

Why choose Adis Pharmacovigilance as your partner?

Industry leading provider:

You are choosing a partner that has more than 30 years' experience in delivering pharmacovigilance content and solutions. Importantly, we have been providing ICSR literature services for more than 15 years to a client base that includes top 20 global pharmaceutical companies.

Safety and security:

Partnering with us allows you to share the business risk of literature monitoring; our ICSR service is aligned with key regulatory guidelines such as the EMA, FDA and ICH.

Quality assured:

Our service has consistently stood up to audit and inspection, with a quality management system that encompasses key quality aspects.

Expert staff:

Our expert 100+ team comprises physicians and pharmacists; most have prior experience in providing pharmacovigilance support services to the industry.

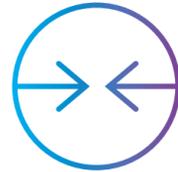
Flexible options:

As your business needs change, we can offer scalability and flexibility in the services and support we provide to cater for the number of products or types of services required.

Personal support:

We offer ongoing consultation to ensure we are always delivering the best possible solution to your organisation.

Adis Pharmacovigilance: Service and security



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Adis Pharmacovigilance - a tailored, tiered service

Entry level: Early alerts

Our experts design and maintain a safety-focused search strategy with the right balance of precision and recall (sensitivity). A weekly automated process triggers literature searches to capture all new content added since the last search was run. Physicians review the search results to identify literature articles containing potential ICSRs. You will receive daily alerts to notify you of relevant literature reports.

Mid-level: Case report summaries

To build on the entry level service, after reviewing the search results we obtain and review the full text article/translation for all potential ICSRs. We then extract key data to create a case report summary, including case narrative, and deliver completed records on a daily basis. You can use our case summaries to expedite your triage and assessment of the ICSRs and make more rapid decisions on further actions.

Premium level: E2B (R3) XML:

If you opt for our premium service, not only do we perform the literature search and review, but our case processing team extract relevant data from the full text article to populate the fields required to complete the E2B (R3) report form. Completed ICSRs are sent to you in the E2B R3 format as XML files, to enable import directly into your pharmacovigilance database. All you have to do is perform a final medical review and you are ready to submit.

If you are ready to take the first step and explore the possibility of working in partnership with Adis Pharmacovigilance please contact us. Together we will review your current processes and determine how we can best support you.

Email pharmacovigilance@adis.com or visit adis.com/pharmacovigilance for further details.



Contact

Literature ICSRs

EARLY ALERTS

CASE REPORT SUMMARIES

E2B (R3) XML

Adis Pharmacovigilance

The expert solution for ICSR literature searches

Monitoring and screening the medical literature to enable effective ICSR reporting puts many pressures on your pharmacovigilance department - from the time and specific expertise required, to constantly battling to meet regulatory deadlines.

Adis Pharmacovigilance are experts in structured literature monitoring and assessment. By working in partnership with us, you can free up your time and have peace of mind that your literature ICSR processes will continue to run smoothly.

Find out more about our ICSR monitoring services

Adis Pharmacovigilance: Service and security

How can Adis Pharmacovigilance support you with your literature ICSR workflow?



EARLY ALERTS

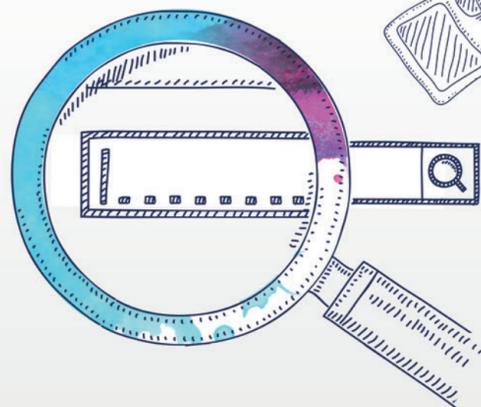
CASE REPORT SUMMARIES

E2B (R3) XML

1. DESIGN SEARCH STRATEGY



2. EXECUTE SEARCH



3. REVIEW SEARCH RESULTS



4. OBTAIN FULL TEXT/TRANSLATION



5. REVIEW (VALID/REPORTABLE)

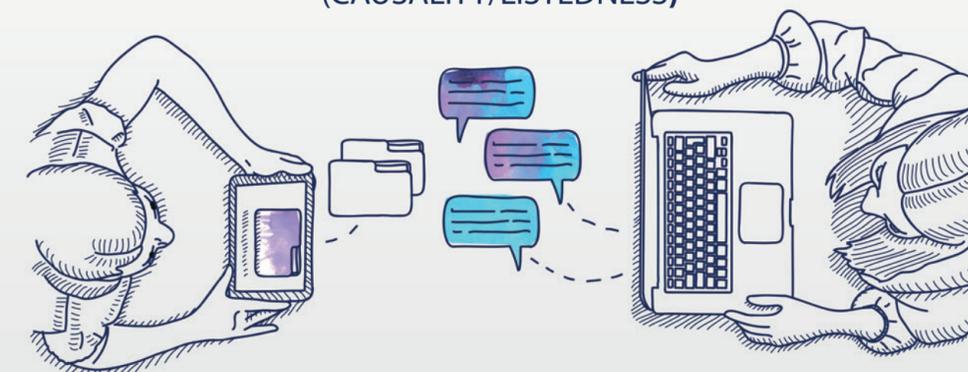
- ✔ We use our tried and tested safety-focused search strategy, giving you peace of mind that relevant ICSRs will be captured
- ✔ You get alerted to potentially relevant ICSRs in the literature as quickly as possible

- ✔ We will review the full text article and identify key data to help you initially evaluate the case
- ✔ The case summary allows you to triage ICSRs further according to seriousness
- ✔ Faster decisions can be made on whether further processing is required

6. CREATE ICSR FORM (E2B)



7. MEDICAL REVIEW (CAUSALITY/LISTEDNESS)



- ✔ We populate the E2B XML based on the full text article, saving you vast amounts of time in data entry
- ✔ The comprehensiveness of the data enables you to rapidly complete processing of the ICSR
- ✔ Faster decisions can be made on subsequent actions required, e.g. based on seriousness categorisation or specific events of interest