Research Proposal

Bachelor Assignment

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Working title:

Evaluating quality of Organon's CRA's training:

A comparison of 'what is' versus 'what should be'

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S0029513

October 2006

Contents

1.   Title

Evaluating quality of Organon's CRA's training: a comparison between theory and practice

2.   Descriptors

Clinical Research Associate (CRA); Evaluation; Human Resource Development (HRD); Pharmaceutical industry; Quality; Training; Vocational Education.

3.   Rationale and relevance

A Clinical Research Associate (CRA) can be considered as the main contact person between the pharmaceutical company e.g. Organon and the institute (usually a hospital) where the clinical trial is conducted. The role of a CRA is to monitor a clinical trial, consequently to verify that safety of subjects is protected, that reliable data are collected and that the trial is conducted in compliance with medical and regulatory regulations (ICH guideline for Good Clinical Practice, 2005).
According ICH/GCP guidelines (2005) only qualified, well trained CRA's are allowed to perform the monitoring tasks, but education is also prescribed from the HRD policy of Organon. The Organon website (2006) also states that Organon realizes that people make the difference and that they stimulate excellence and offer a challenging work environment with numerous opportunities, which inspires professional development and personal growth.
Translation of the HRD policy into daily practice is a line responsibility (Akzo Nobel Human Resources policy statement, 2005), in this case of the Global Clinical Monitoring department. The education for CRA's organized by the Global Clinical Monitoring department consists of several types of training, e.g. lectures on guidelines and procedures, workshops on skills and lectures on scientific knowledge. Updates of guidelines, procedures and scientific knowledge are usually given by (non-interactive) lectures during the yearly international CRA-meeting or provided via e-mail. And recently updates are also trained locally based on presentations prepared centrally. The author wonders whether this type of education is suitable to ensure that CRA's apply the new guidelines, procedures and knowledge in their daily practice. Moreover, the answer on this question is relevant for all stakeholders, including the CRA's themselves, their trainers and line managers and for Organon in general, but also for everybody involved in the clinical trials (investigators, trial staff, subjects) and eventually for the patients. Therefore with this bachelor assignment the theory of educating guidelines, procedures and knowledge will be compared with the experience of CRA's to apply these new guidelines, procedures and knowledge in their daily practice. Consequently the evaluation on quality will focus on the effectiveness of education (Nieveen, 1999). In other words is the quality of education for CRA's sufficient to perform their tasks and can CRA's realize the ambition of Organon?

4.   Background of the study

In this section, some background information on the bachelor assignment will be provided. First of all some information will be given on Organon, the pharmaceutical company where the assignment will be conducted. Second, more information on the education of Clinical Research Associates (CRA's) will be provided. Finally related concepts like 'quality' and 'curriculum' will be explained in more detail in order to set a conceptual framework to evaluate the quality of Organon's CRA training.

4.1. Background of Organon

Organon is a business unit of the multinational Akzo Nobel, but will become an independent company in the near future. Organon Biosciences is the new mother company, which will

consist of Organon (human pharmaceuticals), Intervet (veterinary medicines) and Nobilon (human vaccines). Below the current relation between Akzo Nobel and Organon is explained. Moreover the influence of the HRD vision of Organon on the education of its employees in general and of Clinical Research Associates (CRA's) in particular is described. The place of CRA's and the corresponding 'Global Clinical Monitoring' department within Organon is shown in an organigram.

<u>Organon as pharmaceutical company</u>
Organon, which is based in Oss, the Netherlands, is a global leader in the creation of innovative prescription medicines for gynecology, mental health and anaesthesia products that contribute to the health of people and their quality of life. Organon products are sold in over 100 countries, of which more than half of these countries have an Organon subsidary (website Organon, 2006).

<u>HRD vision of Organon</u>
Organon's HRD vision has been derived from the one of Akzo Nobel. The main objective of Akzo Nobel's HRM policy is to create a winning match between the individual needs and organizational demands (Akzo Nobel Human Resources policy statement, 2006). Organon's business has been built by people and regards their employees as their most valuable resource. They encourage people to take an active role in exploring the boundaries of medical and pharmaceutical research, in the hope that generations to come will enjoy a more secure and healthier future. The website states: "We realize that our people are responsible for the success of our company and we strive to maintain an environment that balances the work and personal needs of our employees" (Website Organon, 2006). Both the Akzo Nobel's HRM policy as the statements from the Organon website show that developing the labor force within the company context is very important. In other words the vision on Human Resource Development is closely linked to the Human Performance Technology. HPT is a method to improve the functioning or performance of people within an organization. Within this approach education is not the standard intervention, but could be one of the solutions to improve the human performance (Kessels & Poell, 2001).

<u>Research and Development</u>
Success in the pharmaceutical industry means, first and foremost, innovation and creativity: the discovery and development of new chemical entities with new mechanisms of action delivering better clinical results. In pharmaceutical terms, Organon is a medium-sized company and its strength depends on its expertise in developing such products. Worldwide, Organon's R&D organization numbers just over 2,500 employees (about 18 percent of the total workforce), of whom 1,350 are stationed in Oss, the Netherlands. The company runs another important research centre in Scotland, and development units in the USA, France, Germany and Japan. (Website Organon, 2006)
Research and development (R&D) is the term given to the discovery, synthesis, testing and full assessment of efficacy and safety of new drugs with new mechanisms of action. It is an expensive process: marketing approval by registration authorities can only be obtained after extensive studies. These clinical trials typically take 10-12 years and can cost well over US$/Euro 800 million. Today, Organon concentrates its R&D efforts in six main areas: gynecology, fertility, neuroscience, anaesthesia, immunology and cardiovascular disease (website Organon, 2005). The organigram (figure 1) below shows in detail how Organon has been organized.

<u>Clinical Research Associate</u>
The Global Clinical Monitoring department is part of the Global Development organization and is responsible for monitoring the clinical trials, done by Clinical Research Associates (CRA's). The department has been divided in three departments responsible for different regions: Japan, North America (US and Canada) and an international region, situated in Oss, responsible for the rest of the world.

A Clinical Research Associate can be considered as the main contact person between on the one hand the hospital where the clinical trial is conducted and on the other hand the pharmaceutical company, e.g. Organon. As explained above the main role of a CRA is to monitor a clinical trial. The purpose of trial monitoring is to verify that:

1. The rights and well-being of human subjects are protected.
2. The reported trial data are accurate, complete and verifiable from source documents.
3. The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP and with the applicable regulatory requirement(s). (ICH guideline for Good Clinical Practice, 2005)

In other words a CRA should have knowledge of different types of guidelines and regulations and also of protocol specific issues. In addition, the CRA needs to have sufficient skills in order to co-operate with investigators, trial nurses and other staff at the hospital and with members of the clinical trial team and with colleagues of other departments within Organon.
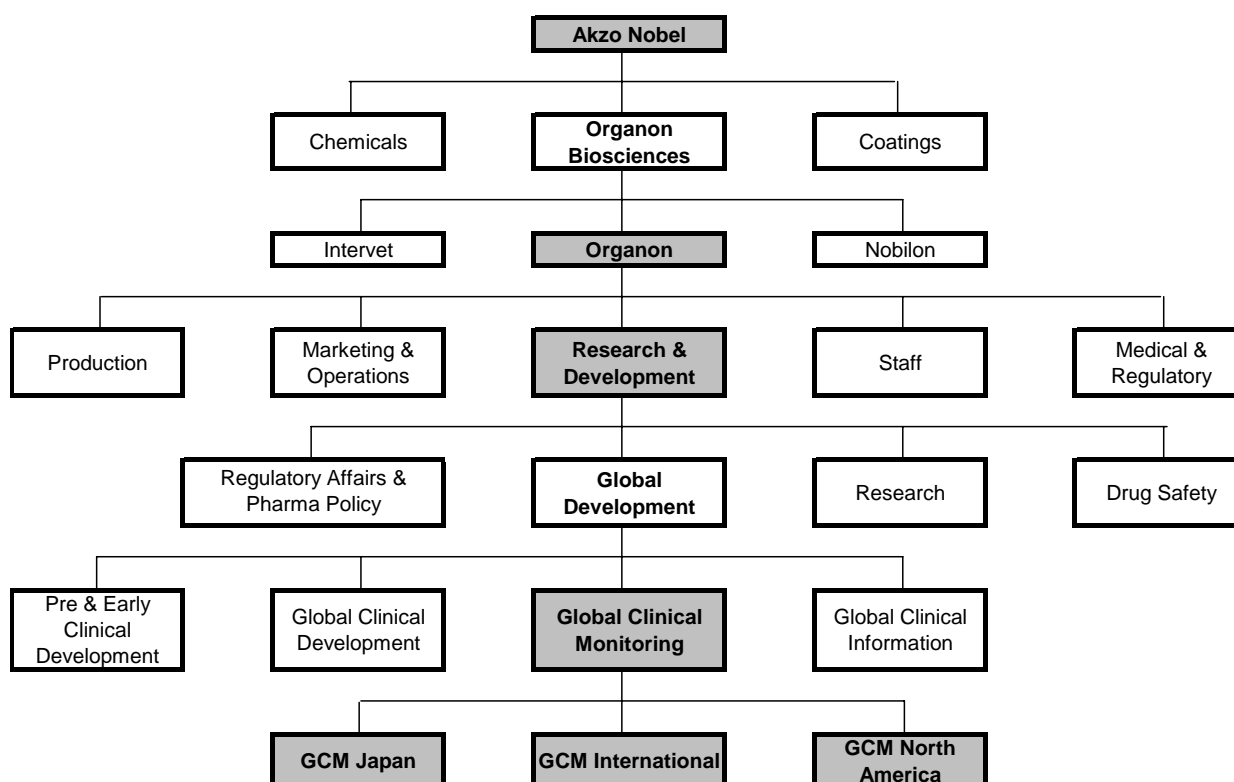

Figure 1: Organigram of Organon

4.2. Types of Education for CRA's

The types of education and training are based on the role of a CRA and among others derived from Organon's HRD policy. The subsequent paragraphs address the education of CRA's in more detail.

Types of education for CRA's

In order to have qualified CRA's available to monitor a clinical trial, training is needed. Within Organon the terms education and training are often used interchangeably. From now on, the term education is used in the sense as defined by Smith and Ragan (1999). *[Education describes all experiences (planned, unintentional, informal etc) in which people learn and the focused educational experiences are called instruction. Instruction can be subdivided in training and teaching. The term training refers to those instructional experiences that are focused upon individuals acquiring specific skills (e.g. toward job competencies) and teaching are those learning experiences that are facilitated by a human being, a live teacher.]*

Organon has a predefined program for CRA's documented in the GCM OP 005 (2006), which concerns education of:

- Guidelines (among others Declaration of Helsinki (General Assembly WMA, 2000) and ICH guideline for Good Clinical Practice (2005) and national regulatory requirements)
- Procedures, like SOPs, OPs and protocol specific procedures; SOPs are interdepartmental Standard Operating Procedures and OPs are department specific Operating Procedures. [*Organon (S)OPs are derived from international guidelines and regulatory requirements and are used to conduct a clinical trial in a standardized way.*]
- Scientific knowledge (protocol specific, compound specific or general)
- Skills, both social (e.g. negotiation skills, working in project teams) and computer skills (use of document management systems and MicroSoft office programs etc).

Education of CRA's is derived from the Human Resources Policy of both Akzo Nobel and Organon and it is considered a line responsibility. In other words education for CRA's is delegated to the Global Clinical Monitoring department, but can be performed by others, e.g. the Clinical Trial Team and/or dedicated trainers from specialized training companies.

Educating CRA's is on the one hand necessary in order to perform the monitoring tasks independently. On the other hand a CRA, as employee of Organon, gets the opportunity to develop him/her.

<u>Working group on improvement of CRA education at Organon</u>

In 2004 a CRA education working group was assigned by the vice president of the Global Clinical Monitoring Department, in order to provide some suggestions for improvement of the current CRA education. In spring 2005, it has been decided to send a questionnaire to all CRA's and their managers (CRMs) of the international region, which used to be called International Monitoring Organization (IMO).

The conclusions from the CRA education working group (personal communication, August 19, 2005) are:

- The GCP workshop, where the initial education on guidelines and Organon (S)OPs is arranged, and the 'Audit and Inspections course' are very much appreciated.
- The lack of initial education on the indication before potential investigators are contracted is seen as the most critical issue by the CRA's. (On average, CRA's have been over four years at Organon and have attended less than one initial CRA education).
- For long-lasting trials, it is mandatory to have regular CRA education, which should focus on monitoring aspects. Moreover no central education is ensured for CRA's starting with an ongoing trial; local support is not always sufficient.
- Education should be an ongoing process, which lasts longer than a 3-4 years program for new CRA's: there is hardly any education for CRA's who have been more than 3-4 years within Organon.
- IMO-meetings are not interactive enough to be an effective place for specific education; another solution is needed for ongoing education of (S)OPs and procedures.

4.3. Conceptual Framework

In order to evaluate the quality of the education for CRA's, it is important to know the meaning of 'quality' in relation to 'education'. Here education is seen as a complete learning plan; which is also described as a 'curriculum'. Moreover CRA education can be seen as company education and therefore the CRA learning plan has been interpreted as a corporate curriculum. When quality is then related to the typology of curriculum representations, a useful framework is available to evaluate the CRA education. Subsequently the evaluation method can be derived from those theories.

<u>Curriculum representations</u>
There are several curriculum representations, among others as originally described by Goodlad (Nieveen, 1999) and as shown in table 1 the adapted curriculum representations by Van den Akker (2004).

Table 1*: Curriculum Representations as Adapted by Van den Akker (2004)*

INTENDED	*Ideal*	Vision (rationale or basic philosophy underlying a curriculum)
	Formal/Written	Intention as specified in curriculum documents and/or materials
IMPLEMENTED	*Perceived*	Curriculum as interpreted by its users (especially teachers)
	Operational	Actual process of teaching and learning (also: curriculum-in-action)
ATTAINED	*Experiential*	Learning experiences as perceived by learners
	Learned	Resulting learning outcomes of learners

Kessels (1993) has interpreted curricula representations for the corporate curriculum, where he defines curriculum in the context of corporate education as:
-   the course of action open to an organization
-   for influencing the necessary skills of employees
-   that contribute to goal oriented changes in their performance and in their work environment,
-   thus striving for a desired impact on the organization
-   by applying planned learning activities and the resulting learning processes.

Since the instruction provided to CRA's can be considered as part of the corporate curriculum, Kessels' (1993) typology will be used. In fact there are two principal curricula:
-   the *ideal* curriculum describes the most adequate learning situations that enable the trainee to develop new skills in order to solve an existing performance problem in the workplace or to prevent a performance problem in the near future.
-   the *attained* curriculum consists of all the effects that are caused by the education programme. The attained curriculum should incorporate the solution to the problem that was stated as the outset of the design process.

<u>Quality criteria</u>
Nieveen (1999) used the curriculum representations of Goodlad for building a framework with three quality criteria: validity, practicality and effectiveness. A curriculum is called *valid* if the material itself (the formal curriculum) is state of the art and all components are consistently linked to each other. *Practical* means that the material can easily be used by the teachers and that it is compatible with the intention of the developers. In other words: is there consistency between the ideal plus formal curriculum on the one hand and the perceived and operational curriculum on the other hand. The third characteristic *effectiveness* focus on the students: do they appreciate the material and does the desired learning take place. According to Nieveen (1999) this could also be described as: is there consistency between the ideal plus formal curriculum compared to the experiential and attained curriculum.
For Organon only few specific developers are involved in realizing the teaching material, moreover the developers are often the teachers as well, especially in case of the lectures on guidelines, procedures and scientific knowledge. However updates of procedures are developed under responsibility of the GCM training manager and trained locally, mostly by the (Associate) Clinical Research Manager. Since the latter educational material is prepared in a standardized way and since the initial education is mostly developed and used by the same persons, it is assumed generally that the material is practical and internally consistent and therefore, this will not be investigated further in this setting. Consequently the evaluation research will focus on the effectiveness of the curriculum.

As stated above, quality of corporate education is of a high level when, according to the interpreted typology of Kessels, the attained curriculum reflects the ideal curriculum (Kessels, 1993). However the ideal curriculum is intangible, because it is an abstract reference model

consisting of the ideas of all stakeholders (managers, supervisors, developers, trainers, and trainees). Also the attained curriculum is intangible, because it is the overall impact on the organization, including effects on colleagues, managers and unintended effects on performance. In other words the total effect of the education is not caused by the education itself and thus the effects can not be recorded in detail. Consequently it is not possible to measure the degree to which the attained curriculum reflects the ideal curriculum (Kessels, 1993).

Luckily it is possible to evaluate a part of the attained curriculum, this visible part is called the assessed curriculum. Evaluation instruments should show a chain of evidence between the experienced learning process, the education results, the effects on performance in the work environment and the impact of these changes on the initial organizational problem posed (Kessels, 1993). These four elements are also described as reaction, learning, behavior and results (Kirkpatrick, 1996). In the same way the i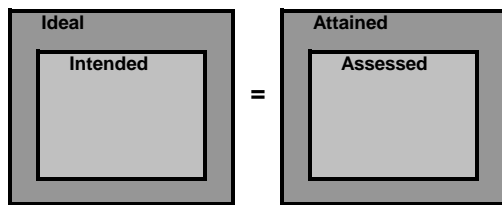deal curriculum can be translated into intended curriculum, meaning the assignment requested by management to design and conduct an education programme that provides a solution to the perceived performance problem in the company (Kessels, 1993). Consequently the measure for quality is the degree of consistency between the intended and the assessed curriculum (Kessels, 1993), see figure 2. This question will be the main question of this evaluation research.

Figure 2:   A curriculum has quality if there is a match between the ideal/intended and the attained/ assessed curriculum

Evaluation method

The typology of the corporate curriculum as stated by Kessels (1993) will be used for this evaluation research. After all the curriculum for a CRA is part of a corporate curriculum, but more important the interpreted typology describes the importance for an organization to achieve its goals via the employees and their work processes, as will be done in this evaluation research.

A short summary of Kessels' typology will be given to understand the link to this evaluation research. Kessels (1993) calls the consistency between the ideal and attained curriculum 'internal consistency'. He unravels both concepts in four system elements which should show logic contingency. In other words a curriculum is internally consistent if there are logic contingencies between the problem in the organization which needs to be solved (a), changes that are needed in the work environment (b), the necessary skills of managers and employees to bring about these changes (c) and the learning situations that facilitate the acquisition of these skills (d). Internal consistency also implies that learning processes should enable employees (e) to acquire skills (f), that influence their perfor-

Figure 3: Consistency between ideal and attained curriculum (Kessels, 1993)

mance (g), so the affected work environment has an impact on the organization (h) (Kessels, 1993), see figure 3. Please note that a broad definition for skills is used here [behavior which is goal-directed, well organized and economical of effort. It is acquired through training and practice rather than being innate or instinctive (Kessels, 1993)]. This definition should not be
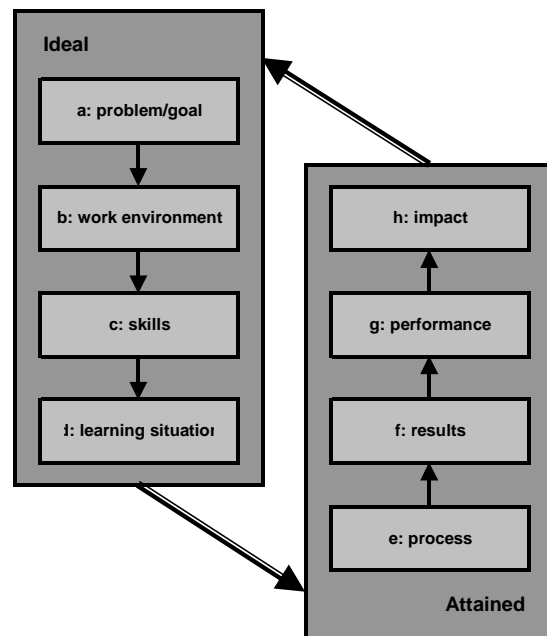
confused with the type of education as derived from Smith & Ragan (1999) and stated in paragraph 4.2.

