ON-LINE COURSE OF GOOD CLINICAL PRACTICE (GCPs) FOR INVESTIGATORS

INTRODUCTION

Good Clinical Practice (GCP) guidelines are an international standard of ethical and scientific quality for the design, conduct, record and drafting of clinical trials reports that involve the participation of human beings. Compliance with this standard ensures the protection of rights, safety and welfare of subjects participating in the trial in accordance with the principles of the Declaration of Helsinki, and also ensures the credibility reliability of the data obtained in a clinical trial. Spanish legislation RD 223/2004 for clinical trials mentions the obligation to apply the rules of GCPs in the planning, conducting, recording and reporting of all clinical trials carried out in Spain.

The course is led by Jesús Frías Iniesta, Professor of the Department of Pharmacology and Therapeutics from the School of Medicine at Universidad Autónoma de Madrid (UAM) and in its design and content Farmaindustria has collaborated, across a workgroup composed by the laboratories Abbott, AstraZeneca, Bayer, Leti, Grunenthal, MSD, Novartis and Sanofi-Aventis.

This course is recognized by the Continuous Training Centre of the Universidad Autónoma de Madrid (UAM) with 2 ECTS. Furthermore, it also has recognition, valid throughout the national Spanish territory of the Health Professions Continuous Training Commission of the Community of Madrid / National Health System, with 3'8 credits.

AIMS OF THE COURSE

This course' general goal is to train investigators and clinical co-investigators in the various aspects of GCP based in ICH E6 Good Clinical Practice guideline (International Conference on Harmonization). It also aims for having the investigators updated and trained in ethical issues and Spanish legislation concerning the conduct of clinical trials.

WHO SHOULD TAKE THE COURSE?

The course is intended for all health professionals wishing to participate in clinical research and clinical trials. It is designed and directed for all those hospital and Primary Care investigators, Research Institutes and Pharmaceutical Industry. It is also useful for ethic committee members, Contract Research Organizations (CROs) staff, Clinical Trials Assistant (CTA), Research Nurses and Clinical Trials Associates (CRAs).

No prerequisites arise for participation or any selection

criteria.

ORGANIZATIONAL ISSUES

The course is organized so that students have an online learning tool, easy and intuitive, accessible anywhere and anytime. The course is 100% online and can be performed continuously or sporadically, so that the speed of development depends on the interest, dedication and the need to finish it in a due date.

The teaching material is organized in nine modules or topics. In each of them there are included a theoretical part, an examination and a frequent questions. At the end of the theoretical part it is possible to find the bibliography used with links to the indexed documents and Bibliography where the student can consult web pages and regulative documents relative to clinical tests in Spain and Europe. In each module´s frequent questions appear practical examples of the most frequent errors or concerns and the most common situations in which investigators deviate from the GCPs in order to provide, a nice way, to consolidate the knowledge acquired in the module with special emphasis on the aspects of the GCPs that are broken.

There is also a tutorial available via email, not in real time, but with short time answer, in which teachers can

respond the questions asked by the students.

The course is in Spanish.

COURSE TOPICS

The course is organized into nine modules. All modules and exams are available online by distance learning tool “e-learning Moodle" placed at the e-learning page of the UAM.

The topics come directly from ICH E6 GCP standards and faithfully review the relevant aspects of this rule, although distributing the information in a more sequenced and didactic way, and oriented primarily to the needs of investigators. It has also been made explicit reference to the legal regulations in Spain in order to complete those aspects of interest to researchers in our country.

Module I: Introduction and Legal Aspects.

Module II: Process of the development of a medicine and main agents inside a clinical trial. Clinical Trial Phases.

Module III: Study Documentation: Essential documentation before, during and after the clinical trial development.

Module IV: Ethical aspects of research.

Module V: Investigator´s responsibilities.

Module VI: Sponsor´s obligations.

Module VII: Study medication usage.

Module VIII: Drug Safety management in Clinical Research.

Module IX: Audits and inspections.

EVALUATION/TEST

Tests are made so that explore the greatest interest issues in each of the modules and ensures that those who complete it, have an adequate knowledge of GCP standards and the Spanish legislation topics that concern clinical investigators.

In each module, and without a specific time to realize it, there is a multiple choice test that should be filled to finish the course. Only after the student has completed the nine modules in the established or desired order, it will be able to obtain a certificate from the UAM and valid for two years from that moment.

Each test must be passed with a score of 100% correct to obtain the certificate. Students have multiple attempts to complete each exam. After each attempt the student

can check the valid answers and errors. The questions will be different and random in every attempt.

HOW TO REGISTER

Those who wish to develop the course must register on the web site of the UAM Foundation (http: // matriculas.fuam.es/matriculauam/Convocatorias.action), or, in case of multiples licenses for public or private organizations, please contact the Foundation (Belen Gonzalez, mgonzalez.fguam@uam.es; Marta Magaz, mmagaz.fguam@uam.es). Once satisfied the fees (85 € for matriculation) you will receive an e-mail with the instructions to complete the matriculation