20 February 2026
Virtual Training

AKADEMIE HEIDELBERG

# Pharmacovigilance in Clinical Trials: A European and DACH Perspective

## Interactive Training

- Understanding the fundamentals of pharmacovigilance and its role in clinical trials
- Overview of the regulatory framework in the DACH region including EU CTR and GDPR
- Practical responsibilities of sponsors, investigators, and CROs in safety data management
- Latest trends and quality assurance in pharmacovigilance including AI and digital tool

**Speaker**

Dr. Joan D'souza
Pharmacovigilance Consultant / Local QPPV
Stufenplanbeauftragte, Freelancer
Zurich

# Pharmacovigilance in Clinical Trials: A European and DACH Perspective

## Program

### What is Pharmacovigilance in Clinical Trials?

- Definition and objectives
- Importance in early development phases
- Stakeholders and high-level responsibilities (sponsor, investigator, CRO)

### Regulatory Landscape in the DACH Region

- EU CTR 536/2014 overview
- Brief country-specific nuances (DE, AT, CH)
- Role of Ethics Committees and GDPR

### Core PV Processes in Clinical Trials

- Safety data collection
- AE, SAE, and SUSAR handling
- Safety reporting timelines (intro only)
- DSUR/ASR (high-level)

### Responsibilities in Practice

- Sponsor vs. CRO vs. investigator responsibilities
- Brief on DSMBs and safety communication

### Real-World PV in DACH Trials

- Case examples or interactive walkthrough (e. g., »What would you report?«)
- National portals/tools (overview only)
- Communication with authorities

### Data Protection and Ethics

- GDPR and consent in clinical trials
- Ethical review requirements
- Emerging AI challenges (brief awareness)

### Quality and Future Trends

- How PV quality is monitored (audits, inspections)
- Common findings and good practices
- Brief outlook: digital safety tools, AI, automation

### Group Exercise or Q&A

- Scenario-based discussion (e. g., »What happens if a SUSAR is missed?«)
- Questions and clarifications

### Wrap-Up and Takeaways

- Key messages summary
- Where to find resources (glossary, templates)

## Aims and Objectives

This interactive online seminar provides a practical introduction to pharmacovigilance (PV) in clinical trials, with a focus on regulatory requirements, stakeholder responsibilities, and safety processes in the DACH region.

Participants will gain a clear understanding of key PV concepts, including AE/SAE/ SUSAR handling, safety reporting, data protection, and the roles of sponsors, investigators, and CROs. The training emphasizes real-world application through case examples, scenario-based discussions, and current challenges such as digitalization and AI in PV. By the end of the course, participants will be equipped to identify safety-relevant events, understand timelines and responsibilities, and navigate the PV landscape in early-phase clinical development.

The seminar is ideal for professionals at all experience levels who are involved in drug safety activities within clinical trials.

## Worth Knowing

### Target Audience

This seminar is specifically designed for professionals working:

- Clinical research professionals
- Pharmacovigilance specialists
- Regulatory affairs officers
- Clinical trial sponsors and investigators
- Contract Research Organizations (CROs)
- Clinical trial coordinators and safety surveillance teams
- Regulatory and legal compliance professionals
- Pharmaceutical industry decision-makers
- External auditors and inspection

Additionally, it is highly relevant for other interested specialist or policy departments, executive board members, external auditors, and service providers.

### Reasons to Join

- You will gain up-to-date know-how on pharmacovigilance requirements specific to clinical trials
- You will receive practical implementation tips for your organization and day-today work
- You will clarify individual questions directly with the expert speaker
- You will benefit from valuable best practices through exchange with fellow professionals

## Our Speaker

**Dr. Joan D'souza**
Pharmacovigilance Consultant/Local QPPV/Stufenplanbeauftragte
Freelancer, DACH region, Zurich

*Dr. Joan D'souza is an accomplished pharmacovigilance and regulatory affairs professional with experience in clinical trials, medical review, safety writing, GxP audits, and compliance. With combined clinical, legal, and scientific training-including a medical degree and a U.S. Juris Doctorate-she offers a strong multidisciplinary perspective. She has worked across U.S. and European regulatory systems in key roles involving case processing, signal management, safety reporting, SOP development, and communication with health authorities in Switzerland, Germany, Liechtenstein, the UK, and Ireland.*

Programme aus dem EMA-Dschungel mit PV-Relevanz
5 December 2025, Virtual Training

Verträge in der Pharmakovigilanz
8 December 2025, Virtual Training

Pharmarecht kompakt: Praxiswissen für Zulassung, Sicherheit und Vertrieb
4./5. February 2026, Virtual Training

Klar, souverän und selbstbewusst
9 February 2026, Virtual Training

Profiling, Psychologie und Sprache wirksam einsetzen
24. March 202, Virtual Training

▶ This and other seminar offers can be found online on our website: *www.akademie-heidelberg.de/online-seminare*

## Further Information

I am happy to answer your questions about this seminar, in-house trainings and our entire program.

Dr. Marion Müller
Phone 06221/65033-28
m.mueller@akademie-heidelberg.de

## Registration form

Pharmacovigilance in Clinical Trials:
A European and DACH Perspective

First name

Name

Position / Department

Company

Adress

Postal Code / City

Telefone

E-Mail

Assistant's name

Date / Signature

Kindly send your regsitration to: **anmeldung@akademie-heidelberg.de**

### Date and Time

Friday, 20 February 2026
9:00 am to 4:30 pm
Online access from 8:45 am
Seminar code: 2602PS604W

### Fee

€ 490,– (plus VAT)

The fee includes access to the seminar as well as the presentation as a PDF file. After the seminar, you will receive a certificate confirming your attendance.

### General Terms and Conditions

Our general terms and conditions apply (as of 01.01.2010). If you wish, we can send these to you. An English version is available upon request.You can also view our general terms and conditions at any time on our website: www.akademie-heidelberg.de/agb

### Procedure

- One day prior to the seminar you will receive an email with a link giving you direct access to the online seminar.
- In order to participate, you do not need to download and install any program. You can dial in directly via Zoom using your internet browser.
- You can ask questions at any time and discuss them with the speakers and other participants via your microphone and camera. Alternatively, you can use the chat to communicate.

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