Lotus CLINICAL RESEARCH® LLC

Better Science. Superior Results.

Method to the Madness: The Impact of Form Design on Data Collection

By Jessica Fraga, Project Manager for Lotus Clinical Research CRO
March 2019

Introduction
We've all felt the frustration of completing poorly designed forms, whether they be online (webforms, EDCs) or on paper (medical intake forms, surveys, contracts). Poor form design not only produces more mistakes, but can even increase the likelihood that the task will be abandoned altogether. Contrast this with the effortlessness of an Amazon check out cart, and the impact of form design on our daily lives becomes readily apparent.

Why talk about something as dull as form design?
Data collection is a cornerstone of Data collection and the means to collect it surrounds us in all aspects of life (hi, Facebook!). This especially applies in clinical trials, where data collection is the foundation of your well-thought-out and overarching study design. Data collection design and form design don't always come up as hot topics during the set-up of a clinical trial. Often the protocol and monitoring progress steal the spotlight. However, a lot of thought and care should go into how we collect data, which ultimately determines how you present it. Everything from the structure and flow of your monitoring reports, EDC design flow, and source documents, impacts data. The point is, if the basic framework and user interface of data collection and reporting are rife with issues, this could negatively impact an otherwise elegantly designed protocol and study drug.

Changing a button increased annual revenues for a web site by $300 million
True story: The tiniest details of user interface matters. Jared Spool wrote a perspective piece for the book, WebForm Design. In this, he detailed that an online ecommerce company (which is not named) had developed a checkout process that involved the user adding various items to their cart, then proceeding through a less than ideal path to checkout. Upon checkout customers would encounter a simple form, which required them to register. Easy right? Not really. I'm sure many of us have encountered such online frustrations. People want to shop and move on, not enter into another binding contract. So, what happened with this company? Usability tests showed that many customers got to this final step and abandoned their purchase. Once web designers fixed this by removing the forced registration page and giving a simple button click option to move on as a guest, the company saw an additional $300,000,000 in sales in the first year (Wroblewski, Web Form Design, 2008).

So what.
So, why I'm I talking about an e-commerce example when I'm supposed to be talking about clinical research? The example serves to illustrate the point that even the smallest details adjusted for the experience with the user in mind matter and could have a heavy impact on the accuracy and completion of your trial's data collection. This is especially important in PROs

(Patient Reported Outcomes) which, in many cases are the PRIMARY endpoint of a clinical trial. Research patients often bring home paper diaries (PROs) to complete. It is critical they have a good understanding of how to complete these special forms, but more importantly, the diaries should be *easy* to use. Of course, there is an extra layer of GCP requirements that affect the design of these forms which can seem tedious (initial and dating, anyone?) but that shouldn't get in the way of laying out clear questions and work flow for the study patient.

The answer

The answer is, there isn't one right answer to form design. In fact, it should be seen an evolving process, with opportunities to learn and improve data collection flow with each iteration. Again, this applies to many aspects of clinical trials: EDC, Monitoring reports, PROS, Source Documentation, Study Drug Accountability, and Lab Requisitions to name a few.

Make it happen

Form design is a ubiquitous part of general life and remains key in clinical research. It can seem daunting to take on re-designs or completely new data collection requests. Some helpful basic checks for a starting point should be as follows:

- **Decide what to include**: Deciding what stays on a form proves to be challenging at times and depends on the form you are designing. How meaningful is the data? EDC requirements are mostly paired down from the source data, which often include extra steps and data to ensure accuracy. It's a balance that deserves detailed conversation which can impact not just data, but time and money.
- **Organize your content with the user in mind**: Who are you collecting data from? Site staff, patients, CRAs? It's important to attempt to walk in someone else's shoes for this one.
- **Lessons learned**: Determine best practices from prior studies. What worked well and what didn't? Were high query rates due to form confusion? Do research site staff have any helpful feedback for improvement? Has anyone asked a patient about their form completion experience?

Once these initial boxes are checked, it's then time to test drive the form. Data Managers often implement User Acceptance Testing, or UAT, as a final phase in EDC development. UAT helps find the "kinks" in the data collection system in real-world situations. However, this type of testing could be useful for other forms designs. Designers of various forms can test-run their format to targeted users and ask for feedback. This testing doesn't always need to be extensive or cumbersome; just keep your form user in mind. A simple conversation with a different perspective it sometimes all it takes.

References:

Wroblewski, Web Form Design, 2008