

Going for Gold in Clinical Research Through Training and Education

Part 2: Ways to Train and Educate Researchers

In the first article of this series, the requirements for training and education were outlined in relation to the International Conference on Harmonisation Guideline for Good Clinical Practice (ICH-GCP) [1]. As a result of these guidelines, we are experiencing the emergence of a knowledge-based culture in the clinical research environment. When we discuss professionalism we are looking at qualification through education and training as a way to ensure quality and excellence in clinical research. However, with so many options available, deciding on the best way to educate a research team can be difficult. (*Clinical Researcher* 2003;3(2):24-9.)

Individuals with the responsibility for making sure clinical researchers are trained and educated in ICH-GCP have a tough task. Site administrators, principal investigators, institutional clinical research managers, sponsors and individuals with a desire to learn have many different educational methods to choose from. Here, we will look at the many teaching methods that are available, most of which can be used either alone or in combination. Naturally, there are advantages and disadvantages to each, but some will suit certain individuals much better than others. It is therefore vital that the person responsible for choosing the method of training is well informed about all of the available options. Only then can trainers

and learners choose the most appropriate teaching methods based upon their individual learning styles and needs.

Training methods

The traditional live classroom

The traditional 'chalk and talk' method remains the most popular method used in university settings. Traditional as it may seem, the live classroom method of learning

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is still very popular with adult learners. The process that we all grew up with in grade school, in which a teacher or trainer is at the front of the room lecturing or explaining to the audience, is a didactic teaching style. Note-taking is a major activity in this learning method. Use of the senses, the art of listening and the skill of summarizing through note-taking are all extremely important for successful information retention with the live classroom method.

Effective learning in the classroom requires that three characteristics be met [2]:

1. The atmosphere in the classroom should facilitate the exploration of meaning. Learners must feel safe and accepted. They need to understand both the risks and rewards of seeking new knowledge and understanding. The classroom must provide opportunities for learner involvement, interaction and socialization, along with a businesslike approach to getting the job done
2. Learners must be given frequent opportunities to confront new information and experiences in the search for meaning. These occasions need to be provided in ways that

Paula Jones-Wright, CreateNet Inc., N.S., Canada



Paula Jones-Wright, BScN, RN, BEd, MEd, CCRC, CCRA, is President of CreateNet Inc., a Canadian company providing training and education to research team members and Good Clinical Practice (GCP) inspections at clinical research sites. She has worked 'in the trenches' as a coordinator, clinical research associate and project manager, and has been an IRB member. She has audited clinical research sites for adherence to GCP and standards in practice, and, over the last 6 years, has trained and educated more than 1500 clinical research team members.

allow students to do more than simply receive information. Students must be allowed to confront new challenges using their past experiences without the dominance of a teacher or giver of information

3. A process of personal discovery should be used to acquire new meaning. The methods used to encourage this discovery must be highly individualized and adapted to the learner's own style and pace of learning

The basic purpose of traditional-style didactic teaching is to achieve the dissemination of concrete information. The classroom setting allows for the delivery of a substantial amount of information to a large audience, and is thus efficient and, in general, economical.

The classroom environment offers a setting in which a lecture and interactive discussion can take place. Lectures held in classrooms are often the cornerstone of training, used in order to communicate theories, facts and ideas to students [3].

The lecture method

The lecture method allows the trainer to present facts in a direct and logical manner. The trainer can, through his/her experience and knowledge, inspire the audience and stimulate thinking in larger open discussions. This method is useful and convenient for larger audiences.

The limitations of lectures are that experts who call themselves such may not actually be experts, and, even if they are, experts are not always good teachers. If the audience is very passive, learning will be difficult to assess.

In order to fully prepare for a lecture, the trainer needs to have a clear introduction and complete summary. The length and content of the lecture need to be carefully planned in order to achieve effectiveness. The speaker should also try to include

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examples and anecdotes in order to help keep the attention of the audience [3].

