INFORMATION

Attendance Fee
800 € Regular
550 € Member of one of the EUFEMED societies
500 € Junior Scientist*

The participation fee is per person. Please note, according to §4 para 22 German turnover tax law, registration and workshop fees are exempt from VAT. Registration fees are charged and collected on behalf of AGAH e. V. All bookings are subject to change.

*under the age of 30

Registration Deadline: 27 August 2023
Maximum number of participants: 25 Guests

Venue
SocraTec R&D GmbH
Im Setzling 35
61440 Oberursel (Germany)

ORGANIZER

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CONFERENCES
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INCENTIVES

PROGRAMME COMMITTEE / SPEAKER

Dr Ruwen Böhm

Medical Director at SocraTec R&D GmbH, Erfurt

Stephan Herrmann

Head of Electronic Data Capture at SocraMetrics GmbH, Erfurt

Dr Andrew Leary

Senior medical expert at regenold GmbH, Badenweiler

Anika Staack

PV Expert at regenold GmbH, Badenweiler

Markus Stoll

Senior Data Standards and Governance Manager at Merck Healthcare Research & Development / Group lead at German CDISC User Group

Click here to register

Die Inhalte der Fortbildungsmaßnahme sind produkt- und/oder dienstleistungsneutral gestaltet. Potenzielle Interessenkonflikte der Referierenden werden in einer Selbstauskunft gegenüber den Teilnehmenden offen gelegt. Der Clinical Data Management Workshop ist eine Eigenveranstaltung der AGAH e. V. und wird nicht durch Sponsoring finanziert. Die Höhe der Gesamtaufwendungen beträgt ca. 13.500 € für die Ausrichtung.
The contents of the training measure are designed to be product and/or service neutral. Potential conflicts of interest of the speakers will be disclosed to the participants in a self-declaration. The Data Management Workshop is an own event of the AGAH e. V. and is not financed by sponsoring. The total expenses for the organisation of the workshop amount to approx. 13,500 €.

AGAH
Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology

AGAH WORKSHOP

APPLIED COURSE IN CLINICAL DATA MANAGEMENT

The interplay of clinical data management with practical data collection on-site, SAE reconciliation and statistical analysis.

15 September 2023

Oberursel, Germany

CONTENT

Also in early phase trials the ultimate goal of Clinical Data Management is to assure that data structure, data collection and quality as well as data analysis adequately support conclusions to be drawn from clinical research. In the end high-quality data should be accurate, suitable for statistical analysis and the structure should follow internationally accepted standards.
Quality by design in clinical data management means a structured interplay of all relevant core documents including the trial protocol, CRF, DMP/DVP/SAP as well as the data base itself.
How to ensure this in early clinical development?

This workshop gives an introduction into the basic principles of clinical data management starting from the trial protocol and ending with the completed data base. Participants will train the knowledge communicated in a practical example together with an experienced team of data managers.
Furthermore, the workshop will offer a first insight into CDISC principles, how this helps to systematically reach a high-quality data structure and in how far this is of relevance for submission procedures.

The workshop has been developed for clinical investigators, project leaders and project managers, monitors and also for phase-I/II experienced study nurses with a certain enthusiasm for data structures who want to better understand the principles of a good-quality data management and how they can contribute already in the planning phase to set-up a data structure following international principles. It covers questions relevant for industry-sponsored studies as well as IITs.

Barbara Schug
Managing Director at SocraTec R&D GmbH, Oberursel

Juliana Brudel
Managing Director SocraMetrics GmbH, Erfurt

Status May 2023. Subject to change without notice.

FRIDAY, 15 September 2023

09:00-09:20 **Welcome and introduction**
R. Böhm, SocraTec R&D, Erfurt

09:20-10:00 **Topic 1**
Clinical Data Management
We start our workshop with the basic principles of clinical data management and their interaction with practical data collection on site. We discuss the most important documents in data management with a focus on (e)CRF design, programming edit checks, performing user acceptance tests and query management.
S. Herrmann, SocraMetrics, Erfurt

10:00-10:45 **Topic 2 - Session 1**
Management of Clinical Safety Data
(2 sessions with a break of 15 minutes)
We will discuss SAEs/SUSARs/risk assessment and coding for EMA and FDA with a particular focus on PK studies. This presentation will show how early detection of potentially liver toxic substances and metabolites impacts the conduct of clinical trials, as well as the link between pharmacology and patient safety via MedDRA coding. A short history of the evolution of the US guidelines for cases of drug-induced liver injury (DILI) will also be included.
A. Staack, regenold GmbH, Badenweiler
A. Leary, regenold GmbH, Badenweiler

10:45-11:00 Break

11:00-11:45 **Topic 2 - Session 2**

11:45-12:45 **Topic 3**
CDISC data requirements
Never heard of CDISC or heard it before and never knew what it actually meant? In this course, you will learn what SDTM and ADaM is. We will guide you through the jungle of documents like controlled terminology, implementation guides and technical conformance guides. You will get an overview about contents and structure of submission packages to regulatory authorities and what that all means for your day-to-day data management activities.
M. Stoll, Merck Healthcare Research & Development / German CDISC User Group

12:45-13:30 Break

13:30-14:30 **Topic 4 - Introduction**
(2 parts with a break of 15 minutes)
You will be divided in small teams to practice the creation of eCRF pages hands-on with focus on error-proof data entry, automatic plausibility checks and data integrity. Based on your designed eCRF, you will then define a possible database structure and discuss that with all participants. You will be guided by experienced data managers during the interactive workshop.
S. Herrmann, SocraMetrics, Erfurt

14:30-15:30 **Topic 4 - Interactive Part 1**

15:30-15:45 Break

15:45-16:45 **Topic 4 - Interactive Part 2**

16:45-17:00 **Conclusion**
R. Böhm, SocraTec R&D, Erfurt