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# GERMAN ePHARMA DAY 2017

## Implementation of Clinical Trial Regulation, EU 536/2014 and National adoption

What lies ahead: Impact on Clinical Trials and Stakeholders



**Wednesday, May 3<sup>rd</sup>, 2017**

**Frankfurt am Main, Germany**

**Lufthansa Flight Training Frankfurt**

Airportring, Gate 24, Buildings 391 and 392 - Frankfurt am Main

Event Managed by



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# Implementation of Clinical Trial Regulation EU 536/2014 and National adoption

## What lies ahead: Impact on Clinical Trials and Stakeholders

The new Regulation marks substantial and important changes in the processes, procedures and documentation necessary for management of clinical trials and relationships between Sponsors, Ethics Committees, Regulatory Agencies and Researchers.

The aim of the new legislation is to streamline bureaucratic aspects through a simple authorization process, involving a centralization of the procedures and the consistent involvement of all Member States.

However, what are the potential impacts on the pharmaceutical industry?

The 8th German e-Pharma day will examine implications of the new Regulation from different viewpoints with a special focus on the national adaptation.

Participants will gain an understanding of both fundamental and practical considerations impacting on drug development strategies, management of clinical trials as well as corporate governance related to implementation of the new Regulation.

Speakers from regulatory Authorities, Ethics Committees, pharmaceutical industry and associations as well as representatives from CROs will be involved.

**Martine Dehlinger-Kremer**, Vice President, Global Medical and Regulatory Affairs, Synteract HCR, **Heike Schön**, Managing Director, LUMIS International and **Herbert Eskötter**, Medical Consultant, scientific board of the event, will lead a panel of experts to share best practices, knowledge and experience in this field.

### Official Language: German

### Who should attend?

Representatives of Pharmaceutical and Biotechnology companies, Clinical Research Organizations, Academic centers, Hospital Centers, and Clinical Technology companies. Especially Clinical Research Professionals, belonging to the following departments:

- Clinical Research and Development
- Quality Assurance
- Regulatory
- Pharmacovigilance
- Clinical Operations
- Statistics and Data Management
- Information Technology
- Market Access

## Implementation of Clinical Trial Regulation EU 536/2014 and National adoption

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### Agenda

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#### Official Language: German

09:00 - 09:30 **Registration and welcome coffee**

09:30 - 09:40 **Welcome from the Scientific board**

**Dr. Martine Dehlinger-Kremer** - Vice President, Global Medical and Regulatory Affairs  
at SynteractHCR

**Dr. Herbert Eskötter** - Medical Consultant

**Heike Schön** - Managing Director at LUMIS International GmbH

#### Speakers confirmed:

**Dr. Thorsten Ruppert** - Senior Manager, Research/Development/Innovation at VFA – Association of  
Research-Based Pharmaceutical Companies

**Clinical Trials - New EU-regulation and its implications for the pharmaceutical industry in Germany**

**Dr. Heike Wachenhausen** - Rechtsanwältin at Wachenhausen Rechtsanwälte Partnerschaft mbB

**Impact of the Clinical Trials Regulation on regulatory functions and contract management**

**Dr. Surendra Gokhale** - Head, EU/International Clinical Trials Regulatory Management and Capability Development Lead  
at F. Hoffmann-La Roche Ltd

