Interactive GCP Virtual Training

SCOPE OF TRAINING

The Good Clinical Practice (GCP) course is designed to prepare research staff in the conduct of clinical trials with human participants.

It is a standard within clinical research business to hold an up-to-date GCP certificate.

This interactive training offers the opportunity to refresh your GCP knowledge to understand better the implications for the quality management system of the sponsor and its suitability for sites in practical terms.

Interactive Good Clinical Practice (GCP) Training
What is new in the ICH-GCP integrated addendum? E6 (R2)

Virtual Training

September 29, 2020 | 10:00 – 17:15 (EET)

INTRODUCTION

The revision of the ICH-GCP Guideline has come into force on the 14th of June 2017. In fact, the revision maintains the original text from 1996 but adds definitions, clarifications on the existing text and especially adds a comprehensive section on risk-based quality management responsibilities of the sponsor.

In this Interactive GCP Workshop, you will learn about the changes and get an opportunity to better understand the implications of these additions for the quality management system of the sponsor and its suitability for investigator sites in practical terms.

Applying the principles of quality risk management will be the topic of an exercise.

This training is for professionals working in clinical trials (Investigators, clinical study teams or referrals, i.e. clinicians, GPs, study coordinators, study nurses), Clinical Research Coordinators, Clinical Research Organizations (CROs), members of Ethics Committees or Competent Authorities, researchers or other research staff.

The participants will have to pass a test to get the Certificate of Completion.

TRAINING DETAILS:

Date/Time: Tuesday, September 29, 2020 | 10:00 – 17:15 (EET)
Location: online. After registering online, you will receive the ZOOM meeting details.
Language: English
Online registration: open until Tuesday, 22nd of September, 17:00 (EET)
Trainer: Ingrid Klingmann, MD, PhD, FFPM, FBCPM- Chairman of European Forum for Good Clinical Practice (EFGCP), EFGCP Consultant & Trainer
Host: Cristina Florescu Moraid, MD, MSc, EuSpLM, MRQA -CEO AVANTYO Institute of Clinical Research
Participation fee: 250 lei (no VAT refund)
Discounts: 5% for over 3 participants and 10% for over 5 participants from the same institution.
For assistance please contact us at anca.bejenaru@avantyo.com, 0726 840 456.

Register now!

Check the red button under the participation fee and make your reservation!
Limited seats. Register by 22nd of September, at 17:00 (EET)!

AGENDA

9:45 – 10:00

- Registration via the waiting room

10:00 – 10:10

- Welcome and Introduction

  Speakers: Ingrid Klingmann, Cristina Florescu Moraid

10:10 – 11:30

- ICH E6 (R2): highlights of the revision and impact on the sponsor's responsibilities. Discussion

Speaker: Ingrid Klingmann

11:30 - 11:40 Bio Break

11:40 – 12:30

- Sponsor obligation: CRO oversight; PI obligation: Site oversight; Discussion

Speaker: Ingrid Klingmann

12:30 – 13:30 Lunch Break

13:30 – 14:30

- Quality risk management plan: Introduction

Speaker: Ingrid Klingmann

14:30 – 14:45 Bio Break

14:45 – 15:45

- Quality risk management plan: a practical exercise in break-out groups

15.45 – 16:15

- Joint review of the break-out group results

Speakers: Ingrid Klingmann, Cristina Florescu Moraid

16:15 – 16:25 Bio Break

16.25 – 17:15

- Final test and review of answers

Speakers: Ingrid Klingmann, Cristina Florescu Moraid

17:15

- End of Training

Register now!

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Limited seats. Register by 22nd of September, 17:00 (EET)!

Attendance only by online reservation. Booking the seat is available after registering on this site (MyAccount).

Note:

Online event | The ZOOM details and instructions will be sent a few days in advance, as well as the support material of the course and a protocol synopsis that has to be read upfront to the training not to lose time during the exercise session.

During the online meeting, the participants' names will be disclosed as they will be split into small groups for an exercise session.

