

Clinical Trial Applications

from Directive to Regulation

**DGRA-Workshop for members
on November 11, 2013
Wissenschaftszentrum Bonn,
Ahrstraße 45, 53175 Bonn**

10:00 a.m. - ca. 5:00 p.m.

Moderator: Dr. Christine Mayer-Nicolai, Merck KGaA

Speakers: Sabine Atzor, Roche Pharma
Prof. Dr. Joerg Hasford, Arbeitskreis Medizinischer Ethikkommissionen
Dr. Ingrid Klingmann, pharmaplex bvba
Prof. Burkhard Sträter, Kanzlei Sträter
PD Dr. Thomas Sudhop, Bonn

Programme:

10.00 a.m. I. Clinical Trial Applications in the EU

- Changes proposed by the Draft Regulation on Clinical Trials
- Experience with Voluntary Harmonization Procedure (VHP) and Comparison with the future process according to the Draft Regulation

PD Dr. Thomas Sudhop, Bonn

11.00 a.m. Coffee break

11.30 a.m. II. Legal Aspects and hot topics linked to Clinical Trials in Europe

- New types of clinical studies, e.g. PAES/PASS (Post Authorization Efficacy/Safety Studies): Legal definitions and what to expect in practice
- Ethics Committees and their role in the assessment of clinical trial applications
- Transparency of clinical trial data and legal implications
- New databases (EudraCT Vol 9, German database acc. to §42(b) AMG and others): What do they have in common? What are the (legal) differences?

Prof. Burkhard Sträter, Sträter Rechtsanwälte

11.45 a.m. III. The assessment of Clinical Trial Applications at BfArM

- The current process in the agency
- How will the new Regulation be implemented?
- Frequently asked questions in CTA assessment
- Statistics on CTAs at BfArM

PD Dr. Thomas Sudhop, Bonn

1.00 p.m. Lunch break

2.00 p.m. IV. The position of German Ethics Committees on the proposed Draft Regulation

- Appreciation and Achievements
- Major Criticisms and flaws of the draft proposal
- Assessment of the proposal of the European Parliament
- Suggestions of the German Ethics Committees

Prof. Dr. Joerg Hasford, Arbeitskreis Medizinischer Ethikkommissionen

2.45 p.m. V. Practical Aspects of the proposed Draft Regulation

- Comparison to requirements in other global regions and resulting problems
- Current and future requirements of CT Registries (EudraCT, Clinicaltrials.gov etc.): What is the added value for the public and how to cope from a sponsors point of view
- Streamlined communication with national Competent Authorities in multi center trials

Dr. Ingrid Klingmann, Pharmaplex bvba

3.30 p.m. Coffee break

4.00 p.m. VI. The pharmaceutical industries position on the proposed Draft Regulation

- State of play at the European Parliament
- What would help pharmaceutical industry to consider Europe for Clinical Trials now and in the future

Sabine Atzor, Roche

4.45 p.m. VII. Questions and Answers

all speakers and participations

ca. 5.00 p.m. End

(Program subject to change without prior notice.)

Informations and Organisational References

p.t.o.

Date:

Monday, November 11 2013

Start: 10.00 a.m.

End: around 5.00 p.m.

Venue:

Wissenschaftszentrum Bonn
53175 Bonn, phone 0228-302 0

Participation fees:

For DGRA members and M.D.R.A. students
course XIV: € 260

The Casino is open for lunch (not included)

Cancellation terms:

Up to two weeks before the first day of the
conference (28.-Oct.-13): € 50; up to one week
before the first day of the conference (4 Nov.-
13): 50% of fee; late cancellations: full
conference fee if a substitute participant (DGRA
member) cannot be put forward.

In the event of cancellation by the organizer, any
fees already paid will be fully reimbursed.

Please note: some of the photographs taken at
the school will be published. We will include a
list of participants in the documentation

Conference language:

English

Room reservation:

A limited number of rooms are available for
participants at special rates in the hotels listed
below. When making reservations (up to 6
weeks before the workshop) please refer to
DGRA.

- Hotel Königshof, Bonn-Innenstadt
Tel.: 0228/26010
- Villa Godesberg, Bad Godesberg
Tel.: 0228/830060
- Hotel Bristol, Bonn-Innenstadt
Tel.: 02 28 - 26 98-0.
- Maritim Hotel, Bonn
Tel.: 02 28 -8108872.

More available rooms for direct booking
www.hrs.de, www.bonn-region.de

Registration:

DGRA members are requested to use the form at
www.dgra.de or contact us at info@dgra.de

DGRA-office

Adenauerallee 15
D-53111 Bonn
Fax: 0228/368 26 47
E-mail: info@dgra.de