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Why Can't It Be Fun?: Making Regulations Enjoyable To Learn.

Wendy Collingbourne

Abstract
SmithKline Beecham has been using CBT for several years to train clinical professionals, and had planned for a CBT program to train these professionals on new regulations, which had come into force and applied for all clinical studies world-wide. Only four months before we were set to launch the program at an international workshop in September 1997, we entered into a contract for the development of the CBT program. The vendor only had one real remit : to "make it as stimulating and as much fun as you can"
This paper will address the exploration of the various approaches which we could have used, and the thought processes which lead to the decision to make it
"cartoon" style, with animations
use exploratory techniques (exclusively) for the learning component
use quiz-show games as a means of reinforcing the learning and
use a board-game as the means of assessment.
An added level of complexity means that the program encompasses different viewpoints, so that users "wear" a particular person (or role) 's spectacles when exploring the screens to find out their responsibilities. They may change whose glasses they are wearing at any time, to read another role's responsibilities regarding the same tasks.

The presentation will include a demonstration of the program.

Introduction

In September 1996, for the first time, a set of internationally agreed regulations for Clinical Research were finalised by the International Committee on Harmonisation (ICH). SmithKline Beecham, as a major pharmaceutical company which has been using CBT for several years, had planned for a CBT program to train clinical professionals on these new regulations, and were set to introduce this program at an international workshop in September 1997. With only four months to go, we entered into a contract for the development of the CBT program. The vendor only had one real remit : to make it as stimulating and as much fun as you can. After all...
"people who enjoy what they're doing, do it better" (Foster, J. 1996)
We desperately wanted to provide an enjoyable learning experience for the end user.

The Source Material, & a Background to the Clinical Trial Process

The source material for the project was the set of Guidelines (Regulations, in all but name) for Good Clinical Practice. These have been reproduced in electronic & hard-copy booklet forms for widespread use. The Guideline's set of requirements are organised into 8 sections :-
1. Glossary
2. The Principles of ICH GCP
3. Institutional Review Boards/Independent Ethics Committee (IRB/IEC)
4. Investigator
5. Sponsor
6. Clinical Trial Protocol & Amendments
7. Investigator's Brochure
8. Essential Documents for the Conduct of a Clinical Trial.

Of these, sections 1 & 2 are background/reference information. Three sections are to do with documents (sections 6, 7& 8). Three sections detail the duties of the people groups (3,4 & 5). However, we know that the Sponsor employs/contracts a Monitor to oversee trial progress & compliance, and it is this Monitor who has direct contact with the Investigator. We thus deduce that there are 4 main 'players' in the clinical trial arena..... the IRB/IEC (to evaluate and approve the trial documentation & procedures), the Investigator (to conduct the trial), the Sponsor and the Monitor.

A sample from the ICH GCP Guideline, on sponsor responsibilities:-
5.5.7 The sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country(ies) where the product is approved, and/or where the sponsor intends to apply for approval(s).
5.5.8 If the sponsor discontinues the clinical development of an investigational product (i.e. for any or all indications, routes of administration, or dosage forms), the sponsor should maintain all sponsor-specific essential documents for at least 2 years after formal discontinuation or in conformance with the applicable regulatory requirement(s).
5.5.9 If the sponsor discontinues the clinical development of an investigational product, the sponsor should notify all the trial investigators/institutions and all the regulatory authorities.

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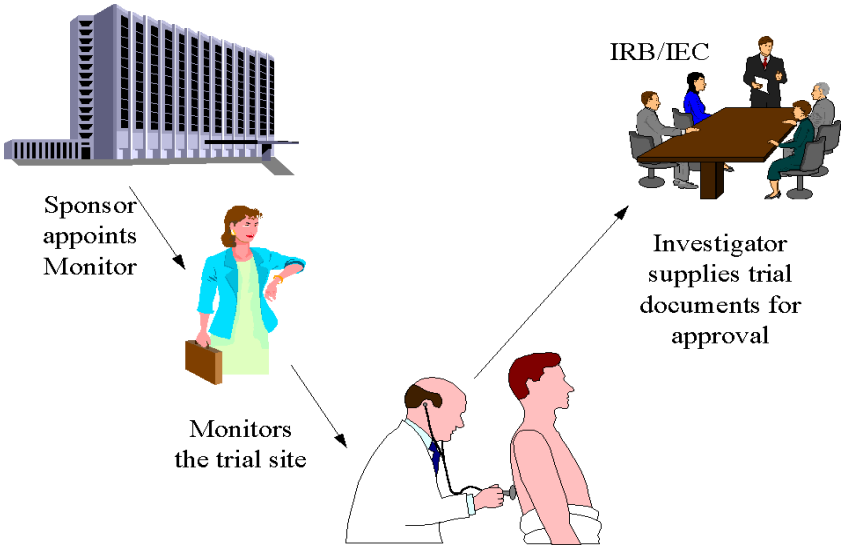