Combining the lecture method with discussion

In order to augment the one-way, and possibly inefficient, nature of lectures, a combination of lectures and discussions can be used. The design should allow audience participation at least at the end of the lecture, or, better still, halfway through the talk. This will allow the audience an opportunity to question the content, clarify information and challenge the speaker. The discussion period should never be eliminated. The quality of the interaction will be limited by the quality of the questions and discussions. Some speakers prepare questions in advance and plant these in the audience in case the discussion does not initiate itself [3].

Self-paced learning modules

Self-paced learning is a good teaching method for students who are driven and independent. Such learners do not need to have a physical instructor present throughout the learning process, and must be extremely self-disciplined. Many independent contractors in our industry have this characteristic and so would do well with this style of teaching.

For this type of teaching module to work, the student needs to know how to learn. One key to the success of independent learning is the development of learning skills and excellent study habits. For this, metacognition—or mental self-management—is needed. This is the art of planning, monitoring and evaluating the learning process.

In this process, learners should be encouraged to identify their best learning styles and to use different learning environments. Completion of the learning cycle is also crucial. This cycle involves the memorization of information, rules and concepts, followed by the assimilation and organization of the new information. The information is then used to analyze, synthesize and problem-solve. The final stage of this process occurs when the independent learner incorporates this information into evaluations, predictions and judgments [3].

A learner's experience of training

"I expected a course on ICH-GCP to be quite dry, but necessary for my job—i.e. that we would go through the document in a perfunctory manner. 'Who willingly wants to spend a whole day on guidelines concerning informed consent and documentation?' was my naïve thought before attending the course.

"However, the trainer's techniques really made the course come alive: it wasn't dry and stuffy at all. She facilitates course participants to recognize their knowledge gap, and their goals in taking the course. The delivery of the course is adjusted throughout the day in order to match the level and needs of her course participants. High on her priority list is to relate the GCP responsibilities to everyone's daily practices.

"Group sessions are very important, since adults learn not just from the instructor but also from the questions and comments of the other course participants. The trainer also encourages a networking environment, which helps participants learn from each other even after the course. We had small group discussions (5 people) as well as larger group sessions (15–20 people).

"The course really helped us to know the international standards, confirm that we're meeting them and help with interpreting them within the framework of our national (Canadian) guidelines. People left the course quite energized and confident that they have the skills to review their current processes and ensure they comply with ICH-GCP.

"Since taking the course, one of the things I have done in my role of organizing educational initiatives is to bring the trainer in to train even more members of our research team. The courses always have a waiting list of physicians, research coordinators, research ethics board members, research pharmacists, etc."

Marleen Van Laethem is one of the first Research Ethics Monitors in Canada, organizing in-house educational initiatives and performing internal study audits at St Michael's Hospital in Toronto, Ont., Canada.

A common example of a self-learning module is the scenario where a learner reads a scientific article in a journal and follows this with a test composed of multiple-choice questions. The answer sheet is then sent by e-mail or fax to the journal or a testing company used by the journal for the validation of new knowledge transfer. The learner can then acquire continuing education units (CEUs) or credits towards their professional designation or status. Another source of self-learning modules is web sites such as WebMD, which will e-mail a module to members. Questions accompanying the module can be completed online for the achievement of continuing medical education (CME) credits for investigators.

Online education

In our industry, the online environment has proven itself in the areas of data capture and recruitment activities. With the growth of technology use in clinical research, innovative educational programs are needed in combination with technology advances in order to effectively develop ways to train and educate research team members [4].

Self-paced learning is achieved with online education, while individual learning plans can be developed with an online tutor. Some online education systems allow the learner, through a membership fee, to have the option of acquiring the latest, most up-to-date information.

Online training allows for an environment that enhances virtual place and virtual time learning. The greatest advantage of technology training is convenience. Investigators often admit to not being able to take time away from clinics in order to attend 1-day courses. Online learning is therefore especially useful for investigators because it is convenient: learners have the ability to choose when learning occurs and where it takes place.

