

CASE STUDY

Professional Services

A Top Pharmaceutical Company

Compliant Monitoring of Adverse Events



SUMMARY

A review of how Elsevier R&D Professional Services helped a pharmaceutical company become more compliant with literature screening requirements.

WHAT ARE THE ESSENTIALS OF COMPLIANT LITERATURE MONITORING?

- 1. Thorough search:** A thorough search strategy with search strings to retrieve information relevant to an extensive set of marketed drugs and therapeutic conditions
- 2. Efficient triage:** An easy-to-use literature management system that supports rapid classification of retrieved articles and quick decision-making
- 3. Full-text access:** The possibility to easily access the full text of the relatively few literature items with adverse event information
- 4. Report tracking:** A means of showing that the Individual Case Safety Reports and Periodical Safety Updates were filed on time

Missing adverse events is not an option

Every pharmaceutical company has to have a solid strategy for screening scientific literature for adverse events involving their products. Missing an adverse event or a reporting deadline will lead to serious responses from regulatory authorities.

Searches have to be broad to capture everything that might be relevant, but this yields large result sets. Therefore, the literature triage method has to be precise enough to allow users to quickly sift through all the search results and identify all of the adverse events for their products.

Dealing with compliance issues

One of the world's top pharmaceutical companies received a warning letter from the regulatory authorities. They had missed articles that mentioned adverse events involving their products and had therefore not filed the required reports. They needed to find a new, more certain strategy for monitoring scientific literature.

Elsevier was able to prepare a fully scalable strategy for literature monitoring and triage that met their needs and gave them the confidence to call for an audit from the regulatory authority that had issued the warning letter.

What was Elsevier's strategy?

Elsevier's Professional Services team programmed search strings to retrieve all of the reports of adverse events matching the desired drugs and therapeutic conditions. These search strings are applied to the Embase database, which includes MEDLINE®, at the company's request. Alerts have been set up to automate the delivery of search results.

Then, the Professional Services team set up a triage strategy that allows the Drug Safety team of the company's Global Pharmacovigilance and Epidemiology (GPE) group to easily review and define the relevance of all the literature and organize it using Elsevier's life sciences literature management solution, QUOSA.

Looking at the Embase and MEDLINE indexing tags for each piece of literature, the Drug Safety team members know whether to discard or to obtain the full text and send it for detailed review. For example, if the indexing is 'animal-only study' or 'in vitro-only study', they can discard it. If it is 'human study' or 'clinical trial', they refer it on. 'Case Reports' are processed in an expedited flow.

Finally, Elsevier helped to expedite the transfer of information to the Corporate Global Safety Database system for case triaging as a new Individual Case Safety Report (ICSR) or an update to an ICSR. Elsevier's solution also facilitated the retrieval of articles marked as relevant for the various safety concerns of the relevant regulatory authorities to which the Drug Safety team have to present Periodical Safety Update Reports or equivalents.

LITERATURE SCREENING, MINING, AND TRIAGE FOR PHARMACOVIGILANCE

Objectives:

