The importance of local literature

In 2017, the European Medicines Agency (EMA) revised their Guideline on Good Pharmacovigilance Practices (GVP) Module VI. Among the changes to pharmacovigilance regulations described in the document was one concerning literature published in local journals:

“There should be procedures in place to monitor scientific and medical publications in local journals in countries where medicinal products have a marketing authorization.”

This EMA requirement can be challenging to meet in an efficient and compliant manner. Among the challenges are:

- Identifying the right local literature sources and monitoring them in alignment with global processes
- Ensuring that all search strategies for that literature are auditable, reproducible and trackable
- Working with local CROs in cases where in-house language capabilities are insufficient
- Ensuring that searches of this select set of literature are performed regularly to maintain Regulatory Compliance

The French local literature module helps Embase® customers overcome these challenges.

French Local Literature Collection

The largest French indexed Literature Collection for enhanced reviewing

The Embase® French Local Literature Collection enables pharmacovigilance and drug safety specialists to align the monitoring of 120 French-language journals for adverse drug reactions and other safety information with their local and global processes. Embase’s unique filters enable users to include or exclude journals from the list. This streamlines literature search, triage and review.

Careful selection and translation

- 120 relevant journals identified based on input from industrial partners, European Medicines Agency (EMA) and Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Full-text articles translated to English using human quality control

Complete discoverability

- Translated full-text articles are manually indexed using the Embase Emtree taxonomy
- All search functionalities can be applied, including Embase’s intuitive query builders such as the Embase PV Wizard and PICO search forms to enable retrievability of the most relevant results
- Email alerts can be created to retrieve new and updated records

The French Local Literature Collection

The French Local Literature Collection enables users to align the monitoring of French-language journals for adverse drug reactions with their local and global processes. This streamlines literature search, triage and review, avoiding time-consuming manual processes.

The module facilitates both in-house and outsourced pharmacovigilance-related literature monitoring.

A highly curated collection

The journals included in the French Local Literature Module are carefully selected in consultation with industrial partners, the EMA and Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM).

Careful, quality-controlled translation and indexing

The French Journals undergo full-text machine translation. Translation quality is measured for accuracy, relevance, consistency, clarity, style and completeness. The translated articles are manually indexed by Elsevier’s medically trained expert indexers with Embase’s Emtree taxonomy to easily retrieve the most relevant articles.

Full Embase functionality

All Embase features can be used to enhance the search experience, including PV Wizard and the PICO search form for intuitive complex query building; search saving, exporting and sharing. Including automatic notifications via email alerts to retrieve new and updated records to support Regulatory Compliance for literature screening.