In addition to the internal consistency one can also distinguish external consistency. External consistency is defined as the amount of agreement the involved parties have on what the problem is and how it can be solved by means of educational provisions. The concept applies to the coherence of the perceptions of managers, supervisors, developer, trainer and trainees of the ideal and attained curriculum (Kessels, 1993). In order to assess the external consistency and to investigate whether the quality of the education for CRA's is valued in the same way; the opinion of many of these stakeholders (e.g. CRA's, line management, policy makers and trainers/developers) will be investigated in this evaluation research. Involving many stakeholders in the evaluation may have another advantage: the evaluation can focus on expectations and benefits important for the stakeholders and eventually it may be easier to use the evaluation conclusions (Knox, 1998).

In the following paragraphs the design of this evaluation research, which will be based on the aforementioned principles, will be explained. Several sub questions will be posted which will measure the quality of the education for CRA's or to put it differently in the next paragraph it will be explained how exactly the intended curriculum will be compared with the assessed curriculum.

5.   Evaluation Design

The conceptual framework for the evaluation research has been explained; consequently in this chapter the evaluation design will be elaborated. The main evaluation question will be the basis for the design and therefore the explanation on this question will precede the more concrete sub questions of the evaluation research. These sub questions plus the evaluation method to answer the question, are listed below.
The evaluation design will be summarized at the end: the table (table 2) shows all evaluation actions and figure 4 relates the evaluation theory to the design of the evaluation research.

5.1. Research questions

The goal for this evaluation research is to investigate the quality of the education for CRA's within Organon. As shown in the previous paragraphs quality of a curriculum can be assessed by comparing the ideal curriculum with the attained curriculum. The literature will give an answer on the ideal curriculum for CRA's concerning the different types of instruction and concerning the fact that CRA's are adult learners. However, it will be difficult to assess the ideal curriculum for CRA's, but the intended curriculum according to the different stakeholders can be assessed. Both the intended and the attained curriculum can be assessed at four different levels: process, results, performance and impact on the organization (Kessels, 1993). Since it is very difficult to measure the impact of the education on the organization, the evaluation will be restricted to the first three levels. Consequently the sub questions focus on the visible part of the attained curriculum: the assessed curriculum.

The concept curriculum is still a bit vague, therefore the curriculum elements as distinguished by Van den Akker (2004) will be used to make the concept more operational. The ten elements are: rationale, aims & objectives, content, learning activities, teacher role, materials & resources, grouping, location, time and assessment, which will be explained below:
- Rationale contains the word 'ratio', which means reason. A rationale can thus be considered as a reasonable justification. The rationale can be considered as a framework for developing the curriculum; it is the explanation <u>why</u> certain curriculum elements are chosen.
- Aims and objectives are the <u>goals</u> for the curriculum.
- Content of the curriculum describes <u>what</u> should be learned.
- Learning activities describe <u>how learning</u> is done by the learners.

- The teacher role means <u>how the teacher</u> is facilitating the learning.
- Materials and resources indicate <u>with what</u> learning is done.
- Grouping explains <u>with whom</u> learning takes place.
- Location determines <u>where</u> the learning takes place.
- Time indicates <u>when</u> the learning takes place
- Assessment focuses on the performance of the students, in other words with assessment one can determine <u>how far</u> the learning has progressed.

Furthermore if the sub questions about ideal and attained curriculum have resulted in an answer, then the consistency between the intended and assessed curriculum can be assessed and a conclusion about the quality of the curriculum for CRA's can be drawn. Hopefully also some recommendations about improvement of the CRA curriculum can be derived from the evaluation research; these will then be listed at the final sub questions.

In summary the following questions will be answered with the evaluation research:

- **What is the quality of the education for CRA's within Organon?**
    - o **What is the ideal curriculum for CRA's?**
    - o **What is the attained curriculum for CRA's?**
- **How can the degree of consistency between intended and assessed curriculum for CRA's be improved?**

Below the focus of the evaluation research is outlined, and then the sub questions which are derived from the main research question on quality of the education for CRA's are listed. First the sub questions about the ideal and attained curriculum will be listed and then some questions about enlarging the consistency between intended and assessed curriculum are shown.

<u>Focus of the evaluation research</u>

The research performed by the CRA education working group (personal communication, August 19, 2005) showed that initial education of guidelines and (S)OPs is well arranged, but that education of updates of these procedures need improvement. At the same time the initial protocol education and education on the indication is most criticized by the CRA's.

In addition GCM management has decided to organize training on social skills locally. Also computer skills can be arranged centrally, but are always trained locally.

In other words this evaluation research will not focus on all aspects of CRA education, but only on the centrally arranged education, which seems to need improvement (CRA education working group, personal communication, August 19, 2005). The evaluation research will thus focus on:

- Updates of guidelines and (S)OPs
- Scientific knowledge (education on compound and indication)
- Initial protocol education
- Updated protocol education

<u>What is ideal curriculum for CRA's according literature?</u>

The education of CRA's consists of instruction of guidelines, procedures, (scientific) knowledge and skills (computer and social skills). Subquestions related to the instruction types are for instances: what is the ideal method for educating updates of guidelines (e.g. ICH/GCP)? What is the ideal method for educating updates of procedures (e.g. (Standard) Operating Procedures –(S)OPs– and protocol specific procedures)? What is the ideal method for educating (scientific) knowledge? However the answer on the corresponding sub questions might be difficult to derive from literature, therefore a more general question will be asked. What is the ideal curriculum for CRA's concerning the ten curriculum elements (as indicated by Van den Akker (2004). If possible, information about educating (CRA's) in other pharmaceutical companies will also be used to answer the above stated question.

<u>What is ideal curriculum for CRA's considering the fact that they are adult learners?</u>

In general employees of a company (e.g. CRA's of Organon) have completed a long education and a lot of courses. In-company education concerns adults and this demands a

different teaching style compared to young learners in school/university (website www.tip.psychology.org, 2004). Literature on adult education or more specifically on adult learning may yield guidelines where the ideal curriculum for CRA's should comply with.

<u>What is intended curriculum for CRA's according to stakeholders?</u>
Stakeholders are staff of Global Clinical Monitoring Department, Clinical Research Managers (CRMs), members of Clinical Trial Teams (CTT), the R&D Training department, HR department of Organon and of course CRA's themselves. A selection of these stakeholders will be interviewed about their opinion of the education for CRA's. Dependent on the group of stakeholders the emphasis will be put on the intended education for guidelines, procedures, and/or knowledge. Again their opinion will be asked on the three levels as indicated by Kessels (1993): process, results and performance.

The staff of Global Clinical Monitoring Department will be interviewed about guidelines, (S)OPs and scientific knowledge. The CRMs will be interviewed about the education line management is responsible for, e.g. (S)OPs, updated protocol information and scientific knowledge. Members of the Clinical Trial Team will be interviewed about the protocol specific procedures and about the knowledge of both the protocol and the compound. Both the HR department and the R&D Training department will be interviewed about general scientific knowledge and the latter also about education of updated (S)OPs. And finally the CRA's will be questioned about the intention of all aforementioned types of education.

<u>What is the assessed curriculum for CRA's?</u>
As indicate by Kessels (1993) the attained curriculum can be assessed at four different levels: process, results, performance and impact on the organization. But the evaluation will be restricted to the first three levels, because it is difficult to measure the impact on the organization. In addition to the three levels, also the ten curriculum components will be used to answer the question what the assessed curriculum for CRA's is.

CRA's are the only stakeholders who can be questioned about the *process*. Their reactions on the types of education will be assessed via the questionnaire.

The best experimental design to assess the *results* of an instruction is to conduct both a pre- and a post test and to randomize the subjects to the experimental or the control situation (Swanborn, 1981). Both in November and December a GCP workshop will be held, where new CRA's get trained on (updated) SOPs and guidelines. They will be questioned before and after the education about one updated topic. Experienced CRA's have been locally trained in the updated (S)OPs and guidelines. Unfortunately for them it is not possible to conduct a pre test. Therefore a quasi-experimental research design will be used, e.g. results on the same updated topic will be assessed via a post-test (Swanborn, 1981). These questions will be part of the questionnaire sent to all CRA's.

The most interesting question of this evaluation research is whether the results of the education lead to the desired *performance*. Performance of CRA's can be observed (rather than assessed via a test); however it will be very difficult to translate desired performance in observed actions. Moreover observing CRA's will take tremendous time, instead it was chosen to question several stakeholders about the performance of CRA's. Probably all stakeholders have an opinion on the performance of CRA's, but it is most logical to investigate this question at all stakeholders who are being part of the Global Clinical Monitoring department. In other words the staff of the Global Clinical Monitoring department, the CRMs and members of the Clinical Trial Teams will be interviewed in order to investigate whether the performance of CRA's has been changed. Of course the CRA's themselves will also be questioned about their perception of changes in their performance.

<u>What is degree of consistency between intended and assessed curriculum for CRA's?</u>
Results from the literature research will be combined with the results from the field research (both interviews and questionnaires) in order to compare the intended curriculum for CRA's with the attained curriculum.

<u>How can the degree of consistency between intended and assessed curriculum for CRA's be improved?</u>

A curriculum can be improved by creating balance between the various components of a curriculum, e.g. content, purpose and organization of learning (Van den Akker, 2004). (These three components can be elaborated into ten curriculum components: rationale, aims & objectives, content, learning activities, teacher role, materials & resources, grouping, location, time and assessment). Another way to search for balance is to couple the curriculum to a higher goal, like knowledge, society and the learner (Van den Akker, 2004):

- Knowledge: which elements within Organon seem essential for learning and future development in such a way that Organon remains strong in developing innovative medicines?
- Society: which societal problems and issues seem relevant for inclusion in the curriculum? Is there a need for education of CRA's from the investigator, trial staff or patient perspective?
- Learner: which elements seem of vital importance for the learner themselves? Which elements are important from the CRA perspective in order to enjoy the education or to develop him/herself or even to remain employed at Organon?

These three questions can be coupled to both the Human Resources policy of Akzo Nobel and to the line responsibility of the Global Clinical Monitoring department. In fact, if either one or all of these three elements knowledge, society and the learner are important, it should be reflected in the rationale, which will then have an effect on the nine other curriculum elements. Eventually this question will result in some recommendations to improve the education for CRA's at Organon.

5.2. Research methods

The quality of the education for CRA's will be measured by assessing and comparing the intended curriculum with the assessed curriculum. To be able to answer this main question of the evaluation research, the question will be split up in several sub questions and three types of methods will be used: literature research, interview and a questionnaire. Quality indicators will be deduced from the literature research (of the sub questions) and will be used to develop the methods for the field research (interview plus questionnaire).

Since the aim of this assignment is to describe the quality of education for CRA's, the evaluation will focus on théir opinion as they are considered to be the most important source. A questionnaire is appropriate to explore a big set of variables in a large number of subjects (Swanborn, 1981). Therefore all CRA's and their line managers will be asked to fill in a questionnaire, this will be in total approximately 200 subjects. Moreover by involving many stakeholders the internal validity can be increased. Increasing internal validity is a statistical concept and means that one can improve the quality of the conclusion out of the evaluation research (Swanborn, 1981).

A small set of questions will be used to conduct a post-test to see if results have been achieved. The GCP/SOP workshop in November and December will have approximately 40 participants, all participating CRA's (probably around 30) will be asked to complete the post-test.

Interviews on the other hand can be used to explore variables in a relatively small group of subjects. Therefore several stakeholders will be interviewed about the sub questions stated above. The plan is to interview one representative from the HR-education department and from the R&D Training department. In addition three CTT-CRA's, CRS's, CRMs and three representatives from the GCM-staff will be interviewed.

Since several stakeholders will be questioned about even more topics of the CRA education, and to control consistency between the different evaluation methods, the questions for the interviews and questionnaire will be developed as 'building blocks' which can be combined. The use of different evaluation methods, in this case collecting both quantitative and qualitative data, is another way to increase the internal validity. The use of multiple methods is often referred to as triangulation (Swanborn, 1981).

In addition to the sub questions described above, also literature will be searched to develop effective evaluation methods. In other words more information will be collected on the best way to evaluate an education program, for instance concerning the quality indicators of evaluation research (e.g. utility, feasibility, propriety and accuracy) as described among others by Nieveen (Kessels & Poell, 2001) and Knox (1998). In addition the implication of the four levels of evaluation (as described by Kessels (1993), Nieveen (Kessels & Poell, 2001) and Kirkpatrick (1996)) will be explored.

5.3. Analysis

Final evaluation results will be used for a SWOT analysis and presented in a Pareto diagram. A SWOT analysis is suitable, since the different stakeholders (as shown in table 2) can relatively easily analyse the strengths, weaknesses, opportunities and threats of the different education (methods) (Owen, 2002). The Pareto method is also known as the 80/20 rule (Owen, 2002). By listing recommendations, derived from the SWOT analysis, the Pareto diagram and the ten curriculum components (Van den Akker, 2003), the Global Clinical Monitoring department can focus on improvements for the education of CRA's that will make the biggest difference.

5.4. Summary

To be able to answer the main questions on quality of education for CRA's and to investigate how the consistency between the intended and assessed curriculum can be improved, several evaluation methods will be used (see table 2, the evaluation matrix). Both the interviews and the questionnaires can contain questions about the different types of CRA education. The literature research will be used to develop data collection tools for the field test (e.g. specific questions for the interviews and the questionnaire).

Table 2: *Evaluation Matrix*

	updated guidelines	procedures			knowledge		
		updated SOPs	initial protocol	updated protocol	protocol	compound	general
interviewing staff of the Global Monitoring dept.	▓	▓					
interviewing dept. R&D training		▓					▓
interviewing HR Organon (PZ)							▓
interviewing CRMs		▓		▓			▓
interviewing CRS + CTT CRAs			▓	▓	▓	▓	
Post-test for participants of the GCP/SOP workshop	▓	▓					
questionnaire for CRAs	▓	▓	▓	▓	▓	▓	▓
literature research	▓	▓	▓	▓	▓	▓	▓

Figure 4 shows the relation between the evaluation theories as explained in chapter four and the evaluation design as described in section 5.1 up to and including section 5.4.
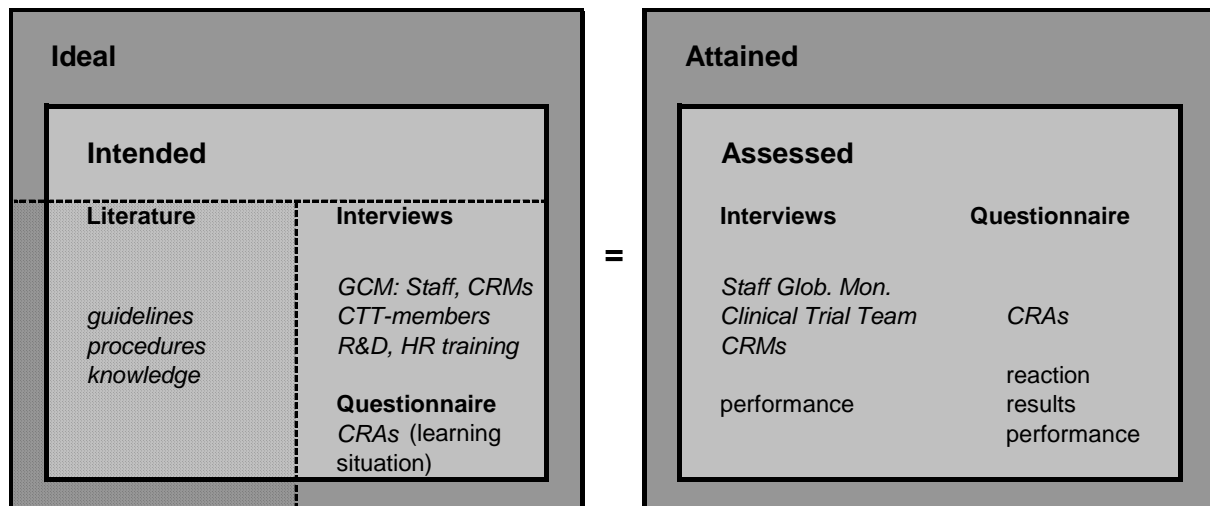
Figure 4: The relation between evaluation theories and design to research the quality of the curriculum for CRA's

5.5. Planning

The planning of the evaluation research is coupled to the timelines of a bachelor assignment for EDMM (Educational Design Management & Media).

- Writing of research proposal   May 2005
- Finalizing research proposal   October 2006
- Conducting literature research   October/November 2006
- Finalizing reporting literature research   End of November 2006
- Conducting field research   November/December 2006
- Finalizing reporting evaluation research   January/February 2006

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Literature Research:

The ideal curriculum for Clinical Research Associates at Organon

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February 2007

Contents

1. Introduction

1.1. Background of Clinical Research Associate education at Organon

This literature research is part of a bachelor assignment for Educational Design Management and Media and conducted at Organon, a small international pharmaceutical company among others based in the Netherlands. The title of the overall research is: "Evaluating the quality of Organon's Clinical Research Associates' education". In this study, the term education is used to describe all experiences (planned, unintentional, informal etc) in which people learn (Smith & Ragan, 1999).

In order to understand the goal for the bachelor assignment and the literature research, one needs to know the essence of education for Clinical Research Associates (CRA's).

A Clinical Research Associate can be considered as the main contact person between the pharmaceutical company e.g. Organon and the institute (usually a hospital) where the clinical trial is conducted. The role of a CRA is to monitor a clinical trial, consequently to verify that safety of subjects is protected, that reliable data are collected and that the trial is conducted in compliance with medical and regulatory regulations (ICH guideline for Good Clinical Practice, 2005).

One way to investigate the education of CRA's is to measure the quality of that education. And in order to measure the quality, it is important to know what exactly curriculum means in this perspective. Thereafter the question on the ideal curriculum can be answered. Then at the end it is possible, using all this information from the literature research to evaluate the quality of Organon's CRA's.

1.1.1. Need for education

In the fast-paced world of clinical research, highly trained and experienced CRA's are vital to the success of any clinical drug development program. Thus the importance of educating staff has been recognized for a long time by the pharmaceutical industry in general and by Organon in particular. The guideline of the International Conference on Harmonisation (ICH) of Good Clinical Practice (GCP) states: "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task" (www.ich.org, 2005).

In summary, education of CRA's is prescribed by ICH/GCP and requested by the continuous changes in clinical development and therefore it is concluded that education is necessary to perform the monitoring tasks.

1.1.2. Type of education

Often the terms education and training are used interchangeably, here the definitions described by Smith and Ragan (1999) are meant. Although education describes all experiences in which people learn, this literature research will focus on the planned learning; these focused educational experiences are called instruction. At Organon the education of CRA's consists of instruction of guidelines, procedures, (scientific) knowledge and (computer and social) skills. In other words it is relevant to know what the ideal curriculum is concerning the different types of instruction. Instruction can be subdivided in training and teaching. The term training refers to instruction in order to acquire specific skills (e.g. job competencies) and teaching are those learning experiences that are facilitated by a human being, a live teacher. As education for CRA's within Organon often stresses acquiring skills needed for the job and in most cases a teacher is involved, for this literature research mainly the general term instruction will be used. For this literature research the term instruction is broader (e.g. includes elements of a curriculum) than normally used in educational technology.

1.1.3. Type of learners

CRA's can be considered as a special learners group, since they are adults. By 1976 the term "adult education", was defined by UNESCO as "…the entire body of organized educational processes, whatever the content, level and method, whether formal or otherwise,

or whether they prolong or replace initial education, in schools, colleges and universities, as well as an apprenticeship, whereby persons regarded as adult by the society to which they belong develop their abilities, enrich their knowledge, improve their technical or professional qualifications, or turn them in a new direction and bring about changes in their attitudes or behavior in the two-fold perspective of full personal development and participation in balanced and independent social, economic and cultural development (UNESCO, 1976, chapt 1 in Titmus, 1999). In other words it is generally accepted that adult learners differ from young learners.

Moreover CRA's can be considered as a special group of adults, in the sense that most of them have also completed a long education and a lot of courses. In other words, it is interesting to know what the ideal curriculum is for adult learners, who have a lot of background knowledge.