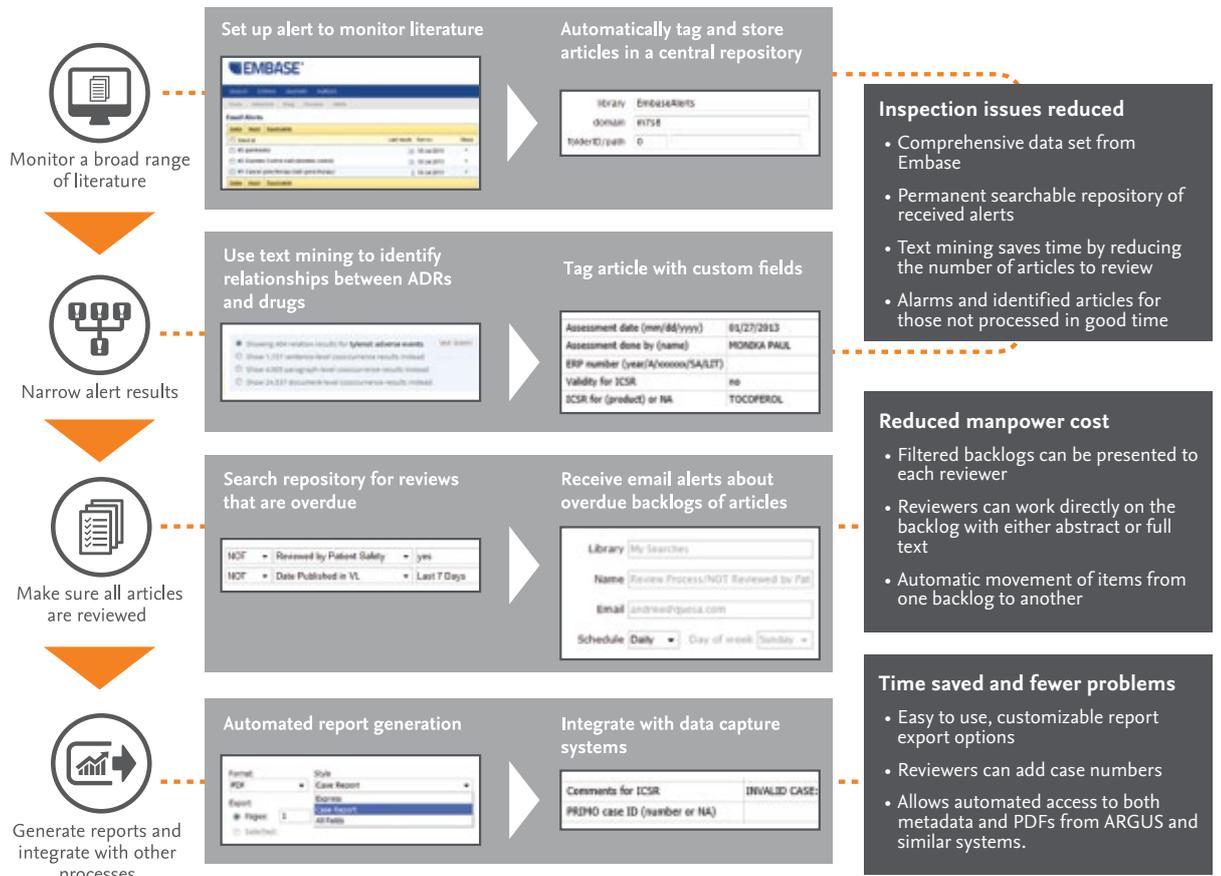
- Monitor safety-relevant literature
- Rapidly identify adverse events
- Submit findings in safety update reports
- Integrate findings into safety database systems