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It is also cost-effective because travel expenses are eliminated. Group learning forums can also be developed online for learning networks and can be made accessible 24 hours a day, 7 days a week.

Online courses can bring training to larger groups of research team members. However, the development of an online learning program is a huge undertaking and is expensive in terms of both finances and time.

Cooperative learning

In a training course, audience participation can be achieved by using cooperative learning, which involves the instructor using smaller groups in order to generate ideas and group discussion. It is essential that the instructor gives learners clear-cut instructions and a concrete task to perform, with enough structure and focus to ensure that the learning task is accomplished within the groups. The trainer should choose groups of 5–6 learners with various viewpoints, abilities, backgrounds and experience. In order to assess the various levels of experience in the group, the attendees can be surveyed by e-mail or fax prior to the course. The trainer will then have access to useful information, such as each attendee's years of experience, their background and any courses already taken. Having a diverse audience will encourage the development of new skills and increase the possibility of achieving the task while facilitating useful interaction. The success of the group depends on the interactions between the learners.

This cooperative learning approach helps to enhance communication skills. These skills include paraphrasing one another's words in order to ensure and verify comprehension, giving and receiving feedback, allowing every member to contribute their own ideas, and refraining from taking over the entire group or allowing another member to do so.

One cooperative learning strategy that is effective is the 'think-pair-share' technique. In this, the audience is encouraged to think about a problem, develop further analysis through hypotheses and then pair-up into groups to share their ideas in order to achieve cooperative group learning [5].

Team learning

Cooperative learning can be used in combination with team learning. Team learning offers a more vigorous workout

of the mind; it is sustained over a longer period of time and the problem solving process is more intense.

The idea behind team learning is to meet the overall learning goals of the entire class by developing group objectives for the course at the start. Each individual is then accountable for helping the team to meet these objectives—this establishes and maintains a sense of team spirit in the classroom community. Team learning is becoming more popular in the corporate world as a means for companies and sponsors to achieve goals, mission statements and overall industry direction. The results achieved through team learning are the result of facilitation, and having a trainer who is an excellent facilitator is the key to successful team building.

An example of team learning is getting a group of clinical research associates together to problem-solve using their collective experience. The facilitator collects up each of the group's solutions from flip charts or computer terminals and then summarizes the group's findings into a useful package that can, for example, be incorporated into standard operating procedures (SOPs).

Brainstorming

This teaching method encourages creative thinking and full participation. It draws on the audience's knowledge and experience, and creates a team spirit. Ideas can generate discussion and lead to further ideas and opinions. This is an excellent training method for discussing clinical research issues in case-study form.

The success of brainstorming is largely dependent on the trainer or group leader. This exercise needs to be facilitated well, in order to maintain the audience's cooperation and attention. The issues need to be carefully selected, and if there is a lack of stimulation the ideas have to be generated from the audience. The trainer must ensure that the group is focused so that something positive is achieved in the time allocated. This will avoid overall criticism and negative evaluation of the session. Attendees can also find it difficult to think 'outside the box'.

Videotapes

Videotapes offer an entertaining way of teaching formal content and raising issues.

Using problem-based learning, life-long learning skills can be developed, which include the ability to find and utilize appropriate resources

However, a video is only as effective as the discussion that follows it. To work well, videos must look professional and raise enough issues to stimulate discussion. To assist this, the trainer can prepare a list of stimulating questions for the audience for after the show [3].

Problem-based learning

Problem-based learning is a teaching method that uses 'real world' examples as a base for students to learn problem-solving and critical-thinking skills and to acquire knowledge about the essentials of the course. Life-long learning skills can be developed, which also include the ability to find and utilize appropriate resources for learning. The teaching process for problem-based learning is thus:

1. The audience is presented with a problem, such as a case study or scenario in clinical research
2. In groups, students organize ideas and previous knowledge that relates to this problem and try to find the broad nature of the problem
3. Learning issues are identified by the questions that are asked by the learners about aspects of the problem that they do not understand.
4. Each group then ranks the learning issues by their order of importance

With this technique, students should be encouraged to discover what they do and do not know about the problem at hand. They should be encouraged to summarize the group issues and to connect new concepts to older knowledge. This activity allows students to see that learning is an ongoing process and that issues that need to be explored are always coming up in practice.

