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regulations for the protection of human research subjects applied to an earlier period in the research process, when the use of a checklist was originally implemented as part of a multicomponent programme intervention being evaluated in a research study funded by HHS.

Finally, OHRP clarified that while the regulations do not apply when institutions are only implementing practices to improve the quality of care, if – at the same time – institutions are planning research activities examining the effectiveness of interventions to improve the quality of care, then the regulatory protections are important to protect the rights and welfare of human research subjects.

GCP training and certification of research professionals in The Netherlands

Just over a year ago, a foundation for e-learning and e-testing for clinical research personnel was set up in The Netherlands. Edgar Smeets met with its founders, JanHasker Jonkman and Cecilia Huisman, to discuss the developments made since its inception.

The foundation – known as *Certificering Klinisch Wetenschappelijk Onderzoek* – was established by Professor Dr JanHasker Jonkman of Groningen University and launched on 9 November 2006.

Q Now that a year has passed since the foundation was set up, could you give a recap of your target group and original objectives?

Our target group is anyone who is, or will be, involved in clinical research activities, eg. (junior) investigators (MDs), non-medical or paramedical staff, research/trial nurses and clinical research associates. Our main objective is to improve the quality of the design and conduct of clinical research, as well as knowledge of GCP. This is being achieved by training those involved in clinical research and testing them on their knowledge of good research practices. We also wanted to establish and maintain systems for certification and examination, which ideally will gain accreditation by the Dutch authorities. We want to increase the attraction of The Netherlands to research policy and decision makers.

Q While starting up, you received impressive support from all sorts of organisations, both academic and governmental. Did this prove useful and what are the tangible results?

The support we received was impressive; it opened doors and with it possibilities. We are currently discussing options to have our examination implemented into existing programmes on legal and regulatory topics in the curricula of all relevant faculties at the Dutch universities (through the Dutch Federation of University Medical Centres). We are also delighted that professionals from respected research organisations, such as the Dutch Healthcare Inspectorate and The Netherlands Association of Pharmaceutical Physicians, have joined our Editorial Board to prepare and write practical real-life scenarios and set valid questions.

Q The Dutch Healthcare Inspectorate, in its 2006 annual report, expressed support for the emerging initiatives for investigator training. It also mentioned that the success rate will be influenced by the motivation of participants. How will you tackle this?

We have identified certain triggers, one of which is the compulsory nature of the training. Training will therefore be part of the curriculum for new students. For those individuals already working in the field, we hope that certification will make them more appealing to sponsors. The exam only takes 90 minutes and has been judged as 'not boring'.

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Q Can you tell us about a pilot that was run at the Amsterdam Medical Centre?

We have actually run two pilots. The first was attended by 29 participants, with a wide range of GCP knowledge. All participants first underwent a GCP refresher course and then took the exam. Analysis of the exam results enabled us to refine the content and to enhance certain aspects of the IT infrastructure. The second pilot (June 2007) involved the exam only; the participants this time were 20 medical students and PhD students who had recently undergone multiday clinical research training where both GCP and GMP were covered.

Q Both the training and exam modules will use 'GCP examples from real-life settings'. What is the reasoning behind this?

The concept behind our examination is 'learning by testing'. Each exam consists of a few test cases accompanied or introduced by a 3-minute video of a real-life scenario; the participant needs to answer 3–5 multiple-choice e-questions. If an answer is wrong, the right answer is given by the computer program. The videos are in Dutch and the exam questions can be in either Dutch or English. Offering everything in English is not one of our current goals, as we believe that researchers need to have enough command of Dutch to explain a study to a potential trial subject.

Q How can we find out if an individual is certified by your foundation?

First and foremost, we expect that any certified professional will (proudly) list the certification on his/her CV. A CV has more status than a certificate, as it shows work experience and/or publications. All certified individuals will be listed in an online register, modelled on the Dutch BIG register (an online public repository listing the membership details of eight groups of health professionals).

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