Fig 1. Interactions & relationships in the trial process

The IRB/IEC's remit is to protect the rights of subjects, and thus they are primarily involved prior to the start and at completion, and have no direct involvement in the trial. The only contact they have is with the Investigator, and then only when he/she needs their approval for a change to the trial. (see Fig 1.)

The Design - First Thoughts

The Vendor's initial suggestion was to devise a learning structure around the final 7 of these 8 main sections as discrete modules/'chapters'. However, by our first team meeting the proposal had altered to considering a time-aligned approach, playing out the responsibilities through the clinical trial process, i.e. from pre-trial to completion of the trial.

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SB warmed quickly to the idea that the Guidelines should be put in perspective - i.e. within the trial process, and suggested this include individual perspectives so that learners could follow parallel tracks, and go through the trial process as either the Investigator, the Sponsor, or the Monitor. (Due to their lack of direct involvement throughout the trial, IRB/IEC duties would be covered under a 'general' category).

The idea of parallel tracks was also to enable switching at any time, so that you could, say, examine what the Investigator did prior to trial start, but then switch to the Monitor's track to see what they also did then, or later when the trial started. This seemed to lend itself to an uncluttered view of the trial, while providing all the necessary roles & duties specified in the Guidelines.

This required SB to "sift" through the Guidelines, categorising each statement into its stage in the trial process and its 'ownership' (i.e. whose duty it was) . This, unfortunately, highlighted weaknesses in the content of the guidelines - it appeared as if the Monitor had little to do (not true in practice!) since most of their duties were hidden under the sponsor. Also, there were many times when there were "empty" chunks of track - periods of time where the regulations didn't detail specific duties for one/more of the roles - so there was great danger of having no corresponding task in the same time slot/period to switch to (see Fig. 2). The track into which you switched may have to force you to jump ahead in the process, in order to find the learning content for that track. Unfortunately, if you then chose to switch back (especially if it was immediately after switching track the first time) you were more than likely to have missed a core portion of the learning.

