Data Transparency: Its Impact on Clinical Trials

Effectively facing with the new environment of clinical studies

14 - 15 September 2020 - Berlin

210€ Early Bird discount
for enrolment by 17/08/2020

Course Language: English

Berlin

Germany

Monday 14 and Tuesday 15 September 2020

08:30-18:00

*Taking part in our training courses, you support **"The Vase of Flowers"** project*

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Introduction

Data transparency in clinical trials has become an essential requirement for anyone involved in clinical studies. Although many pharmaceutical companies had spontaneously provided the opportunity to access data collected during their clinical trials to anyone who requested it, policy 0070 of the European regulatory agency (EMA), section 801 of the Food and Drug Administration's Act (FDAAA), the initiative Restoring Invisible and Abandoned Trials (RIAT), the requests by the International Committee of Medical Journal Editors (ICMJE) and the European regulation on clinical studies (536/2014), have made mandatory the effective management and publication of the data collected in clinical trials. The policy 0070 *"on publication of clinical data for medicinal products for human use"* has made the publication of the main documents sustaining the registration dossier of new products mandatory; its final goal is making publicly available the data collected during each clinical trial which was used for registration purposes. An analogous approach is the one followed by the FDA, other regulatory authorities, the ICMJE and the main medical-scientific congresses that require, together with the publications that report the results of each clinical trial, also the protocol, patient's level data, and the methods used for their analysis. This new approach makes mandatory to redefine both the management of company's confidential data and patient's personal by the clinical study sponsor. A challenge to be effectively faced for its translation to communication effectiveness. This course aims to provide practical tools to manage the new clinical trial environment in a proactive and effective way.

To whom it may concern

All company figures involved in the development, registration and reporting of clinical trials on products for medical use including:

- Clinical Operations
- Regulatory
- Medical Affairs
- Clinical data registration
- Statistics
- Scientific Communications
- Medical Information
- Clinical Information
- Marketing
- Compliance
- Quality assurance
- Pharmacology
- CRM
- Transparency
- Legal
- Data management
- Real World Data

Type of Training

Interactive workshop with on-train exercises and application to participant's daily activities.

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Course Language

The course will be in English.

Programme

Course Language: English

- Opening remarks
- Collection of expectations
- Individual questionnaire compilation
- The principles of clinical research
- Public reputation of pharmaceutical companies
- Patient's requests
  - The informed consent
  - All trials
- Analysis of the individual questionnaire and discussion
- The ICMJE
- The requests of the International Committee of Medical Journal Editors (ICMJE)
- Registration of study protocols
  - Clinical studies registries
  - Publication of clinical trials results
  - Non-interventional studies
- The regulations on the publication of the results of clinical trials through the world and their implications
- Data sharing initiatives
  - EFPIA
  - PhRMA
  - The RIAT
- The EMA approach
  - EMA Policy 0070

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- The FDA approaches
  - Section 801 of the FDAAA
- Clinical study reports and clinical investigation reports
- The CRF
- Confidential data
- Individual patient's data
- The statistical implications
  - The SAP
- The companies' point of view
- How information is published
- Establish Strategic Timelines for Publications Development and Publishing
- Practical exercise
  - Understand Quantified Risk Assessments
  - Create Data Anonymisation Strategies
  - Manage the EMA Timeline
- Verification of expectations and conclusions

Agenda

Day 1

8:30 - 9:00	Participants registration
9:00	Course commences
10:45 - 11:00	Coffee Break
13:00	Lunch
16:15 - 16:30	Coffee Break
18:00	End of day 1

Day 2

8:30	Course commences
10:15 - 10:30	Coffee Break
12:30	Lunch
15:00 - 15:15	Coffee Break
16:30	Q&A and Conclusion

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Lecturer

Andrea Rossi, *Freelance International Scientific Communicator*

Andrea has a degree in Biology from Florence University. After a brief spell at the University, he started working in the Italian Affiliate of Eli Lilly as a Clinical Research Associate. In the years that followed he was responsible for Statistics, Health Outcomes and Medical Information. Andrea has been working as Medical Writer since 2003 beginning in Italy and, then, becoming responsible of worldwide scientific affairs in a biosimilar company based in Switzerland. He is author of more than 350 disclosures and acknowledged for his contribution in several others. From 2007 to 2009 he was on the coordination board of BIAS (Biometristi Italiani Associati) and has been a European Medical Writers Association (EMWA) member since 2004. Andrea acts as trainer for statistics and medical writing in some Italian specialisation schools in medicine and has been a speaker at national and international conferences. Andrea leads workshops for and is past-president and ambassador of EMWA.

Participant experience

Participants should be aware of the basic principles governing clinical trials and the regulations to be used for the approval of new medical products in Europe.

At the end of the training, you will be able to:

- Manage the principles of clinical data sharing
- Evaluate the implications for ensuring resources needed to effectively and efficiently address data transparency needs
- Transform new legislative requirements into an opportunity to improve image and company's productivity

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TO REGISTER FOR THE COURSE YOU CAN FILL IN AND SEND

THE REGISTRATION FORM OR DIRECTLY **REGISTER ONLINE:**

REGISTRATION FEES:

- ☐ Early bird: **€ 1.570,00*** until 17/08/2020
- ☐ Ordinary: **€ 1.780,00***
- ☐ Freelance – Academy – Public Administration**: **€ 890,00***

***For Italian companies: + 22% VAT**

The fee includes: tuition, teaching materials, lunches and coffee breaks, organizational office assistance, attendance certificate.

****Early Bird discount not applicable to Freelance – Academy – Public Administration fee**

Methods of payment

The full amount must be paid on registration to EasyB s.r.l by bank transfer or by credit card. If paying by bank transfer please attach proof of payment to the registration form. Bank transfer payable to:

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (BG)

P. IVA **03633040161**

Banco BPM - Filiale di Carobbio Degli Angeli

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Terms & conditions

Terms of payment The registration fee must be paid at the time of registration. Confirmation of course 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.

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 course date. Cancellations will only be valid if made in writing. 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. LS Academy reserves the right not to accept registrations not compatible with the event's target audience.

The course will proceed with a minimum of 8 participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

In accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, we inform you that EasyB S.r.l. (with headquarter in Via Roma 20, Alzano Lombardo, Bergamo, Italy, VAT number IT03633040161) will use your personal data voluntarily provided by you only with the consent and in compliance with the principles dictated by the European Regulations on the protection of personal data for sending newsletters, for marketing purposes (sending advertising material, market research and commercial communication) and for communication purposes to third parties (lecturers), also for marketing goals. You can read the complete information, including your rights and the procedures for the exercise of the same, following this link.

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