is the first automation used across J&J multi-sectors (Pharma and MD) and was developed in close partnership with JNJ Clinical Operations, Pharma Global Clinical Operations, Janssen R&D Bio Research Quality Control and Janssen R&D TMF Team. Thousands of incoming requests have been processed and counting.