

Safety First – Integrated Safety Solutions for Medical Products: Pharmacovigilance

Helping you ensure medical product safety compliance

Drug Recalls. Regulatory Sanctions. Lawsuits.

Due to recent high-profile drug safety problems, the pharmaceutical industry is faced with greater regulatory enforcement and increased accountability demands for the protection and welfare of patients. This changing climate requires companies to take a more proactive approach to drug safety and pharmacovigilance. Companies simply cannot afford to overlook any vital safety information about their products.

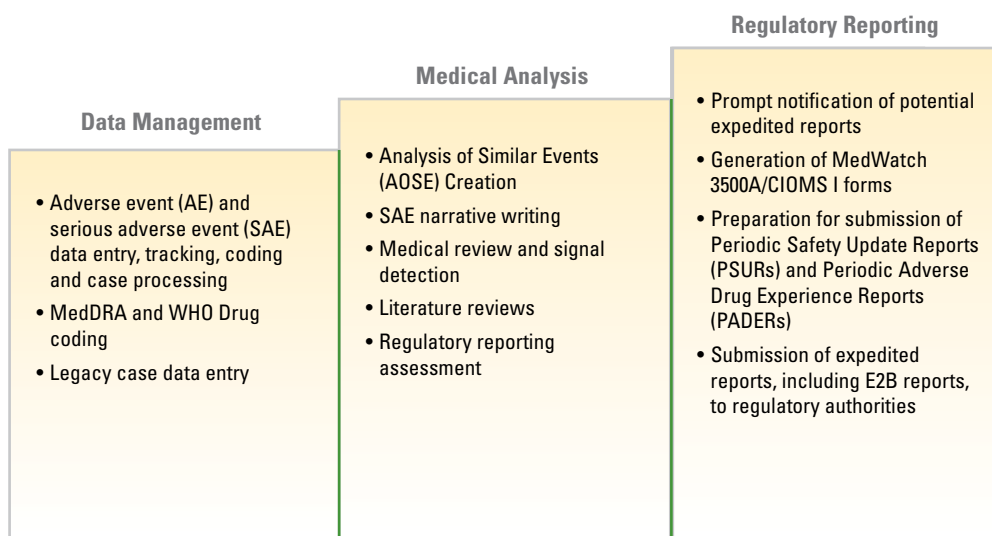
Experience You Can Trust

Our pharmacovigilance team is eager to help you develop and implement effective medical product safety programs. Our experienced team of professionals will work collaboratively with you to develop a comprehensive safety management plan, so you can be confident your company is protecting its patients and reputation. Our in-depth knowledge of FDA regulations and ICH guidelines enables us to help you effectively develop and manage your safety processes to ensure regulatory compliance.

RTI-HS Pharmacovigilance Services

Improving Your Integrated Safety Plan at Every Step

Good pharmacovigilance practices start with a good plan. RTI-HS provides complete drug safety management, from premarketing through postmarketing, that will guide your product development and commercialization decisions.



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Reputation and Integrity Matter

When choosing a partner, you need to know you are working with a trusted organization that delivers quality results in an objective, meaningful manner. Our pharmacovigilance clients know these principles are “business as usual” for us. Our clients appreciate that we pay attention to their needs and provide quality deliverables on time and within budget. We follow the FDA’s Good Pharmacovigilance Practices guidelines and focus our work products on the end user, so practitioners and patients can fully realize the risks and benefits associated with a particular remedy.

Electronic Adverse Event Reporting

We have the flexibility to use our clients’ proprietary or licensed electronic reporting systems, or we can use Argus Safety™, a leading technology for SAE and AE case management and reporting. Our Argus Safety license allows us to provide a fully validated 21 CFR Part 11 compliant system that is fully configurable to accommodate your specific needs and supports multiple products and studies. Moreover, routine backup and disaster recovery systems and procedures are in place, which is essential for safeguarding your data.

Our pharmacovigilance team can also assist US clients with other case reporting options, such as manual reporting, if it better meets their needs.

Expect Excellence

RTI-HS is small enough to provide truly personalized service, yet large enough to have all of the necessary resources to effectively implement your product safety management plan. You’ll benefit from our collegial work environment and straightforward, efficient processes. Here, you can expect a project team that is focused on meeting your objectives and that remains intact from the initial kick off to completion of your project. We’ve set the bar high for ourselves and are committed to your satisfaction every step of the way.

Benefit from Our Pharmacovigilance Services

Our pharmacovigilance team has experience helping a variety of global medical product companies, including:

- Small to large pharmaceutical and biotech companies
- Generic drug manufacturers
- Small to large contract research organizations

To learn more about our capabilities, please visit us online at www.rtihs.org, email us at rtihealthsolutions@rti.org, or call one of our offices listed on the front.