

3rd School

Clinical Documentation

Introduction to the current and upcoming regulatory framework for clinical trials

November 02 & 03, 2020

Virtual Event

Speakers:

Prof. Dr. Thomas Bieber, University Hospital Bonn, Bonn

Dr. Martin Coenen, University Hospital Bonn, Bonn

Dr. Klaus Eckhardt, Rome

Dr. Ingrid Klingmann, Pharmaplex, Brussels

PD Dr. Thomas Sudhop, Federal Institute for Drugs and Medical Devices, Bonn

Programme November 2, 2020

- 9.00** **Introduction to the Clinical Drug Development Process Leading to the Label**
Dr. Ingrid Klingmann
- 09:45 Bio break
- 09:55** **Basics of Clinical Trials Phase I to IV**
Dr. Ingrid Klingmann
- 10:40 Coffee break
- 11.00** **Informed Consent Process and Data Protection**
Dr. Ingrid Klingmann
- 11:40 Bio break
- 11.50** **Ethical Review Process for Clinical Trials in Europe**
Dr. Ingrid Klingmann
- 12.30 Lunch
- 13.30** **Good Clinical Practice**
Dr. Martin Coenen
- 14:15 Bio break
- 14:25** **Management of Trial Documents: from Essential Documents to Trial Master File**
Dr. Martin Coenen
- 15:30 Coffee break
- 16:00** **Quality Management in Clinical Trials**
Dr. Klaus Eckhardt
- 16:45 Bio break
- 16:55** **Audits and Inspections**
Dr. Klaus Eckhardt
- 17:30 End of Day 1

Programme November 3, 2020

09:00 Safety Data Collection and Assessment

PD Dr. Thomas Sudhop

09:40 Bio break

09:50 Safety Reporting in Clinical Trials

PD Dr. Thomas Sudhop

10:30 Coffee break

**11:00 Current Clinical Trial Legislation: Directive 2001/20/EC and
Commission Directive 2005/28/EC**

Dr. Ingrid Klingmann

12:00 Bio break

12:10 Clinical Trial Authorisation and Reporting

PD Dr. Thomas Sudhop

13:15 Lunch

14:15 Upcoming Clinical Trial Legislation: Regulation 536/2014

Dr. Ingrid Klingmann

14:45 Bio break

14:55 Coordinated Assessment Procedures: from VHP to Pilot Projects

PD Dr. Thomas Sudhop

15:30 Coffee break

16:00 Clinical Development Strategies

Prof. Dr. Thomas Bieber

17:30 End

Information and organisational references

Date:

Monday, November 2nd, 2020

Start: 9.00 a.m.

Tuesday, November 3rd, 2020

End: ca. 5.30 p.m.

Venue:

The workshop is an online workshop via Zoom. You will receive the login data by mail one week before the event.

Participation fees:

For DGRA members and M.D.R.A. students: 390 €, for non-members: 540 €

Cancellation conditions:

Cancellation will incur a handling fee of 50€.

In case of short-term cancellation (2 weeks before) 50 % of the registration fee will be charged.

One week before the event the full fee has to be paid, unless a substitute participant (DGRA member) is named.

In case of cancellation by the organizer, already paid fees will be refunded in full.

Workshop language:

German

Registration:

Please use the form at

<https://dgra.de/deutsch/fortbildung/?nav=fortbildung>

Registration of non-members please by mail to info@dgra.de

DGRA-Office

Adenauerallee 15

D-53111 Bonn

Fax: 0049 - 228 - 368 26 47

E-mail: info@dgra.de