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The need for training in clinical research

Clinical studies provide key support for the implementation or rejection of novel medical interventions by regulating authorities and serve as the basis for the practice of medicine for most medical professionals. Over the last decades, however, methodological issues in design and interpretation of clinical trials have become increasingly demanding. Likewise, high demands have been imposed on clinical researchers by the current regulatory legislation on the conduct of clinical trials. Therefore, professionals who aim to have an active role in clinical research or to develop a deeper understanding of data from clinical studies have to devote considerable effort in order to keep up with current methodological standards.

Although most physicians and researchers have a basic understanding of clinical research, many frequently applied tools, e.g non-inferiority designs, Bayesian approaches or ethical aspects of research involving human beings are not easily understood. Thus, clinical researchers have to be updated regularly on (1) ethical requirements of clinical research, (2) formal requirements of GCP, including the guidance given by EU directive 2001/20/EG in 2002 and (3) novel statistical and methodological techniques applied in clinical trials.

Training opportunities in clinical research

There are a number of basic and advanced courses available worldwide. These courses range from 2-day training seminars to full postgraduate MSc or PhD-track programmes.

Overall, participants should acquire knowledge and skills about the following topics: classical phases of clinical research, phase I-IV, toxicology and pharmacology, the value of pre-clinical data and the related requirements according to applicable European regulations, placebo-control in clinical trials, new drug development, principles of pharmaceutical research, medical needs and product discovery, patient information and consent, development of scientifically sound study protocols, clinical trial design and methodology, randomisation, stratification and blinding, surrogates and clinical endpoints, biometrics and sample size calculation, patient protection (Declaration of Helsinki, the ethical review board, patient information and informed consent, insurance and confidentiality), adverse event reporting, role of the investigator brochure, CRF development, CRF and data handling, quality assurance in clinical trials (monitoring, inspections and audits), responsibilities according to GCP, GCP compliance, and credibility of clinical trial data.

Complementary training tracks are also available that focus on clinical epidemiology (observational studies), public health, international health, disease control, health economics and management, evidence-based medicine, health outcome research. Such tracks allow professionals to tailor their training to their specific professional role as primary researchers, regulatory bodies, or health policy makers.

Some selected training programmes:

www.meduniwien.ac.at/akh/klpharm/ (Dept. Clinical Pharmcology, MUW, Vienna, Austria)
www.vscr.at (Vienna School of Clinical Research, Vienna, Austria)
www.instituteofclinicalresearch.com (Institute of Clinical Research, Marlow, UK)
www.eccrt.com (European Centre for Clinical Research Training, Brussels, Belgium)
www.lshtm.ac.uk/eph/ (London School of Hygiene & Tropical Medicine, Dept. of Epidemiology and Population Health, UK)
www.fhs.mcmaster.ca/ceb/ (McMaster University, Dept. of Clinical Epidemiology and Biostatistics, Hamilton, ON, Canada)
www.hsph.harvard.edu/ (Harvard School of Public Health, Boston, MA, USA)