

CASE STUDY

Literature case tracking



Business Solutions with Technology Edge

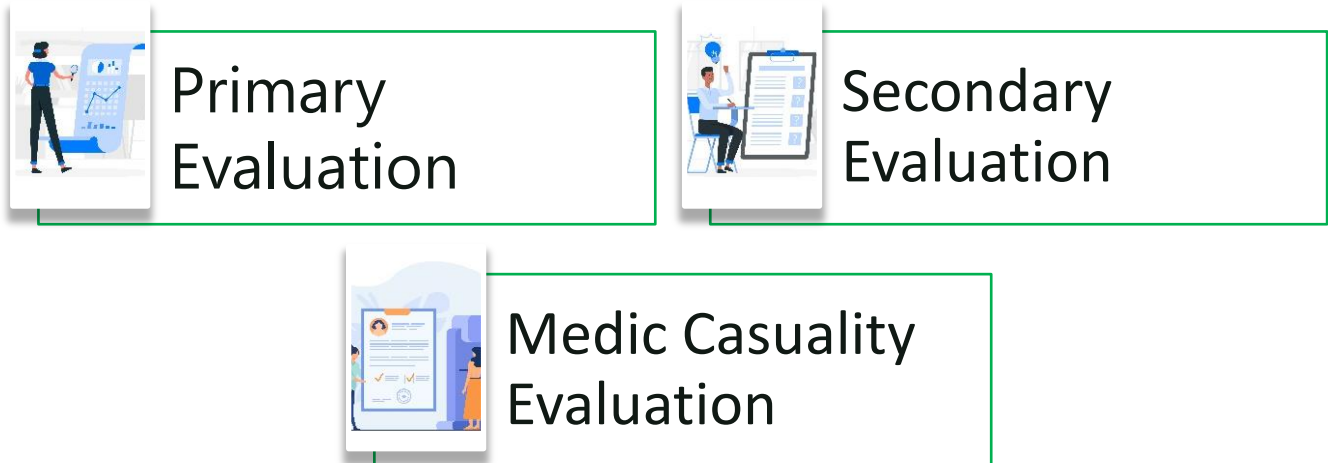
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Introduction

Literature case tracking is an integral aspect of every literature case processing team of PV service provider/MAH.

There are several ways to perform literature case tracking, but routine way of tracking and processing literature cases is Multistage literature evaluation technique.

There are several steps involved in the “Multistage literature evaluation technique”



Literature data bases (Like PubMed & EMBASE) Screening for identification MAH & Product specific literature articles which involves prospective screening and retrospective screening



This will be done initially by forming literature search strings (in PubMed/EMBASE) unique to the company suspect product with various filter conditions in the string to narrow down the specific search



1. Fetching the search string specific article list from PubMed & EMBASE involves,
2. Downloading the abstract of each searched article with all MeSH terms and author details with citations
3. Downloading the full text article if it is available for further evaluation



1. Creation of an Excel sheet for all the of the downloaded (product specific) abstracts & Articles (with their titles).
2. Preparation of source document folder (Full text article repository & PDF abstracts)



Primary Evaluation for filtering MAH specific valid ICSRs on Excel sheet only by primary evaluation of abstract and full text article if available (Selections & Rejections of valid and invalid Lit. cases) (Advanced Entry person role)



1. Secondary Evaluation (Mostly done by QCs)- Secondary reassessment for the primary evaluated articles & abstracts from data entry, it will be a QC activity to validate the causality and events captured by Advanced Entry user)
2. Selection of a valid Literature ICSR from the data (All the activities are Excel sheet based)



1. Medic assessment for finalization of Author causality implication & Finalization of selected literature article for further ICSR creation
2. Final triage and prioritization of Valid literature cases as per their seriousness, listedness, and causality
3. Processing of Literature Cases as per regulatory timelines (Day-15 & Day-07) in Safety database

Major Literature Surveillance Software's currently present in the market (Marketed Use cases):

1. Litpro Lifespher Safety: (Aris Global)

1. Intelligent automation for medical literature monitoring and assessment
2. A full-service, automated medical literature database screening solution

LifeSphere LitPro automates the process of

- a. Identifying and retrieving all relevant journal article details from accessible bibliographic databases such as Embase and MEDLINE/PubMed, among others
- b. Scanning the selected information sources for pertinent safety information
- c. Assessing the attribution to determine if there is a relationship between an event and a medicinal product
- d. Recognizing and extracting key data points for use as part of the creation of an ICSR or follow-up report to an existing case within a safety database
- e. Fulfills regulatory requirements by automating literature surveillance, event identification, data extraction and case creation
- f. It performs duplicate check of abstracts to identify unique and new relevant abstracts for each search. In addition, the duplicate check process includes/excludes ICSRs identified via the EMA medical literature monitoring process.
- g. It establishes a central repository for weekly hits to generate customized reports. Companies can also generate a report of marked articles
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2. Drug Safety Triager: (By Dialog Solutions)

1. Intelligent automation for medical literature monitoring and assessment
2. All literature references related to medicinal product safety undergo a systematic review process which automatically captures and appends a non-editable audit trail to the record
3. Its machine learning models help to make the literature review process carried out in Drug Safety Triager quicker, more efficient and more thorough
4. Using NLP (Natural Language Processing), it's machine learning models automatically identify references in scientific literature that meet the criteria for valid ICSRs, Aggregate Reports or Safety Signals
5. It eliminates duplicated and inconsistent references and can reduce the literature to be reviewed by safety scientists and physicians for aggregate reports and safety signals by up to 70%.
6. Literature references entered into Drug Safety Triager flow automatically through the workflow and are organized in an intuitive and easy to use way.
7. E2B R3 output to case processing
8. Enhanced reference deduplication

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