1.2. Conceptualization of Quality for Education

As stated above, it is necessary to instruct CRA's in a proper way. In order to have highly qualified CRA's, it is necessary to provide instruction of good quality. However the term 'quality' is in itself a vague concept. Therefore, to clarify the concept of quality for this literature research, the term is related to the typology of curriculum representations. The Latin word 'curriculum' refers to a 'course' or 'track' to be followed. In the context of instruction, where learning is the central activity, the most obvious interpretation of the word curriculum is then to view it as a course or 'plan for learning' (Van den Akker, 2004). When the definition of curriculum used by Marsh & Willis (1980) is interpreted freely, then curriculum is an interrelated set of plans and experiences that a learner undertakes under the guidance of the company.

Goodlad proposed a curriculum typology, which has been adapted by Van den Akker (2004) and now distinguishes the three levels of intended, implemented and attained curriculum. Each of the three levels can be divided in two sub levels as shown in table 1.

Table 1: *Curriculum Representations as Adapted by Van den Akker (2004)*

INTENDED	*Ideal*	Vision (rationale or basic philosophy underlying a curriculum)
	Formal/Written	Intention as specified in curriculum documents and/or materials
IMPLEMENTED	*Perceived*	Curriculum as interpreted by its users (especially teachers)
	Operational	Actual process of teaching and learning (also: curriculum-in-action)
ATTAINED	*Experiential*	Learning experiences as perceived by learners
	Learned	Resulting learning outcomes of learners

Kessels (1993) has interpreted these curricula representations for the corporate curriculum. Since the curriculum for CRA's is company relate and thus can be considered as part of the corporate curriculum, this adapted typology will be used. In fact Kessels distinguishes two principal curricula for corporate curriculum: the ideal and attained curriculum.

The ideal curriculum describes the most adequate learning situations in order to solve an existing or future performance problem. The attained curriculum consists of all the effects that are caused by the training program. The goal of the overall research is to investigate the quality of the education for CRA's within Organon. And Quality of a curriculum can be assessed by comparing the ideal curriculum with the attained curriculum.

In order to assess the quality of the curriculum for CRA's, this literature research will be used to investigate what the ideal curriculum for Organon CRA's is. Thereafter the ideal curriculum will be compared with the attained curriculum, which will be investigated with field research.

1.3. Conceptualization of Curriculum

Curriculum is a plan for learning and can be investigated on different levels: from macro level (society), via meso level (institution) and micro level (classroom/course) to nano level (individual) (Van den Akker, 2004). This literature research focuses on meso level and in lesser extent on micro level, because these levels are closely linked to the instruction of CRA's. After all the meso level is decided by (departmental) management and the micro level is derived from this policy, moreover details on course level are filled in by the GCM-department themselves.

Van den Akker (2004) points out the relatively simple curriculum definition of Walker which includes three major planning elements: content, purpose and organization of learning. However, Van den Akker elaborated on this definition and distinguishes ten different components: rationale, aims & objectives, content, learning activities, teacher role, materials & resources, grouping, location, time and assessment, which will be explained below:

- Rationale contains the word 'ratio', which means reason. A rationale can thus be considered as a reasonable justification. The rationale can be considered as a framework for developing the curriculum; it is the explanation <u>why</u> certain curriculum elements are chosen.
- Aims and objectives are the <u>goals</u> for the curriculum.
- Content of the curriculum describes <u>what</u> should be learned.
- Learning activities describe <u>how learning</u> is done by the learners.
- The teacher role means <u>how the teacher</u> is facilitating the learning.
- Materials and resources indicate <u>with what</u> learning is done.
- Grouping explains <u>with whom</u> learning takes place.
- Location determines <u>where</u> the learning takes place.
- Time indicates <u>when</u> the learning takes place
- Assessment focuses on the performance of the students, in other words with assessment one can determine <u>how far</u> the learning has progressed.

These ten curriculum components are shown in the spider-web model (see figure 1), indicating a relation between the components and at the same time showing the vulnerability of the underlying connections. The relevance of these components varies across the previously mentioned curriculum levels and representations. For instance the macro-level usually focuses primarily on the rationale, aims & objectives and content. The component of learning activities, teacher role, and materials & resources are a core of the micro-curriculum.
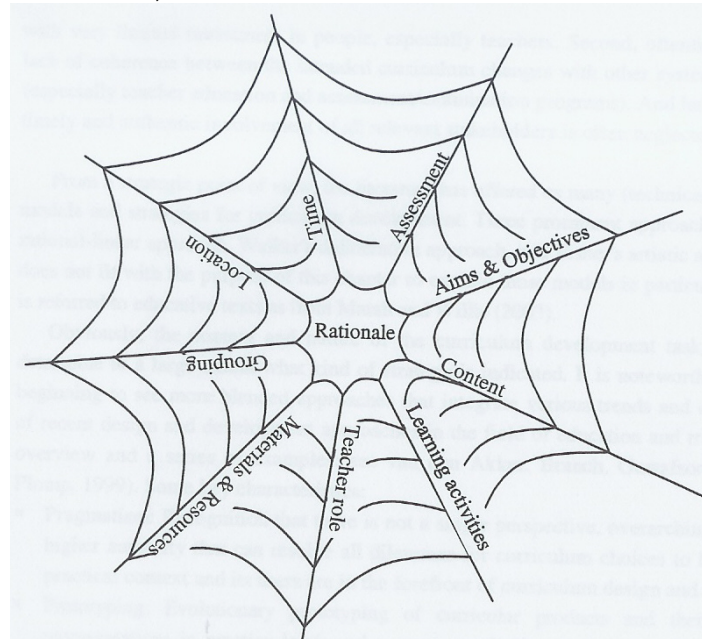

Figure 1: Spider Web model showing the curriculum components (Van den Akker, 2004)

The meso or institutional level has to consider all components including their coherence, to ensure successful implementation. The component 'assessment' is also related to all levels, because coupling of assessment to the rest of the curriculum seems critical for successful curriculum change (Van den Akker, 2004).

Van den Akker (2004) represented the ten curriculum components in a spider web to make clear that all components are linked to each other, but also to illustrate that every chain is as strong as the weakest link. In other words it is rather complicated to develop the curriculum in a balanced, consistent and sustainable manner.

1.4. Goal of this literature review

In conclusion there is a clear need for CRA's to have planned learning or better to receive instruction. Knowing that CRA's can be considered as adult learners with a lot of background, it is relevant to know more about adult learning theories.

And in order to determine the quality of education for CRA's, it is important to know if the attained curriculum corresponds with the ideal curriculum. The spider web for curriculum elements will be used as a framework to investigate the ideal curriculum, thereby focusing on the meso and micro level. Only eight elements will be used to answer this question. Since 'grouping' is dependent on the 'learning activities', these two elements will be combined. Also the elements 'time' and 'location' are closely linked to each other and are therefore considered as one element, The curriculum elements to be investigated are: rationale, aims & objectives, content, learning activities & grouping, teacher role, materials & resources, location & time and assessment.

In conclusion the questions to be asked in this literature research are:

- **What do the adult learning theories tell about instructing adult learners?**

- **What do the curriculum elements of the 'Spider Web Model' ideally look like?**

Finally the information of paragraph two about adult learning theories and the information in paragraph three about the spider web curriculum elements will be translated to the ideal curriculum for CRA's.

1.5. Methodology of Literature Search

The search for literature consisted of 4 steps.

Firstly, it started with investigating the correct literature databases and collecting the right search terms. Eventually both educational literature databases (Educational Resource Information Center, Psycinfo, Psychology and Behavioral Sciences Collection) and pharmaceutical / biomedical literature databases (Medline, Embase, Current Contents, Derwent Drug File, Biosis previews, and the full-text databases Science Direct-Elsevier, Institute of Scientific Information-Thomson) have been consulted. The search terms which have been used consist of all kinds of synonyms for instruction and education (including continuous education) combined with different terms related to the pharmaceutical industry. This included searching for information about instructing (CRA's) in other pharmaceutical companies.

Secondly, a literature search was performed on adult education, and here the website www.tip.psychology.org, listing all types of learning theories, yielded a lot of extra information on this topic, e.g. about 'andragogy' of Knowles and the 'CAL model' of Cross.

The third source for finding (recent) literature was using the references listed in the relevant publications and checking regularly the updates of relevant journals on education in the pharmaceutical industry.

Fourthly, the collection of the library of the faculty 'Gedragswetenschappen' has been scanned (by using University of Twente Library Catalogue and PiCarta), especially on the basis of the search terms 'curriculum', 'corporate education' and 'adult education'.

Thus the ideal curriculum for CRA's at Organon will be based on theories from both educational and pharmaceutical scientific literature.

2.   Adult learning theories

2.1. Introduction on adult learning

In-company training concerns adults and this demands a different teaching style compared to young learners in school/university (website tip.psychology.org, 2004). Unfortunately there is no single theory that explains all of adult learning, but there are a number of frameworks or models, each contributing something to the understanding of adults as learners (Merriam & Caffarella, 1999).
Adult learners differ from young learners, for instance employees of a company (e.g. CRA's of Organon) have completed a long education and a lot of internal courses. One can expect that adult learners have more background knowledge than young learners.
On the other hand over the years, adults might face changes in the senses (e.g. impairment in hearing and vision) and the central nervous system (e.g. decline in reaction time and memory functions) (Merriam & Caffarella, 1999).
For some adults the abovementioned cognitive and physical differences are more interfering then for others. After all employees, also within Organon, are adults from approximately 25-65 years. Probably the most striking difference, irrespective from age, is based on the socio-cultural setting. An adult learner has a different view on learning because of having a different life than a young learner. Therefore the adult learning theories considering the socio-cultural aspects are discussed below.

2.2. Learning theories for adults

2.2.1.   Andragogy
Knowles proposed a new technology of adult learning and called it andragogy, meaning "the art and science of helping adults learn" (Knowles, 1980; Merriam & Caffarella, 1999). Andragogy is based on five assumptions about the adult learner:
1. As a person maturates his or her self-concept moves from that of a dependent personality toward one of a self-directing human being.
2. An adult extends his/her experiences, which is a rich resource for learning.
3. The readiness of an adult to learn is closely related to the developmental tasks of his or her social role.
4. There is a change in time perspective as people mature: and adult would like to apply his knowledge immediately and is thereby more problem than subject centered in learning.
5. Adults are motivated to learn by internal factors rather than external ones.
Some of the implications of Knowles' technology (Knowles, 1980; Merriam & Caffarella, 1999) for learning activities with adults are that there should be an atmosphere where adults feel accepted, respected, and supported and where both teachers and students can pose questions and learn from each other. Moreover adult students can help in assessing their learning needs, the planning and implementation of the learning experiences, and the evaluation of those experiences (Knowles, 1980; Merriam & Caffarella, 1999).

2.2.2.   CAL model
The CAL (Characteristics of adults as learners) model is developed by Cross (Cross, 1982; Merriam & Caffarella, 1999). Based on differences between children and adults, the model consists of two classes of variables: personal characteristics and situational characteristics. Personal characteristics have physical, psychological, and socio-cultural dimensions and consider the growth and development from childhood into adult life. Situational characteristics focus on variables unique to adult participants – for example, part-time versus full-time learning and voluntary versus mandatory participation (Cross, 1982; Merriam & Caffarella, 1999).

2.2.3.   Theory of margin
McClusky's theory of margin (Merriam & Caffarella, 1999) states that adulthood is a time of growth, change and integration in which balance is sought between the amount of energy needed and the amount available. In other words there is a balance between the load of life,

which takes energy, and the power of life, which means dealing with the load. The 'margin in life' is the energy left over when load is divided by power. To be able to learn, an adult must have some margin of power "available for application to the processes which the learning situation requires". Since learning in adulthood is often a function of changing roles and responsibilities and physical and mental development, McClusky's theory can be used in understanding this link between development and learning. This model does not directly address learning itself but rather when it is most likely to occur (Merriam & Caffarella, 1999).

2.2.4.   Proficiency theory

Proficiency, as defined by Knox, is the "capability to perform satisfactorily if given the opportunity" and this performance involves some combination of attitude, knowledge and skills. The related interactive components are: the general environment, past and current characteristics, performance, aspiration, self, discrepancies, specific environments, learning activity, and the teacher's role. Both teachers and learners can benefit from an analysis of the discrepancy between current and desired levels of proficiency (Merriam & Caffarella, 1999).

2.2.5.   Learning process

Jarvis's model begins with an adult's life situation or more correctly, an adult's experience. The model is based on a discrepancy between biography (all that a person is at a particular point in time) and experience – "an incident that a person is unprepared to handle". This inability to cope with the situation is the basis of all learning (Merriam & Caffarella, 1999). The model of the learning process begins with a person moving into a social situation in which a potential learning experience occurs. Depending on the response (either negative or positive) the situation results in learning. According to Jarvis, learning is situated in a social context and is an interactive phenomenon, not an isolated internal process (Merriam & Caffarella, 1999).

2.2.6.   Motivation

The intrinsic motivation for learning can be increased by elaborating on the three factors that enhance intrinsic motivation. These factors are choice, which means that learners have had some opportunity to initiate and/or direct their own learning. The second factor is positive feedback, which must be in a context where they feel autonomous. (Informing people that they are doing well at learning a task will not increase their intrinsic motivation if they do not feel they have decided for the activity themselves). And the last factor is optimally challenging learners, which means allowing them to aim for learning tasks that are moderately difficult to achieve. Challenges that are too easy, do not use their abilities effectively and result in boredom and disinterest. On the other hand, challenges that are too difficult are stressful and might cause anxiety (Knox, 1993).

2.3. Conclusion on adult learning theories

Discussing the adult learning theories, shows that they are built on the premise that there is a natural tendency for people to learn, thereby controlling their own destiny. In addition adult learning theories state something about the modeling aspect and the locus of control over the learning activity (Merriam & Caffarella, 1999).

The most important characteristics for adult learning, as indicated by Beaman (1998), Cross (1982), Jones-Wright (2001), Knowles (1980), Merriam & Caffarella (1999), Taekman et al (2004), Zemke & Zemke (1984) and Zmeyov (1998) are:

- Adults learn from their own experience.
- Learning by adults is strongly influenced by the (social) context of his/her life and are therefore more problem then subject oriented. Preferably the learning result should be immediately applicable.
- Adults are internally motivated (and thus learn voluntarily).
- Adults should be actively involved in their learning process (they preferably work together with the teacher in all phases of the learning process like planning,

realization, evaluation and correction). The interpersonal interaction is not limited to trainer-to-student interaction, but can also involve student-to-student interaction.

- Adults are self-directed learners and should create an individual learning program, thereby interacting with the information.
- Adults learn better in a comfortable atmosphere.

3.   Ideal curriculum according the Spider Web concept

One way to investigate the ideal curriculum for CRA's at Organon, is to explore each curriculum element of the spider web as represented by Van den Akker (2004). Therefore below the explanation of these ten curriculum elements will be repeated. First the element itself will be explained and secondly the corresponding options for this element will be discussed. Then this elements will be translated for CRA's in general, which is described in paragraph four and finally in paragraph five the translation of the curriculum elements is made for CRA's at Organon.

3.1. Rationale

To understand 'rationale' in the curriculum perspective, the general term will be explained. Rationale contains the word 'ratio', which means reason. A rationale can thus be considered as a reasonable justification. In this context the rationale is a framework for developing the curriculum; it is the explanation why certain curriculum elements are chosen.
From the curriculum perspective the rationale contains the justification from three focal points (Van den Akker, 2004; Marsh & Willis, 1980), namely:

1. The nature of the subject matter itself or in other words 'what to exclude/what to include'? The knowledge should have an accurate representation of the external reality ("the academic and cultural heritage") (Marsh & Willis, 1980). In conclusion the subject matter should be useful; it should be clear why the subject matter has value for today or even the future. The rationale should describe what the curriculum is about and what the approach for the subject matter is.
2. The society: which problems and issues seem relevant for inclusion from the perspective of societal (current and future) trends and needs? (Van den Akker, 2004) Thus the curriculum should contain knowledge that can be applied in the world; it should be useful (Marsh & Willis, 1980). After all, the society in which one lives, determines what a person needs or wants to learn and also what his/her opportunities are and how learning might take place (Merriam & Caffarella, 1999).
3. The learner: which elements seem of vital importance for learning from the personal and educational needs and interests of the learners themselves (Van den Akker, 2004)? It is developmental growth in its broadest sense, the combination of physical, cognitive and affective growth (Marsh & Willis, 1980).

Knowing the three concepts of a rationale, it is interesting to know how a rationale can be developed. Learning theories can be used as a basis, because they explain a certain belief how learning is organized and which elements are involved. Especially the perspective of society and the learner is dependent on the learning approach chosen. There are a lot of different learning theories, but they can be divided in four broader categories: the behaviorist, cognitivist, humanist and social learning orientation (Merriam & Caffarella, 1999).

The behaviorists base their learning theory on three assumptions: first of all learning is shown by a change in behavior. Second, it is the environment and not the learner him/herself, shaping one's behavior. And finally, "the principles of contiguity (how close in time two events must be to get linked) and reinforcement (any means of increasing the likelihood that an event will be repeated) are central to explaining the learning process". The purpose of education is to produce behavioral change in a desired direction by modeling the

environment ensuring contiguity and reinforcement. Thorndike, Pavlov and Skinner were all representatives of this orientation (Merriam & Caffarella, 1999).

According to cognitivists, "The human mind is not simply a passive exchange-terminal system where the stimuli arrive and the appropriate response leaves. Rather, the thinking person interprets sensations and gives meaning to the events that impinge upon his consciousness". Thus learning involves the reorganization of experiences in order to make sense of stimuli from the environment. A major difference between cognitivists and behaviorists is the locus of control over the learning activity: for cognitivists it lies with in the individual learner and for behaviorists it lies in the environment (Merriam & Caffarella, 1999). The purpose of education from this perspective is to develop the capacity and skills to learn better. Piaget, Ausubel, Bruner and Gagne are well known cognitivists.

Humanist theories consider learning from the perspective of the human potential for growth. Humanists refuse to accept that behavior is predetermined by either the environment or one's subconscious. Humanists believe that human beings can control their own destiny and will strive for a better world. In other words behavior is the consequence of human choice and because humanists believe that people have a natural tendency to learn, they can design a true learning society. The purpose of education according the humanists is to stimulate human beings to become 'self-actualized and autonomous' (Merriam & Caffarella, 1999). Maslow and Rogers have contributed a lot to learning from this orientation.

Finally there is the social learning orientation, which states that people learn from observing other people. Provided that these observations take place in a social setting. Therefore social learning is also called observational learning. This type of learning is influenced by the four processes of attention, retention or memory, behavioral rehearsal, and motivation. From the social learning perspective, learning is to model new roles and behavior (Merriam & Caffarella, 1999). Bandura and Rotter have developed their own theory based on this orientation.

If these four orientations are translated into practice, then there will be some differences in the way learning (including the teacher's role) is organized. From the behaviorist orientation, it means that behavioral objectives will be set; competency based education can be considered as an example. The cognitivists, on the other hand, will focus on the structure of the learning activity. This perspective can be considered as 'learning to learn'. The humanist orientation will emphasize the development of the whole person, in the hope that this will facilitate learning. For the last orientation, observative learning, new roles and behavior are modeled; socialization and mentoring are thus important elements (Merriam & Caffarella, 1999).

Apart from the traditional learning orientations, as outlined above, one can also base the rationale on educational approaches on the 'human resource development' perspective. Human resources is an economical term and refers to the labor force. Human resource development is thus the development of the labor force and should be considered as a particular form of learning, namely learning within a company setting.
Since the word human is in the term 'human resource development' one could think that this approach is based on the humanist orientation. This could be true, but it means much more, after all it might also contain 'competency based learning', 'learning to learn' and mentoring. In other words it is not so clear what exact theory forms the basis for the human resource development perspective. Anyway, the educational approaches from human resource development perspective are no learning theories itself, but should be considered as translations from the four types of learning theories into learning (or even broader 'development' within an organization. Depending on the approach, it is more closely linked to for instance the humanist theories, where another approach is more based on the behaviorist theories.

