11th December 2026 · 9:00 a.m. – 3:00 p.m.
Virtual Training

AKADEMIE HEIDELBERG

Signal Management: CTs and Post-Marketing

Ensuring PV Compliance Through Effective Audit Strategies

Regulatory and Industry Best Practices

- **Signal management procedure: Identify, assess and document safety signals, ensuring review, escalation and risk mitigation**
- **Signal management in clinical trials: Ongoing monitoring of trial safety data to detect risks and report findings to regulators**
- **Signal detection methods: Techniques to identify safety signals**
- **Signal Evaluation and assessment: Techniques to evaluate and assess safety signals**

Speaker

Philipp Ansorge
Head Pharmacovigilance
Market Acess Lead, Luminance Health
Basel, Switzerland

Farima Barmaki
Drug Safety and
Pharmacovigilance
Consultant

Signal Management: CTs and Post-Marketing

Program

- Definitions
  - Key pharmacovigilance terminology used in signal management
- Signal Management Procedure
  - End-to-end pharmacovigilance process for identifying, validating, assessing and documenting safety signals
  - EU signal confirmation, data sources, triage checklist, validation, noise filtering and prioritisation
  - Off-label use, medication errors, OTC products
  - Escalation
  - Drug Safety Committee review and risk minimization
- Signal Detection Methods
  - Approaches to identify safety signals across multiple data sources
  - Qualitative review and quantitative methods (disproportionality analysis, frequentist/Bayesian)
  - Statistical metrics, detection tools and defined criteria for signal identification
- Signal Management in Clinical Trials
  - Ongoing safety monitoring during clinical development
  - Limitations of solicited reports and management of signal noise
  - Key Emerging Trends from Adaptive Clinical Trials and implications for pharmacovigilance teams
- Regulatory Requirements for Signal Notification
  - Overview of global requirements for reporting safety signals
  - FDA, EMA/MHRA and Swissmedic submission timelines
  - Timely submission, assessment and communication of validated signals
- Signal Tracker
  - Tracking of status, ownership, prioritisation and assessment history
  - Traceability, documentation and cross-functional pharmacovigilance communication

Good reasons to attend

- You gain up-to-date knowledge on specific requirements related to Signal Management in PV
- You receive immediately applicable implementation tips for your institute and department
- You clarify open questions for your department or institute with the speaker
- You receive valuable practical tips through exchange with other practitioners

Aims and Objectives

This webinar provides a practical and comprehensive overview of signal management in pharmacovigilance, aligned with current regulatory expectations in post marketing and clinical trial settings. Participants will gain insight into key principles, processes, and tools used to identify, evaluate, and communicate safety signals across the product lifecycle.

The session will cover the end-to-end signal management process, including detection, validation, prioritisation, evaluation and assessment, escalation, and governance.

Participants will review key signal detection methods, including qualitative approaches and quantitative techniques, supported by commonly used metrics, tools, and criteria.

Finally, the session will highlight how signal information is reflected in PBRERs and RMPs, key regulatory notification requirements across FDA, EMA/MHRA and Swissmedic, and the role of signal tracking systems in ensuring transparency and traceability.

Worth knowing

Target audience

- Pharmacovigilance and Drug Safety personnel
- Quality Assurance and Quality Management personnel
- Regulatory Affairs personnel
- Clinical Safety and Clinical Operations
- Auditing and GxP Quality Functions
- Pharmacovigilance Service Providers
- Pharmaceutical, Biotechnology, and Medical Device Companies as well as other interested departments or key areas, executives/board members and external auditors

Our Speaker

Philipp Ansorge
Head Pharmacovigilance, Market Access Lead
Luminance Health, Basel, Switzerland

Philipp Ansorge is the Head Pharmacovigilance and Pharmacovigilance Responsible Person at Luminance Health and provides cross-functional strategic advice across Quality Assurance and Pharmacovigilance. He leads the development and implementation of robust pharmacovigilance systems that ensure the safety and compliance of pharmaceutical products throughout their lifecycle. With his broad knowledge of the regulatory requirements for drug safety in various jurisdictions, he provides guidance to clients, ensuring timely identification, evaluation, and mitigation of safety risks.
Philipp has successfully taken on numerous mandates throughout his career. These include roles such as Swiss Responsible Person (for Medicinal Products and ATMPs), Pharmacovigilance Responsible Person, EudraVigilance Responsible Person, and EU-QPPV. Philipp is an experienced auditor and has successfully hosted several inspections by health authorities.

Farima Barmaki
Drug Safety and Pharmacovigilance Consultant

Senior pharmacovigilance leader with extensive experience in global clinical safety, signal management, benefit-risk evaluation, risk management, and regulatory strategy across the product lifecycle. Experienced in supporting complex development and post-marketing programmes, leading cross-functional safety initiatives, and providing expert training on signal detection and benefit-risk assessment to health authorities.

MedDRA – Hands-on
September 22, 2026, Online Event

Women in Research – Empowerment, Visibility and Mental Strength
October 6, 2026, Online Event

Programme aus dem EMA-Dschungel mit PV-Relevanz
October 27, 2026, Online Event

Was nicht im Risk Management Plan steht
November 10, 2026, Online Event

Beton meets BtM: Pharmabauprojekte
December 1, 2026, Online Event

DSUR and PSUR/PBRER
December 4, 2026, Online Event

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

Further Information

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

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Registration Form

Signal Management: CTs and Post-Marketing

Last Name

First Name

Job Title

Company / Orgnaization

Street Address / No.

Postal Code / City

Phone Number

Email Address

Assistant's Name

Date / Signature

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

Date and Time

11th December 2026
9:00 a.m. to 3:00 p.m.
Online access from 8:45 a.m.
Seminar code: 26 12 PS718 W

Fee

€ 990,– (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.

Special fee: € 890 ,– (plus applicable VAT) for registrations received by August 31, 2026.

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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