

Training Dutch Academic Investigators – status update and future plans

By Edgar Smeets, PhD, CCRA, MICR

Clinical Research Consultant, Smeets Independent Consultant – SIC

Introduction / Background

Within the last ten years, all eight Medical University Faculties have merged one to one with their Academic Hospital, forming eight University Medical Centres (UMCs) (Figure 1). Each UMC operates as a legally private entity, and has responsibilities for teaching and training, for clinical research, and for patient care.

The Dutch Federation of University Medical Centres (NFU) acts as the umbrella organisation for all eight UMCs. The NFU recognised the need for the young/starting clinical researchers in the UMCs to be better trained on GxP aspects, as this would contribute to the quality of the research being carried out.

In 2005, the so called BROK committee was established. This committee established the exam requirements in June of 2006, after which so-called BROK courses started to be organised in the UMCs. Although the content of the courses may vary per UMC, the examination is identical to all course participants.

The web-based exam was developed and validated by MediaVision BV, with input from all relevant parties in the country.

An estimated number of 100 new staff members per year (usually PhD students) will start their research in human subjects (per one UMC). These individuals are the target 'audience' of the course and examination. Researchers from allied organisations are free to join as well.



Figure 1: The Netherlands. The eight UMCs are: Amsterdam (2x), Rotterdam, Leiden, Maastricht, Nijmegen, Utrecht, and Groningen

| Affiliation | # exam participants |
|--|---------------------|
| UMC St. Radboud (Nijmegen) | 204 |
| AMC (Amsterdam) | 128 |
| UMC Maastricht | 97 |
| Erasmus MC (Rotterdam) | 84 |
| UMC Utrecht | 28 |
| other (regional hospitals, high school etc.) | 52 |

Table 1: Numbers of exam participants by affiliation

Conclusion

(GCP) Training and certifying young Dutch academic researchers is well underway, with a uniform course offered in the majority of the eight University Medical Centres, and the online exam already done by over 500 participants. Further momentum is added to this initiative, with the UMCs and Dutch Ethics Committees starting to require certification in place, before the proposed research may be conducted in their clinics.

The BROK¹ Courses

Till date, courses (duration 3-4 days) have been organised in five of the UMCs. The first UMC to start was the AMC in Amsterdam. The company Profess BV will ultimately be responsible for the course in six of the eight UMCs.

The Examination

The web-based exam consists of three cases (of total six cases to choose from by MediaVision representative), with a total of 80 questions. It takes the mean participant 92 minutes to complete the exam (range 52-123).

Till date, the exam has been done by 541 participants from the five UMCs and by 52 participant from other organisations (Table 1)

The mean score is 84% of the 80 questions (range 64-97%), with 68% of the participants passing the exam, to whom a certificate was awarded.

Names (per UMC) of certified researchers are listed on an online public register ('BROK register'²).

Future Plans / Spin-off

- one of the UMCs (Nijmegen) soon will make certification compulsory for all researchers working with human subjects (so not only the starting ones), Rotterdam to follow soon
- Ethics Committees at the UMCs tend to make certification compulsory for each researcher submitting a trial
- three regional hospitals soon will join the training and examination program.

Acknowledgement

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¹The abbreviation stands for 'Basiscursus Regelgeving & Organisatie voor Klinisch onderzoekers' which can be translated to 'Introduction Course on Regulations and Organisational Aspects for Clinical Researchers'

²see www.nfu.nl / de UMCs / BROK register