

# PharmaFORUM

## Webcast Clinical Trials

### **THE UPCOMING WEBCASTS AT A GLANCE**

- Contracts & Agreements
- IT Systems: Risk Management and Validation
- Practical Advice for Risk-based Monitoring
- Safety Reporting in Clinical Trials
- GCP Audits and Inspections
- Data Protection

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### **YOUR BENEFITS**

- One live webcast with clinical trial experts every month
- Consolidated information in a short period of time at your work place
- Possibility to directly interact with the speaker via chat

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## Concept

Do you work in clinical trials? Then we would like to invite you to our live webcast series in which experts from clinical research will inform you about the latest updates and trends in clinical studies within and beyond the ICH region. You will receive information on the design and conduct of clinical trials, as well as practical tips for successful collaboration at the interfaces to other areas.

You will meet our experts in a virtual conference room. Each meeting will be held as a 1.5 - 2 hour live webcast, presenting the latest news with supporting presentation slides (also for your personal download). Your practical questions will be addressed directly via the chat function, coordinated by the meeting's chairperson.

Are you unable to attend one of the webcasts? No problem! After each live meeting, you will be able to retrieve the recorded webcast (audio and presentation) from our eLearning Centre, using your personal password. This allows you to review each presentation at any time and as often as you like. An optional multiple-choice test finalises each webcast, giving you the possibility to receive a personal certificate.

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## Your experts in 2020

### Dr Andreas Jabs

Alegri Intl. Service GmbH, Frankfurt  
Principal Consultant/Manager

### Alexander Maur

Kanzlei am Ärztehaus Frehse Mack Vogelsang,  
Cologne  
Lawyer

### Melanie Blessing

Boehringer Ingelheim Pharma GmbH & Co. KG,  
Biberach  
Head of Supply Chain Management  
CardioMetabolic, Global Clinical Trial Supplies Unit

### Bettina Schopf

PHARMALOG, Institut für klinische Forschung  
GmbH, Ismaning  
Head of Clinical Monitoring

### Dr Sybille M. Eibert

Senior Expert Medical Writing, Basel

### Angela Hartmann

Senior Expert Pharmacovigilance, Darmstadt

### Prof. Sebastian Harder

Ethikkommission der Landesärztekammer  
Hessen, Frankfurt

### Silja du Mont

Regierungspräsidium Freiburg

### Karsten Sternickel

PAREXEL International GmbH, Mörfelden-Walldorf  
Director, Project Management, Real World Evidence

### Dr Liana Iatridou-Oster

PRA Health Sciences, Mannheim  
Director of Quality Assurance

### Dr Carsten Schwenke

SCO:SSIS, Berlin  
Statistical Consultant

### Prof. Kurt Racké

Medizinische Fakultät der Universität Bonn, Bonn  
Chairman of the Ethics Committees

<b>Your Programme</b>	<b>Date</b> (Starting 10:00 German time)	<b>Your Expert</b>
IT Systems in Clinical Trials: Risk Management and Validation	23 March 2020	Dr Andreas Jabs
Contracts & Agreements for Clinical Trials <ul style="list-style-type: none"><li>Structure and content of contracts for beginners</li></ul>	1 April 2020	Alexander Maur
Investigational Medicinal Product: EU GMP Annex 13 Versus Regulation EU No 536/2014 <ul style="list-style-type: none"><li>Present and future challenges for clinical investigational products</li></ul>	7 May 2020	Melanie Blessing
Practical Advice for Risk-based Monitoring	15 June 2020	Bettina Schopf
Clinical Data Publication – EMA Policy 0070 <ul style="list-style-type: none"><li>Protected Personal Data (PPD) and Commercially Confidential Information (CCI)</li></ul>	7 July 2020	Dr Sybille M. Eibert
Data Protection in Clinical Trials: The Point of View of the Ethics Committee	10 August 2020	Prof. Sebastian Harder
GCP Audits and Inspections: What is Currently in Focus?	17 September 2020	Silja du Mont
Digital Data Generation – Using Apps und Wearables in Clinical Trials	6 October 2020	Karsten Sternickel
Trial Master File <ul style="list-style-type: none"><li>Implications of the new EMA-guidelines</li><li>Requirements for electronic data archiving</li></ul>	25 November 2020	Dr Liana Iatridou-Oster
Update Statistics: Effects of the ICH E9 (R1) Addendum on the Study Design <ul style="list-style-type: none"><li>Estimands and sensitivity analysis in clinical trials</li></ul>	8 December 2020	Dr Carsten Schwenke
Cooperation with Ethics Committees in Germany and Europe	22 January 2021	Prof. Kurt Racké
Safety Reporting in Clinical Trials <ul style="list-style-type: none"><li>Reporting in clinical trials vs. non interventional studies (NIS)</li></ul>	5 February 2021	Angela Hartmann

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## HOW TO REGISTER

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Fax +49 6221 500-555

www.forum-institut.com/pharma-webcast-clinical-trials

## REGISTRATION

Yes, I want to join the

- PharmaFORUM Webcast Clinical Trials  
(you will receive a confirmation email  
with your login details)
- Yes, I agree that FORUM Institut may inform me  
about events and relevant expert content by:  
 email; and/or  telephone.  
I may withdraw my consent at any time.

Name

E-Mail (required for your login details)

Position

Company

Street address

Postal Code/City/Country

Tel. No.

Date, Signature

### Fee:

Membership of the PharmaFORUM Webcast  
Clinical Trials is available for one year.

**The annual membership fee of € 1.800**

(plus German VAT) for twelve webcasts is due upon  
registration.

Membership is automatically extended by one year,  
unless written notice has been submitted no later  
than six weeks before the end of the membership.  
A 12-month membership may be started at any time.

**If you are interested in a group account,  
please contact us.**

### Benefits:

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time at your workplace
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via chat
- Multiple-choice test after each webcast letting  
you obtain a personal certificate

## CANCELLATION POLICY

Our general terms and conditions apply  
(as of 01.01.2016) and are available upon request.  
We can send them to you anytime or you can find  
them online at [www.forum-institut.com/t&c](http://www.forum-institut.com/t&c)

## YOUR CONTACT



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