The four approaches (human performance technology, competence management, competence development and knowledge production) define how education is the basis for human resource development (Kessels & Poell, 2001).

<u>Human performance technology</u> is a method to improve the functioning or performance of people within an organization. This technology focuses on the work behavior (performance) and is stated in terms of results or productivity. Education of the work force is not a standard intervention, but can be one of the solutions to improve the human performance (Kessels & Poell, 2001).

<u>Competence management</u> is to ensure exploitation of the employees in a department or team, according to the strategy and goals of the company. Competence management has a focus on the coupling to the strategy of the organization and within <u>competence development</u> there is more space for personal competences, however for both approaches the organization is responsible for the goals of learning and working (Kessels & Poell, 2001).

<u>Knowledge productivity</u> is about the integrated process of learning and working which yields knowledge development. Self direction and personal responsibility are thereby getting more important for both learning and working (Kessels & Poell, 2001).

Kwakman (In Kessels & Poell, 2001) has developed a learning theory concerning professionals, which is an employee with specific work content and an own set of work activities. Professionals could therefore be considered as a typical set of human resources. Learning for professionals means adding something to existing experience or expertise. This could mean new knowledge, new skills, new insight, a new opinion or point of view to certain issues. Kwakman relates her theory to the existing learning orientations, she states: "The consequence of this theory is that learning is not always observable. Secondly, it is the learner him/herself who determines if and what is being learned. And third, learning is not only the result of conscious activities".

3.2. Aims & Objectives of the curriculum

With aims and objectives the goals for the curriculum are listed. In fact herewith the outcome of the curriculum is described.

Of course the goals for a curriculum are directly related to the initial 'problem'. Analyzing the discrepancy between the problem and the outcome is also known as needs assessment. Three primary models of needs assessment are considered: discrepancy-based, problem-based and innovation-based (Smith & Ragan, 1999). The traditional 'discrepancy model' for needs assessment determines whether there is a gap between what learners should know or be able to do and what learners are currently able to do. And then to determine which of these gaps should be addressed with the design and development of new instruction. The problem-finding or problem-solving model is also described as the 'crisis' model. Someone (an administrator, client, or an employee) has identified that a problem exists for the organization in achieving its mission. Finally the innovation model examines changes or innovations in the educational system or organization and determines whether new learning goals should be added to the curriculum to accommodate these changes or innovations (Smith & Ragan, 1999). The latter, innovation–based, is also recognized by Kwakman (In Kessels & Poell, 2001) for professionals: "innovation learning is needed because of constant changes in their profession and within their organizations". She distinguishes two other reasons for learning of professionals. Professionals strive to the best solution on the basis of their qualities and experience. In other words, the quality of their output improves if their personal qualities will improve. The last important reason to learn is because of the development of the professional career. It is not only the organization requesting improvement, but also the professional him/herself (Kessels & Poell, 2001).

Another way to distinguish different type of goals is linked to the desired outcome, for instance there are cognitive, skill and attitude goals (Smith & Ragan, 1999). Usually the learner environment is a combination of these different kinds of goals. Moreover cognitive

goals can be divided in declarative knowledge ('to know that'), procedural knowledge ('to know how') and conditional knowledge ('to know when') all in combination with motivation (Kessels & Poell, 2001).

3.3. Content

Content of the curriculum describes what should be learned. Lowyck (In Kessels & Poell, 2001) states that domain specific content should be correct, complete, clear, logical, consistent, functional and contains an optimal amount of new information. Thereby it is important to assess the amount of expertise of the learners. In case of experts, the focus is on the content itself, which can be presented in a non-linear way. However, in case of novices, then the content should be more structured, thus with clear definitions and examples, related to former knowledge, using case studies and an adapted sequence. Preferably the content should be presented in a linear way (Kessels & Poell, 2001). Depending on the topic the content can be organized in a chronological order or according the causal relationship, as long as it retains logical integrity (Marsh & Willis, 1980).

Instruction can focus on several types of content, like declarative knowledge, concept learning, principle learning, procedures, cognitive strategies, attitude change, motivation and psychomotor skill learning (Smith & Ragan, 1999). Because of the nature of the tasks of a CRA, here the focus is on procedures and (scientific) knowledge, which both include concept and principle learning.

3.3.1.   Instruction on procedures

According to Smith & Ragan (1999) the theoretical basis for instruction of learning procedural rules should start with an introduction, in which the procedure can be described or demonstrated or previewed in chunks. It is also important to describe the range of applicability and to emphasize the efficiency and reliability of the procedure. The body of the instruction then starts with a review of sub procedures or related principles. Then the procedure should be explained in detail (complex procedures should be simplified, the order of steps should be indicated and critical characteristics of situations requiring the procedure should be identified). The instruction can be concluded by reviewing/summarizing the major steps of the procedure and relate the procedure to more complex procedures. If needed the instruction can be finalized with an assessment, then common errors and misconceptions should be identified (Smith & Ragan, 1999). Please remember here that with instruction both training (acquiring skills) and teaching (facilitation by a live teacher) is meant.

3.3.2.   Instruction on scientific knowledge

Knowledge is information which is known and/or can be applied. Knowledge consists of descriptions, concepts, hypotheses, principles, theories. What is seen as knowledge is determined by culture. Since we nowadays live in an information world, knowledge is very important. Scientific knowledge is characterized by the fact that the knowledge is gained by research. Instructing scientific knowledge could mean instructing declarative knowledge, concept learning and principle learning.

When declarative knowledge is instructed, it is important to link the new knowledge to existing knowledge, organize it and to elaborate on new information. When instructing concepts, it is helpful to provide a concept map and thereby explaining superordinate and subordinate concepts. Moreover it is important to provide examples and non examples and to explain the process of generalization and discrimination. Instructing principles requires explanation of underlying concepts and their relation. In addition explain which concept changes when another is being changed and provide information under which conditions the rule should be applied. It is best to identify relevance to daily lives or current problems (Smith and Ragan, 1999).

3.4. Learning activities and grouping

Learning activities describe how learning is done by the learners. One can consider this aspect on different levels, for instance the delivery methods itself can be considered. Bolhuis

and Simons (in Kessels & Poell, 2001) distinguish several forms of learning processes: learning by direct experience; learning by social interaction, learning by theory and learning by reflection. In organizations often a combination of these activities is used in practice. Within 'Human Resource Development' there is also a distinction between 'on-the-job-training' and 'off-the-job-training'. And finally the preferred learning style has influence on the learning activity. When discussing learning activities on different levels (learning processes, on- and off-the-job-training and learning preferences), it is clear that the delivery methods can be divided in a different way. Finally grouping will be discussed here, because grouping is mainly dependent on the learning activity.

3.4.1.   Delivery methods

Here the distinction in delivery methods is made between classroom activities, audiovisual media, experiential methods and self-paced or computer-based training (DeSimone, Werner & Harris, 2002).

Lecture and discussion are probably the best example of classroom activities. The lecture method means that a teacher or other subject-matter expert is presenting information to a (larger) audience. Although this is a very efficient method, it can be boring for the audience. This learning activity is particular useful in communicating conceptual knowledge and less in facilitating attitudinal and behavioral changes. Discussion is a two-way communication where learners can receive feedback and clarification and they can share their point of view by interacting with each other and the teacher. A survey on effectiveness of different teaching methods showed that students perceived the traditional, didactic lecture as the least effective method. By involving the students actively within the lecture time, the format was enhanced. It is good to know that giving some form of handout already increased the active learning and participation (Butler, 1992).

Audiovisual media can illustrate complex events by showing details, which are difficult to communicate in other ways. This media can be divided in static media (like printed materials, slides and overhead sheets), dynamic media (like video, CD and audio) and telecommunication (like instructional TV, tele- and video conferencing).

Experiential methods are characterized by active engagement of the learner. Examples hereof are case studies, business games and simulations, role plays, behavior modeling (observing supervisors and coworkers who serve as a role model) and outdoor education (which have a strong focus on group problem solving and/or team building).

Finally there are computer based training media, of which computer-aided instruction (CAI), E-learning and intelligent computer-assisted instruction (ICAI) are examples. CAI, based on electronic workbooks or CD-ROM, differs from ICAI, because the latter can react on the learners' response pattern and analyze errors made by the learner. E-learning means technology-based training and most of these trainings make use of either Intranet or Internet technologies (DeSimone, Werner & Harris, 2002).

Variety in learning preferences is another factor which can be taken into account when discussing delivery methods. Roughly three types of learners are distinguished: auditory, visual and kinesthetically learners. Approximately 10% to 30% of the population can be considered as auditory learners, which means that they learn best with their ears. This type of learner can maintain focus during lectures because they are learning in their preferred style. However 70%-90% of the audience belongs to one of the other two types of learners. In other words it is worthwhile considering the effectiveness of audio-only lectures. Visual learners learn best when their eyes are engaged. They need to see charts, graphs, words, photos, and movies for information to reach long-term memory. Kinesthetic learners need to move their entire body to most effectively retain new information. Role playing, skits, quizzes, activity sheets and group projects are best for them. Thus it is best to incorporate the audience's preferences when deciding the delivery method. And remember that independent of the delivery method, retention dramatically diminishes, when presentations last 60 minutes or longer without providing a break (Lansink, 2005).

3.4.2.   Learning processes

Learning by experience means experiencing what is happening in the environment, observing how the environment is structured and functions, and participating in the environment. Also 'trial and error' and 'hands-on learning' are examples of learning by direct experience. Moreover Taekman et al (2004) found that interactivity (such as simulation) is desirable compared with traditional methods of teaching and showed that simulation as additional training resulted in increased confidence. Learning by experience is also applicable for instructing procedures; after explaining the (sub) procedures in detail, the learner should practice them. (And within a classroom setting the teacher can then provide feedback) (Smith & Ragan, 1999).

The second learning process is learning by social interaction, in which the active interaction between people plays a central role. It is learning together, from and by each other. This can be done in different ways like co-operation, discussion and dialogue.

In case of learning by theory, the third learning process, one needs to translate the theory (defined as abstract, generalized, systematic information) back to the reality. However, this might cause incorrect transfer or understanding and it can decrease motivation. Despite these disadvantages, Bolhuis and Simons state that it should not be excluded, but it could be more imbedded in learning by experience and social interaction. After all learning by theory is not as important in workplace learning as it is in formal educational setting. In other words organizations should facilitate exchange of implicit knowledge and experience, and ensure that these implicit knowledge and experience becomes explicit and is exchanged. In such a cycle learning by theory is mixed with other forms of learning.

Learning by reflection is the last form of learning processes and can be done by asking questions. Critical reflection can be an individual activity (asking questions to yourself), but also combined with social interaction (asking questions to others). Except that critical reflective learning might cause more depth and a broader understanding, it might also cause renewal or discussion of obvious knowledge (Kessels & Poell, 2001).

3.4.3.   On-the-Job versus Off-the-Job-training

Off-the-job-training is any instruction conducted outside the normal work setting; a lot of these learning activities fall even into classroom-training. The advantage of off-the-job-training is that a lot of different delivery methods can be used (lecture, discussion, audiovisual media, computer-based training and most of the experiential methods). This also means that the setting can be adapted in such a way, that it is tailored to the working situation without facing any physical constraints, safety problems or distraction. Moreover the instruction can be delivered to a larger group of learners than in the workplace setting. Unfortunately off-the-job-training is usually more expensive (due to travel and development costs) and it makes the transfer more difficult because it has fewer similarities with the work setting (DeSimone, Werner & Harris, 2002).

Training on the job is a mixed form of learning by experience and learning by social interaction, since the training takes place at the workplace and the learner is then guided by his manager or an experienced colleague. In fact any type of one-on-one instruction between coworkers or between the employee and the supervisor is on-the-job-training. One of the best known examples of on-the-job-training is the guild system in the Middle Ages of the guild master with his mate (Kruijd, Kessels & Smit, 1991). Coaching and mentoring are also examples of on-the-job-training. Unfortunately on-the-job-training is often performed informally without formal structure or planning. On the other hand, if on-the-job-training is well arranged, it facilitates the transfer of learning, because the learner can immediately practice his new tasks in the work setting. In other words 'the learning environment' is the 'performance environment' (DeSimone, Werner & Harris, 2002). Moreover, these results will be quicker obtained and longer retained. Another advantage is the improved communication between new and experienced colleagues. The increased flexibility is a last advantage: training can be planned whenever possible; consequently 'just-in-time' training is possible. Of course the guide should be suitable, because his/her quality determines the success rate of

on-the-job-training. (Kruijd, Kessels & Smit, 1991). In practice learning is often a mix of on- and off-the-job-training.

Also Kwakman (in Kessels & Poell, 2001) pleads for learning competencies in the work situation. After all professionals develop new knowledge and skills traditionally via reading of their specialist literature, visiting conferences and following courses or trainings. The results of courses and training are often disappointing, but also the nature of the knowledge and skills which need to be learned, request a more direct link to the work context. Consequently the workplace is an important context for learning to improve quality (Kessels & Poell, 2001). Although professionals learn from all activities they conduct each day, they also learn by reflection and social interaction, because then they can explicit experience from practice. Making this knowledge explicit is an important demand for creating new knowledge, thus for learning. Professionals learn by interacting with for instance colleagues, clients and managers. Situations which can lead to reflection are those situations where the professional act individually, like in reading, writing, using internet, creating a plan or reporting. (Kessels & Poell, 2001).

3.4.4. Grouping

The types of grouping described by Smith and Ragan (1999) are tutoring, individualized (adaptive) instruction, interactive small groups, recitation groups and lecture. Both tutoring and individualized instruction involves one student, but they differ in the interaction: interaction with a private teacher respectively with materials (e.g. computer technology). (Intelligent) computer-assisted instruction is an example of individual (adaptive) instruction. Interactive small groups, recitation groups and lecture are all group learning, the difference is in the number of learners and accordingly the amount of interactivity. The smaller the group, the higher the incidence and variance of interactivity.

3.5. Teacher role

The teacher role means how the teacher is facilitating the learning.

Teacher-directed methods are one extreme and learner-directed methods are the other extreme for support in learning. Examples of teacher-directed methods are lecturing and demonstrating and an example of a learner-directed method is self-instruction, laboratory activities and computer simulation. Discussion, inquiry and debating are mixed methods (Kessels & Poell, 2001; Hofstein & Walberg, 1995).

In case of on-the-job-learning, often experienced colleagues or managers function as coach or instructor. In many cases a clear selection procedure is lacking. Usually coaches/mentors are chosen for their experience, specific knowledge or because they are available (Lodewyck in Kessels & Poell, 2001).

Apart from the teacher role, it is also good to know what the qualifications are for a good instructor for adults. The four corner stones for an instructor for adults are expertise, empathy, enthusiasm and clarity. These qualifications are skills (and not personality treats) and can therefore be learned and improved upon through practice and effort. First of all, instructors should know something beneficial for adults and they should know their subject well. Adults do not expect instructors to know everything, but they do want an honest understanding of what they are learning because they may apply so much of it. Adult learners learn in response to their own needs and perceptions, not those of their instructors. Empathy is the skill that allows instructors to meet this formidable requirement for motivating instruction. The definition for empathy is "when the teacher has the ability to understand the student's reaction from the inside, a sensitive awareness of the way the process of education and learning seem to the student". An enthusiastic instructor is a person who cares about and values his subject matter and teaches it in a manner that expresses those feelings with the intent to encourage similar feelings in the learner. Emotion, energy and animation are visible in this person's instruction. An enthusiastic instructor can be a powerful, inspiring force for adult learners. An instructor demonstrating clarity has the power of language and organization. An instruction can be considered clear if it can be understood and followed by

most of our learners. Clarity can also be demonstrated if the instructor provides a way for learners to comprehend what has been taught if it was not clear in the initial presentation (Knox, 1993).

3.6. Materials and Resources

The sixth curriculum element is materials and resources and indicates with what learning is done. Only recently educational materials contained separate types of information (text, images, sound), closed programming (linear sequence) and coupled to time and place (learner coupled to physical location). Moreover the norm was a linear presentation of information by a teacher. Nowadays there is multimedia, which allows a mixture of information and the way it is presented. However, Lodewyck (In Kessels & Poell, 2001) states that one should ensure that the technological possibilities should be transformed in technological learning possibilities.

In case of on-the-job-learning, Van der Klink states, it is most efficient to use as many sources of the workplace as possible, for instance handbooks, databases, memos. After all, after the education the learner will use the same sources. Sometimes it is necessary to develop additional material like worksheets, assignments and instructions. Then this material should be adjusted for use at the workplace (Kessels & Poell, 2001).

3.7. Location and Time

Location determines where the learning takes place. Location can mean the context of learning of which there is a choice between off-the-job versus on-the-job-learning. More often a combination of these types of learning is chosen, in which on-the-job-learning is more structured and allows both open and planned learning (Kessels & Poell, 2001).

The other meaning is the physical location: are the learners sitting together in one classroom or are they all at home connected from different geographical locations via the internet to a central computer? Distance education can free students from the limitations of space and time and has a record of success in both high- and low-income countries (Kirkpatrick, 1996).

Timing (or when learning takes place) is another curriculum element. Timing of learning has a lot of different aspects; it is about duration, repetition and planning. Again this curriculum element depends on the learning activity. The duration of instruction is directly coupled to the activity: for instance a lecture about diving cost less time than practicing it in the ocean. However planning of the learning is at least as important. For instance is the learning split in several parts, is repetition necessary, should there be a certain amount of time in between learning activities? And what about timing in relation to the requested performance: is instruction immediately available if requested or is the course only conducted once a year?

3.8. Assessment

Assessment focuses on the performance of the students, in other words 'how far has learning progressed?' Examples of methods for assessment are tests with paper and pencil or computer-based and these tests can be based on an essay, on norms or criteria or performance. Learning can also be measured with simulation, like case study, role playing, via an assessment center. The third way to assess is via exercises either by self-assessment or done by the instructor (Freeman & Lewis, 1998).

There are many different purposes for assessment: to select (or to certificate) and to diagnose (to describe or to aid learning) and to improve teaching. Assessment to certificate relates to the function of confirming that a student has reached a particular standard. Assessment in these and similar circumstances certifies that a particular level of performance has been achieved; this can be linked to a license to practice. Assessment can also help students to learn. Among others, it gives students practice so they can see how well they are achieving learning outcomes and it helps students to diagnose their strengths and areas that need to improve. And finally assessment information can help the instructor to

review the effectiveness of all the learning arrangements (Dousma, Horsten & Brants, 1997; Freeman & Lewis, 1998).

Some areas in which performance tests may be needed are skills, work habits and scientific attitudes. These areas can be assessed in different situations, like naturalistic situations (a real life context) and at the other end of the spectrum is the assessment of performance in artificial circumstances. Work-based learning is not a method of assessment, but rather a context within which various assessment methods may be used (Freeman & Lewis, 1998).

In case of self-directed learning, the acquired knowledge is tested by criteria, set by the learner him/herself. On the one hand the knowledge should be important for building the knowledge domain, but it should also be important for the own career and it should be transferable to improve functioning at the workplace (Kessels & Poell, 2001).

Assessment can also be done more extensively on different levels. For instance Kraiger, Ford & Salas (1993), state that there are basically two questions if an assessment is conducted at the end of the training: whether training objectives were achieved (learning issues) and whether accomplishment of those objectives results in enhanced performance on the job (transfer issues). Kirkpatrick's model can be used to distinguish effect in total on four levels: reaction, learning, functioning and organizational level (Kirkpatrick, 1996).

4.   Translation of the curriculum elements for CRA's in general

Since CRA's can be considered as a special type of learners, namely adult learners, this has consequences for the different elements of the spider web for the curriculum. The information derived from the adult learning theories and from scientific (e.g. pharmaceutical) literature will therefore be incorporated per curriculum element. In addition author's own reasoning will be added here in order to get a clear picture of the ideal curriculum for CRA's in general.

Although other pharmaceutical companies might not have the ideal curriculum for CRA's, it is at least illustrative how the (updated) training for (new) CRA's is arranged. In addition it might generate ideas on how training for Organon CRA's can be improved. Therefore below in box 1, a collection of instruction of CRA's in several pharmaceutical companies is given.