The trainer needs to guide and coach the learners in order to explore questions and encourage group interactions. The success of such group activities is dependent on group size.

Determining the most appropriate learning method for individuals

The following questions can be used to determine the best style of learning for any given person:

1. Do you prefer the trainer to be at the front of the room lecturing and explaining information to you?
2. Do you think that note-taking should be a major part of the learning process?
3. Do you need to use your senses when learning?
4. Are you able to listen attentively?
5. Are you good at summarizing information?
6. Can you easily retain the information given out by a lecturer?

If you answered yes to 4 or more of the above then you are suited to the live classroom teaching method combined with lectures

1. Are you a driven and independent student?
2. Are you comfortable without a physical instructor being present throughout the learning process?
3. Are you extremely self-disciplined?
4. Are you aware of how you learn?
5. Have you developed excellent study habits?
6. Do you usually plan, monitor and evaluate your learning?

If you answered yes to 4 or more of the above then you are suited to self-paced learning modules

1. Do you like to be able to learn at any location and at any time?
2. Is the convenience of learning important for your busy schedule?
3. Would you enjoy a group-learning forum online?
4. Do you find it difficult to take time away from work to attend courses?
5. Do you find traveling to attend courses impossible?
6. Do you want to acquire the most up-to-date information?

If you answered yes to 4 or more of the above then you would do well learning with an online education program

1. Do you enjoy being in a small group in order to generate ideas and group discussion from other learners?
2. Do you like to meet with other learners who have a variety of viewpoints, abilities, backgrounds and levels of experience?
3. Do you want to interact with other people taking a course?
4. Do you desire to share your ideas with others during a course?
5. Do you like to problem solve in groups?

If you answered yes to 4 or more of the above then you would do well learning with a cooperative or a team-learning program

1. Do you need to become involved in the identification of your individual learning needs?
2. Do you like to identify learning objectives and outcomes in order to measure your learning?
3. Do you want to have direct involvement throughout the learning process?
4. Do you want to be given the chance to test your ideas?
5. Do you like to take risks when learning?
6. Are you a creative thinker?

If you answered yes to 4 or more of the above then you would benefit from a course that offers problem-based learning

The trainer needs to make a decision, based on class size and the knowledge level of the audience, to determine the degree to which the interaction is student directed versus trainer directed. In a smaller group situation it is easier to allow for more course time for this interaction. Trainers need to become facilitators and must watch for learners who are dominating the group's learning time.

Problem-based learning is the type of classroom organization needed to support a constructivist approach to teaching and learning. Savoie and Hughes, writing about a process that they used to design a problem-based learning experience for their students, describe the following actions for creating such a process [6]:

1. Identify a problem suitable for the students
2. Connect the problem with the context of the students' world so that it presents authentic opportunities
3. Organize the subject matter around the problem, not the discipline
4. Give students responsibility for defining their learning experience and planning to solve the problem
5. Encourage collaboration by creating learning teams
6. Expect all students to demonstrate the results of their learning through a product or performance

Fundamental concepts for integration into training methods

Student planning

Presenting information to learners through lectures does not in itself ensure that learning has taken place. Adult learners especially need to become involved in the identification of their individual and group learning needs. They need to be encouraged to identify learning objectives and outcomes so that

Teaching methods need to be designed so that they are congruent with the relative strengths and weaknesses of learners—the focus of the process of learning should be delivery rather than content

they can measure the progress of their learning. The attendees must be engaged: teaching strategies that require the students' direct involvement must be used. The learners should be given the chance to test their ideas, take risks and become more creative in their thinking. Allowing this level of input by the students will promote learning [7].