**CT Regulation in Europe - Big Pharma Company preparedness - Roche experience**

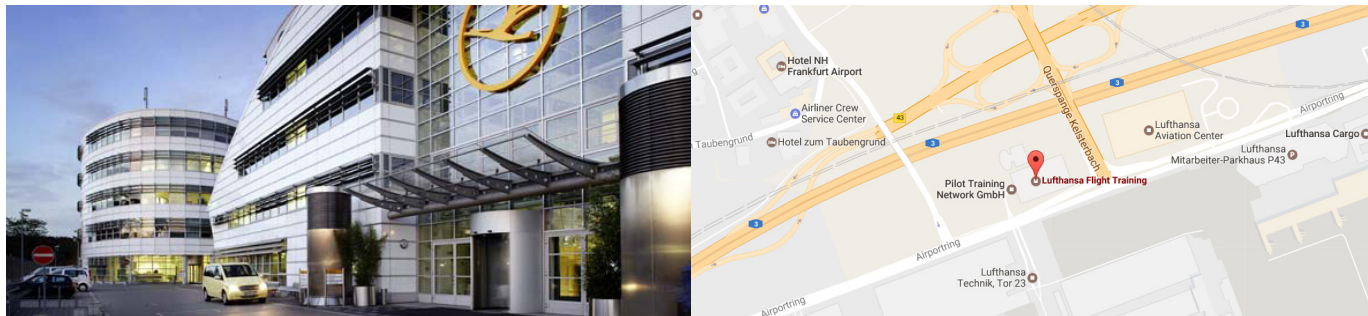
**Dr. Ludwig Baumann** - Director Regulatory Affairs at SynteractHCR

**EU Portal and Database – User Acceptance Testing and status of implementation**

Further information will be available soon

## How to reach the conference venue

Venue | **Lufthansa Flight Training Frankfurt** | Airportring, Gate 24, Buildings 391 and 392 - Frankfurt am Main, Germany



The Lufthansa Flight Training Center Frankfurt is located at Frankfurt Airport, easily accessible by road (highway) or rail (two train stations directly at the airport).

### Directions by car

Take either of the A3, A5 or B43 highways and follow the signs for "Frankfurt Flughafen" and then for "Tor 21-31".

### Directions by train and bus

#### Regional trains (S8 or S9)

From the Regional Railway Station: Either take a taxi, or proceed to the bus stop 25 or 11-13 and take the complimentary shuttle bus "WEST (Tor 25/27)".

#### National/International trains (InterCity (IC), Intercity-Express (ICE))

From the International Railway Station: Proceed to the Regional Railway Station, then follow the directions above.

### Directions by plane

**From Terminal 1:** Either take a taxi, or proceed to the bus stop 25 or 11-13 at Arrival Hall A and take the complimentary shuttle bus "WEST (Tor 25/27)".

**From Terminal 2:** Take the Sky Line to Terminal 1. Then either take a taxi, or proceed to the bus stop 25 or 11-13 and take the complimentary shuttle bus "WEST (Tor 25/27)".

[For further information, please download the Pocket Guide](#)

For further information please visit the conference [website](#) or contact the organization offices:

**Ilaria Butta** Phone: +39 (0)35.4123594 | Mail: [ilaria.butta@LSacademy.it](mailto:ilaria.butta@LSacademy.it)

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[Download the Events Summary 2017](#)

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ePHARMA DAY  
2017

- **Online:** please register here <https://germanepharmaday2017.eventify.it/orders/new>

In this case, you can choose to pay by credit card or by bank transfer.

- **By email or fax:** please fill the registration form below for each attendee and send it by email: [ilaria.butta@LSacademy.it](mailto:ilaria.butta@LSacademy.it) or by fax: **+39(0)35.4501262** In this case, you can pay by bank transfer.

### ■ € 595,00 Early Bird fee until 3rd April 2017

■ € 710,00 Ordinary fee (after 3rd April 2017)

■ € 540,00 Patronage members fee (Association \_\_\_\_\_)

■ € 390,00 for Academy, Public Administration, Freelance (please, specify \_\_\_\_\_)

*The fee includes: seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, welcome coffee, networking lunch, coffee break, organisational office assistance, certificate of attendance.*

### For any additional information, please contact:

Ilaria Butta

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### Payment by bank transfer

The full amount must be paid on registration to EasyB S.r.l. by bank transfer. If you pay by bank transfer, please attach proof of payment to the registration form.

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### Terms of payment

The registration fee must be paid at the time of registration. Confirmation of event admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants or registrations of roles that are not included in the target of the event.

### Cancellation

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the event date. Cancellations will only be valid if made in writing (by email). Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

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