Intermezzo: Instruction of CRA's in other pharmaceutical companies

At *ICI Pharmaceuticals* the majority of new CRA's are attached to a specific team which is then responsible for his or her training. To encourage some interaction between different teams there are regular seminars to which all CRA's are invited. These are interactive sessions that allow either one team to present its recent findings to the others, or another department to discuss an area of interest to all CRA's, e.g. data handling, regulatory affairs, etc (Sayers & Blake, 1989).

In 1985 *Glaxo* established a three-part intracompany Professional Development Program. The first part of this program is the Core Program which facilitates assimilation of new employees into productive roles in clinical research and support areas. The goal of the Core Program is to provide new employees with a rudimentary understanding of Good Clinical Practices (GCPs) and corporate standard operating procedures (SOPs) (White & Cocchetto, 1992). Three years after the successful introduction and growth of the Core Program, a Continuing Education (CE) Program was initiated. The objective of the CE Program is to provide a series of elective courses that offer advanced training in administrative, managerial, and scientific areas relevant to clinical drug development. Compared with the Core Program, course topics in the CE Program are narrower to provide greater depth of instruction on more specific skills and functions. An underlying goal of this program is to support and encourage professional development of CRA's (White & Cocchetto, 1992).

The basic medical division training course at *Wellcome Research Laboratories* consists of informal presentations encouraging questions and discussion about company structure, drug development, current projects in Medical Division, protocols, trial design, data collection, resource management etc. Twelve sessions of a maximum of 2 hours are spread over 4-5 weeks and conducted two or three times each year. The speakers are experienced CRA's selected from within the Medical Division and hand-outs are available for all sessions building into a reference manual (Mullinger, 1990).

Box 1: Collection of different types of CRA instruction at pharmaceutical companies

4.1. Rationale

Although there is no clear rationale on educating CRA's in the pharmaceutical industry, it is clear that the approach from different theories is linked to learning in the pharmaceutical industry. First of all instructing CRA's can be developed according the cognitivist's theory: CRA's are usually highly educated persons and used to interpret their experiences; in fact the locus of control lies in them. Secondly, the humanistic education is linked to the pharmaceutical industry, because in order to meet the organizational goals the employees are needed. Therefore personal development is not only important, but also logical. And at the same time social learning approach is applicable, because CRA's often learn by coaching and/or mentoring. In other words it depends on the philosophy of the pharmaceutical company which approach will dominate.

If the focal points of knowledge, society and the learner are translated into the context of education of CRA's, it is clear that society partly dictates the content of the education. After all ICH/GCP (2005, p 9) states that "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task". The location where the clinical trials are conducted, usually hospitals, can also be considered as part of the society. In other words conducting a clinical trial in for instance Argentina probably requests different application of the guidelines for Good Clinical Practice than conducting the same trial in Canada.

The subject matter should be the most accurate representation of both human experience and the natural world (Marsh & Willis, 1980). Therefore the knowledge which should be educated differs between different pharmaceutical companies, because they focus on different medical indications. A company with experience in oncology will have a different curriculum than a company with history in hormone research. When Kwakman's theory (in Kessels & Poell, 2001) is translated for CRA's, subject matter is also partly determined by them (e.g. by learning from selected literature). However she also recognized the need for innovation learning: there is a constant change in the profession and within the organization of the professional and this is not different for CRA's. And because CRA's are professionals it means that the job is complex, and that standard solutions are not available. There are many non-routine situations, which ask for a unique solution, which are usually solved by the CRA themselves, because they have a lot of autonomy and a big responsibility for their job.

Finally the CRA self can justify the learning him/herself. Being a professional, the CRA knows that the quality of his/her output (based on their qualities and experience) can only improve if the personal qualities will improve. And to facilitate such self-directed learning, it is best that CRA's create an individual learning program (Merriam & Caffarella, 1999).

4.2. Aims and objectives

When discussing the goals for the curriculum of CRA's, it becomes clear that all types of goals can occur: cognitive, skill and attitude goals. In other words it is more the needs assessment as described by Smith and Ragan (1999) which determines the aims and objectives than the type of goals. Elaborating on these models for needs assessment, it seems that the 'discrepancy model' is especially applicable for novice CRA's and for CRA's working in a new indication. The innovation–based model however, is mainly applicable for experienced CRA's and in lesser extent to new CRA's. After all the guidelines and

procedures applicable to CRA's, are constantly changing and educating updates in a timely manner is therefore very important. Thereby adults prefer to apply their knowledge immediately when they are learning.

Learning for professionals means adding something to existing experience or expertise. This could mean new knowledge, new skills, new insight, a new opinion or point of view to certain issues. Accordingly, learning is not always observable and not only the result of conscious activities (Kwakman in Kessels & Poell, 2001). And when the aims and objectives are tangible, rapid and effective training can be complicated by the diversity of backgrounds among entry-level CRA's (White & Cocchetto, 1992, Mullinger, 1990). In conclusion, aims and objectives should ideally be designed to suit the individual, based on previous experience and background (Sayers & Blake, 1989; Spilker, 1990).

4.3. Content

4.3.1.   Instruction on procedures

Content of the curriculum can be divided in instruction on procedures and on (scientific) knowledge. To start with procedures, one should know that pharmaceutical companies have described all of their procedures as 'Standard Operating Procedures', so called SOPs. Usually the "read and understand" method is uses for training SOPs. This means that employees read SOPs and sign thereafter a form stating that they have read and understood the information. However this method involves some risk. For instance, it is not clear what 'understand' means and how understanding will translate into performance? Secondly, it may not be clear if employees think the procedure is vaguely described or even unclear. In addition there is the problem of reading in English when this is the second or even third language of the employee. In conclusion, probably only few employees can really learn their job by reading an SOP. Therefore Beauchemin, Gallup & Gillis (2001) suggest to have a competency based approach to training, which includes: identifying required competencies, stating objectives and describing the outcome of the training. After the training the acquired competencies of a representative group can be evaluated against the stated competencies (Beauchemin, Gallup & Gillis, 2001).

Sayers and Blake (1989) advise to start the training in SOPs with an internally organized introductory course. Following this initial introductory course, specific coaching sessions should be organized. During these regular meetings recent problems, new areas of interest, or changes in regulations or company's procedures can be discussed. The idea of these subsequent sessions are expanding and reinforcing knowledge.

Some training programs focus on specific aspects of a study, such as monitoring or site start-up. The monitoring practical is the most difficult part of the training module to organize, but seems to be the part attendees enjoy most. This segment can begin with a short lecture on the challenges of monitoring a specific study and emphasizing the differences with this type of sites as opposed to sites for other indications. A "hands-on" practical follows the lecture and includes a series of mock patient charts, which are used as source documents. Project teams are presented with a set of completed case report forms (CRFs) for each mock chart and are invited to monitor the CRFs, looking for errors. One or two errors are "planted" per CRF page and the audience enjoys finding the errors and discussing the corrections. Prizes can be offered for finding the errors thus encouraging audience participation. Frequently, the audience finds errors that the trainers were not aware of (Sietsema, 2005).

According to Smith and Ragan (1999) it is also important to describe the applicability and to emphasize the efficiency and reliability of the procedure. In case of complex procedures it can be discussed in chunks and then the critical characteristics of situations requiring the procedure should be identified.

Since CRA's have a lot of autonomy and a big responsibility for their job, they luckily find solutions for the (non-standardized) situations they are facing. By that, they develop 'knowing-in-action', which is implicit knowledge (Kessels & Poell, 2001). To develop the CRA's general management skills (like presentation, time and project management and

influencing/negotiation skills), both external and within-company courses can be used [Sayers & Blake (1989); Talbot (2003)].

4.3.2.   Instruction on scientific knowledge

Apart from the procedural instruction, it is also important to provide instruction on scientific knowledge, e.g. concerning the therapeutic area (Sayers & Blake, 1989). What is most important, is linking the new information to prior knowledge by explaining relation to the concepts. Most CRA's have already a lot of relevant background knowledge, but it is always illustrative to identify relevance to daily lives or current problems. In general providing scientific knowledge for CRA's, does not require special instruction. In daily practice, however, there is often no instruction arranged. Then CRA's have to rely on learning from reading the Investigator's Brochure (containing specific compound information) and the protocol (containing all trial information, including the indication and other medical information).

4.4. Learning activities and grouping

Bolhuis & Simons (Kessels & Poell, 2001) conclude that the best way of learning activities is to combine several learning activities. In other words not only learning by experience, but combined with learning by social interaction, learning by theory and learning by reflection (Kessels & Poell, 2001). However it is good to know that adults learn predominantly from their own experience (Merriam & Caffarella, 1999), which includes all activities they conduct each day. In other words organizations should facilitate exchange of implicit knowledge and experience, and ensure that these implicit knowledge and experience becomes explicit and is exchanged. Making this knowledge explicit is an important demand for creating new knowledge, thus for learning. In such a cycle learning by theory can be mixed with other forms of learning (Kessels & Poell, 2001).

Nowadays, training of entry-level CRA's is often on-the-job-training, either done by mentorship, informally or formally. This process involves a senior CRA providing intensive one-on-one instruction to an entry-level employee (White & Cocchetto, 1992, Karlberg & Lui, 1997). After all, learning relies heavily on direct observation, followed by practice (i.e., "see one, do one" approach) (White & Cocchetto, 1992). However, the Association for Clinical Research in the Pharmaceutical Industry (ACRPI) felt that the unstructured training 'on-the-job' of the past is no longer adequate to produce effective, efficient and highly motivated CRA's capable of meeting the more rigorous demands of modern clinical research (Mullinger, 1990). Kwakman does plead for learning competencies in the work situation, because professionals develop new knowledge and skills traditionally via reading of their specialist literature, visiting conferences and following courses or trainings. The nature of the knowledge and skills which need to be learned, request a more direct link to the work context. Consequently the workplace is an important context for learning to improve quality (Kessels & Poell, 2001).

Anyway for CRA's, being adult students, the learning activities should be in an atmosphere where they feel accepted, respected, and supported and where both teachers and students can pose questions and learn from each other. Grouping is of minor importance, as long as the atmosphere is comfortable. On the other hand adults should be actively involved in their learning process and that is easier in a group with possibilities for interaction, which are usually the smaller groups (Knowles, 1980; Merriam & Caffarella, 1999).

Adults are internally motivated and thus learn voluntarily, however one should question whether that is the case for CRA's. After all, there is always a part of instruction, which is mandatory and can not be chosen by the CRA him/herself.

And the challenges they face should be adjusted to the level of the CRA's to prevent boredom and interest on the one hand and stress and anxiety on the other hand (Knox, 1993). In that perspective instructing updates of guidelines and SOPs can be difficult.

4.5. Teacher role

CRA's will face all types of instruction, including both teacher-directed methods (e.g. lecturing) and learner-directed methods (e.g. self-instruction). Instructing scientific knowledge for instance, is often lecturing, which could be done by an internal trainer, or to invite an external expert (Sietsema, 2005). Traditionally new CRA's are guided by an experienced colleague and can learn by mentorship, behavior modeling (White & Cocchetto, 1992, Karlberg & Lui, 1997). Usually coaches/mentors are chosen for their experience, specific knowledge or because they are available, thus a clear selection procedure is lacking (Lodewyck in Kessels & Poell, 2001). However, it is important that this on-the-job-training is structured; selecting a qualified instructor for adults is part of that. The instructor should have expertise, empathy, enthusiasm and clarity (Knox, 1993).

According to Sietsema (2005) the ideal method for educating (updates of) protocol specific procedures, is to use project teams that already have conducted one or more studies in the same therapeutic indication. The reality however, is that many companies today cannot afford to have indication-specific project teams hanging around waiting for the next trial. As a result, there is increased emphasis on the ability to provide high-quality, relevant training – usually on short notice– to newly formed project teams as they begin to execute a study. Moreover the audience is involved to counsel the presenters to avoid routine topics. Ongoing focus groups and feedback continue to help strengthen these training modules (Sietsema, 2005).

4.6. Materials and Resources

It is most efficient to use during the instruction as many sources (handbooks, databases, memo's and for the CRA's SOPs) of the workplace as possible, because the learner will use these same sources. In case additional materials (like worksheets, assignments and instructions) need to be developed, they should be adjusted for use at the workplace (Kessels & Poell, 2001). However, in daily practice maintaining up-to-date materials for CRA's can be a major challenge in view of both resource demands and the changing research and regulatory environments (White & Cocchetto, 1992).

For CRA's it is suggested that once a general level of operational competence is reached, it should be reinforced at regular intervals, possibly by discussions with professionals, (formal) seminars, by providing books and articles or self-instructional manuals covering the latest therapeutic advances and research finding, clinical development, changes in guidelines, etc (Sayers & Blake, 1989; Spilker, 1990). Of course training materials must be current, organized and stimulating (White & Cocchetto, 1992).

4.7. Location and Time

The curriculum elements location and time are strongly dependent on the learning activities, which can be derived from both the rationale and the aims & objectives. Anyway it is clear that all elements should be logically contingent with each other.

Instruction of a CRA should not only occur in the first few weeks of employment, but it should be an integral part of the development program throughout his/her career (Sayers & Blake, 1989; Spilker, 1990; Mullinger, 1990). This continuous training is not only needed to maintain/improve the standards of conducting clinical trials, but also to maintain efficient administration; to develop and motivate individuals; to maintain and/or improve company's image both internally and externally and to develop and maintain team effectiveness and spirit (Mullinger, 1990).

A potential problem for the approach to design an individually education program, is lack of time available within a team to allow for detailed and personalized training programs (Sayers & Blake, 1989). This problem of manpower applies both to the trainer and the student.

Since it is too expensive to use indication-specific project teams and make them responsible for instruction in a new clinical trial, it is important that newly formed project teams provide high-quality, relevant training on short notice (Sietsema, 2005). On the other hand with on-

the-job-training performed by colleagues instruction can be planned whenever possible, consequently 'just-in-time' training is possible (Kruijd, Kessels & Smit, 1991).

4.8. Assessment

There are many different purposes why progress of the student should be monitored. The purpose of assessment can be to select, to certificate, to describe, to aid learning and to improve teaching [Dousma, Horsten, & Brants (1997); Freeman & Lewis (1998)]. Since several functions of assessment exist, one should select the correct function(s). The rationale, then determines which learning activity should be assessed and under which condition.

Incorporating pre-training and post-training competency tests in training programs may have an advantage in monitoring improvement and overall competence of CRA's (White & Cocchetto, 1992). Certification is also an important reason for assessment, because the tasks performed by CRA's are partly dictated by international guidelines, like ICH/GCP and with a certificate the CRA can confirm that he/she has reached a particular standard.

5. Translation of the curriculum elements for CRA's at Organon

Now that the essence of instruction for Clinical Research Associates (CRA's) has been discussed and the meaning of curriculum elements has been outlined, the ideal curriculum for Organon CRA's will be described. Where applicable the ideal curriculum from both theory and practice point of view are discussed.

Each paragraph will end with a short summary of the ideal curriculum for that particular element. This summary will act as basis for the empirical part of the total research, in which the attained curriculum will be investigated.

5.1. Rationale

So far, Organon does not have a rationale for educating CRA's within the company. There is a policy for educating CRA's, documented in 'Operating Procedure 5', but this document mainly contains the purpose and procedure of instruction and can not be considered as a rationale (GCM Operating Procedure 0005, 2006). However, there is a HRD vision (derived from Akzo Nobel), which states "The main objective of Akzo Nobel's HRM policy is to create a winning match between the individual needs and organizational demands" (Akzo Nobel Human Resources policy statement, 2006). Moreover Organon's website states: "Organon's business has been built by people and regards their employees as their most valuable resource. We realize that our people are responsible for the success of our company and we strive to maintain an environment that balances the work and personal needs of our employees" (Website Organon, 2006). From learning theory perspective, this HRD vision can be characterized as a *humanistic approach*. At the same time Akzo Nobel and thus Organon is using a monitoring system (Performance & Development Dialog) for all its employees, assessing six standard competences (result oriented, service directed, quality, innovation, teamwork, and respect for values). Although it is strange to have the same set of competences for all employees, knowing they have all different job requirements, it shows that the HRD perspective *human performance technology* is also supported. And although this HRD perspective contains some elements from the *behaviorist's learning theories*, it is concluded that the humanist learning theories and the derived HRD perspective 'Human Performance Technology' can be considered as the basis for a rationale. Moreover this perspective is linked to the *learning theory of professionals*, developed by Kwakman. The theory emphasizes that the professional, caso quo the CRA, has a lot of autonomy and a big responsibility for their job (Kessels & Poell, 2001). And since the purpose of education, according the humanists is to stimulate human beings to become 'self-actualized and autonomous', the puzzle is complete (Merriam & Caffarella, 1999).

Describing the rationale from a humanist perspective and including the three focal points of the nature of the subject matter, the society and the learner (Van den Akker, 2004; Marsh & Willis, 1980), the rationale for CRA's at Organon can be:

Education of the CRA is organized in such a way that the CRA can develop him/herself, which will facilitate learning. He/she is able to fulfill all his/her responsibilities as a CRA. The CRA has sufficient up-to-date background knowledge on both the compound and the indication of the clinical trial; he/she is responsible for. The knowledge will be among others based on "the boundaries of medical and pharmaceutical research". Eventually this knowledge will help society, so that "next generations to come will enjoy a more secure and healthier future". Of course the education is also directed to the local regulations and applicable guidelines. Finally the CRA will be involved in the education process to improve the personal qualities and experience and thereby improving the output. Socialization and mentoring are therefore important elements to model new roles and behavior. (Citations are from Organon's HRD vision, published on the website; www.organon.com, 2006)

5.1.1.   Summary of rationale

- Education of CRA is organized in such a way that CRA can develop him/herself overall
- Education of CRA is organized in such a way that CRA has sufficient up to date background knowledge on compound and indication of the clinical trial
- CRA will be involved in the education process
- Education of CRA is organized in such a way that he/she can improve his/her personal qualities and experience
- Education of CRA is organized in such a way that socialization and mentoring are important elements

5.2. Aims and objectives

Initially the aims and objectives for a new CRA will be based on the discrepancy model, which means that it needs to be determined whether there is a gap between what learners should know or be able to do and what learners are currently able to do and whether these should be addressed with the design and development of new instruction (Smith and Ragan, 1999). In consultation with the CRA, the learning goals will be set, based on his/her previous experience and background. The objectives will not be limited to procedural and scientific knowledge, but will also include personal development.

For experienced CRA's within Organon the aims and objectives need to be updated regularly for continuous monitoring of personal and organizational needs. These learning goals are predominantly based on innovation, either personally or from the professional perspective. After all "innovation learning is needed because of constant changes in their profession and within their organizations" (Kwakman, in Kessels & Poell, 2001).

5.2.1.   Summary of aims and objectives

- The discrepancy is determined between what CRA should know/do and what CRA does know/is able to do
- The learning goals will be set in consultation with the CRA
- The objectives include personal development
- Aims and objectives are updated regularly to align personal and organizational needs continuously

5.3. Content

When instructing procedural or scientific information, it is important to assess the amount of expertise by the learners. When the level of expertise is low, the content should be more structured and when the expertise is higher, one could focus on the content itself, as long as it retains logical integrity (Kessels & Poell, 2001; Marsh & Willis, 1980). In both cases it is best to identify the relevance to current problems, the CRA's are facing.

Concerning instruction of procedures, the content should not be limited to the procedure itself, but it also important to describe the applicability and to emphasize the efficiency and reliability of the procedure (Smith & Ragan, 1999).

As discussed by Kwakman, professionals and thus CRA's have a lot of implicit knowledge, which they have developed by finding solutions for non-standardized situations. It would be a good idea to exchange this type of content. When Organon is going to use this approach, CRA's should be invited more to determine the content of instruction.

