HOW DIGITAL UX IN CLINICAL TRIALS CAN IMPROVE MEASURES

In this article, Ben Cox, PhD, Head of Digital Design at Team Consulting, discusses the key challenges, principles and advantages of following a user-experience approach to digital health technologies in clinical trials.

In recent years there has been an increasing interest in decentralisation and the use of digital health technologies (DHTs) for clinical trials. These new tools, devices and apps are offering ongoing improvements to existing trials and have the potential to offer new methods for conducting better trials for the future.

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When conducting clinical trials, the aim is to measure more meaningful outcomes – but what exactly makes a meaningful product or experience? Increasingly, meaningful outcomes are a primary focus in clinical trials, referring to the aim of gathering data that are going to add value, such as by providing accurate insights into a subject's symptoms or health. The aim is for these data to lead to better outcomes – something that DHTs have significant potential to help with.

WHAT ARE THE OPPORTUNITIES FOR DIGITAL HEALTH TECHNOLOGIES IN CLINICAL TRIALS?

One of the key advantages of DHTs with respect to clinical trials is that they allow more measurements to be taken at a subject's home, which can lead to an increased participation rate and access to more vulnerable populations, such as children or the elderly. Take-home instruments and measurement devices also allow for increased data frequency and the ability to gain "real world" validity, with less reliance on more subjective reported data from subjects.

Digital biomarkers, such as wearables and apps, allow for more realistic measures to be captured from trial subjects, with more objectivity, frequency and efficiency compared with traditional trials. Not only can these measures provide far deeper insights, they also have the potential to improve subject adherence and retention and increase clinical capacity, with research showing a significant increase in willingness to participate in mobile or decentralised trials among participants.[1]

THE CHALLENGES OF DIGITAL HEALTH TECHNOLOGIES IN CLINICAL TRIALS

As well as opportunities, the adoption of DHTs presents several challenges for developers, sponsors and end users alike.

Navigating a Complex Multistakeholder Environment

There are already many players involved in clinical trials, and digital approaches often present their own complex landscape on top of that, with many stakeholders and users across organisations and regions, each with different needs and expectations. It is often the case that pharma companies looking to incorporate DHTs will partner with tech or digital health companies, introducing multiple systems and applications from multiple vendors. As such, introducing new tools and ways of working into a somewhat fragmented ecosystem can prove to be a real challenge for the industry.

Tolerability and Usability

In almost all contexts, users desire to complete tasks with a minimal amount of effort – clinical trials are no different.

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Clinical trial teams are, however, often expected to work with multiple products and systems, and most are uninterested in becoming application experts. Subjects may themselves be required to manage different instruments and devices for extended periods of time in accordance with complex protocols, while remaining engaged throughout. Common user experience (UX) challenges that face connected health apps, including onboarding, engagement and retention, must therefore be addressed in the design of tools for clinical trials. The key is to develop products and systems that are both powerful and easy to use.

DEVELOPING MEANINGFUL PRODUCTS

In the broadest sense, digital products are designed to be useful to a user. However, the term "meaningful products" refers to the need for a product to resonate with people's needs and match their values. While this aspiration might be a stretch to fully realise in the context of clinical trials, the careful application of UX design tools and methodological frameworks can provide benefits to all stakeholders throughout the different stages of a study, ultimately helping to drive towards a more successful outcome.

The opportunities for DHTs are clear and unprecedented but their potential can only be fully realised if they are developed with all end users in mind. When designing a digital product, it is crucial to perform due diligence in understanding the user. Product experiences are only meaningful if they are created with the user in mind, meaning the priority should be on features and services that cater to user needs.

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BOX 1: KEY ELEMENTS & PRINCIPLES OF A UX APPROACH

Research – Perform user research to understand user profiles, including capabilities, limitations, goals, expectations and tasks.

Understand Needs – Capture and understand all the critical needs of users.

Understand the Context – Understand the specific locations and conditions in which the solutions will be used.

Validate – Collaborate and continuously evaluate both the problem space and the solution (as it emerges) with stakeholders, users and subject matter experts.

Factor Complexity – Understand how the solution may integrate with existing workflows.

Examine Tools and Data – Explore the full range of tools, systems and data that may be used in conjunction with the solution.

Balance Innovation – Identify opportunities to innovate whilst being mindful of existing validated systems and established practices.

Design – Generate ideas and concept solutions based on user-derived evidence and prototype to bring concepts to life.

work of the clinical trial. One of the biggest decisions regarding a digital product or service development is actually one of the first ones, "What exactly is the problem (or problems) you are solving?"

Is the idea for the product something that rises internally from the developer's organisation, or is it based on some real evidence or user insight? What is the desired outcome? Does it lower user effort and save time or, in the best case, could it create new ways of thinking and working, and change someone's daily routine for the better? For a successful digital product or service, it does not matter how well designed and pixel perfect it is if it fails to offer some real tangible value to its user.

UX APPROACH TO DIGITAL HEALTH TECHNOLOGIES IN CLINICAL TRIALS

A UX approach to design involves developing a deep understanding of the end users and use context through research, organising information, wireframing and more, all with the goal of meeting user needs robustly and elegantly. It involves putting users at the centre of the design and development process, and establishing an iterative cycle of research, design and evaluation (Box 1).

TYPICAL PROJECT TIMELINE

There are a number of key activities when thinking about the integration of new digital tools and new ways of working in a clinical trial context. Typically, a small team of UX researchers and designers will work

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in close collaboration with a development and clinical trial team, spending anything from a few weeks to a few months working through these stages to reach a decision about what functionalities can be included in the design and start offering some real value to users.

