

GERMAN ePHARMA DAY 2018

Future perspective in Clinical Research:

are you ready for the next decade?

Tuesday, June 19th, 2018

Frankfurt am Main

InterCity Hotel Frankfurt Airport

Am Luftbrückendenkmal 1 - Cargo City Süd Frankfurt am Main, Germany

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ABOUT

Official language: German

Future perspective in Clinical Research: are you ready for the next decade?

The world of clinical research is in a phase of profound transformation.

The acceleration of scientific knowledge in recent years is leading to an exponential increase in the number of clinical trials with new drugs. This increase in studies is associated with a profound methodological transformation, which leads to overcoming the classical model of development based on the sequentially managed phases for individual New Chemicals Entities and New Biological Entities. To ensure rapid access to patients for new drugs and to contain high development costs, regulatory authorities, FDA and EMA, show a readiness to accept new approaches ranging from new experimental designs, to early access models, to management of some aspects of the development with a "risk based" approach, up to the opening of the use of Real Word Evidence data. In this context, the operators involved in the management of clinical research are facing new important challenges.

- What is the evolution of skills, processes and tools in pharmaceutical & biotech companies, CROs and research centers, also in view of the regulatory changes taking place?
- What organizational changes will the stakeholders in clinical research have to face and which are the priority areas?
- How much does the technological evolution in digital health care, will influence the way of doing clinical research?
- What is the point of view of investigators/physicians, study nurses, research coordinators and data managers working in this sector who are experiencing this transformation?
- · Changing role of patient involvement in clinical trials
- The right balance between complexity, speed and quality: Is Germany ready to cope with the transformation in clinical research?

The Scientific Board



Dr. Martine Dehlinger-KremerVice President, Global Scientific and Medical
Affairs at Synteract & EUCROF President



Dr. Herbert Eskötter

Medical Consultant



Heike Schön

Managing Director at LUMIS

International GmbH

Will lead a panel of experts to share best practices, knowledge and experience in this field.

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

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AGENDA

Future perspective in Clinical Research: are you ready for the next decade?

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09:00 - 09:30	Registration
09:30 - 09:40	Welcome from the Scientific Board Dr. Martine Dehlinger-Kremer - Vice President, Global Scientific and Medical Affairs at Synteract & EUCROF President Dr. Herbert Eskötter - Medical Consultant Heike Schön - Managing Director at LUMIS International GmbH
09:40 - 10:20	Marcus Schwabedissen - Chief Operation Officer (COO) at Q-FINITY Oliver Herrmann - Chief Executive Officer (CEO) at Q-FINITY Digital transformation in the clinical world. From analog to digital and beyond!
10:20 - 11:00	Valdo Arnera - Scientific Advisor and General Manager at ERT Geneva What have we learnt about future eClinical Technology Adoption in Clinical Trials from the implementation of eDiaries and how does it help to predict the future?
11:00 - 11:30	Coffee break
11:30 - 12:10	Nancy Meyerson-Hess - Associate Partner at admedicum Business for Patients The Changing Role of Patient Involvement in Clinical Trials
12:10 - 12:50	Alexander Puschilov - Managing Director at Viomedo The future in patient recruitment - it's already here (kind of)
12:50 - 13:50	Networking lunch
13:50 - 14:30	Prof. Dr. Heike Wachenhausen - Rechtsanwältin/Attorney at Law at Wachenhausen Rechtsanwälte Partnerschaft mbB Title available soon
14:30 - 15:10	Artem Andrianov - CEO at Cyntegrity Evolution of RBM- Risk-based Quality Management
15:10 - 15:40	Coffee break
15:40 - 16:20	Dr. Thorsten Ruppert - Senior Manager Research/Development/Innovation at vfa - Association of Research-Based Pharmaceutical Companies New EU-regulation on clinical trials - Status and implications for the pharmaceutical industry in Germany
16:20 - 17:00	New session will follow soon
17:00 - 17:15	Conclusions

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HOW TO REACH THE CONFERENCE VENUE

InterCity Hotel Frankfurt Airport

Am Luftbrückendenkmal 1 - Cargo City Süd - Frankfurt am Main, Germany

Arriving by airplane

Airport: Frankfurt Rhein-Main Airport/FRA The hotel offer guests a shuttle bus service from and to the passenger terminals 1 + 2 (fee required). Daily from the hotel to the terminals 1 + 2 every 30 minutes from 4:45 h onwards. Last trip from terminal 1 to the hotel is at 0:30 h. The bus ride takes approximately 8 minutes per route.

Terminal 1 Exit B5 on the arrival level Terminal 2 Exit D/E 6

Arriving by train

Train station: Frankfurt/Main Airport At the airport please take the shuttle bus from terminal 1 stop B5 or from terminal 2 stop D/E.

Arriving by car

Navigation device | Am Luftbrückendenkmal 1/Cargo City Süd 60549 Frankfurt

Via the GPS coordinates | Longitude: 8.584 Latitute: 50.027

Please be aware that in many navigation systems this street name still does not exist.

Via A5 (Basle, Frankfurt/Main) | Take the exit 23 "Zeppelinheim, CargoCity Süd"

Car park | Public car park is available next to the hotel.



OPPORTUNITIES

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For further information

Please visit the conference website or contact the organisational offices:

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Two ways to register

Online

please register here
https://germanepharmaday2018.lsacademyevents.it/orders/new
In this case, you can choose to pay by credit card or by bank transfer

By email o fax

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

- € 655,00 Early Bird fee until May 18th, 2018
- € 765,00 Ordinary fee (after May 18th, 2018)
- € 570,00 Patronage members fee (Association _____
- € **430,00** 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 | ilaria.butta@LSacademy.com Phone: +39 (0)35.4123594

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■ I wish that my data (name, surname, job position and company) are inserted in the list of attendees distributed the day of the event

Invoicing details

Terms & Conditions

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.

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Date _