



## Pharmacovigilance services – single case handling

A-consult has many years of pharmacovigilance expertise from working with small and large pharmaceutical companies.

We focus on quality and medical expertise in our daily work.

### A-consult offers:

- Pharmacovigilance database
- Full case processing of spontaneous and clinical trial adverse events
- Expedited reporting

Our staff has several years of experience in adverse event processing and is trained in the use of ARISg and Eudravigilance Webtrader. We can host your safety data in our database, thereby removing your need for expensive installation and set up in-house.

We offer efficient management of clinical trial SAEs on a trial by trial basis. By using our database we offer consolidation of all SAEs across a clinical trial programme ensuring effective monitoring of trial programme safety, complete Development Safety Update Reports and compliance with GCP.

Our case processing service may include any or all of receipt, assessment and triaging, coding, data entry, quality control, medical review, follow-up, expedited reporting and reconciliation.

Expedited reporting requires up-front planning and trained personnel. We can perform the registration and set up of the electronic reporting routes. Our experienced and trained personnel ensures that expedited reporting meets the regulatory requirements, whether electronic or hard copy.

Our service concept is full-scale and flexible. We strive to match your needs whether it means full outsourcing or insourcing of A-consult staff in your organisation.

*Your challenges – we bring you to a safe landing*

LET US BRING YOU TO A SAFE LANDING

A-consult group is an European consultancy organisation founded in 1983, with a team of 40 highly educated and experienced employees in Denmark and France. A-consult a/s, situated in Denmark, has serviced more than 200 companies and handled regulatory tasks in more than 80 countries. A-consult a/s is offering professional regulatory affairs and product safety service to companies working with food, nutraceuticals, food supplements, cosmetics and pharmaceuticals.



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