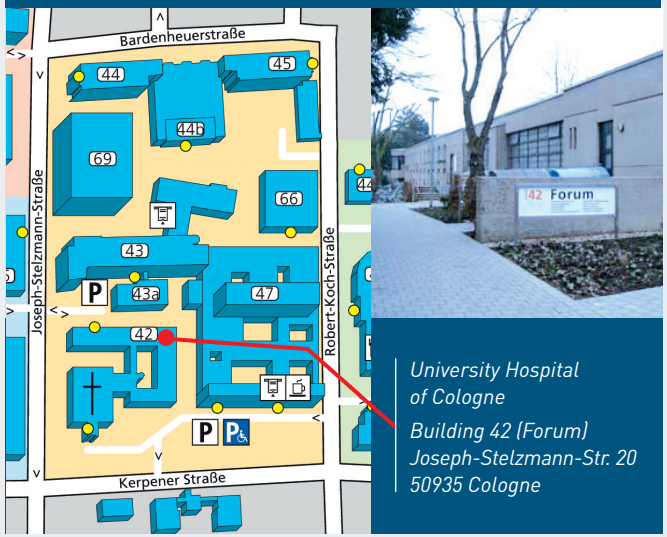
KKS Netzwerk
Koordinierungszentren für Klinische Studien

University Hospital of Cologne

Location Plan



University Hospital of Cologne
Building 42 (Forum)
Joseph-Stelzmann-Str. 20
50935 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.

Central office

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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)

14. March 2014 | 10:30 – 17:00 | Cologne
Forum | University Hospital of Cologne | www.kks-netzwerk.de

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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.

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. Dr. 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
Coordination Centre for Clinical Trials (KKS Leipzig), University of Leipzig, Germany

Dr. Ursula Paulus
The Clinical Trials Centre Cologne (ZKS Köln), University of Cologne, Germany