ORGANISATION

Attendance Fee
300 € Regular
230 € Member of AGAH
180 € 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.

Registration Deadline: 25 May 2021
Maximum number of participants: 25 Guests

Venue
Online Course @ ´Microsoft Teams`
-you will receive your personal login data-

Date
1 June 2021 | 13:00 PM - 17:00 PM
2 June 2021 | 13:00 PM - 17:00 PM

FAQ and Information

ORGANISER

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PROGRAM COMMITTEE / SPEAKER

Juliana Brudel

Head of Data Management at SocraMetrics GmbH
Erfurt, Germany

Dilshat Djumanov

Director of Data Science at Richmond Pharmacology
London, UK

Stephan Herrmann

Head Electronic Data Capture at SocraMetrics GmbH
Erfurt, Germany

Dr Dagmar Kottig-Roth

Principal Data Standards and Governance Manger,
Global Clinical Data Sciences at Merck KGaA
Darmstadt, Germany

Dr Barbara Schug

Managing Director at SocraTec R&D GmbH, Oberursel
and at SocraMetrics GmbH, Erfurt, Germany

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 Data Management Workshop ist eine Eigenveranstaltung der AGAH e. V. und wird nicht durch Sponsoring finanziert. Die Höhe der Gesamtaufwendungen beträgt ca. 4.500 € 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. 4,500 €.

AGAH
Arbeitsgemeinschaft für angewandte Humanpharmakologie e.V.
Association for Applied Human Pharmacology

AGAH WORKSHOP

APPLIED COURSE IN DATA MANAGEMENT

1 and 2 June 2021

- ONLINE -

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 rele-vance 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 and at SocraMetrics GmbH, Erfurt, Germany

Status April 2021. Subject to change without notice.

Day 1 · TUESDAY, 1 June 2021

from 12:45	Dial in
13:00-13:15	**Welcome and introduction** *Barbara Schug, Oberursel/Germany*
13:15-14:15	**Topic 1: Clinical Data Management** We will start our workshop with the basic principles of clinical data management. We discuss the most important documents in data management and their interplay with focus on (e)CRF design, programming of edit checks, performance of user acceptance tests and query management. *Stephan Herrmann, Erfurt/Germany*
14:15-14:30	**Discussion**
14:30-15:15	**Topic 2: DMC in early phase clinical trials: Safety Monitoring Board** CDM is more than just eCRF design and query management. CDM involves project management of DM aspects and planning and organization of the Safety Monitoring Board especially in the field of SAD and MAD first-in-human trials. The presentation will focus on practical aspects of the early phase DMC like composition, which data are to be presented and evaluated as a listing or graphs, data quality requirements, how are stopping rules defined, dosing steps, extension of a cohort after each dosing step but also continuous monitoring in an MAD design will be discussed. *Dilshat Djumanov, London/UK*
15:15-15:30	**Discussion**
15:30-15:45	*Break*
15:45-16:45	**Topic 3: CDISC data requirements** Never heard of CDISC? 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. *Dagmar Kottig-Roth, Darmstadt/Germany*
16:45-17:00	**Discussion**
	End of Day 1

Day 2 · WEDNESDAY, 2 June 2021

from 12:45	Dial in
13:00 - 14:00	**Topic 4: Study Protocol** After you learnt, what data management means and what you should take care about, let us talk about protocol writing. We will discuss how to define endpoints and parameters adequately so that the eCRF can well be designed. But we will also show limitation where specific expert knowledge is needed to set-up the CRF even with a well written protocol due to the complexity of certain endpoints. *Barbara Schug, Oberurselt/Germany*
14:00-14:15	**Discussion**
from 14:15	**Interactive Part Introduction** *Julia Brudel and Stephan Herrmann Erfurt/Germany* 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.
15:15-15:30	*Break*
15:30-16:00	**Team work in groups**
16:00-16:30	**Presentation of results (one group)** *Julia Brudel and Stephan Herrmann Erfurt/Germany*
16:30-16:45	**Conclusion** *Barbara Schug, Oberursel/Germany*
16:45	**Open Q & A Session and networking** After discussion of results you are invited to a post-meeting get-together with a little surprise from the organisers.
	End of Day 2