Certificates | A "**GCP-Certificate of Completion**" will be issued for you if you pass the test. If you do not pass the test you will receive a "GCP-Certificate of Attendance". **To have a full valid certificate for clinical trials, you need to receive a "GCP-Certificate of Completion".**

After the completion of the course, the certificate will be available to be downloaded from each participant account on www.avantyo.com.

Discounts and assistance | Please contact us: info@avantyo.com, anca.bejenaru@avantyo.com, 0726 840 456.

Download here the flyer of the training

Not sure how to book? Click here for instructions in Romanian.

Newsletter

In order to be always informed about AVANTYO courses and events, please subscribe to our newsletter.

Waiting list

If you would like to be placed on a waiting list for the next course or you need something else, please let us know at info@avantyo.com. Do not forget to mention your specific education needs in clinical trials.

SPEAKERS

INGRID KLINGMANN, MD, PHD, FFPM, FBCPM
PHARMAPLEX bv, EFGCP, PharmaTrain Federation

Ingrid Klingmann, MD, PhD, European Forum for Good Clinical Practice (EFGCP), Pharmaplex bv, Brussels, has 30 years of practical experience with planning and performance of clinical trials from a sponsor and investigator perspective in the pharmaceutical industry, CRO and academic institution. Through her activities in multi-stakeholder not-for-profit organisations like EFGCP, she

gained broad experience in ethical, quality and regulatory challenges in clinical research and possible approaches to solutions.

- Physician, specialized in General Medicine, Clinical Pharmacology and Pharmaceutical Medicine with over 30 years of experience in different senior medical, operational and managerial functions in the pharmaceutical industry, CROs and clinical trial sites with focus on clinical trial design and management, ethical and regulatory aspects.
- Since January 2003 she has her pharmaceutical development and site management support consulting company.
- Dr Klingmann is Chairman of the Board of the European Forum for Good Clinical Practice (EFGCP). On behalf of EFGCP she was and is involved in different FP7- and IMI-funded projects (ICREL, PatientPartner, PharmaTrain, EUPATI, Combacte-NET, PARADIGM and ConCEPTION) and with her company in the FP7-funded paediatric LENA project. Her broad professional background as a physician with experience in patient care, clinical development, site management and patient engagement enables Dr Klingmann to bridge the gaps between the interests and skills of all different stakeholders in medicines development to develop new patient-relevant treatments more efficiently.
- Dr Klingmann is also President of PharmaTrain Federation, the not-for-profit organisation focussing on global standardisation and improvement of post-graduate training in medicines development sciences. She also teaches on different clinical research and regulatory affairs topics in diploma and master courses at the University of Bonn, Germany, University of Basel, Switzerland, and the Université Libre de Bruxelles, Belgium.

HOST

CRISTINA FLORESCU MORAID, MD, MSC, EUSPLM, MRQA
CEO AVANTYO Institute of Clinical Research, Romania President of Clinical Trials Symposium

- Dr Florescu Moraid got her Medical Doctor Diploma in 1998 from „Carol Davila" University of Medicine and Pharmacy in Bucharest, Romania and was accredited as Laboratory Medicine Specialist in 2005 and as Senior Laboratory Medicine Specialist in 2011, by the Romanian College of Physicians.
- She got her Master of Science Diploma for Hospital and Medical Management in 2006, accomplished the Postgraduate School of Clinical Trials Management - Gdansk in 2012 and the Postgraduate Leadership Development Program at University of Sussex - UK, in 2014.
- Dr Florescu Moraid was responsible for clinical trials operations at Synevo Central Lab, the clinical research wing of Swedish Medicover Group as Regional Director for Romania, Moldova, Bulgaria and Serbia between 2005 and 2018. She has been organizing Synevo Clinical Trials Symposium for 11 years.
- Since the beginning of 2019, she is Co-founder of Avantyo - Institute of Clinical Research and CEO of Camina Medical Experts, developing tailored CT services for pharma sponsors, CROs and mid-size biotech companies. She is also a member of the Events and Training Working Group of EUCROF (European CRO Federation).
- She is invited as a speaker for different scientific events and acts as an active advocate for increasing awareness over the importance of developing clinical trials for the patient's benefit.