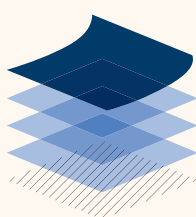


French Local Literature Module

This new module allows pharmacovigilance groups to align the monitoring of French-language literature for adverse drug reactions with their global process.

Careful selection and translation

- 100 relevant journals identified based on input from industrial partners, the EMA and ANSM
- Full-text articles translated using human-aided machine translation with human quality control



Full discoverability

- Translated full-text articles are manually indexed using Emtree®
- All search functionalities can be applied, including PV Wizard and the our PICO query form
- Email alerts can be applied



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:

“...market authorization holders should have 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 so that no event is missed

To help our customers overcome these challenges, we're introducing new local literature modules to Embase.

The French Local Literature Module

Our first module is the French Local Literature Module. It enables users to align the monitoring of French-language journals for adverse drug reactions with their global processes. This streamlines literature search, triage and review.

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 content undergoes full-text human-supported machine translation. Translation quality is measured for accuracy, relevance, consistency, clarity, style and completeness. The benchmark for translation is 98% and quality can reach 99.6%.

The translated articles are manually indexed with Emtree.

Full Embase functionality

All Embase features can be used to enhance the search experience, including PV Wizard and the PICO search form for complex query building; search saving, exporting and sharing; and email alerts to improve regular screening.

For more information, visit:

elsevier.com/embase.