Is Interactivity in Clinical Research Training Necessary?

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Overview

Interactivity. It is the buzzword of the e-learning and training world. The more the better when it comes to including it in a training course, right? Google shows over 5.6 million results for the terms interactivity and training. Instructional designers are taught early that it is good and necessary for their courses. All major course development tools support it, and nearly every major vendor touts it. Given this, what is interactivity and is it really needed? This whitepaper will explore whether or not it is needed for training development in clinical research and if so, what interactivity truly is and how to best include it.

When we talk about interactivity and the fact that it is beneficial, what we are really talking about is the fact that users that interact with content rather than passively observe are more likely to remember what they interacted with. This comes from a body of research over the years and, quite frankly, is pretty hard to refute. However, it is not the only way to learn. Think of the History Channel or any educational television program. Watchers do not interact with the content, yet many have learned from these types of modalities for years. Why? Well, more often than not, it is because the content is well written and engaging. Other factors do come into play, e.g., motivation, however these programs are well-organized, well-written, and very succinct. There is no extraneous content provided and the instructional objectives are well-supported by the content.

What does well-written content look like? First, the content must be organized in a logical fashion. If little to no content exists, start with a learning goal, a set of learning objectives, and a content outline, and then add additional content to support the outline. Listed below is a sample outline from a GCP course. Note the flow, the introductory and historical nature of the outline, and the supporting text.

- What is Good Clinical Practice?
- Purpose of Good Clinical Practice

  The purpose of Good Clinical Practice is to provide public assurance that:
  - the rights, safety, and well-being of trial subjects are protected; and that
  - clinical trial data are credible

  The purpose of GCP is based on the protection of people participating in trials and the protection of people who will be using the products approved under the standard.

- Predecessors to GCP
  - Hippocratic Oath (circa 400 B.C.)
    - Written as a guideline for the medical ethics of doctors
    - Promotes respect to the patients as well as the promise to treat them to the best of the physicians' ability
  - Drug Importation Act (1848) enacted – Prevented import of adulterated drugs to US
  - Bureau of Chemistry established (1862)
  - Biologics Control Act (1902)
    - Enacted in response to contaminated vaccines that led to tetanus outbreaks and children deaths
    - Required premarket approval for biologics
- Pure Food & Drug Act of 1906
  - Pure Food & Drug Act (1906)
    - Spawned by publicity of Harvey Wiley's "Poison Squad" experiments and public outcry over publicized unsanitary conditions of meat-packing plants

    - Prohibited interstate commerce of misbranded and adulterated food and drugs
    - Required correct labeling of drugs; prohibited false claims
    - Required labels to include list of dangerous ingredients only
    - Did not require premarket safety or efficacy testing
- Federal Food, Drug & Cosmetic Act of 1938
  - The Federal Food, Drug, and Cosmetic Act of 1938
    - Enacted in response to public outcry over the Elixir Sulfanilamide tragedy
    - Extended the authority of the Food, Drug and Insecticide Administration to cosmetics and medical devices
    - Required new drugs to be shown safe before marketing under a New Drug Application (NDA)
    - Still in effect, amended, today
- The Nuremberg Code (1947)
  - Response to unethical WWII Nazi experiments
  - Consists of 10 points defining legitimate medical research, including the following key provisions:
    - Subjects must voluntarily consent to participation
    - Experiments should be designed for the good of society
    - Unnecessary suffering/harm to subjects should be avoided
    - Risks should be outweighed by potential benefits
    - Research should be conducted only by qualified scientists

If content does exist, begin to work back to see if you can create an outline and learning objectives. Often you will find that this exercise will help to quickly visualize why the existing content is in such poor shape. Pay close attention to screen titles, topics, and sub-topics to ensure the content supports the title. If you are going to explain the process of Informed Consent, then by all means do so.

In the following example, we have a slide titled “What is a CTD?”