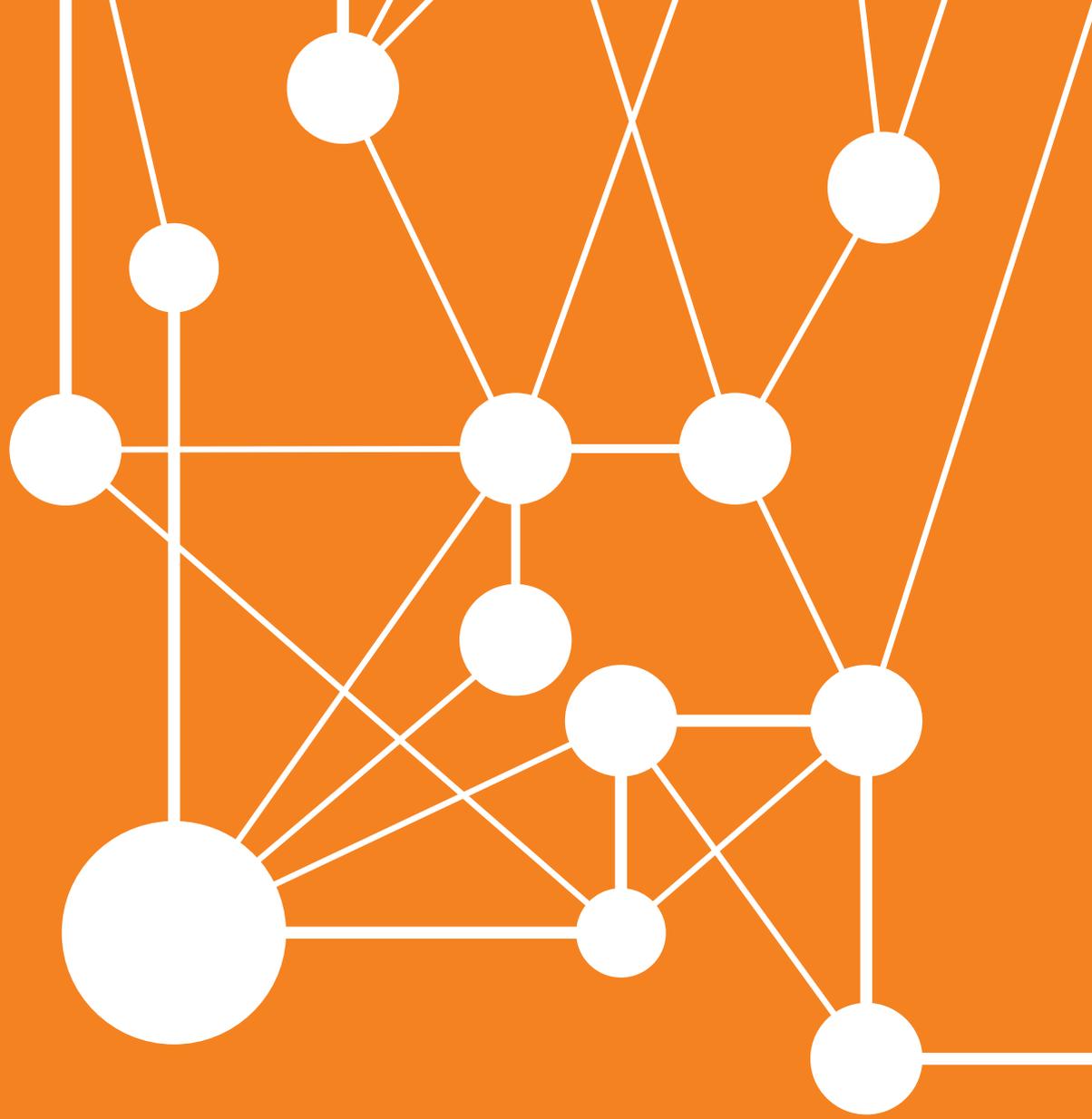
As these have highly regulated schedules, Elsevier ensured that QUOSA was set up to help the Drug Safety team to meet the deadlines, keep track of the correct data lock dates, and provide evidence of compliance with the time limits by datestamping the receipt of search results.

What was the outcome?

Just 15 days after the implementation of the new system, the GPE group at the company felt confident enough to call for a new audit, which was performed 6 months later. The results fully satisfied the concerns of the regulatory agency.

This is the type of confidence that is essential for regulatory and medical affairs teams at pharmaceutical companies — the confidence that professional consultancy in strategy design provides.





Visit elsevier.com/products/solutions/professional-services
or contact your nearest Elsevier office.

ASIA AND AUSTRALIA

Tel: + 65 6349 0222

Email: sginfo@elsevier.com

JAPAN

Tel: + 81 3 5561 5034

Email: jpinfo@elsevier.com

KOREA AND TAIWAN

Tel: +82 2 6714 3000

Email: krinfo.corp@elsevier.com

EUROPE, MIDDLE EAST AND AFRICA

Tel: +31 20 485 3767

Email: nlinfo@elsevier.com

NORTH AMERICA, CENTRAL AMERICA AND CANADA

Tel: +1 888 615 4500

Email: usinfo@elsevier.com

SOUTH AMERICA

Tel: +55 21 3970 9300

Email: brinfo@elsevier.com