

ICRs eLearning Module 'ICH GCP for Investigators' – a pilot study

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Introduction

In today's clinical research world, training of investigators can be performed / conducted online. Booking a time on everyone's agenda, international travel to centrally organised investigator meetings, sponsor staff trips to sites, etc. can be minimised or avoided altogether, with savings on the trial budget.

Since a few years, the Institute of Clinical Research sells the online module 'ICH GCP for Investigators'¹.

The research question was if this module is suitable for use in relatively (GCP-) inexperienced physicians already conducting clinical research.

Method

The aim was to 'recruit' 8-10 physicians matching the entry criteria listed in Table 1. Each would be offered a complimentary slot (paid for by SIC) on the eLearning module, and sent a questionnaire via e-mail.

The reality was that the module was offered to 7 physicians (one German, six Dutch), of whom 5 made it to the exam plus returned their answers.

A. Introduction	RESULTS
1. My age is:	33 years (28 - 42)
2. My previous experience / experience till date in conducting / assisting with clinical trials is: (years) (months) (none)	11.6 months (5 - 18)
3. How many clinical trials have you conducted / assisted with? (number)	1 (1 - 1)
4. In what field of medicine were these trials conducted? (free text)	nephrology, neurology, gynaecology, dermatology (2)
B. The e-Learning Module – Learning part	
6. All pages in the module took me (hours) and (minutes) to read/understand.	170 minutes (105 - 240)
7. It took me (number) of login sessions over (period of time) to read and understand all pages in the module.	2 logins over 2 days
C. The e-Learning Module – exam part	
8. The exam / the 20 questions were answered by me in: (minutes)	23 minutes (10 - 60)
9. In order to answer to the 20 questions, I looked back to re-read the learning pages: (yes/no)	4 'no', 1 'yes'
10. If 'yes' to question 9: How many times did you look back?	twice
11. I passed on my first examination attempt: (yes/no), with a % score of:	2 'yes' with 75 and 95%
12. If 'no' to question 11: I had to correct my answer to (number) exam questions	7 (4 - 9)
13. If 'no' to question 11: After that, I passed my (second) attempt: (yes/no), with a % score of:	2 'yes' with 75 and 100%
D. The e-Learning Module – general	
14. The e-learning module met my expectations: (yes/no)	4 'yes' out of 4 answers
15. The course was useful for me personally: (yes/no)	5 'yes'
16. I plan to list the training on my CV and attach a copy of my certificate to it: (yes/no)	4 'yes', 1 'no'
17. The exam was difficult: (yes/moderately/not at all)	1 'yes', 2 'mod', 2 'not at all'
18. I would recommend this e-learning module to colleagues: (yes/no)	4 'yes', 1 'no'
19. I would rather do an e-learning module myself than attend to the GCP training session at an investigator's meeting: (yes/no/don't know)	4 'yes', 1 'no'
20. Before the invitation by SIC, I knew the ICR: (yes/no)	5 'no'
21. Now that I have done this module, and learned about ICR, I plan to visit the ICR webpages in the future: (yes/no)	3 'yes', 1 'no'

Table 1: Entry Criteria

Entry Criteria:

- relatively inexperienced in the clinical research arena
- no previous GCP training attended
- being able to (1) run the module and try to obtain the certificate in their own time but within about two weeks (mid February 2009 - start of March 2009), and (2) return a 21 items questionnaire via e-mail.

Conclusion

This pilot study shows that – being offered complimentary participation in an online training programme – relatively inexperienced physicians are willing to spend an average of 3 hrs. on learning, and consider it useful. The majority prefers the online option over attending to a (usually shorter) training session at an investigator meeting. The exam was moderately to

not difficult, with 50% of the participants gaining certification after one attempt, and the other 50% after two. Nearly all would recommend the module to colleagues and will list the training on their CV.

Offering ICRs online training to investigators is an option to consider, when aiming for working with GCP certified investigators.

¹ from the ICR webpages: The objective: To increase subject knowledge for Investigators including the consequences for non-compliance. Learning outcome: By the end of this module you will know what the requirements of the Investigator are under ICH GCP. Its aim is to explain what the the ICH GCP guidelines are, and to explore the meaning of the requirements. The programme is clear and simple in design and gives full instructions for use.