- What is a CTD?
- CTD = Common Technical Document
- Organized into five modules:
- Module 1: Regional Information (EU, US, JP)
- Module 2: CTD Summaries
- Overall CTD Table of Contents and Introduction
- Quality Overall Summary
- Nonclinical Overview and Summary
- Clinical Overview and Summary
- Module 3: Quality (Chemistry, Manufacturing, Controls)
- Module 4: Nonclinical Study Reports (early development safety)
- Module 5: Clinical Study Reports (late development safety & efficacy)

On the surface, this slide looks fine. The content presented does list the components of the Common Technical Document. However, upon closer inspection, we see that the title does not accurately reflect what is presented on the screen. The slide would be more appropriately entitled “Elements (or Sections)

of the Common Technical Document (CTD)". It is also important to know whether the CTD has even been defined or if it has been listed as a learner prerequisite knowledge. If not, a brief explanation stating what the purpose the CTD fulfills in standardizing clinical submissions is warranted.

When talking about interactivity and increasing learner comprehension and retention, motivation can play a key part. Not just initial motivation, but also the things that can be added to a course to increase the desire to learn. Perhaps an inspiring introductory video, or explaining what a successful clinical trial looks like and would mean to an Investigator. A quick explanation of the ramifications of failure can do wonders to light a fire under the apathetic student. Looking back on the history of clinical trials and the evolution of regulated trials, we quickly see that much is derived from Nazi Germany and the experiments that were conducted during that time. Plenty of attention-getting material exists in the public domain to highlight the point that GCP is an important part of research today.

Looking further at interactivity, it is important to understand that clicking something does not make it interactive and furthermore does little to improve a learner's comprehension. All too often do we see courses that require a click here, a mouse-drag there and the course is labeled highly-interactive. Nonsense. Interactive courses require that the learner not only read/hear the instruction, but can make use of it during the instruction through manipulation. It is this manipulation of the learning material that allows the learner to create their own construct of the content. In so doing, they are committing the content to memory in their own meaningful way.

In the screen below, we see an example of how a learner could practice dosing a study subject based on lab values and determining whether they selected the correct dose of study medication. Feedback is given based on the dosage selected and the correct answer is provided. This exercise then goes on to simulate the entire study and this patient's lab values across all study visits.

Tumor Dosing Exercise

	ANC (/mcl)	Platelets (/mcl)	SGOT (U/l)	SGPT (U/l)	Alk Phos (U/l)	Total bilirubin (mg/dl)	Creatinine (mg/dl)	CPK (U/l)
Upper Limit of Normal			35	35	120	1	1.2 (mg/dl)	150
Toxicity Grade 1			≤ 2.5ULN	≤ 2.5ULN	≤ 2.5ULN	≤ 1.5ULN	≤ 1.5ULN	≤ 2.5ULN
Toxicity Grade 2			≤ 5ULN	≤ 5ULN	≤ 5ULN	≤ 3ULN	≤ 3ULN	≤ 5ULN
Toxicity Grade 3			≤ 20ULN	≤ 20ULN	≤ 20ULN	≤ 10ULN	≤ 6ULN	≤ 10ULN

Cycle 1

	ANC (/mcl)	Platelets (/mcl)	SGOT (U/l)	SGPT (U/l)	Alk Phos (U/l)	Total bilirubin (mg/dl)	Creatinine (mg/dl)	CPK (U/l)	Dose Prescribed (mg/m2)	Score	Correct Answer
Cycle 1 Day 1	3500	214000	40	60	88	0.6	0.7	55	N/A	Incorrect	0.58
Cycle 1 Day 8	2000	140000	60	65	95	0.9	0.8	140	0.49	Incorrect	0.58
Cycle 1 Day 15	1100	100000	70	70	110	1.8	1.2	88	0	Correct	0
Cycle 1 Day 22	900	78000	40	40	180	2.1	0.6	110	0.40	Incorrect	N/A

Submit Answers

Some other ideas for introducing the concept of manipulation to the area of clinical research:

- Try having users order the steps of a procedure needed for the study
- Match a list of terms to a helpful acronym for remembering the IC process
- Present a scenario that includes a protocol deviation and ask the learner to provide next steps
- Interact with screen elements to successfully reconstitute a drug
- Select possible negative outcomes of improper application of GCP Correct an improperly completed CRF

As you can see, these are just some examples of interaction that can help to reinforce key concepts and procedures needed for conducting clinical research. Implementing this type of interactivity is not easy. It requires mastery of the subject matter, careful attention to the right mix of interactivity vs. didactic instruction, and the tools needed to create the interaction. However, done correctly, this type of training can very quickly lead to mastery of the subject matter and improved performance by the learner.