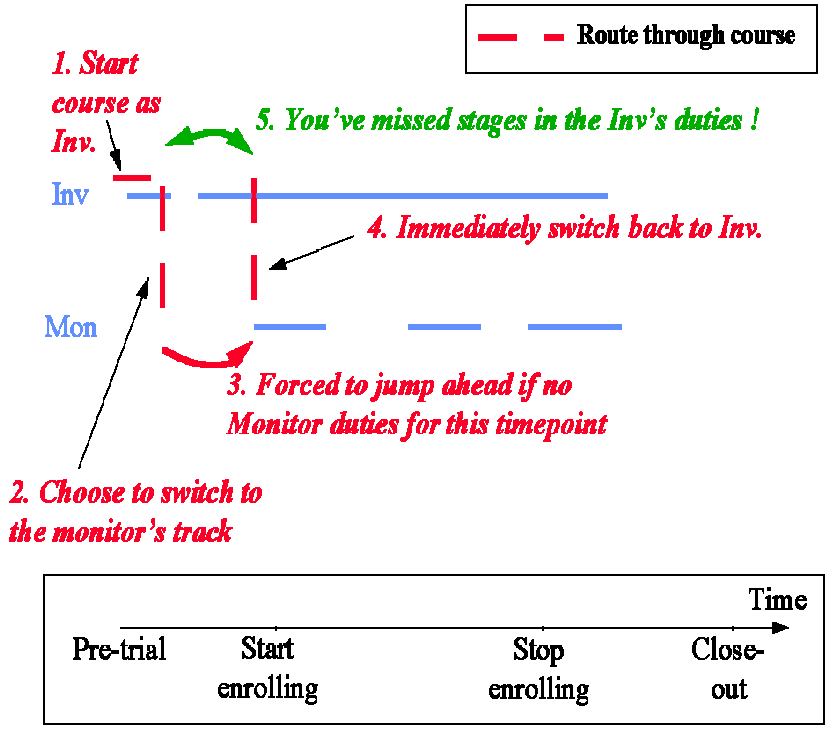

Fig 2. Problem in switching between parallel tracks

Having realised the potential for missing out important duties by this approach, and in order not to communicate any misleading messages such as "there's nothing for the investigator to do at this point", we realised we needed a different approach. We wanted to keep the concept of moving through the trial process, but needed to create the feel of multiple activities happening - regardless of whose track you were on. We therefore wanted certain discreet stages in the trial process to be represented by a stage "picture", and then combined all the activities covered by the parallel tracks into components - to be represented by relevant items in the picture - which would be visible even if those duties weren't the responsibility of your chosen role.

The learner would still view the information for a given (chosen) role, but be aware of all the events occuring at that stage (since they would all be represented in the picture). The learner would still be free at any time to change to another role. "Switching tracks" therefore now became "changing roles", but staying within the same picture frame of the course.

So, now we had a concept, the next thought was 'style'.

Regulations are Boring

"Informal humour is frequently regarded ... as a way of expressing serious intent and of conveying serious information without appearing to do so" (Mulkay, M., 1988)

We all know how tedious it is to plough through a technical manual, or a list of procedures to follow. How much more tedious can you get than to be training on a set of "do's" and "don'ts" ? The decision to go to cartoon style picture menu's was an easy one, when listening to comments such as Mulkay's. Cartoon-style humour, after all, allows a seemingly non-dictatorial approach to be taken to what is, in essence, a long set of rules.

"Consider designs where the learner is not presented with information in a linear format, but rather discovers information through active exploration in the program." (Orr, K.L., Golas, K. C., Yao, K., 1993)

Now we were moving away from a linear (albeit triple-track) route through the process, to a semi-linear, semi-discovery approach. Each of these picture menus was to be a recognisable scene from a trial stage, with hotspots areas which would reveal the duties of the chosen role. Moving the mouse over the hotspots (e.g. a Medication trolley) would reveal a summary list of topics to appear. Clicking once would 'fix' the topic list and enable exploration of the duties and responsibilities of the current role, where each portion of learning would be further illustrated by a topical graphic.

"Although realistic graphics may help to increase student motivation, designers should consider other approaches when it comes to gaining or focusing attention. Focusing attention is one of the primary aims of educational materials. People will often attend to information based on physical characteristics ... and the extent to which the information is unique" (Kwinn, 1997)

All the pictures and illustrations were to be created using a graphic artist, rather than to rely on any pre-existing material clipart or images. We wanted a "fresh" look, and felt that any use of existing material could so easily cause the learner to switch off. One way of guaranteeing interest was to present them with brand new images throughout the entire programme.

We also needed on screen some way of knowing which role you were in and being able to change your role (or point of view) at any given time. Our vendor came back with the idea of learners "wearing" a particular person (or role)'s spectacles when exploring the screens to find out their responsibilities. They may change whose spectacles they are wearing at any time, to read another role's responsibilities regarding the same (or other) tasks.

Navigation

We're all familiar with the Windows™ "standard" for navigation : produce a toolbar! However, we were fortunate to have a creative Instructional Designer working on this project (we chose the vendor for their creativity) and their idea was to incorporate all navigation within the stage picture. Moving on was to be via a door on the right. Help was via the phone. Exit (or going back) was via the Window on the left, etc. Each

stage was, however, also fundamentally different as it was a different scene - which gave a problem as to how to introduce consistent navigation. Although each scene was different, certain features (Help, etc) would be kept 'standard', but the placings of the others (main menu) would be in approximately the same part of the screen, although using a different mechanism. Since each was clearly labelled, this didn't actually detract from the 'comfort zone' for the learner.

Furthermore, moving the mouse over a navigation 'zone' causes an animation to 'kick in', while clicking on a navigation zone to execute it invokes a more extreme/imaginative animation. The learner thus begins to play with the navigation and is enticed to explore the tool, all the while building their confidence.

The end result is an attractive-looking, fun, exploratory and entertaining method of learning.

