Introduction

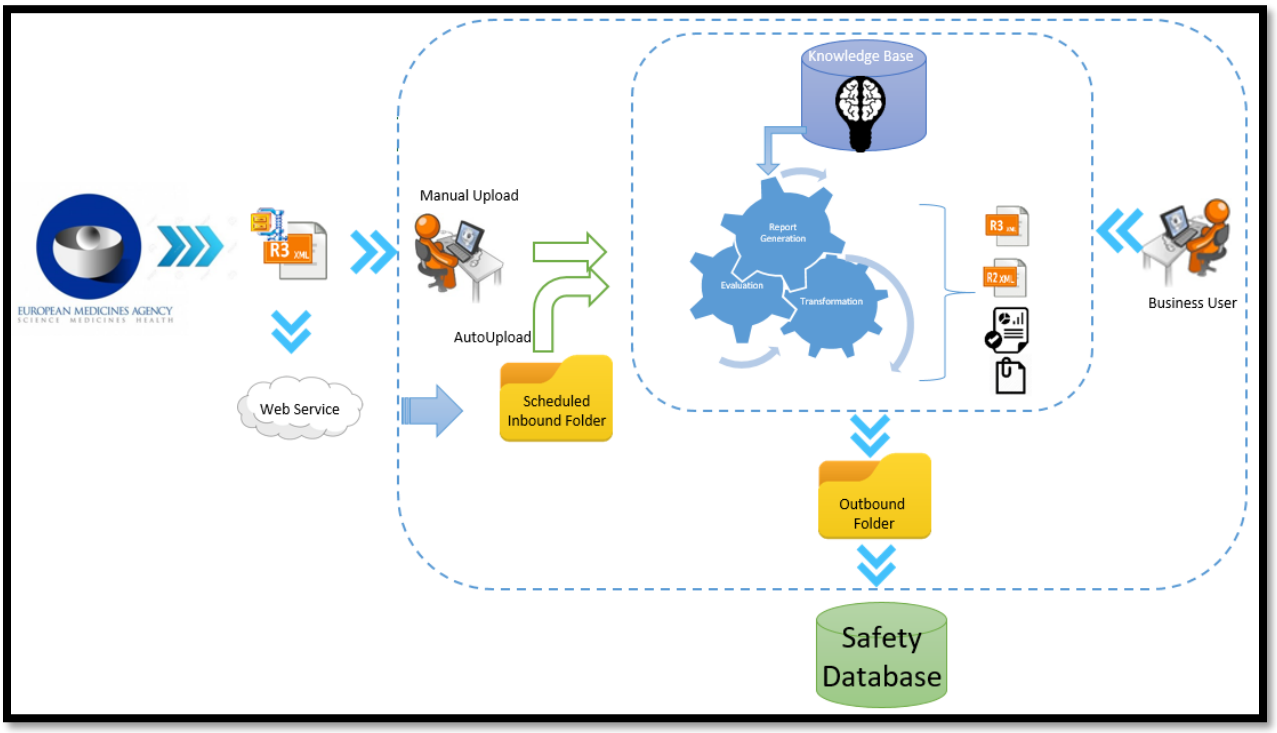
With the ever evolving regulations and a big leap towards improving patient's safety, the updated European Union (EU) pharmacovigilance legislation brought about significant changes to electronic reporting and monitoring requirements for suspected adverse reactions, to support better safety monitoring for medicines and a more efficient system for stakeholders. Marketing Authorizations Holders (MAH) are required to download medical literature from EMA, cherry-pick applicable cases, assess, evaluate and process in their local pharmacovigilance/safety system and finally report back any potential suspected adverse reaction.

The MAH are required to monitor selected medical literature for reports of suspected adverse reactions belonging to medicinal products containing their active substances. MAH are required to screen all the MLM reports published by EMA to identify cases belonging to them

Hence forth there is a need for Monitoring MLM/E2B R3 cases, extract, identify, process and submit relevant cases belonging to MAH. MAH are responsible for matching/identifying and triaging and further process the cases further into safety system for submission.

Re-Trans is a unique state of the art, simplified solutions to meet all the EMA regulatory requirements.