5.3.1.   Summary of content
- The amount of structure is based on the expertise of the CRA
- The relevance to current problems is identified
- In case of a procedure, the content, applicability, efficiency and reliability are covered
- CRA's are invited to exchange their implicit knowledge (concerning recent problems, new areas of interest and/or change in regulations and Organon's procedures)

5.4. Learning activities and grouping

The best way of learning activities is to combine learning by experience, by theory, by social interaction and by reflection. A very useful method is learning by theory mixing with learning by experience: implicit knowledge and experience of the CRA's should be exchanged. Making this knowledge explicit is an important demand for creating new knowledge (Kessels & Poell, 2001). In other words Organon should facilitate exchange of implicit knowledge. Sayers and Blake (1989) confirm the importance of regular meetings, in which recent problems, new areas of interest or change in regulations or company's procedures can be discussed.

For professionals, it is important to link the learning activities to the work setting, because developing new knowledge and skills are traditionally linked to the workplace (Kwakman, in Kessels & Poell, 2001). This means that the mentoring/coaching system (guidance by experienced colleagues) is an effective learning activity.

Grouping itself is not so important, but to ensure interaction, so that CRA's can be actively involved in their learning process, small groups are preferred (Knowles, 1980; Merriam & Caffarella, 1999).

5.4.1.   Summary of learning activities and grouping
- Learning activities are a mix of learning by experience, by theory, by social interaction and by reflection
- Exchange of implicit knowledge is facilitated by organizing regular meetings
- Learning activities are linked to the work setting
- CRA's are guided by experienced colleagues via coaching/mentoring
- Learning activities should preferably take place in small groups to enhance interactivity

5.5. Teacher role

When lecturing is used to instruct (scientific) knowledge, this suitable learning activity can be done by an (external) expert. And since CRA's are adults, it also important that the instructor has empathy, enthusiasm and clarity (Knox, 1993). In other words, if at Organon the Clinical Trial Team is made responsible for instructing involved CRA's in protocol specific knowledge and/or procedures, it is important to select them on these qualities. The clinical trial team must have detailed understanding of the (virtual) training process and an organized approach (Scheible & Pozsgai, 2002). Too often it is believed that expertise in practice will translate into proficiency in training (McLeod, Steinert, Meagher & McLeod, 2003).

When use learning activities as on-the-job-training, it is practical, time and cost-efficient to use experienced colleagues. However, also this colleague should not only be chosen on his experience, knowledge and availability but also be selected for his didactic qualities.

5.5.1.   Summary of teacher role
- The instructor has empathy, enthusiasm and clarity
- Experienced colleagues (part of the Clinical Trial Team) responsible for instructing CRA's, should have didactic qualities

5.6. Materials and Resources

As mentioned before, it is most efficient to use during the instruction as many sources (handbooks, databases, memo's and for the CRA's SOPs) of the workplace as possible, because the learner will use these same sources. In case additional materials (like worksheets, assignments and instructions) need to be developed, they should be adjusted for use at the workplace (Kessels & Poell, 2001). Active learning and participation can easily be increased, by providing these handouts upfront (Butler, 1992).

5.6.1.   Summary of materials and resources
- Use as many sources of the workplace as possible
- Adjust additional instruction material for use at the workplace
- Provide handouts upfront of the instruction

5.7. Location and Time

Instruction of CRA's should be a continuous process and preferably in the work situation. Thus the location for on-the-job-training should be the (local) office, but it is at least as important to provide guidance at the hospital where the monitoring activities take place. The advantage of this on-the-job-training is also that instruction can be planned whenever possible; consequently 'just-in-time' training is possible.
Concerning timing of the instruction, Mullinger (1980) acknowledged that instruction is not only necessary when a CRA starts the job, but also needed to maintain/improve the standards of conducting clinical trials. Moreover it is needed to maintain efficient administration; to develop and motivate individuals; to maintain and/or improve company's image both internally and externally and to develop and maintain team effectiveness and spirit.
In principle there is no ideal time and location in itself, but the timing and location of an instruction is dependent on the learning activity. Therefore it is important to logically link time and location to the activity. If more e-learning will be used, this will have a lot of advantages concerning time and location because the instruction can take place at any place and any time. And because of the continuous need for instruction 'just-in-time' training should also be preferred within Organon.

5.7.1.   Summary of location and time
- Instruction of CRA's is a continuous process
- Instruction is located at the work situation (both at the office and the hospital)
- Time and location are logically linked to the learning activity
- Just-in-time training should be preferred when instruction involves continuous updates

5.8. Assessment

From the humanistic approach Organon should assess CRA's to certificate (according ICH/GCP guidelines), to select (to monitor if human performance and output of the organization have been improved), to aid learning (to assist CRA's in their learning process) and to improve teaching (to see if the selected instruction is the correct intervention to be used). The rationale determines which learning activity should be assessed and under which condition. Consequently at the same time the CRA's output can be monitored both on organizational and personal level.

Incorporating pre-training and post-training competency tests in training programs may have an advantage in monitoring improvement and overall competence of CRA's (White & Cocchetto, 1992).

5.8.1.   Summary of assessment

- CRA's should be assessed to certificate
- CRA's should be assessed to check if the output of the organization and personal performance have been improved
- The condition of and the assessment itself should be linked to the learning activity
- Pre- and post tests can monitor improvement and overall competence of CRA's.

6.   Discussion

6.1. Search results

To answer the question of the ideal curriculum for CRA's at Organon by literature research, different sources have been used. Literature from educational literature databases and the library of the University of Twente was very helpful in conceptualization of quality of education and of curriculum. However, the translation of these curriculum elements for CRA's was difficult, because there is little literature on training of employees within the pharmaceutical industry. The literature, which is available, covers the actual practice or it emphasizes the importance to train on ICH/GCP and internal procedures. It does not explain *how* guidelines and procedures concerning clinical research should be trained.

6.2. Conclusion: ideal curriculum for Clinical Research Associates at Organon

The ideal curriculum for CRA's at Organon consists of instruction based on the humanistic perspective, which means that education is to stimulate the CRA's to become self-actualized and autonomous (Merriam & Caffarella, 1999). Accordingly CRA's should be more involved in the whole process of learning in order to meet both the organizational and individual needs. When improving the content of the instruction, it is important that the learners, the task, the environment and the learning objectives will be analyzed. When developing the learning activities, it is important to plan a balanced mix of activities. And when conducting these activities (especially in lecturing), corresponding material should be provided upfront to enhance participation and thus learning. Learning by experience should be extended, because the CRA's have a lot of implicit knowledge (based on background and experience), which need to be exchanged in order to create new (organizational) knowledge. On-the-job-training is preferred, since CRA's as professionals develop new skills and knowledge usually in the workplace setting. Of course, experienced colleagues involved in the mentoring and coaching process should also be selected for their didactic qualities, like enthusiasm, empathy and clarity. Instructing CRA's is a continuous process, not only prescribed by the continuous updating of guidelines, procedures and scientific knowledge, but also to improve current processes and to keep the CRA's motivated. And finally a competency based assessment of the instruction afterwards ensures a translation of the content into the performance.

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Evaluating the Quality of Organon's

Clinical Research Associates Education

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Abstract

Is the quality of education for Clinical Research Associates (CRA's) sufficient to perform their tasks and can CRA's realize the ambition of Organon? The evaluation has focused on the quality of education. Therefore curriculum elements have been investigated, namely: rationale, aims & objectives, content, learning activities & grouping, teacher role, materials & resources, location & time and assessment. A literature research has been performed to assess the ideal curriculum and the conclusion thereof is used as input for the questionnaire to the CRA's in order to assess the attained curriculum. The most important conclusion is that CRA's should be more involved in their education, the curriculum should contain training on the indication and education should continue for more experienced CRA's.

The goal for this research is to evaluate the quality of the education for Clinical Research Associates (CRA's) employed at Organon. First the background of CRA's will be given and then the conceptual framework for education and quality will be explained. Quality has been defined as the correspondence between the ideal and the attained curriculum, hence these curricula will be compared.

A Clinical Research Associate can be considered as the main contact person between the pharmaceutical company e.g. Organon and the institute (usually a hospital) where the clinical trial is conducted. The role of a CRA is to monitor a clinical trial, consequently to verify that safety of subjects is protected, that reliable data are collected and that the trial is conducted in compliance with medical and regulatory regulations (ICH guideline for Good Clinical Practice, 2005).

In the fast-paced world of clinical research, highly trained and experienced CRA's are vital to the success of any clinical drug development program. Moreover the guideline of the International Conference on Harmonisation (ICH) of Good Clinical Practice (GCP) states: "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task" (www.ich.org, 2005).

Currently the education[1] for CRA's organized by the Global Clinical Monitoring department consists of several types of training, e.g. lectures on (updates of) guidelines and procedures, workshops on skills and lectures on scientific knowledge, e.g. at protocol-specific CRA trainings or at the yearly international GCM-meeting. The question is whether this type of education is suitable to ensure that CRA's apply the new guidelines, procedures and knowledge in their daily practice. The answer on this question is not only relevant for the CRA's, their trainers, line managers and for Organon in general, but also for everybody involved in the clinical trials (investigators, trial staff) and eventually for the patients. In other words, is the quality of education for CRA's sufficient to perform their tasks and can CRA's realize the ambition of Organon? Consequently the evaluation on quality will focus on the effectiveness of education (Nieveen, 1999).

Table 1: *Curriculum Representations as Adapted by Van den Akker (2004)*

INTENDED	*Ideal*	Vision (rationale or basic philosophy underlying a curriculum)
	Formal/Written	Intention as specified in curriculum documents and/or materials
IMPLEMENTED	*Perceived*	Curriculum as interpreted by its users (especially teachers)
	Operational	Actual process of teaching and learning (also: curriculum-in-action)
ATTAINED	*Experiential*	Learning experiences as perceived by learners
	Learned	Resulting learning outcomes of learners

The term quality is related to the typology of curriculum representations. The Latin word 'curriculum' refers to a 'course' or 'track' to be followed. In the context of instruction, where learning is the central activity, the most obvious interpretation of the word curriculum is then to view it as a course or 'plan for learning' (Van den Akker, 2004). When the definition of curriculum used by Marsh & Willis (1980) is interpreted freely, then curriculum is an interrelated set of plans and experiences that a learner undertakes under the guidance of the company. Goodlad proposed a curriculum typology, which has been adapted by Van den Akker (2004) and now distinguishes the three levels of intended, implemented and attained curriculum. Each of the three levels can be divided in two sub levels as shown in table 1.

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[1] In this study, the term education is used to describe all experiences (planned, unintentional, informal etc) in which people learn (Smith & Ragan, 1999). The research focused on the planned learning; these focused educational experiences are called instruction.

Evaluating the Quality of Organon's CRA education

Kessels (1993) has interpreted these curricula representations for the corporate curriculum. Since the curriculum for CRA's is company related and thus can be considered as part of the corporate curriculum, this adapted typology will be used. In fact Kessels distinguishes two principal curricula for corporate curriculum: the ideal and attained curriculum. The ideal curriculum describes the most adequate learning situations in order to solve an existing or future performance problem. The attained curriculum consists of all the effects that are caused by the training programme.

The goal of the overall research is to investigate the quality of the education for CRA's within Organon. Nieveen (1999) used the curriculum representations of Goodlad for building a framework with three quality criteria: validity, practicality and effectiveness. As stated in the proposal (Homminga, 2006) only the quality criterion 'effectiveness' will be investigated. Effectiveness focuses on the students: do they appreciate the material and does the desired learning take place. According to Nieveen (1999) effectiveness could also

Figure 1: a curriculum has quality, if there is a match between the ideal/intended curriculum and the attained/assessed curriculum?

be described as: is there consistency between the ideal plus formal curriculum compared to the experiential and attained curriculum. Or when translated to the corporate curriculum is there consistency between the ideal curriculum and the attained curriculum? Since both the ideal and the attained curriculum are intangible, as stated by Kessels (1993), the visible part will be investigated, namely the intended respectively the assessed curriculum, see figure 1.
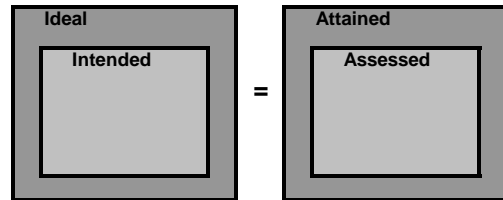
In order to have a more practical definition for curriculum, the ten different curriculum components as distinguished by Van den Akker (2004) will be used in the comparison of the intended and assessed curriculum: rationale, aims & objectives, content, learning activities, teacher role, materials & resources, grouping, location, time and assessment. These ten curriculum components are explained below and shown in the spider-web model (see figure 2), indicating a relation between the components and at the same time showing the vulnerability of the underlying connections.

- Rationale contains the word 'ratio', which means reason. A rationale can thus be considered as a reasonable justification. The rationale can be considered as a framework for developing the curriculum; it is the explanation why certain curriculum elements are chosen.
- Aims and objectives are the *goals* for the curriculum.
- Content of the curriculum describes *what* should be learned.
- Learning activities describe *how learning* is done by the learners.
- The teacher role means *how the teacher* is facilitating the learning.
- Materials and resources indicate *with what* learning is done.
- Grouping explains *with whom* learning takes place.
- Location determines *where* the learning takes place.
- Time indicates *when* the learning takes place
- Assessment focuses on the performance of the students, in other words with assessment one can determine *how far* the learning has progressed.

Figure 2: Spider Web model showing the curriculum components (Van den Akker, 2004)

Only eight elements will be used to answer this question. Since 'grouping' is dependent on the 'learning activities', these two elements will be combined. Also the elements 'time' and 'location' are closely linked to each other and are therefore considered as one element, The curriculum elements to be investigated are: rationale, aims & objectives, content, learning activities & grouping, teacher role, materials & resources, location & time and assessment.

In-company training, including the education for CRA's, concerns adults and this demands a different teaching style compared to young learners in school/university (website tip.psychology.org, 2004; Titmus, 1999). Unfortunately there is no single theory that explains all of adult learning, but there are a number of frameworks or models, each contributing something to the understanding of adults as learners (Merriam & Caffarella, 1999). The most important characteristics for adult learning, as indicated by Beaman (1998), Cross (1982), Jones-Wright (2001), Knowles (1980), Merriam & Caffarella (1999), Taekman et al (2004), Zemke & Zemke (1984) and Zmeyov (1998) and explained in the literature research (Homminga, 2006) have been implemented in the conclusion on the ideal curriculum for Clinical Research Associates at Organon.

The Ideal Curriculum for Clinical Research Associates at Organon

The ideal curriculum for CRA's at Organon consists of instruction based on the humanistic perspective, which means that education is to stimulate the CRA's to become self-actualized and autonomous (Merriam & Caffarella, 1999). Accordingly CRA's should be more involved in the whole process of learning in order to meet both the organizational and individual needs. When improving the content of the instruction, it is important that the learners, the task, the environment and the learning objectives will be analyzed. When developing the learning activities, it is important to plan a balanced mix of activities. And when conducting these activities (especially in lecturing), corresponding material should be provided upfront to enhance participation and thus learning. Learning by experience should be extended, because the CRA's have a lot of implicit knowledge (based on background and experience), which need to be exchanged in order to create new (organizational) knowledge. On-the-job-training is preferred, since CRA's as professionals develop new skills and knowledge usually in the workplace setting. Of course, experienced colleagues involved in the mentoring and coaching process should also be selected for their didactic qualities, like enthusiasm, empathy and clarity. Instructing CRA's is a continuous process, not only prescribed by the continuous updating of guidelines, procedures and scientific knowledge, but also to improve current processes and to keep the CRA's motivated. And finally a competency based assessment of the instruction afterwards ensures a translation of the content into the performance.

Method

As explained in the introduction the ideal curriculum has been assessed by means of a literature research. The literature research was used to develop a rationale to be discussed with GCM-management to assess the intended curriculum. And finally CRA's have completed a questionnaire to assess the attained curriculum; also the questionnaire has been based on the curriculum elements derived from the literature research. At the end the ideal curriculum has been compared with the attained curriculum.

Assessing the Intended Curriculum by Means of Interviews

As concluded at the literature research (Homminga, 2006), Organon does not have a rationale from curriculum point of view, therefore a rationale was developed based on the literature, current policies and companies' HRD vision (Akzo Nobel Human Resources policy statement, 2005). In other words the intended curriculum has only been assessed for the curriculum element 'rationale'. The new rationale has been sent to the interviewees for preparation purposes and was used to facilitate the discussion with management about the intended curriculum. The interviewees were selected from higher management of GCM, namely the vice-president of GCM and four Regional Clinical Research Directors (one from the US and Japan and two from Europe) and three staff members, among others the training manager. The interviewees were requested to respond on the rationale elements: responsibility for the education (CRA versus GCM); the content and method of the education and the relation of education to the CRA tasks. Based on the reactions of the interviewees, the rationale has been adjusted.

The initial developed rationale, concluded from the literature is: *Education of the CRA is organized in such a way that the CRA can develop him/herself, which will facilitate learning. He/she is able to fulfill all his/her responsibilities as a CRA. The CRA has sufficient up-to-date background knowledge on both the compound and the indication of the clinical trial, he/she is responsible for. The knowledge will be among others based on "the boundaries of medical and pharmaceutical research". Eventually*

this knowledge will help society, so that "next generations to come will enjoy a more secure and healthier future". Of course the education is also directed to the local regulations and applicable guidelines. Finally the CRA will be involved in the education process to improve the personal qualities and experience and thereby improving the output. Socialization and mentoring are therefore important elements to model new roles and behavior. (Citations are from Organon's HRD vision, published on the website; www.organon.com, 2006)

Table 2: *Conclusion of the Literature Research per Curriculum Element*

Rationale
Education of CRA is organized in such a way that CRA can develop him/herself overall
Education of CRA is organized in such a way that CRA has sufficient up to date background knowledge on compound and indication of the clinical trial
CRA will be involved in the education process
Education of CRA is organized in such a way that he/she can improve his/her personal qualities and experience
Education of CRA is organized in such a way that socialization and mentoring are important elements
Aims and objectives
The discrepancy is determined between what CRA should know/do and what CRA does know/is able to do
The learning goals will be set in consultation with the CRA
The objectives include personal development
Aims and objectives are updated regularly to align personal and organizational needs continuously
Content
The amount of structure is based on the expertise of the CRA
The relevance to current problems is identified
In case of a procedure, the content, applicability, efficiency and reliability are covered
CRA's are invited to exchange their implicit knowledge (concerning recent problems, new areas of interest and/or change in regulations and Organon's procedures)
Learning activities and grouping
Learning activities are a mix of learning by experience, by theory, by social interaction and by reflection
Exchange of implicit knowledge is facilitated by organizing regular meetings
Learning activities are linked to the work setting
CRA's are guided by experienced colleagues via coaching/mentoring
Learning activities should preferably take place in small groups to enhance interactivity
Teacher role
The instructor has empathy, enthusiasm and clarity
Experienced colleagues (part of the Clinical Trial Team) responsible for instructing CRA's, should have didactic qualities
Materials and resources
Use as many sources of the workplace as possible
Adjust additional instruction material for use at the workplace
Provide handouts upfront of the instruction
Location and time
Instruction of CRA's is a continuous process
Instruction is located at the work situation (both at the office and the hospital)
Time and location are logically linked to the learning activity
Just-in-time training should be preferred when instruction involves continuous updates
Assessment
CRA's should be assessed to certificate
CRA's should be assessed to check if the output of the organization and personal performance have been improved
The condition of and the assessment itself should be linked to the learning activity
Pre- and post tests can monitor improvement and overall competence of CRA's.
Each item had five answer-categories: strongly agree, agree, neutral, disagree and strongly disagree.

Assessing the Attained Curriculum by Means of Questionnaires

In order to reach as many CRA's as possible a questionnaire has been developed based on the literature research about the ideal curriculum of CRA's (Homminga, 2006). In table 2 the conclusion of the literature research per curriculum element has been listed. For each curriculum element the summarized conclusion has been transformed to a set of suitable questionnaire items. After

transformation of each conclusion into clear items and review by experts (an educational specialist and a line manager of GCM), the questionnaire consisted of 58 items.