Small groups

Adult education practice has always supported the use of small groups in learning. Groups allow teamwork to be promoted and encourage cooperative and collaborative learning. Groups reflect the important process of learning from peers and they allow all learners to become interactive in discussions while assuming a variety of roles during the learning process. It is important for the trainer to observe group interactions in order to ensure that each group has a goal and direction in mind. The trainer must also be aware of any group interactions that are negative for the group learning process, such as one member of the group taking over [3].

Panel of experts

Standard single-speaker lectures can be improved by having a panel of speakers to present different opinions and provoke better discussions. A frequent change in speakers will help to keep the audience's attention.

Each member of the panel should be a good speaker, and their personalities should not overshadow the content. The speakers should be presented in a logical order based on the material discussed, and there should always be a main lecture coordinator to focus the panel, introduce the speakers and summarize the information discussed.

Learner-centered or teacher-directed delivery

Learner-centeredness is a distinguishing feature within adult education. Cervero and Wilson identify that, "At the heart of practice is the adult learner... The highest professional and moral principle for adult educators is to involve learners in identifying their needs." [8]. This implies that traditional teaching practices are not considered appropriate for adults. The learning theory is shifting from transmission of a fixed body of knowledge to a focus on lifelong learning as an essential habit of the mind [9].

Trainers can vary their use of teacher-directed and learner-centered approaches depending on which best serves the learners' needs. Teaching methods need to be designed so that they are congruent with the relative strengths and weaknesses of learners. The focus of the training session should be the students and their ability to learn, and the focus of the process of learning should be the important area of delivery rather than the content itself.

The trainer needs to be flexible and adaptable for the students rather than expecting the students to adapt to the content. In this way, the responsibility for learning is placed on the learners themselves. The trainer will then be able to facilitate learning rather than being a gatekeeper of knowledge. Trainers do not need to become a world authority on a subject to be able to encourage a collaborative learning process in which new knowledge is explored, discovery is achieved and learners are satisfied by learning new ideas and skill sets.

In *A Different Kind of Classroom*, Robert Marzano makes six assumptions about creating a learning-centered classroom [10]:

1. Instruction must reflect the best of educational knowledge about how learning occurs
2. Learning involves a complex system of interactive processes that includes different types of thinking

The training debate

This article is the second in a series on training and education in clinical research. Here, we have outlined the ways in which researchers can be trained and educated. Future articles will discuss the validation of knowledge comprehension, adult learning principles and the cost issues involved in training research teams.

Whether you are a trainer, an investigator or team member who has received training (or would like training but don't really understand the benefits or what is involved), an individual with responsibility for ensuring site training, or an auditor or regulator—we want to hear your views, comments or anecdotes about training. Contact us at: pointsofview@clinical-researcher.com


3. What we know about learning indicates that instruction focusing on large, interdisciplinary curricular themes is most effective
4. The curriculum should include explicit teaching of higher-level attitudes and perceptions, and mental habits that facilitate learning
5. A comprehensive approach to instruction includes at least two distinct types of instruction: teacher-directed and student-directed
6. Assessment should focus on students' use of knowledge and complex reasoning rather than their recall of low-level information

Summary

Successful clinical research education requires the commitment of trainers to teaching using established educational principles, and of research team members to learning. Only in this way will clinical research improve.

Help is also needed from universities, sponsors, government leaders, research sites and accredited associations that have the power to shape an environment that is conducive to best practice in clinical research education.

It is worth remembering this maxim: "Knowledge, grounded knowledge, is science; it represents objects which have been settled,

ordered, disposed of rationally. Thinking, on the other hand, is prospective in reference. It is occasioned by an unsettlement and it aims at overcoming a disturbance." John Dewey, 1859–1952, American philosopher and educator [11]. 

Address for correspondence: Paula Jones-Wright, President, CreateNet Inc., 118 Ochterloney Street, Dartmouth, N.S., Canada, B2Y 1C7.
E-mail: pjwright@createnetinc.com

Next in the series:
Good Training Practice (GTP)

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