First anniversary of the Dutch free e-learning module 'Onderzoekswijs'

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Background and Rationale

The free training module 'Onderzoekswijs' was launched a year ago (on 03 December 2012) by the Dutch Competent Authority (the CCMO).

The module, intended for those interested/involved in Investigator-Initiated Trials, contains the following six themes: 'do I need to submit my research trial?'; 'submitting a trial'; 'multi-centre trial'; 'performing a trial'; 'SAEs and SUSARs'; and 'other applicable laws and regulations.' Four of the six topics start off with a video clip.

The first anniversary of this initiative prompted me to approach the CCMO in order to (informally) evaluate their 'product'. I interviewed the subject-matter expert at CCMO, analysed Google Analytics (GA) reports kindly provided by the CCMO's ICT staff, and also approached the organisers of the 'BROK course,' a compulsory training for any person involved in clinical research.

> "BROK stands for 'Basiscursus Regelgeving & Organisatie voor Klinisch onderzoekers,' (Introductory Course on Regulations and Organisational Aspects for Clinical Researchers)."

Site Feed-back Options, Site Visitors, Visiting Trends

Each theme covered has a visitor 'feedback' button, and the website has a 'contact' option. Each theme also offers a 'test your knowledge' quiz, that directly tells the user if their answer is correct or not. This offers no official certificate whatsoever, and the results are not saved. Therefore, information from the quizzes, unfortunately, cannot be analysed.

During the first full year, the site was visited 19,397 times by 8,538 unique visitors. The average visitor looked at 6.3 pages per visit, and spent roughly 14 minutes on the site.

The most popular theme is 'do I need to submit my research trial', followed by 'submitting a trial', and thereafter 'SAEs and SUSARs'. This popularity listing is mirrored by the frequencies with which the feedback button was used.

The contact option was used approximately 5 times, and the total number of feedback topics received was 120. The questions were all posted in Dutch. Each of the visitors using these buttons received a personalised message in return, via e-mail.

Two interesting time trends are seen in the GA reports (see Figure 1): the site attracted slightly more visitors in Autumn and Winter (as compared to

Spring and Summer) and the numbers of visits spiked around the dates of BROK examination (see Insert). The latter observation is not surprising, as Onderzoekswijs is being discussed/offered as a means of extra training by training faculty, at each BROK training course.

Although all information in this e-learning course is in Dutch, the site also attracts visitors from countries where Dutch is not spoken. Furthermore, the referral-option to the training site as present on the CCMO website, accounts for approximately 25% of visitors.

Discussion

The CCMO is satisfied with the results obtained in the first year of the eLearning site. Although training investigators and others involved in the actual conduct of clinical research is not the primary objective of this initiative, the CCMO had foreseen that this site might fill a knowledge gap. The number of visitors the site has attracted within its first year shows, that it does, indeed, do so. Whilst it is difficult to conclude that the users are predominantly those involved in investigator-initiated trials, the number of feedback requests on the two most basic modules suggests they are.

This eLearning site has caused a shift in administrative work procedures at the CCMO, that asks for further consolidation; Instead of CCMO's 'clients' phoning the administration desk during office hours, a quite substantial and separate stream of questions now reaches them via the modules' feedback option.

In 2013, the BROK course online examination was taken by 2038 candidates. It is obvious that the spikes in visits shown in the GA graph (see Figure 1) reflect their visits to Onderzoekswijs - visits aimed at preparing and testing their knowledge.

The content of the modules was not amended during the first year, but at least one change is foreseen in the near future - the inclusion of training materials on medical devices. The CCMO website, restructured in November 2013, already provides substantial background to the use of medical devices in research, and – as opposed to Onderzoekswijs it is now almost fully bi-lingual (Dutch and English).

For further information, visit www.ccmo.nl

Attending the course and obtaining the certificate is compulsory for any person involved in clinical research in Dutch academic hospitals. The Dutch Federation of University Medical Centres (NFU) has been offering this course since 2006, and is in charge of its examination and certification management. Although the content of the courses may vary per University Medical Centre (UMC), the web-based examination (since 2007) is identical for all course participants. Names of certified researchers at each medical centre are listed on an online, public register 'BROK® register', kept by NFU.

To date, 6973 persons have successfully passed the BROK examination (given as central sessions). In 2013, 2038 candidates took part in the examination, of whom 1779 passed (i.e. a 87% pass rate).

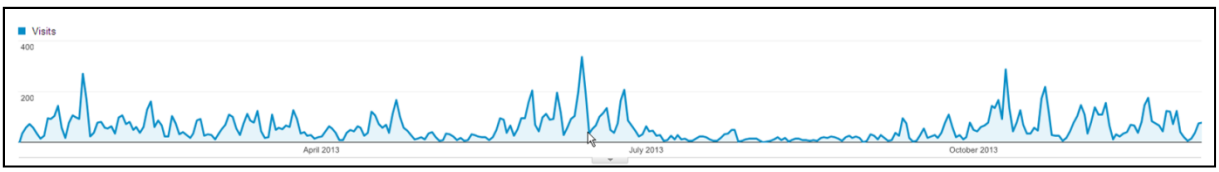

Figure 1. Google Analytics. Onderzoekswijs site. Visits over time in the first year.

In 2013, examination sessions (number) took place in: January (2), February (6), March (6), April (4), May (4), June (8), July (1), September (4), October (7), November (7), and December (5).

Edgar Smeets PhD, CCRA, MICR, is a clinical research consultant, working as a freelancer, based in the Netherlands. Edgar has worked in this field since 1997, and joined ICR in 2002. In 2006 he became MICR, and shortly thereafter he joined the Editorial Board of CRfocus, as an International Correspondent. It's been Edgar's interest to share information on Dutch clinical trial affairs, with the ICR membership, and he is looking forward to continue this with the newly appointed editorial board.

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- May 21 - Clinical Trials Administration - Beyond the Basics (C22)
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- September 10 - Risk-Based Monitoring (C28)
- September 17 - Remote Monitoring (C29)
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