The first part of the questionnaire concerned demographic data like sex, age, region, 'years of experience as CRA' and 'years of experience as CRA within Organon'. The second part consists of the 48 items derived from the literature research and the last part were four open questions to indicate for each curriculum element the education with the highest and poorest quality, including the reason for the qualification.

The questionnaire has been sent to all CRA's employed at Organon at February 2007 and a copy was sent to their line managers [consisting of Regional Clinical Research Directors (RCRDs), the (Associate) Regional Managers [(A)RMs] and the Clinical Research Managers (CRMs)]. In total 210 questionnaires have been sent out, of which 173 have been sent to CRA's and 37 to their line managers. Although the questionnaire has been primarily developed for the CRA's, also their line managers were invited to complete the questionnaire. Their results will be pooled, since most of the line managers have also worked as a CRA and are still closely related to the CRA function. The instruction to complete the questionnaire stated the purpose of the total bachelor assignment and asked the CRA's to answer the questions from their own experience.

Analysis of the Results

The link of the literature research with the abovementioned method for the field research has been summarized in figure 3.

First of all the discussion with management and GCM staff about the rationale has been summarized. And then their reactions have been used to create an update of the rationale.

The results of the questionnaire have been analyzed on descriptives. The distribution of the demographic categories (first 6 items) has been used to verify whether the group of responders was representative for the whole Organon CRA population. The means of the responder group and total population were compared with a One-Way ANOVA. Moreover three of the factors, namely age, region and 'years of experience as CRA within Organon' are expected to influence the perception on CRA education and thus these factors have been used to analyze the results on the curriculum elements in more detail. Whenever the correlation of one of these factors is significant for an item, an additional explanation has been given.
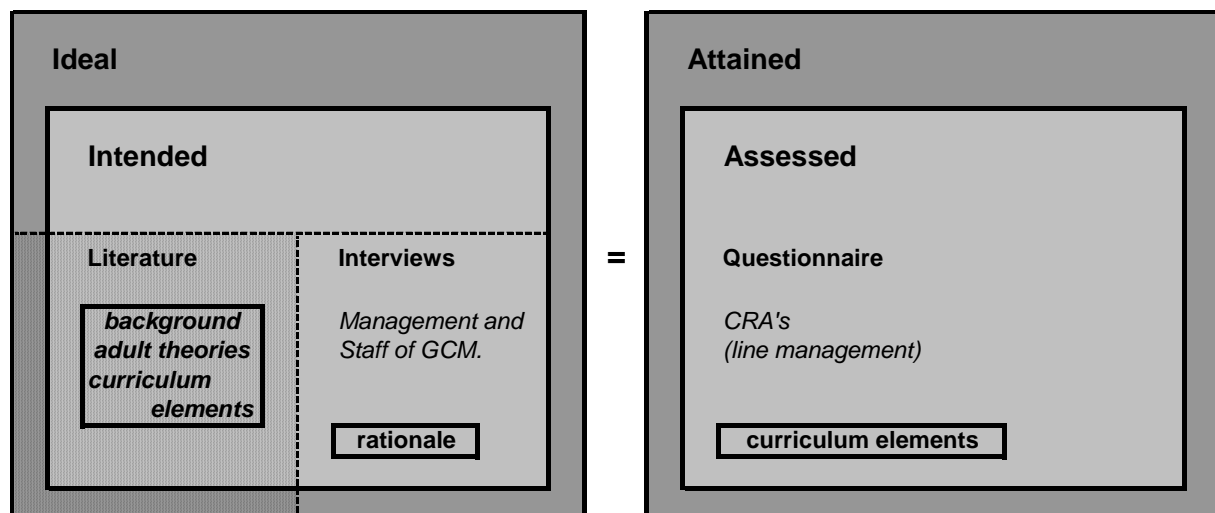
Figure3: Summary of the method to compare the ideal with the attained curriculum

The results on the remaining items have been analyzed in more detail. The median is indicated for each item, because it considers ordinal data. The goal for this field research was to verify the correspondence of the ideal curriculum for CRA's with the attained curriculum for CRA's. Therefore all items which have been answered with (strongly) disagree by 15% or more of the respondents are considered of lower quality. This percentage of 15 is chosen to exclude the items where only a few responders (strongly) disagree and at the same time select the items where the (strong) disagreement is striking. These latter items have been discussed in more detail in the result section.

The scores of the education of high and poor quality per curriculum element have been listed and used as input for the discussion.

Finally to ensure that the questionnaire is a reliable instrument, the scales were analyzed on reliability per category of items. A Cronbach's alpha above 0.600 has been considered as a set of reliable items.

Results

Assessing the Intended Curriculum: Discussion with Management on Rationale

Several people from staff and management (from different regions) were asked to respond on the proposed rationale. Many of them responded that the rationale was described well, but was not really new. They were of the opinion that several elements of the rationale (especially concerning content) were already described in either (Standard) Operating Procedures [(S)OPs] or in (local) policies on training.

Everybody agreed that it is the responsibility of GCM to align the training in such way that the ICH/GCP guidelines are met in a timely manner, consequently that CRA's have sufficient background knowledge to perform their job and to assist trial staff in performing their job. This also includes training in social skills related to the job, in other words that the CRA can work with their environment (within the team, with their manager, with the investigator and other trial staff etc). On the other hand, some of the interviewees were of the opinion that only training of procedures and protocol training etc. are a global GCM-responsibility and that general training in the indication (and corresponding compounds) are a local GCM responsibility. Anyway it was recognized that training on indication is also important to keep the CRA's interested and motivated. One of the interviewees thereby focused on the role of e-learning in the pharmaceutical industry, because all CRA's not working in a central office would then benefit from a global e-learning system.

Mentoring (learning from peers) could be a solution to guide (especially new) CRA's, but the mentors should have then the required capabilities to perform such a task. For instance, the mentors should be able to indicate how many guidance and which form of guidance is needed for the (new) CRA.

Some of the interviewees emphasized that the training for new CRA's is organized well, but that the development for more experienced CRA's and the other roles within GCM (e.g. Clinical Trial Assistants and Clinical Research Managers) need some improvement. For instance, it was suggested to provide a route for management trainees, project management or other future perspectives. Or as one CRA suggested at the questionnaire "establish a curriculum to be followed from start at the company through their development with their career goal in mind".

Anyway most of the interviewees agreed that the training for CRA's (on a global level), should be improved in such a way that it is more situational, individualized based training. (maybe even aligned to learning style, speed/ease of learning etc). For Japanese CRA's for instance additional training on English language skills should be added.

Most of the interviewees were also of the opinion that GCM has a broader responsibility in developing the CRA. The current tool of Performance & Development dialog is considered as a suitable method to assist the CRA in their whole development (as far as requested by the CRA). After all, as some of the Regional Clinical Research Directors explained, it is the CRA's own responsibility to develop him/herself, but it is line management responsibility to be aware of the possibilities for further development. Another interviewee replied that the P&D dialog could indeed help in investigating gaps of development, but that it is not clear who is eventually responsible to fill the gap. One interviewee commented that management has also a task in providing sufficient training time.

Few of the interviewees suggested to even extend the GCM responsibility in developing CRA's, e.g. to offer a course for people with a low stress threshold. Or, in the scope of 'a sound mind in a sound body', the company could provide sport facilities in order to improve the output of the organization. Only few of the interviewees were of the opinion that GCM is only responsible for the job-related competencies.

The citation derived from the Organon website that: "*the knowledge will be among others based on 'the boundaries of medical and pharmaceutical research'. Eventually this knowledge will help society, so that 'next generations to come will enjoy a more secure and healthier future'.*" was considered a less understandable statement. For some the description itself was not clear or even too limiting, while

others were of the opinion that the CRA's from GCM could never directly meet this requirement and therefore this statement was not so appealing to them.

There were hardly any opinions concerning a philosophy for CRA training, most reactions on the rationale related more or less to the content of the training. However, one interviewee emphasized that the output of training should affect the return on investment. While another said that CRA's should enjoy their job and have fun and a third emphasized the importance of continuous development. By realizing these latter goals, the output would automatically be improved.

General Results on Assessing the Attained Curriculum

The questionnaire has been used to assess the attained curriculum as perceived by the Clinical Research Associates (CRA's) at Organon. The questionnaire has been sent out to all 210 CRA's and their management. In total 100 completed questionnaires have been received back, which is 47.6 %. From the line managers and the staff from Global Clinical Monitoring (GCM) in Oss, 10 out of the 37 (=27.0%) questionnaires have been received back. The CRA's have completed 90 out of 173 questionnaires, which is 52.0%. For the analysis the results from management have been pooled with the data from the CRA's.

Table 3 *Frequency of Demographic Factors*

Frequency of demographic factors (valid percentage)						Number
Sex	male			female		
	32,0			68,0		100
Age (years)	20-29	30-39	40-49	50-59	> 59	
	10,2	46,9	33,7	7,1	2,0	98
Region	North America	Latin America	Europe	Japan	Asia Pacific	
	14,1	14,1	55,6	14,1	2,0	99
Organon experience (years)	< 1	1-3	3-5	5-10	> 10	
	10,1	18,2	31,3	30,3	10,1	99
Total experience (years)	< 1	1-3	3-5	5-10	> 10	
	6,1	10,1	24,2	42,4	17,2	99
Number of companies	0	1	2	3	4	>4	
	52,0	26,5	11,2	7,1	1,0	2,0	98

From the 100 completed questionnaires, a third has been answered by male CRA's and two third by female CRA's. The majority (±81%) of the CRA's who have completed the questionnaire is between 30 and 50 years of age and based in Europe (55.6%). The respondents have a lot of experience as CRA within Organon, more than 60% has 3-10 years of experience. The details on these demographic factors are shown in table 3.

When comparing the means of the responder group and total population, the analysis of variance (One-Way ANOVA) shows that there is no significant difference between groups, except for the factor 'total CRA experience', see table 4.

Table 4: *Analysis of Variance*

Is research group representative?	
factor	**Significance**
sex	0,647
age	0,902
region	0,354
experience as CRA Organon	0,574
experience as CRA total	0,000

Table 5: *Reliability of the Questionnaire*

Reliability questionnaire		
curriculum element	nr of items	Cronbach's alpha (α)
rationale	8 (nr 7-14)	0,7692
aims & objectives	7 (nr 15-21)	0,8282
content	8 (nr 22-29)	0,8386
learning activities & grouping	9 (nr 30-38)	0,6965
teacher role	3 (nr 39-41)	0,7734
materials & resources	3 (nr 42-44)	0,6375
location & time	7 (nr 45-51)	0,8380
assessment	3 (nr 52-54)	0,5551*
assessment without item 52		*0,9032*

Results on Curriculum Elements

The reliability of the items is analyzed for all eight categories. As shown in table 5 the questionnaire is reliable for all categories except for the curriculum element 'assessment'. When deleting item 52 of this category, also the items of this category are reliable.

The answer of each item is expressed as percentage of all respondents, as shown in table 6. For some questions there were missing values; in those cases the percentage has been adjusted to the total number of answers for that particular question. The median of each item is also analyzed and indicated in bold in table 6. For most items the median is 'agree'; however for some items this is 'neutral'. Whenever an explanation is given about a particular item, the item number is also indicated. In addition, table 7 shows the qualifications and suggestions per curriculum element.

Table 6: *Percentage per Item and Response Category*

Percentage per item and response category	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	number of items (n=)
Rationale						
7 Training within Organon helps me to develop myself as a whole person	7,1	**49,0**	28,6	14,3	1,0	98,0
8 Training within Organon provides me sufficient background knowledge on the compound	4,1	**55,7**	27,8	11,3	1,0	97,0
9 Training within Organon provides me sufficient background knowledge on the indication	3,1	**50,5**	29,9	14,4	2,1	97,0
10 I have the opportunity to give input and affect the content of the training made available to me	4,1	23,7	**43,3**	27,8	1,0	97,0
11 I would like to have the opportunity to give input and affect the content of the training made available to me	18,8	**58,3**	20,8	2,1	0,0	96,0
12 Within Organon training is available to help me improve myself	8,2	**43,9**	37,8	7,1	3,1	98,0
13 Within Organon I am gaining valuable experience	27,6	**53,1**	15,3	4,1	0,0	98,0
14 Mentoring is an important element in my training	13,7	**37,9**	24,2	20,0	4,2	95,0
Aims and Objectives						
15 Before I receive training, the discrepancy between what I should know and what I do know is determined	2,1	13,5	**43,8**	33,3	7,3	96,0
16 I create learning goals for myself	9,2	**63,3**	21,4	6,1	0,0	98,0
17 I take part in determining my learning goals	10,3	**63,9**	21,6	4,1	0,0	97,0
18 My learning goals include personal development	18,6	**51,5**	20,6	9,3	0,0	97,0
19 My learning goals are updated regularly	8,2	**42,9**	36,7	10,2	2,0	98,0
20 My learning goals are updated regularly to align my personal needs	4,1	**42,3**	37,1	15,5	1,0	97,0
21 My learning goals are updated regularly to align Organon's needs	6,2	**53,6**	27,8	11,3	1,0	97,0
Content						
22 The structure of the training is tuned to my learning needs	3,1	26,0	**47,9**	20,8	2,1	96,0
23 The training I receive is relevant to the problems I face at work	3,1	**59,2**	26,5	11,2	0,0	98,0
24 When procedures are trained, I am also trained in when to apply the procedure.	6,1	**55,1**	29,6	9,2	0,0	98,0
25 When procedures are trained, also the efficiency and reliability of the procedure is covered	2,0	29,6	**46,9**	19,4	2,0	98,0
26 I am encouraged to share my knowledge and experience on issues related to my work	12,2	**56,1**	20,4	10,2	1,0	98,0
27 I am encouraged to share my knowledge and experience when we move into an area of work that is new to the company	9,4	**40,6**	34,4	12,5	3,1	96,0
28 I am encouraged to share my knowledge concerning changes in regulations	10,2	**46,9**	34,7	7,1	1,0	98,0
29 I am encouraged to share my knowledge and experience on Organon's procedures	8,2	**52,6**	27,8	11,3	0,0	97,0
Learning activities and Grouping						
30 Training consists of a mix of learning activities, so that I can learn by experience, by theory, by reflection and from others	10,3	**49,5**	24,7	13,4	2,1	97,0
31 I like to learn by experience (try it yourself)	23,5	**59,2**	12,2	4,1	1,0	98,0
32 I like to learn by theory (lecture, reading from books/publications)	10,1	**61,6**	22,2	6,1	0,0	99,0
33 I like to learn by reflection (thinking over)	15,3	**61,2**	22,4	1,0	0,0	98,0
34 I like to learn from others (via role modelling and discussions)	21,4	**63,3**	11,2	4,1	0,0	98,0
35 Formal structures exist within Organon to facilitate exchange of my knowledge with colleagues	2,0	26,3	**46,5**	19,2	6,1	99,0
36 Learning activities are linked to my work setting	1,0	**55,1**	32,7	9,2	2,0	98,0
37 There are sufficient learning activities taken place in small interactive groups	1,0	30,3	**31,3**	34,3	3,0	99,0
38 There are sufficient learning activities where I am guided by experienced colleagues via coaching/mentoring in my work	3,0	30,3	**32,3**	28,3	6,1	99,0
Teacher role						
39 The trainer has empathy, enthusiasm and clarity	4,3	**46,8**	40,4	7,4	1,1	94,0
40 Experienced colleagues who are responsible for training me, know how to train.	4,1	34,0	**42,3**	17,5	2,1	97,0
41 Members of the Clinical Trial Team who are responsible for training me, know how to train.	4,1	29,9	**47,4**	17,5	1,0	97,0
Materials and Resources						
42 During training sufficient sources (materials) of the workplace are used	6,1	**52,0**	34,7	5,1	2,0	98,0
43 Additional instruction material is adjusted for use at the workplace	5,2	43,8	**37,5**	12,5	1,0	96,0
44 Handouts are provided before the training.	4,1	**49,0**	20,4	25,5	1,0	98,0
Location and Time						
45 Training is a structural element in my career at Organon	11,2	36,7	**35,7**	14,3	2,0	98,0
46 Training is located at the work situation and thus also at the office	3,1	**54,6**	33,0	7,2	2,1	97,0
47 Training is located at the work situation and thus also at the hospital	1,0	31,6	**40,8**	23,5	3,1	98,0
48 Within Organon the location of the training (on-the-job versus off-the-job) is logical	2,1	41,2	**41,2**	13,4	2,1	97,0
49 When there are updates of procedures, training is provided in time	11,1	**47,5**	22,2	19,2	0,0	99,0
50 When there are updates of regulations / guidelines, training is provided in time	11,1	**44,4**	27,3	17,2	0,0	99,0
51 When there are updates of scientific knowledge, training is provided in time	5,1	17,3	**36,7**	35,7	5,1	98,0
Assessment						
52 The training is concluded with an assessment	2,0	30,3	**37,4**	26,3	4,0	99,0
53 An assessment would be useful to check if my personal performance has been improved at a certain time	7,1	**43,4**	41,4	7,1	1,0	99,0
54 An assessment would be useful to check if the output of Organon has been improved at a certain time	10,2	**43,9**	39,8	6,1	0,0	98,0

Percentages in bold indicate the **median** for that item
15% ≤ Percentage of disagree + strongly disagree ≤ 20%   Percentage of disagree + strongly agree ≥ 20%

Rationale

In general CRA's (strongly) agree with the items on the rationale, they can improve themselves and gain valuable experience. Details on the score of this curriculum item are listed in table 6. Not all CRA's agree that training helps them to develop as a whole person. Moreover only 27.8% of the respondents feel that they have the opportunity to give input and affect the content of the training made available to them (10). Although 77.1% of all CRA's would like to have the opportunity to do this (11). Also mentoring is not an important element in the training (14) for many CRA's. CRA's with less Organon experience do more (strongly) agree with items 9, 10 and 14 then the CRA's with more Organon experience. CRA's from Europe more (strongly) disagree with item 9 than their colleagues from other regions.

Table 7: *Qualifications and Suggestions from CRA's on their Education*

	Qualifications and suggestions from CRA's about their education	
	suggestions on rationale	
*	establish a curriculum to be followed from start at the company through their development with their career goal in mind	
*	training should be done through a training department with documentation recorded in a training management system	
	qualifications and suggestions on aims and objectives	**reason**
+	GCP/SOP workshop	clearly defined objectives
+	negotiation skill course	achievable goals
−	training during GCM meeting	no training goals
	"I have a strong feeling that we are simply 'thicking the box of having been trained' as opposed to really being trained"	
*	Tailor training to previous experience	
	"focus on what the learner is to come away from the session versus trying to teach them everything"	
	qualifications and suggestions on content	**reason**
+	GCP/SOP workshop	a lot of real life examples
+	negotiation skill courses	good relation between theory and practice
+	advanced GCP / audit and inspection course	a lot of usefuel information
+	anesthesia / TOF watch training	content also helpful in personal life
−	training during GCM meeting	not tailored to the level of the CRA's (either too easy or too difficult) not focused on new information and no examples
−	e-CRF training	too theoretical (not much use in practice)
*	training should reflect as much as possibly daily life, improve therapeutic area training, sharing information and experience should be systematically organized, learn structurally from audits and inspections, add English skill training for Japanese CRA's.	
	qualifications and suggestions on learning activities and grouping	**reason**
+	GCP/SOP workshop	interactivity, preferably small groups (to feel at ease to speak out), good combination of activities (group work, lecture, role plays, providing examples)
+	negotiation skill course	
+	advanced GCP / audit and inspection course	
−	training during GCM meeting	not interactive, no demonstration or practical training, very large groups, no discussions.
*	Excercises after the training, allow time for self study, improve interactivity, workshops during GCM meetings, initiate small taskforce groups to discuss experience, use web-trainings at the office or training via internet, more local trainings	
	qualifications and suggestions on teacher role	**reason**
+	GCP/SOP workshop	trainers keen to share knowledge/experience
+	negotiation skill course	professional trainers
+	advanced GCP / audit and inspection course	well prepared qualified trainers
−	training during GCM meeting	sometimes inexperienced speakers, boring presentations
*	Provide 'train the trainer' courses, learn scientific information from experts, don't appoint trainers because they have time, but because of their proven teaching skills and knowledge of the specific area.	
	qualifications and suggestions on materials and resources	**reason**
+	GCP/SOP workshop	sufficient material used close to the real situation
+	e-CRF training	good training materials and exercises
−	e-CRF training	supplies used not working, bad selection of training tools
*	Provide material in advance and not only slides but also additional material (publications) and more reference material available during monitoring.	
	qualifications and suggestions on location and time	**reason**
+	GCP/SOP workshop	the facilities
+	advanced GCP / audit and inspection course	duration is not too long
−	training during GCM meeting	updates nog conducted in a timely manner
*	well equilibrated ratio between duration and scheduled time, repeat trainings (so that questions can be asked which couldn't at the first time because of poorer knowledge, provide trainings more frequent to be more flexible, more distance learning and less in-house training, regularly updates of training (not only when updates are available), schedule training sufficiently in advance according future needs	
	qualifications and suggestions on assessment	**reason**
+	presentation on guideline for preparing monitoring visits	opportunity to test knowledge after the training
−	training during GCM meeting	no assessment at the end
*	more assessments/tests to check knowledge	

+ = training perceived as highest quality; **−** = training perceived as poorest quality; ***** = suggestions.

