

AGAH e. V. Webinar*

Wednesday, 8 July 2026 · 17:30-19:00

The AGAH is a specialist medical and academic organization focused on the development of exploratory medicinal product and on human pharmacological research. The digital AGAH Mebinars (*Member Seminar) aim to discuss these topics not only within the AGAH Community, but also with all interested participants.



Applied Pharmacovigilance in Clinical Trials – Inspection-Ready in Practice

When you conduct clinical research, it's a regulatory requirement to be familiar with—and correctly apply— core pharmacovigilance rules and processes. In this practical webinar, we explain the pharmacovigilance duties during the conduct of clinical trials and how to set up compliance end-to-end.

You'll learn how to address key regulatory expectations and deliverables, including CIOMS form, EudraVigilance/EVWEB, ICH E2B, ICH E2F, ICH E3, and spontaneous reporting. We'll also cover critical recurring trial safety responsibilities such as DSUR, medical literature monitoring, and essential oversight roles including the QPPV and the German Stufenplanbeauftragter.

Beyond the theory, we'll walk through an inspection-focused toolkit needed when setting up a clinical trial: Safety Management & Communication Plans, SAE/AE intake and SAE forms, follow-up workflows, reconciliation touchpoints, escalation pathways, and safety governance—including how protocol-defined pausing/stopping rules are handled in practice.

Please feel free to submit your questions in advance by 3 July 2026 via the registration form.

[Registration ↗](#)

Organiser AGAH e. V. www.agah.eu
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AGAH-Member Free
Regular 40 EUR¹

From 17:15 Dial-in via **Microsoft Teams**
(We recommend using the MS Teams app.)
You will receive the dial-in link on 6 July 2026 at the email address you have provided.

Speakers **Caroline Matthey**
SocraMetrics GmbH
Dr Ruwen Böhm
SocraTec R&D

1 GENERAL TERMS AND CONDITIONS FOR REGISTRATION

Registration

After completion of the registration with CSi Hamburg GmbH, as a mandated service agency, a binding contract between the participant and AGAH e. V. becomes effective. Participation AGAH Member: free of charge. The Regular registration fee (40 EUR) is per person, according to §4, para. 22, German Turnover-Tax Law exempt from VAT and charged and collected on behalf of AGAH e. V., Goer- nestraße 30, 20249 Hamburg/Germany (taxpayer ID number: DE25876120). The participant will receive a written confirmation/invoice with paying details first and have to pay the registration fee within the payment period.

CANCELLATION

AGAH-Member: If you are unable to attend the web seminar, we kindly ask you to cancel in writing to agah-meetings@csihamburg.de

Regular registration: Cancellations made up to 2 weeks prior to the start of the event are free of charge; any cancellations received after this time will not be refunded. All refunds will be settled after the event. A substitute participant can be accepted at any time. All changes or cancellations must be submitted in writing to CSi Hamburg GmbH.

Data use and storage

The personal data you provide will only be used by CSi Hamburg GmbH to fulfil the contract and will be handled in accordance with the provisions of the Ger- man Data Protection Regulation (DSGVO). For the duration of the contractual relationship, the service provider may store and use the personal data of the participants in compliance with the applicable data protection regulations. The collection, storage and processing of your personal data is necessary for your regi- stration for the web seminar. Your data will be used exclusively for the purpose of organising and conducting the event. Your data will only be passed on to third parties if they are directly involved in the running of the event and if the organisa- tional progress makes this necessary (organiser). The legislative body requires us to obtain your active consent. Within the registration process, participants give their consent for their surname, first name and institution/company to be stored in the list of participants. You will receive information about the data we have stored about you without having to give a reason and you can have this data blocked, corrected or deleted at any time. You can also revoke your consent to the use of your data at any time without giving reasons. Please send your written re- vocation, stating in detail which data records are to be deleted, to: CSi Hamburg GmbH, Goernestraße 30, 20249 Hamburg or info@csihamburg.de.

The web seminar will take place via an online meeting platform: Microsoft Teams. Please note that this platform may belong to a company based in the United States of America. Your data will be passed on to the service provider for use. Due to a possible location in the United States of America, the same data protection regulations as in Germany do not apply.

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The organising party cannot be held responsible for any costs, damages or ex- penses that may be incurred by registered persons as a result of the postpone- ment or cancellation of the event.

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