

WORKSHOP

Quality-by-design

Key factors for the success of
a clinical trial and safeguard for
patient safety and data quality

ORGANIZED BY THE
Network of Coordinating Centres for Clinical Trials
(KKS-Netzwerk) → www.kks-netzwerk.de

14. March 2014 | 10:30 – 17:00 | Cologne

University Hospital of Cologne | Building 44b | MTI-Hörsaalgebäude



Workshop Programme

- 09.30 **Registration**
- 10.30 ■ **Welcome and introduction**
 Ursula Paulus/Oana Brosteanu
- 10.50 ■ **Planning of risk-based quality management
 measures for a clinical trial - Reflection paper
 from the EMA inspectors working group**
 Gabriele Schwarz, BfArM, Germany
- 11.50 ■ **SPIRIT 2013 Statement: defining standard
 protocol items for clinical trials**
 Douglas Altman, Oxford University, UK
- 13.00 **Lunch**
- 14.00 ■ **Comprehensive study specific risk assessment,
 use of quality endpoints and learning from a study
 bug depository**
 Dirk Hasenclever, University of Leipzig, Germany
- 15.00 **Coffee Break**
- 15.15 ■ **Panel discussion**
 Chair: Meinhard Kieser/Walter Lehmacher
 Participants: Gabriele Schwarz/Douglas
 Altman/Dirk Hasenclever/Oana Brosteanu
 Followed by plenary discussion
- 17.00 ■ **Summary/End of Workshop**

Chairs

Prof. Meinhard Kieser

Institute for Medical Informatics and Biometry (IMBI),
University of Heidelberg, Germany

Prof. Walter Lehmacher

Institute of Medical Statistics, Informatics and Epidemiology
(IMSIE), University of Cologne, Germany

Speakers

Prof. Douglas Altman

Centre for Statistics in Medicine, Oxford University, UK

Dr. Dirk Hasenclever

Institute for Medical Informatics, Statistics and Epidemiology
(IMISE), University of Leipzig, Germany

Gabriele Schwarz

Federal Institute for Drugs and Medical Devices (BfArM),
Germany

Dr. Oana Brosteanu

Coordinating Centre for Clinical Trials (KKS Leipzig),
University of Leipzig, Germany

Dr. Ursula Paulus

Clinical Trials Centre Cologne (ZKS Köln),
University of Cologne, Germany



Quality-by-design

Building more quality into the process of preparing and conducting clinical trials, whilst taking account of a risk-based approach, becomes increasingly important in clinical research.

It has been shown that many findings during audits and inspections could have been prevented if the study protocol had provided clear, comprehensive and unambiguous procedural guidance and information for everybody involved. This is also the central recommendation of the recently published SPIRIT 2013 Statement.

The workshop will present an overview of key factors to be considered when planning a clinical trial. It will introduce the background and the contents of the EMA Reflection paper on risk based quality management in clinical trials. Ideas for a comprehensive study specific risk assessment will be developed.

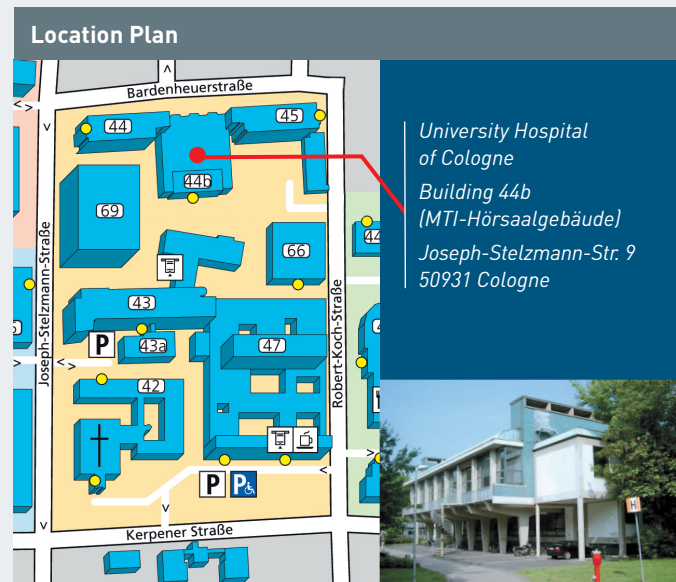
Participants will have the opportunity to engage in a panel discussion with the speakers, including a member of the SPIRIT-Group and a representative of the German competent authority BfArM.



Participants of the workshop

Clinical scientists involved in the planning and set-up of clinical trials and quality measurements for clinical trials, i.e. Principal investigators and investigators, trial coordinators, project managers, biostatisticians, monitors and data managers from academic institutions and industry.

University Hospital of Cologne



→ http://www.uk-koeln.de/fileadmin/user_upload/Lageplaene/lageplan_uniklinik_koeln.pdf

Accommodation

Recommendations of hotels in Cologne

→ <http://www.kks-netzwerk.de/termine-veranstaltungen/kksn-workshops.html>

Attendance fee

Members of the KKS Network: 150 €
Academic institutions, Authorities, Health professionals: 300 €
Companies, CROs and Associations: 550 €
Students: 50 €

KKS-Network

The Network of Coordinating Centres for Clinical Trials (KKS-Network) is a consortium of 18 Coordinating Centres for Clinical Trials (KKS) and Centres for Clinical Trials (ZKS) at German universities/university hospitals and the German Surgical Trial Network (CHIR-Net).

The members of the KKS-Network were funded with the objective to build and organise the infrastructure required for the planning and conduct of clinical trials in academia. The KKS/ZKS aim to increase the quality of clinical trials by providing experienced and dedicated staff for clinical trials as well as the supporting infrastructure (e.g. project management, data management, biometry, SAE-Management, IT, quality management).

The KKS-Network contributes to the discussion of recent papers on risk-based quality management; members of the KKS-Network e.g. head a German project which deals with risk-based monitoring (ADAMON).

Contact and registration

To register, please fill in the registration form at

→ <http://www.kks-netzwerk.de/termine-veranstaltungen/kksn-workshops.html>

Should you have any questions, feel free to contact us.

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