Patient safety in focus

Competence Center

Safety & Vigilance

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Clinical Research

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Safety & Vigilance

The requirements in drug and medical device safety are complex. Our team, equipped with many years of extensive experience and up-to-date specialist knowledge, is well-prepared to work with you to find tailor-made solutions for your needs. We are eager to provide project-related, short-term or long-term support for your team by fully adapting to your specific requirements.

Our services:

- Support in all areas of Safety & Vigilance (pre- and post-authorisation/CE marking)
- Creation & maintenance of safety-relevant documents
- Case processing including follow-up & authority submission
- Data entry and maintenance in safety databases (e.g. EudraVigilance, ARGUS)
- Safety writing (e.g. ASRs, DSURs)
- Signal detection & evaluation
- Training on patient & drug safety
- Implementation of regulatory requirements and communication with all stakeholders involved

Project Highlights

#1 - Where complexity meets competence.

For one of our clients, we processed safety reports in the context of legal cases. This involved extracting and processing the relevant information from large amounts of data relating to the cases. The follow-up was carried out in close cooperation with the law firm involved.



Our focus on your Safety & Vigilance aspects



Competent, flexible, individual

In today's world, every project comes with new and unique challenges, making the one-fits-all approach rarely applicable to any study. When it comes to the area of Safety & Vigilance, multiple factors - both direct and indirect - influences the services required. Let us know what is in focus of your project and we discuss the possible strategic approaches e.g.

- **Integration of the patient's perspective**
- **Linking of different data sources**
- **Addressing specific requirements related to application and dosage of the product in question**

We are pleased to offer our support right from the start of a new project, drawing on our vast experience we have gathered over the years from a wide range of projects and studies successfully completed for our various clients.

Project Highlights

#2 – Tailored safety – fit for any project dimension.

First in Human
Medical Device
10 Patients
13 Cases

Non-interventional Study
Medicinal Product
> 3.000 Patients
19.900 Case Reports

Medicinal products, medical devices and more



Same commitment, unique solutions.

It is not always easy to comply with regulatory and internal company safety requirements without external support. We are fully committed to our joint projects. However, you retain complete control over the processes used and the scope of activities, as we are a medium-sized company and can respond flexibly to your requirements.



- Screening for safety events (e.g. social media, advisory boards, company internal databases) and/or Case processing incl. Narrative Writing
- Flexibility regarding the Safety Database (Database entry according to your specifications in your Database or WN Safety Database)
- Safety-related reports for medicinal products/medical devices according to country specifications (e.g. D, CH, F, UK)
- Complete reporting to Competent Authorities via EudraVigilance (ICSR) and CTIS (ASR) for all regulatory required report types



Project Highlights

#3 – Efficiency by design.

In studies where few safety-related events are expected our long-standing partnerships with customers are particularly beneficial. When setting up the first project, we consciously consider its transferability to other projects with this customer. This allows us to reduce costs in the long term.

Our strengths:

With over a decade of reliable experience in the Safety & Vigilance sector, our talented and committed staff excel in efficient coordination, driven by work ethics characterized by diligence, knowledge, and a strong sense of responsibility.

- By aligning your specific needs with our established and proven standard processes we provide effective and efficient solutions for your projects.
- Our experts integrate seamlessly into your existing frameworks, collaborating closely with your team.
- We are dedicated to ensuring that your medicinal products or medical devices safety goals are met with accuracy and in compliance with regulatory standards, by maintaining constant communication throughout the process.

Contact us today to discuss how we can support your Safety & Vigilance needs – safely, efficiently, and with confidence!



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