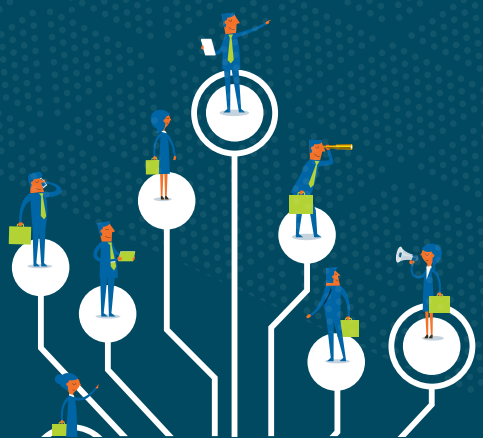
Ashfield

Pharmacovigilance

Agile, scalable drug safety services you can trust



Patient safety is your priority – and ours. We can help you look after patients and ensure you meet regulatory requirements, thanks to a comprehensive range of pharmacovigilance services. These include:

- Adverse event reporting
- Global case processing
- Regulatory intelligence
- Risk management
- Literature searches
- Trending and signal detection
- Global aggregate reports
- Medical reviews and writing
- Pharmacovigilance consulting
- SDV (source data validation)/ reconciliation
- Regulatory submissions

We collaborate with you to create the services that best meets your needs, scaling them up or down as your requirements change.

A highly qualified team deliver our services in strict accordance with the Ashfield Quality Management Framework and rigorous compliance processes.

Ashfield provides access to a dedicated team of people handling your cases. Having a core team enables them to know your drug inside and out while providing a single point of contact.

Clinical trials management including:

- **ICSR management**
- **Medical review of ICSRs**
- **AOSE writing**
- **DSURs**
- **Data trending and analysis**
- **SUSAR unblinding**
- **Database reporting**
- **SAE reconciliation**
- **Regulatory submissions**
- **Preparation of Investigator / Ethics Committee letters and packets**

>99%
Cases submitted on time

200,000+
Cases processed annually

1,000+
Aggregate reports completed annually

900+
Generic and Rx products supported

No 483s
Or critical findings

For more information contact:
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UDG Healthcare plc