PHARMED

Module 10

20 - 21 February 2019

For more information please contact :

Mrs Bahija JELLOULI
PHARMED – ULB CP611Route de Lennik, 808
1070 Bruxelles-BELGIUM

E-mail: pharmed@ulb.ac.be - Phone : 32 2 555 62 29

The courses take place in Brussels, at
IBIS BRUSSELS ERASMUS HOTEL
Route de Lennik 790 – 1070 Brussels
Phone : 32-02/523 62 82

Clinical trials reporting and auditing

- Data interpretation and writing the final study report
- Clinical trials in developing countries-challenges and opportunities
- Audits of clinical trials
- Clinical research and the art of scientific writing
- An investigators network : the EORTC

http://www.ulb.ac.be/medecine/pharmed/

DATA INTERPRETATION AND WRITING THE FINAL STUDY REPORT
Marc DE LONGUEVILLE

This lesson will go through different aspects of the Clinical Study Report, a written description of a trial/study of any therapeutic, prophylactic or diagnostic agent conduct in human subject, in which the clinical and statistical description, presentation and analyses are fully integrated into a single report. With a focus on some practical examples .

CLINICAL TRIALS IN DEVELOPING COUNTRIES-CHALLENGES AND OPPORTUNITIES
Eckart W. SCHWARZ

Traditionally, the majority of clinical development activities sponsored by multinational pharmaceutical companies have been carried out within the context of developed countries. This situation appears to be progressively changing, with more and more clinical trials being conducted in developing countries. Conduct of clinical trials in developing countries must not only follow the same stringent ethical and procedural standards as countries in the developed world, but also, and equally importantly so, there must be a “fair benefit” to study subjects and communities involved. Informed Consent procedure must be followed. Post trial access to study drug has been a controversial topic. Many angles need to be considered, for instance, to whom should this be extended (trial subjects or entire population), and for how long (until launch or life-long)?

AUDITS OF CLINICAL TRIALS
Ingrid KLINGMANN

Setting up a sound clinical quality system to conduct clinical trials is not only crucial but a regulatory requirement for the sponsor and the investigator site. A review of the systems used in clinical trials and the common audit findings will be presented.

CLINICAL RESEARCH AND THE ART OF SCIENTIFIC WRITING
Ann HEPBURN

Publication of experimental results is one of the most important (and one of the most often neglected) aspects of clinical research. Putting data and conclusions logically onto paper is a difficult task for many researchers. This course will give advice on :

Marc de LONGUEVILLE
MD, PhD, FFPM, MBPCM, Sr Medical Director Immunology, UCB BioPharma SPRL

Eckart W.SCHWARZ
MD(M.B.,Ch.B.), M.Phil., D.Sc.(Hon), Senior Vice President, Global Regulatory Platforms and Delivery, Philadelphia, USA

Ingrid KLINGMANN
MD, PhD, FFPM, FBCPM, Managing Director, Pharmaplex bvba, Chairman of EFGCP's Board

Anne HEPBURN
Ph.D. in Medical Biology, ULB, Director scientific writing and regulatory affairs, 4Clinics Belgium

WEDNESDAY
20 February 2019

Welcoming participants
9.30-10.00

Data interpretation and writing the final study report
Marc de LONGUEVILLE
10.00-13.00

Quality compliance and risk management in clinical research
Eckart SCHWARZ
14.00-15.50

Coffee break
15.50–16.10

Clinical trials in developing countries
Eckart SCHWARZ
16.10-18.00

THURSDAY
21 February 2019

Audits of clinical trials
Ingrid KLINGMANN
09.00-10.50

Coffee break
10.50–11.10

Audits of clinical trials
Ingrid KLINGMANN
11.10-12.00

Lunch
12.00–13.30

Clinical research and the art of scientific writing
Anne HEPBURN
13.30-15.30

Coffee break
15.30–15.50

Specificities of investigator-initiated trials:the EORTC example
Denis LACOMBE
15.50-16.50

- pre-writing preparation
- how/where to start when writing a manuscript for publication
- presentation of data/text
- submission to a « peer-review » journal, dealing with the reviewer's comments.

Preparation of review documents for regulatory submissions will also be discussed.

AN INVESTIGATORS NETWORK : THE EORTC

Denis LACOMBE

Denis LACOMBE
M.D., M.Sc., EORTC Director General, Brussels

The European Organisation for Research and Treatment of Cancer (EORTC) is a not for profit research organization which conceives and conducts multidisciplinary and international investigator initiated trials in all cancer types. The scientific agenda is mostly oriented towards optimizing therapeutic strategies, unmet clinical needs and rare clinical situations. Such scientific agenda is complementary to that of the commercial sector which aims at drug registration primarily. The organization represents a network of more than 900 hospitals and universities coordinated by the EORTC HQ based in Brussels. The EORTC runs at any time around 50 clinical trials open to patient entry in 30 countries ,which accrue several 1000s of new patients every year. EORTC is acquainted with all aspects of independent trials from funding to execution and reporting. Scientific and operational strategies of Investigator Initiated Trials will be presented and discussed