Aims and objectives

The CRA's who have completed the questionnaire (strongly) agree about the items on creation and update of learning goals. They would only like to have the learning goals updated to align more their

personal needs (20). The most striking finding is that the discrepancy between what the CRA should and does know is not determined before the training; almost 40% of the CRA's disagrees with this item (15). The details on the scores about aims and objectives are listed in table 6.

Content

The structure of the training is not always tuned to the learning needs (22) or as some CRA's illustrate, the content of the training during the GCM meeting is either too easy or too difficult. As shown in table 6, the content of the training is relevant to the work and the CRA's feel encouraged to share their knowledge and experience, except when there is an area of work that is new to Organon (27). More than 20% of the CRA's older than 40 years disagree with the latter item. Finally more than 20% of the respondents are of the opinion that efficiency and reliability of a procedure is not covered (25); this is especially true for CRA's with more Organon experience.

Learning activities and grouping

When the items on learning activities (31 u/i 34) are viewed, it becomes clear that the respondents seem to like all types of learning activities and that there is no strong preference for any of them. However more than 15% of the respondents is of the opinion that training does not consist of a mix of learning activities (30). In addition almost a quarter of the CRA's who have completed the questionnaire disagree that formal structures exist to exchange knowledge with colleagues (35). Finally almost 35% of the respondents disagree that sufficient learning activities take place in small interactive groups (37) or are guided by experienced colleagues (38), see table 6. CRA's with less than 3 years of Organon experience more (strongly) agree with the latter item compared to their more experienced colleagues. The amount of learning activities in small interactive groups is region dependent: almost two-third of the CRA's from North America disagree with item 37, while CRA's from Latin America and Japan have answered this item more with (strongly) agree.

Teacher role

The respondents, especially the older ones and the CRA's with more Organon experience, are not so convinced that experienced colleagues (40) or CTT-members (41) know how to train, see table 6.

Materials and resources

The CRA's who have completed the questionnaire have answered the items on materials and resources with (strongly) agree as shown in table 6. Except that 26.5% of them disagrees with the item that handouts are provided before the training (44). Again CRA's with more than three years of Organon experience have less often scored this item with (strongly) agree.

Location and time

As shown by the grey lines in table 6, the respondents have not answered the items about curriculum elements location and time with (strongly) agree. First of all for more than 15% of them training is not a structural element in their career (45). Especially CRA's older than 40 years of age or with more than 5 years of Organon experience disagree with this item. More than a quarter of the CRA's have indicated that training doesn't take place at the hospital (47). In addition 15% of the respondents is of the opinion that the location of the training is not logical (48). Furthermore the items on timing of updates have not been answered with (strongly) agree; especially the updates of scientific knowledge are not trained in time (51). Again the more experienced Organon CRA's have less often answered items 49 u/i 51 with (strongly) agree. In addition three quarter of the Japanese CRA's disagree with this item, while two third of the Latin American CRA's do agree with it.

Assessment

In general the responders (strongly) agree with the items about assessment, except for item 52 that training is concluded with an assessment, see table 6. Approximately 80% of the CRA's of North America agree with items 53 and 54.

Discussion

Method

In total 100 of 210 questionnaires have been completed and returned, this response-rate of 47.6% is considered good, but the results need to be considered carefully because the non-response has not been evaluated. As shown with the analysis of variance the responders were a good representation for the

whole population of CRA's at Organon, except for the factor 'total experience as CRA'. The conclusions in relation to this factor are to be considered with care.

Out of the reliability analysis it becomes clear that the questionnaire is a reliable instrument because the items per curriculum element are internally consistent. This also means that the results of the questionnaire can be considered reliable for this CRA population of Organon. Concerning the validity, the questionnaire should be considered with more care, since only an expert-review has been used to evaluate the items of the questionnaire. Below some additional factors which might threaten the validity are discussed.

Phrasing the answers with '(strongly) agree, neutral, (strongly) disagree' was not always easy for the analysis. For most questions the median was 'agree'; maybe this could be explained by the tendency to answer questions positively (Swanborn, 1981)? Since CRA's with experience in several companies are expected to be more critical and more than half of the CRA's have only experience within Organon and can not make any comparison with other companies, this might explain the positive tendency. It would have been interesting to see the correlation between the scores on the items and the number of companies the CRA's have worked for. However, only one quarter of the CRA's has worked for more than two companies, therefore this correlation has not been analyzed. Or maybe the explanation for the high frequency of (strongly) agree lies in the non-response (Swanborn, 1981)? Because of the relatively high response for an (e-)mail questionnaire (approximately 50%), the non-response has not been investigated. Maybe the CRA's who have a lot to complain didn't respond and the CRA's who are satisfied did. In other words the validity of population should be considered carefully.

The answer 'neutral' could be interpreted in several ways: sometimes this answer has been chosen because the item was not stated clearly enough or too ambiguous. Others have chosen this answer because they didn't know what to answer and the third option is that the answer should neither be 'agree' nor 'disagree'. The Japanese CRA's have indicated that their English need improvement and at the same time they have answered the items more with 'neutral' than the CRA's from the other regions. Consequently this could mean that not all of the statements were understood correctly by the Japanese CRA's, although the RCRD commented that not reading, but writing and speaking is difficult for them. Above examples all show that the validity of the instrument might be threatened by incorrect understanding of the items, also known as content validity. To improve the content validity, the questionnaire should upfront have been evaluated not only by experts, but also by a small group of responders. Another explanation for the high frequency of 'neutral' for Japanese CRA's lies in the cultural difference: maybe the Japanese CRA's are not used to provide their opinion? On the other hand CRA's from Latin America more often (strongly) agree with items than CRA's from other regions; is that also culturally determined? Or could this difference be explained by the fact that the CRA's from Latin America are less critical because they have relatively little Organon experience?

The way the items were scored by the CRA's, also depends on which type of training is considered or taken in mind. Especially the more experienced CRA's have had a lot of different trainings, which probably have been evaluated in different ways and therefore, as one CRA remarked, "it can be difficult to provide a general assessment". In addition training exists in many forms and is not always a formalized training in a class room setting. Maybe a conversation with a local product manager is not perceived as compound training by the CRA, despite of the intention of the product manager to provide knowledge and thus to consider it a compound training. These examples show that coincidence is another factor which might threaten the validity of the instrument.

CRA's with shorter Organon experience often more (strongly) agree with the items compared to CRA's with a longer Organon experience. Again this could be explained by the fact that the more inexperienced CRA's are less critical, but it could also be explained by the fact that within Organon the training in the first two years is well formalized and for more experienced CRA's there is hardly any (mandatory) training arranged.

In general the opinion on trainings of high and poor quality were consistent, but now and then a particular training was scored as 'high quality', while by another as 'low quality'. This can partly be explained by the different setting of a course, for instance the anesthesia training has been evolved over time and the presentations at the GCM meeting are given by a lot of different speakers. On the other hand also the learning style and/or preference of the CRA are of influence on the score of a training and this difference in score will most probably continue for future trainings.

Evaluating the Quality of Organon's CRA education

Comparison of Ideal versus Attained Curriculum

Rationale

Several aspects of the proposed rationale are not recognized by the CRA's. This could partly be explained by the fact that also some members of the GCM-staff and the higher management didn't agree with these items. Therefore an updated rationale will be listed at the end of the discussion. Anyway CRA's are not only willing, but also should have more opportunity to give input and affect the content of the training. After all the CRA, being a professional, knows that the quality of his output (based on their qualities and experience) can only improve if the personal qualities will improve. And to facilitate such self-directed learning, it is best that CRA's create an individual learning programme (Merriam & Caffarella, 1999). Concerning content, this should be the most accurate representation of both human experience and the natural world (Marsh & Willis, 1980). When translating this to the world of the CRA's it means that more background on the indication should be trained. In summary CRA's should have influence on the content of the training and it should consist more out of training on the background of the indication.

Aims and objectives

For each new CRA it is best to be determine whether there is a gap between what learners should know or be able to do and what learners are currently able to do and whether these should be addressed with the design and development of new instruction (Smith and Ragan, 1999). Almost 41% of the CRA's (strongly) disagrees with the corresponding item and some of them remarked that the training was not always tailored to their level. In other words the aims and objectives for new CRA's should be more tailor-made and less standard and based on existing knowledge and experience. In addition each course as part of the curriculum, should have clearly defined, achievable aims and objectives.

According to the ideal curriculum the learning goals should also be set in consultation with the CRA and not be limited to procedural and scientific knowledge, but also include personal development. Most CRA's agree with the corresponding items (16 u/i 21). This is not true for item 20 stating that the learning goals are regularly updated to align the personal needs. CRA's with more Organon experience have answered abovementioned item less often with (strongly) agree. Especially for the more experienced CRA's the aims and objectives need to be updated regularly to create innovation learning based on constant changes in their profession and within their organizations (Kwakman, in Kessels & Poell, 2001). It is considered logical that the CRA's update their learning goals, because all CRA's have to give input for the development part of the Performance & Development Dialog-system (Akzo Nobel, 2005). The P&D Dialog system is a suitable tool to update more frequently the learning goals for more experienced CRA's and to align the updates of the learning goals more to the personal needs.

Content

More than 20% of the CRA's feel that the structure is not tuned to their learning needs. Ideally the structure should be adapted to the amount of expertise: when the level of expertise is low, the content should be more structured and when the expertise is higher, one could focus on the content itself, as long as it retains logical integrity (Kessels & Poell, 2001; Marsh & Willis, 1980). One type of structure is to apply the correct balance between theory and practice; the courses which are considered to be of high quality are appreciated because the correct balance.

As Smith & Ragan (1999) stated, instruction of procedures should not be limited to the procedure itself, but it also important to describe the applicability and to emphasize the efficiency and reliability of the procedure. Most CRA's confirm that they are also trained in when to apply the procedure, but the efficiency and reliability of the procedure is hardly trained. Consequently training of procedures could be improved by also paying attention to the efficiency and reliability of the procedure.

As discussed by Kwakman (in Kessels & Poell, 2001), professionals and thus CRA's, have a lot of implicit knowledge, which they have developed by finding solutions for non-standardized situations. In order to learn from each other, it would be ideal to exchange this type of content. Luckily approximately 60% of the CRA's agree that they are being encouraged to share the knowledge and experience they have on issues related to work, concerning changes in regulations, on Organon procedures and in a little lesser extent on issues related to an area of work that is new to the company. Unfortunately the CRA's aged between 40 and 49 years less often (strongly) agree with these items.

The recommendation regarding content is to adapt the amount of structure to the amount of expertise, thus more structure for a novice and less structure for a CRA with expertise. And thereby selecting a good balance between theory and practice. In addition Organon should continue encouraging the CRA to exchange knowledge and experience, especially for the older CRA's, for instance, by having them (co-)determine the content of the instruction.

Learning activities and grouping

Despite the fact that more than half of the CRA's is of the opinion that training consist of a mix of learning activities, this mix can be improved. CRA's would like to increase the number of learning activities with social aspects, like learning in small interactive groups and learning from experienced colleagues. At the same time these learning activities can be seen as 'formal structures to facilitate exchange of knowledge with colleagues', after all adults learn predominantly from their own experience (Merriam & Caffarella, 1999).

Some CRA's indeed proposed to preserve the corporate memory by systematically organizing the exchange of knowledge and experience. Small taskforce groups could be initiated to discuss all kinds of relevant topics or the learning points from audits and inspections, which could subsequently be made available to all CRA's.

Teacher role

The most striking conclusion concerning the teacher role is that between 15% and 20% of the CRA's have doubts about the didactic qualities of their trainers, being it either CTT-members or their experienced colleagues. Consequently they suggest that 'train-the-trainer'-courses should be provided and that trainers should not be appointed because of their available time, but because of their proven training skills [among others, empathy, enthusiasm and clarity (Knox, 1993)]. In addition external experts could be invited to instruct scientific knowledge (Sietsema, 2005).

Materials and Resources

Most CRA's are satisfied that sufficient materials and resources of the workplace are used or even adjusted for that, after all after the training the CRA will use the same sources (Van der Klink in Kessels & Poell, 2001). Some CRA's suggested to use more additional reference material during the training. For CRA's it is indeed suggested to reinforce the knowledge by regular intervals either by discussions with professionals, attending seminars or by providing books, articles and/or self-instructional manuals (Sayers & Blake, 1989; Spilker, 1990). Moreover a quarter of the CRA's disagrees that handouts are provided before the training; the latter could easily be adapted in future trainings. By providing the material upfront, it might stimulate active learning and participation. It goes without saying that training materials must be current, organized and stimulating (White & Cocchetto, 1992). In conclusion: provide handouts before the training and provide additional material after the training (even in regular intervals), that is current, organized and stimulating.

Location and Time

The location for the training or better the division between on-the-job versus off-the-job training does not always seem logical to the CRA's. More than 25% of the CRA's disagrees that training also takes place at the hospital, although they spend half of their working time there. The advantage of on-the-job-training performed by colleagues is that 'just-in-time' training is possible (Kruijd, Kessels & Smit, 1991). Also the time (both duration and timing) of the training could be improved. For especially the more experienced CRA's, training is not a structural element in their career. Instruction should indeed be an integral part of the development program throughout the career of a CRA (Sayers & Blake, 1989; Spilker, 1990; Mullinger, 1990). After all continuous training is not only needed to maintain/improve the standards of conducting clinical trials, but also to develop and motivate individuals; to maintain and/or improve company's internal and external image and to develop and maintain team effectiveness and spirit (Mullinger, 1990). And for most of the CRA's training of either procedures, regulations/guidelines, but especially of scientific knowledge is not provided in time. Sietsema (2005) confirms that it is important that newly formed project teams (e.g., a CTT) provide high-quality, relevant training on short notice. The solutions suggested by the CRA's relate to more frequent training (not only when updates are available) and more repetitions, but they also relate to more distance-learning. Distance education can indeed free CRA's from the limitations of space and time (Kirkpatrick, 1996) as currently faced by a global company as Organon.

Consequently more on-the-job-training should be added, including training at the hospital. Training for more experienced CRA's should be extended. Training (updates) should be provided more frequently, especially concerning scientific knowledge. By using a larger variety in learning methods/ activities, e.g. by providing e-learning the CRA's can be trained in a more flexible way, e.g. at any time at any place.

Assessment

Although the majority of CRA's agrees that an assessment would be useful to check if the personal performance has been improved and to check if the output of Organon has improved, only one third of the CRA's agrees that the training is concluded with an assessment. However, this item (52) should be considered with care because of the reliability. Anyway some CRA's suggest adding more assessments and/or tests to check their knowledge. Considering the fact that ICH/GCP guidelines require education and that this demand within most pharmaceutical companies has been translated in documentation of training and/or providing certificates, it seems logical to conduct an assessment to prove that a CRA has reached a particular standard (Dousma, Horsten & Brants, 1997; Freeman & Lewis, 1998). Another reason is to test the acquired knowledge and thereby improving the functioning at the workplace (Kessels & Poell, 2001). The rationale determines which learning activity should be assessed and under which condition. Anyway it is clear that by concluding more trainings with an assessment the CRA's output can be monitored both on organizational and personal level.

Conclusion

Quality of the CRA education at Organon

When comparing the ideal curriculum with the attained curriculum, it becomes clear that almost each curriculum element of the education for CRA's at Organon has aspects of good and poorer quality. These specifics, including suggestions for improvement are discussed in the recommendations section below. Still a general conclusion can be drawn about the quality of the CRA education at Organon. The curriculum elements for which the ideal curriculum corresponds with the attained curriculum and thus are considered of good quality are: aims & objectives; materials & resources and assessment. The curriculum elements with more discrepancy between ideal and attained curriculum and thus need improvement and are of poorer quality, are: learning activities & grouping and location & time. And the remaining curriculum elements have been scored between good and poor quality: rationale, content and teacher role.

Update of proposed rationale

The updated rationale is based on the interviews with GCM-staff and higher management:
Education of the CRA is organized in such a way that the ICH/GCP guidelines are met in a timely manner, consequently that CRA's have sufficient up-to-date background knowledge (including social skills) to perform their job and to assist trial staff in performing their job. CRA can develop himself, which will facilitate learning. The training should be situational, individually based, depending on the previous knowledge and experience. Education should be a continuous process in order to keep CRA's motivated and interested. Experienced CRA's should have the opportunity to develop in a requested direction, like project management, line management or clinical research. Socialization and mentoring are important elements to model new roles and behavior, however the mentors should have the required capabilities to perform such a task. The current tool of Performance & Development Dialog is a suitable method to assist the CRA in their whole development. The development is not persé limited to job-related competencies.

Recommendations to improve the curriculum of CRA training at Organon

In summary CRA's should have influence on the content of the training and it should consist more out of training on the background of the indication. The aims and objectives for new CRA's should be more tailor-made and less standard and based on existing knowledge and experience. In addition each course as part of the curriculum, should have clearly defined, achievable aims and objectives. The P&D Dialog system is a suitable tool to update more frequently the learning goals for more experienced CRA's and to align the updates of the learning goals more to the personal needs. The recommendation regarding content is to adapt the amount of structure to the amount of expertise, thus more structure for a novice and less structure for a CRA with expertise. And thereby selecting a good balance between theory and practice. In addition Organon should continue encouraging the CRA to

exchange knowledge and experience, especially for the older CRA's, for instance, by having them (co-) determine the content of the instruction. Preserve the corporate memory by systematically organizing the exchange of knowledge and experience. Small taskforce groups could be initiated to discuss all kinds of relevant topics or the learning points from audits and inspections, which could subsequently be made available to all CRA's. 'Train-the-trainer'-courses should be provided and trainers should not be appointed because of their available time, but because of their proven training skills. And experts could be invited to instruct scientific knowledge. Provide handouts before the training and provide additional material after the training (even in regular intervals), that is current, organized and stimulating. More on-the-job-training should be added, including training at the hospital. Training for more experienced CRA's should be extended. Training (updates) should be provided more frequently, especially concerning scientific knowledge. By using a larger variety in learning methods/ activities, e.g. by providing e-learning the CRA's can be trained in a more flexible way, e.g. at any time at any place. The rationale determines which learning activity should be assessed and under which condition. By concluding more trainings with an assessment the CRA's output can be monitored both on organizational and personal level.

Suggestions for future research

Although the questionnaire is considered a reliable instrument, it could be improved. For instance to split up the category 'neutral' into three categories like 'no opinion'; 'do not understand item' and 'neutral'. When using these subcategories the results can be analyzed in more detail. Another solution to prevent misunderstanding is translating the items in the local language for those countries which have a poorer understanding of English. After updating the questionnaire, it should be evaluated by both experts and a sample of the responder group. Another suggestion for future research is to investigate the non-responder group in more detail.

This research has now focused on the education for CRA's at Organon at this moment. Since the questionnaire has been considered as reliable instrument, it might be good idea to repeat the evaluation research after a few years (e.g. after changes have been implemented) or compare the CRA education at Organon with the CRA education at other pharmaceutical companies.

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