HOW TO FOLLOW A UX APPROACH

Unstructured Research

When it comes to user interviews, subject matter expert reviews and desk-based research, following an unstructured research approach may sound counter-intuitive. However, the aim here is to mitigate preconceptions and uncover valuable unknowns. A structured approach to research can lead to bias towards certain users and certain problems. By following a freeform process, interviews can be conducted across

different levels of hierarchy in a clinical trial context to explore each user situation, enabling the researchers to fully interrogate the problem space.

It is important to ensure that all users have a seat at the table, ranging from site staff and subjects all the way up to global sponsor leads. It can also be important to consider the full trial lifecycle and all phases of the study. This can be a challenge given limited time and resources, so this is where subject matter experts can be invaluable for representing multiple user profiles. From here, workflows can be mapped, challenges and opportunities can be identified and user roles can be understood. This leads to user role definition.

User Role Definition

Personas are typically documented in UX projects, but when working on DHTs for clinical trials it can often make sense to take a more pragmatic approach and define user groups or profiles instead. This involves spending less time exploring how a user thinks or feels and focusing more on behaviours and goals in order to document profiles based on stakeholders' knowledge of the user (rather than direct research data). This approach allows for rapid identification of key differentiators between user roles and enables developers to implement measures that help to provide contrast between them. Examples of user roles could include editor, reviewer and viewer roles for study setup, with differentiated submitter and viewer roles for study data.

Task Modelling

Prior to mapping out user journeys, it is useful to build an understanding of the processes and tasks involved for each user group. Task modelling can provide a more flexible framework with which to consider the steps that is agnostic of the platform or interface that a user is interacting with. When setting up a digital tool in a new trial, there can be many different steps and several approaches, some sequential and some not, so task modelling helps to provide a clearer picture of these steps and workflows. It also helps to mitigate any bias the research and design team may develop regarding the way a certain interface works.

User Journey Maps

When solving problems for users, it is important to understand where the problems arise in their current journey. A journey map is a visualisation of the process that a user goes through in order to accomplish a goal. Building from task models, journey mapping can be used to highlight the unique steps in a user journey and record the potential frustrations or obstacles that users may encounter at a particular point.

Blueprints

Blueprints are well suited to helping with the integration of new tools in clinical trials, given the number of actors and the complexity of system interactions and data transfers involved. They are used to visualise the interactions between the end user and "back-stage" actors and systems for a specific user journey. This enables a clearer understanding of the product and provides a systemic view for capturing vital details that relate to other systems and data, as well as keeping the focus on the users who will be interacting with it at different stages in the process.

Landscape Reviews

In any product development, it is useful to understand what other developers are doing in the space. Landscape reviews provide insight into potential competitors and identify common features and problems they appear to be solving. This process can also help to uncover hitherto unrealised opportunities, as well as highlight potential overlaps and therefore mitigate the building of redundant features. For example, a common feature developers may wish to include is a messaging or communication system. However, this can often turn out to be burdensome for users who already work with multiple products, as it is another messaging system they need to check on top of the others that they are already engaged with. It is important to avoid overlapping with other systems and weigh up the benefits each feature will bring against the burden they will place on end users.

Feature Definition and Wireframing

Following confirmation of the research findings, inputs are taken for translation to a feature set that enables users to achieve their goals. This is the phase to dig deeper into the problem space, to create multiple different scenarios, outcomes and prototypes of the product or service and to gather feedback from key stakeholders. The design team should begin wireframing low fidelity screens and regularly share them with subject matter experts and technical stakeholders to make sure that they understand the problem and that the solution makes sense.

This is an iterative process, where the main goal is to learn something new from each hypothesis or prototype and improve

the solution based on learnings. The look and feel of the screens is less important at this stage, with the primary aim being to confirm what content needs to appear on each screen, as well as any screens that are unnecessary or could be consolidated. Once the team is confident that a desirable concept solves the problem, it is time to make a decision about the smallest set of functionalities that can be built and start offering some real value.

CONCLUSION

DHTs in clinical trials can provide benefits to all stakeholders throughout the different stages of a study and, ultimately, help drive towards a more successful outcome. Despite this, integrating new tools and new ways of working into a complex multistakeholder environment is challenging. In order to realise the potential benefits of DHTs in clinical trials and capture more meaningful measures, it is key to put users and stakeholders at the heart of the development and trial design process. By following a UX approach, developers can identify and validate problems – and develop more meaningful digital products to solve them.

ABOUT THE COMPANY

Team Consulting is a leading medical device design and development consultancy focusing on the pharmaceutical and healthcare industries. Team is an expert in drug delivery device development and works with companies both large and small across Europe, the US and beyond. Combining its expertise and experience in industrial design, engineering and human factors, Team develops medical devices from early concept through to commercial launch. Team is accredited to ISO 9001:2000 and 13485:2003.

REFERENCE

1. Perry B et al, "Patient Preferences for Using Mobile Technologies in Clinical Trials". *Contemp Clin Trials Commun*, 2019, Vol 15, Article 100399.

ABOUT THE AUTHOR

Ben Cox, PhD, is Head of Digital Design at Team Consulting. He works with a cross-functional group of designers, researchers and engineers to craft engaging and intuitive interfaces, and to optimise the user experience of medical devices. With a background in human factors and user-centred design, Dr Cox focuses on the user experience and interface from product vision to implementation. Previously, Dr Cox has worked in several design consultancies, as a clinical scientist and design engineer in the UK NHS, and has conducted extensive research for DePuy Johnson & Johnson. He has a BEng degree from Cardiff University (UK) and an MSc and PhD in Biomedical Engineering from the University of Leeds (UK).