Assessment

Sandra Wills (University of Wollongong) has stated
"A learning environment is ... an active environment that involves the learner in a challenge or a mission. This design model is most often seen in computer games but it can be harnessed for more educational outcomes"

In a presentation on "Edutainment: How & Why Gaming Helps Learning" at the SALT Interactive Multimedia '97 Conference, Marita Decker stated "44% of the US population play PC games" and, within companies, "42% MIS managers play more than 1 game per week" (and that mostly middle managers on US$40-50K). Decker also stated the benefits of playing games, which are "reduced stress", "challenging the mind" and "stimulating creativity". She also stated that Roger Shank of the Institute for Learning Sciences had deduced "motivation and interest provide a link to memory".

If this was so, and we believed it was, then we should obviously apply this approach to our "dry" material. The vendor had already used a board game concept in other computer-based learning programmes, and to great effect. The vendor also suggested that for re-inforcement of learning, we have a post-test at the end of each trial stage. However, they also suggested we use a gaming approach for those too, so that any and all assessment in the programme would be 'fun'-based.

The Quiz Show

The Vendor came up with the idea of the post-stage Quizzes borrowing their ideas from a TV Show broadcast in the UK in the 1960's called "Call My Bluff" TM. This show used to pose a question, about the definition of a particular word, to a panel of three who would then in turn, each read out their given definition for the word. The opposing team had to identify the one correct reply from the three definitions given. The art of the game was thus spotting which two opposing members were "calling their bluff" with incorrect answers. The post-stage Quizzes took-on this concept, with a Quizmaster posing a questions, and three characters answering differently. By moving their mouse over the contestants, the learner could get to read each response, and then click on the person who they believed had the correct answer.

This post-stage Quiz was reached via a Quiz book graphic within the trial stage picture. These Quizzes however, were also practice-runs for the later, final assessment - the Board Game.

The Assessment Game

The means of measuring and assessing learner knowledge is via a board game. The game uses a random dice, and a marker which is moved along squares (Fig 5.). For an element of chance, The Monopoly™

Community Chest/Chance™ concept has been thrown in, for which money is rewarded or subtracted. When one of these Chance™ squares is landed on, a random "audit finding" appears - which will either give reward or subtract cash, depending on the audit finding.

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Fig. 5. The marker is moved along the squares based on the dice throw.

If a Question square is landed on, a question is posed which must be answered in order to proceed. The questions posed in the game use an almost identical format to the end-stage Quizzes - with the Quizmaster posing a question to his panel, and the panel each answering differently (see Fig. 4)

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Fig.4 The Game© using the Call My Bluff™ format for Questions.

Each question also has a cash value associated with it, related to the complexity of the question. Consultation with the learning content is permitted before answering - but at a price - since the consultation fee is immediately subtracted from the question's cash value. The Game itself is meant to be played on completion of the learning, though it may be played at any time. Since it contains a pool of questions from

which a random sub-set are drawn each time it is played, it can be re-played many times without the exact same set of questions ever occuring.

Cross Reference Materials

In addition to a HELP facility, explaining about the screens & how to navigate, the full ICH GCP Guidelines are available at any time, embedded into the program in electronic format.
During a learning topic, a click on the ICH GCP Booklet graphic contained in the stage picture will bring the user to the relevant cross-reference, or, where the learning is based on a sub-clause, into the general section containing the sub-clause. Thus little or no further navigation is required to read the ICH GCP Guideline statement which directly supports the learning content.

Furthermore, actual practice in certain (most!) countries is, on occasion, more stringent than the requirements laid down by the ICH GCP Guidelines. To ensure that this tool didn't mis-communicate by not pointing out these extra requirements, we included "National Variances" for USA, Japan, France & Germany. Firstly, these extra requirements were obtained from SB employees in the local countries, and then the SB development team rationalised where they applied in the learning content. Country Flag graphics were placed on all the learning pop-ups which became 'active' when a country variance kicked-in.

Since the ICH GCP Guideline contained a Glossary embedded within it, this has been preserved in the electronic on-line version, and easy access provided. A simple search facility was deemed necessary by SB , and so was also programmed into the Guideline reference facility.

Conclusion

The gamble paid off. SB employees have (literally!) queued up to get their hands on the tool. Feedback has been extremely positive, and although there were initial doubts that we even needed such a tool (everyone had already been issued with a 46-page booklet) the demand has proven the validity of the approach. The only reaction has been, on occasion, to the somewhat "dark-side" of the humour (but then this was a British team !)

Users have been overheard saying "I didn't know learning could be so much fun" !

It's certainly an approach to learning that we will use again.

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