PROGRAMME OUTLINE

Non-clinical safety / Clinical Safety / Pharmacovigilance

- The minimal nonclinical safety package to support FIH trials
- Risk assessment using the non-clinical safety package
- How to read, understand and contribute to an Investigator's Brochure (IB)
- The set-up and conduct of safe early phase clinical trials and selection of the appropriate population
- Assessment, evaluation and reporting of safety data from early clinical trials
- Defining pharmacokinetic (PK) endpoints / exposure limits and safety biomarkers for early phase trials
- Development safety update reports (DSUR) and risk management plans
- Significant medical emergencies in early clinical trials
- Characteristic safety issues involved in the development of biologicals and advanced therapies

Phase I Principal Investigator Training (non-oncology drugs)

- Obtaining approvals and governance
- Clinical risk assessment based on available data
- Adaptive designs and amendments
- Delegation and PI oversight
- AE evaluation, reference safety information SAE/SUSAR reporting
- Quality systems and mandatory GCP training
- Volunteer recruitment
- Contracts and monitoring
- Data management and analysis; safety review committees
- CSR writing and publications

ORGANISING SOCIETIES

The organizing societies provide a highly qualified faculty. All faculty members are experts in Early Phase Medicines Development.

AGAH e.V. - https://www.agah.eu

AHPPI - http://www.ahppi.org.uk/

BAPU - http://www.bapu.be/en

AFPT - Le Club Phase 1 - https://clubphase1.com

ORGANISATION

- Modules are taught from easily accessible teaching venues in major European cities in Belgium, France, Germany and the United Kingdom
- Estimated fees for training are between €300-500 per day
- Travel expenses and lodging are not included in participation fees
- Courses will start in Winter 2019/2020
- All six modules will be offered within two years

HOW TO REGISTER FOR COURSES

https://www.eufemed.eu/training/

CONTACT

EUFEMED Office
Rue de l'industrie 4
B-1000 Brussels
Belgium

info@eufemed.eu

EUROPEAN FEDERATION FOR EXPLORATORY MEDICINES DEVELOPMENT

CERTIFICATE/DIPLOMA

in Human Pharmacology

CONCEPT OF TRAINING

EUFEMED is developing a modular training course in Human Pharmacology leading to qualifications at the certificate (15 ECTS) and diploma (30 ECTS) level (ECTS refers to European Credit Transfer and Accumulation System).

The training course is intended for physicians, biopharmaceutical scientists and healthcare professionals working in early phase clinical research and would also suit investigators intending to fulfil the role of Principal Investigator for First in Human (FIH) trials.

The course content was derived from and is aligned with the syllabus of the PharmaTrain diploma / MSc in Pharmaceutical Medicine / Medicines Development Sciences. PharmaTrain is a not-for-profit organisation assessing the quality of courses in the biopharmaceutical sector, based on a syllabus jointly developed with the Faculty of Pharmaceutical Medicine, UK and IFAPP (International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine).

EUFEMED has drawn together a training faculty of experienced course instructors from its member associations and from invited guest lecturers.

Three modules are required for a EUFEMED Certificate and six modules for a EUFEMED Diploma in Human Pharmacology.

Each module will consist of between 4 to 7 days of lectures and exercises:

- Pre-course reading will be required
- Each module will include the conduct of case studies and team exercises and will conclude with a multiple-choice examination
- Post-course assignments will reinforce the learning process

MODULAR STRUCTURE OF TRAINING

The content in the PharmaTrain syllabus was evaluated for applicability and relevance to training in Human Pharmacology and gaps were identified and closed. At present, six overarching human pharmacology training modules were defined:

- Module 1: Introductory Course in Exploratory Medicines Development
- Module 2: Pharmacokinetics (PK) / Pharmacodynamics (PD) / Biomarkers
- Module 3: Regulatory Issues / Ethics / GxP / Quality Assurance
- Module 4: Study Design / Exploratory Development Plan / Clinical Operations / Data Management / Statistics
- Module 5: Non-clinical safety / Clinical Safety / Pharmacovigilance
- Module 6: Phase I Principal Investigator Training

The EUFEMED syllabus maintains close alignment with the PharmaTrain course in order to support the goal of recognition by PharmaTrain. This is intended to ensure European acceptance of the EUFEMED human pharmacology course.

PROGRAMME OUTLINE

Introductory Module

- Early phase medicines development process, ethical and regulatory prerequisites
- Basic concepts of PK and PD, early phase trial designs
- Non-clinical safety pharmacology and toxicology
- Dose finding, dose escalation, and stopping criteria in the first-in-human (FIH) trial
- Basic concepts of data management and biometrical analyses

PROGRAMME OUTLINE

Pharmacokinetics (PK) / Pharmacodynamics (PD) / Biomarkers

- Pharmacokinetics: an in-depth discussion of drug Absorption, Distribution, Metabolism and Excretion
- Compartmental versus non-compartmental analysis of PK data
- Preclinical models predicting human ADME
- Pharmacodynamics at a molecular, organ and population level
- Biomarkers: what's in a name?

Regulatory Issues / Ethics / GxP / Quality Assurance

- GCP in the context of current and future EU legislation
- Clinical Trial Authorisation and reporting requirements
- GMP Annex 13
- Quality Management System
- Clinical Trial Master File
- Vendor management
- Independent safety and data monitoring (DSMBs)
- Data integrity, traceability and security
- Clinical Trial Reports and archiving
- Inspections

Study Design / Exploratory Development Plan / Clinical Operations / Data Management / Statistics

- Early Phase Clinical Development Plans
- Organisation, management and administration of an early phase trial site
- Common early phase trial designs (e.g. FIH with SAD & MAD, food effect, ADME, TQT, BA/BE)
- Translating a protocol into a site study plan
- IMP and sample management
- Quality Management at the site
- Statistical concepts in early phase development