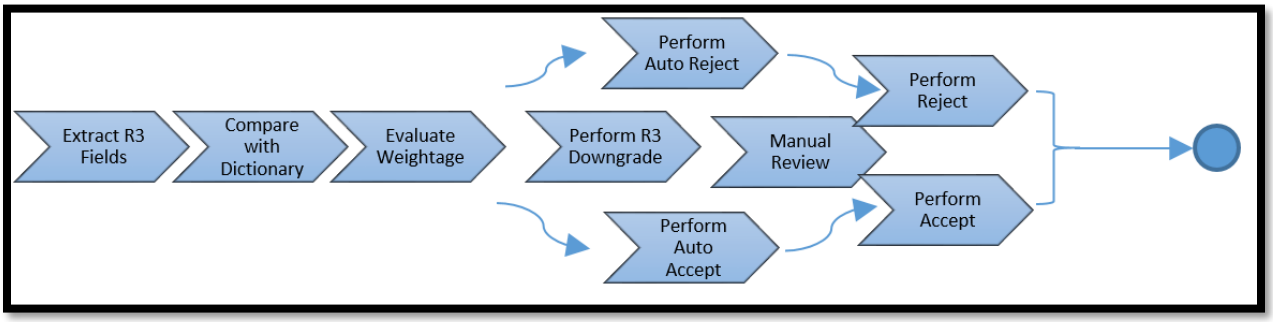
Re-Trans



- Re-Trans is an innovative Auto-match, Triaging, Monitoring & BFC Conversion of MLM literature/R3 to quickly achieve compliance with an evolving E2B R3 regulations from EMA. The application provides seamless integration with most of the leading safety systems and meets all the latest regulations.
- Compares cases in MLM/R3 files against approved company maintained master product dictionary (MPD) and accurately identifies MAH cases by using latest robust Robotic Process Automation (RPA) mechanisms.
- It applies various Complex Search/Matching Algorithms, Artificial Intelligence (AI) and Machine Learning techniques.
- System has robust search algorithm that evaluates weightage based on execution.
- Re-Trans - Seamless, Simple yet powerful tool to helps organizations to meet new regulatory requirements.
- Re-Trans is a pre-validated tool offered as a cost effective solution for companies with safety databases that requires cherry-pick cases and also that are unable to import *E2B R3 files*.
- Re-Trans also eliminates the immediate need to upgrade the Safety Databases and bring quick compliance with zero changes to their current Safety Systems.
- Re-Trans is fully compliant with *EMA* latest regulations and brings an innumerable efficiency and case monitoring, tracking, triaging and audit related capabilities. Its comparison reports, transformation- mapping flexibility and configurable settings wins hands down over other competing solutions in the market.

- Re-Trans comes in various offering models to suite every sized customer's needs. We offer both hosted, on premise and other workable business models to meet each customer's requirements.
- Re-Trans remains the clear choice of customers and wins hands down over its competition.

How Re-Trans Works:



Re-Trans first extract data from R3 file received against Dictionary (MPD – Master Product Dictionary), evaluates weightage that helps in triaging and evaluating if the case is relevant or not with statistics. Also system can be automated to accept or reject cases. Re-Trans also further performs transformation from *R3 to R2* with all required comparison report and data loss report. The transformation is as per *EMA regulatory guidelines* yet the integration is in such a way that if there is any upgrades or changes it can be easily applied without upgrading the full system.

Key Features of Re-Trans:

- Gives full compliance with EMA requirements and is up to date with latest regulatory updates. The tool comes with pre-validated installation set with ready to market availability.
- System can be fully automated where input this system can be connected directly with EVWeb and the output can be directed to Safety system.
- System has capability to process both, ether XML files or Zipped XML files from EMA.
- The System is user friendly and has multi-file selection capacity and; EU backwards forwards conversion (BFC) element mapping.
- Zero data loss due to erroneous conversions. No Data is lost during transmission and it has tracking functions to show all the stages of data transmission.
- Cloud access and a lot of functions including archiving and reconciliation of reports.
- It has uploading and dual downloading functions.
- Automatic conversion and transmission, also translation of errors are captured.
- Supports data migration and dual downloading (R3 and R2 Formats)

- Comes with simple workflow tracking/processing capabilities to streamline/mimic real time case handling. This can be further customized as per individual business needs.
- Provides full report reconciliation capabilities with both EMA downloads and Safety System imports.
- Fully customizable to adapt various requirements as per need.
- User friendly with various comparison reports.
- Multiple file upload with drag/drop features.
- Conversion logic is implemented out of the box. Any further changes can be incorporated without upgrading application or patches.
- Can be configured for fully automated process with seamless integration with Safety Systems.
- Customized Transformation Profiles, Supports multiple set of rules based on authority level.
- Label in comparison reports are configurable as per Business user needs.
- Detailed log to analyze performance, failures etc.,
- Detailed reconciliation reports with visualizations.
- Interface for triaging, monitoring and safety integrations.
- Pre-validated On cloud and on premises.
- Fully CFR Part 11 complaint.

Comparison Summary

Features	Re-Trans	Others
Triage & BFC, both Combined	Y	N
Search by Events & Drugs	Y	N
Simple workflow	Y	N
Machine learning - Acceptance	Y	Y
Machine learning - Rejection	Y	N
Customize Algorithm weightage & Evaluating weightage	Y	N
Auto Process on qualifying weightage	Y	N
Safety system reference updates	Y	N
Search, Filter based on Ref. Updates	Y	N
Reconciliation Report includes Ref. Updates	Y	N
Process ICSR XML or Zip file	Y	N
Progress monitoring of Zip files, logs	Y	N
Duplicate Checks	Y	N
Alerts & Notification of various events	Y	N
Detailed of Drug and its children data with comparison status	Y	N
Event details of case	Y	N
Multi-tenancy support for CRO	Y	N
Generate Comparison report	Y	Y
Filtered view of comparison report	Y	N
Customized labels for Comparison report	Y	N
Extract & Process Individual Cases	Y	N
CFR Part 11 Complaint	Y	N
Archive Transactions	Y	N
Integrations with Safety System for AER/Case No. Update	Y	N

Reference

- http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/06/WC500229805.pdf
- http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000633.jsp&mid=WC0b01ac05808ce84c