PHARMED

Module 9

23 - 24 January 2019

For more information please contact :

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

Conduct of Clinical Trials

- Set-up and monitoring of clinical trials
- Management of investigational medicinal products
- Patient adherence and persistence in trials and practice
- Outsourcing of clinical trials and contract management

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

SET-UP AND MONITORING OF CLINICAL TRIALS

Marc de LONGUEVILLE & Marah WAJSKOP

This course analyses the many tasks that must be performed by the investigator and the sponsor before the study starts and during the trial. The specific roles of clinical research associates (CRAs) and of contract research organisations (CROs) will be emphasized.

MANAGEMENT OF INVESTIGATIONAL MEDICINAL PRODUCTS

Yves GEYSELS

This course gives answers to the question of which regulatory aspects are important throughout the product development cycle. What are the GMP requirements at various stages of product development. The course deals with various GMP aspects that are important for the production process of pharmaceutical products. Finally it discusses the different regulatory standards required during the various phases of product development (clinical phases I, II and III) and how IMP's are released for the use in clinical trials.

PATIENT ADHERENCE AND PERSISTENCE IN TRIALS AND PRACTICE

Bernard VRIJENS

Poor adherence to chronic-use drugs is a long-neglected worldwide problem of striking magnitude that occurs in 3 different forms: (a) non-initiation of dosing; (b) episodic omissions of single or sequential doses; (c) short persistence with dosing meant to continue indefinitely. The relative importance of these deviations results repeatedly in: biased clinical study results, poor outcomes of drug treatment, emergence of drug resistance, added costs of health-care. The complexity of adherence-related sciences, as well as its richness, results from the fact that it operates across the boundaries between many disciplines; i.e. economics, pharmacometrics, medicine, pharmacy, nursing, psychology, sociology. In practice, given the economic burden of poor adherence, health systems must evolve to meet the challenge of achieving satisfactory adherence to therapeutic drug regimens. The recent uptake of mobile-health, big data analysis, and personalized medicine, if well integrated into the care system, should facilitate patient-tailored intervention required to achieve optimal exposure to therapeutic drug regimens.

OUTSOURCING OF CLINICAL TRIALS AND CONTRACT MANAGEMENT

Rachel EMERSON

Get this right and a new medicine can be available for patients more quickly and efficiently. This part of the course will investigate the CRO market, approaches to procurement and contracting, and investigate the questions why contract out; how; what to do and importantly what not to do. Vendor search, selection, contracting, negotiation and oversight will each be discussed.

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

Marah WAJSKOP
Associate Director, Clinical Project Management at UCB Pharma SA

Yves GEYSELS
Ph.D., Director Clinical Operations, Bone Therapeutics, Gosselies, Belgium

Bernard VRIJENS
Ph.D., CEO, AARDEX Group, Liège Science Park, Belgium, Invited professor, Liège University, Belgium

Rachel EMERSON
Independent Pharma Consultant, freelance medical writer Schweich, Rhineland-Palatinate, Germany

WEDNESDAY 23 January 2019

Welcoming participants
9.30-10.00

Set-up of clinical trial
Marc de LONGUEVILLE & Marah WAJSKOP
10.00-13.00

Set-up of clinical trial
Marc de LONGUEVILLE & Marah WAJSKOP
14.00-16.00

Management of investigational medicinal products
Yves GEYSELS
16.00–18.00

THURSDAY 24 January 2019

Set-up of clinical trial
Marc de LONGUEVILLE & Marah WAJSKOP
09.00-10.50

Coffee break
10.50–11.10

Monitoring a study
Marc de LONGUEVILLE & Marah WAJSKOP
11.10-13.00

Lunch
13.00–14.30

Monitoring a study
Marc de LONGUEVILLE & Marah WAJSKOP
14.30-15.30

Patient adherence and persistence in trials and practise
Bernard VRIJENS
15.30-16.30

Outsourcing of clinical trials and contract management
Rachel EMERSON
16.30-18.30