# CONDUCTING USER EXPERIENCE INTERVIEWS DURING A CLINICAL TRIAL

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Over the course of two years, the author and colleagues conducted user experience (UX) research as part of two clinical trials. This paper describes the research methodology, the challenges encountered, the rewards, and the lessons learned from the experience. The subject of the clinical trials was a novel treatment for a degenerative disease that has no cure and few successful treatments. The trials involved pairs of patients and caregivers and lasted up to 12 months. The ability to compare the perceived effectiveness of the treatment and changes in quality of life with the clinical endpoints helped guide the design of the treatment regimen, and the experience was rewarding for the UX researchers themselves.

**Introduction**

Over the course of two years a medical device manufacturer conducted two simultaneous clinical trials in the U.S.. The trials focused on a novel treatment for a degenerative disease that has no cure and few successful treatments. The trials involved pairs of patients and caregivers and lasted up to 12 months. The dosages for each trial were different, and for one of the trials a third of the patients received a placebo.

In addition to collecting the safety and efficacy data required for their regulatory approval, the company felt there was much to be gained by understanding patients' and caregivers' experiences with the treatment, so they planned a series of user experience (UX) interviews. The author and other team members were hired to conduct these interviews and report the results.

**Methodology**

Each patient-caregiver pair was interviewed three times: once within a month of joining the clinical trial, once about halfway through, and once soon after they finished. Since the participants were distributed geographically, some interviews were conducted in person at their homes while others were conducted remotely via phone or video. The interviews were in-depth, lasting 60 to 90 minutes each.

Because the trials lasted several years due to rolling enrollment, the make-up of the research team changed over time, but in general there were five people involved: The project manager at the device company (who was also an interviewer), two consultants (including the author) and two note-takers (an intern and a contractor). Whenever possible the note-taker was there in person (for in-home interviews) or on the phone/video. However, all interviews were audio recorded and could be transcribed after the fact if necessary. Some of the researchers were on the West Coast and some were on the East Coast of the U.S.. Biweekly team calls as well as shared online calendars and spreadsheets helped the team to stay coordinated.

**Interview Topics**

Each interview followed a detailed script. Topics covered during the first interview included:

- Introductions, background, and typical daily routine
- Motivation to participate in the trial
- Baseline of their symptoms
- Experience with trial onboarding and treatment instructions
- Treatment routine
- Feedback on the design of the device
- Feedback on support tools and resources

The mid-study interviews covered:

- Adherence to the treatment over time
- Changes in daily routines to accommodate treatment
- Perceived changes in symptoms (if any)
- Specific questions about the treatment
- Quality of life assessment

The final interviews covered:

- Overall experience of participating in the trial
- Quality of life during and after the trial
- Perceived changes in symptoms (if any)
- Strategies to help with adherence over time
- Feedback on potential changes to the design of the device
- Opinions on treatment effectiveness versus daily burden

**Challenges**

*Additional paperwork*. One of the biggest challenges with conducting UX research as part of a clinical trial was the additional paperwork required. For example, the moderators were required to fill out, scan, and upload Patient Encounter Forms any time they spoke with patients or caregivers. The researchers had not anticipated this extra effort, but learned to plan time for these paperwork activities. One solution was the creation of lengthy and detailed checklists to organize activities before, during, and after each interview. The institutional review board (IRB) also required the research team to keep hard copies of all uploaded data forms and mail them to the device manufacturer for archiving.

*Rolling enrollment of patients*. Another challenge was the rolling enrollment onto the clinical trials. The medical device manufacturer expected the first participants to be onboarded in May, but the process took longer than expected; the first interview was not conducted until September. After that, participants were onboarded at varying rates over time,

and additional clinical sites were added in other U.S. cities (for a total of five sites). This meant that some participants were just starting the clinical trial while others were finishing, and ultimately, the UX research took longer than expected.

*Inclusion of a placebo group*. As mentioned earlier, one third of patients in one of the two trials were given a placebo. It was imperative to the study's integrity that the researchers and participants were unaware of who received the placebo. As such, the interviewers needed to use very specific wording when asking about any perceived effects of the treatment.

*Participant permission to be audio recorded and/or photographed*. For the in-home interviews, the research team hoped to take a few photos of participants' daily treatment processes and environments to enhance the findings. When they were enrolled in the trial, patients and caregivers were asked to check a box on the consent form if they agreed to be photographed or recorded. Unfortunately, the clinical trial staff who were unfamiliar with UX methodologies did not clearly explain the purpose of the recordings and photographs. Because of this many of the first cohort of participants declined. After recognizing this issue, the UX team recommended changes to the consent forms and enhanced clinical staff communication. This resulted in more participants consenting to photographs because they understood the purpose.

*Patient confidentiality*. While always a concern with UX research, patient confidentiality was heightened due to participation in an IRB-approved clinical trial. Elaborate processes for uploading documents, recordings, and photos were required to ensure confidentiality and anonymity. The research team passed documents to clinical trial staff who then interacted with RedCap clinical trial software. Also, when able to take photos, we could not do so with smartphones because of cloud connections, so we had to dust off our digital cameras.

*Sensitive subject matter*. The researchers experienced challenges due to the sensitive subject matter discussed during the interviews. The new treatment aims to slow the progression of a debilitating condition that negatively impacts the families it touches. Many of our interviews examined the struggles, fears, and hopes experienced by these individuals. Often the patients or caregivers began to cry, which took an emotional toll on the research team. Acknowledging this sadness and sharing stories during internal weekly meetings provided an outlet for the research team so that the emotional burden did not affect subsequent interviews.

*The COVID-19 pandemic*. When two years of UX research were nearly complete, the COVID-19 pandemic struck and everyone was in lock-down. The option for any in-home visits, of course, came to an abrupt halt. Luckily, the researchers were already adept at conducting remote phone and video interviews due to geographic dispersion. That said, the results of the interview data around daily routine and quality of life were impacted for the last participants in the clinical trials, and several were never able to be off-boarded at their clinics in person.

**Results**

Partway through the study the UX project manager at the medical device manufacturer convened an interim in-person data synthesis session. During the session the team covered the walls of a conference room with profiles of the patient-caregiver teams they had met thus far. Participants were given pseudonyms rather than numbers to increase realism and empathy. Photos, quotes, and anecdotes were cut into squares for affinity diagramming and analysis of trends, key take-aways, and important insights. The UX project manager then took that information and created several presentations to internal stakeholders.

At key milestones and at the end of each clinical trial, the user experience findings, such as perceptions of changes in symptoms and quality of life, were analyzed alongside the actual clinical data that were being collected. The ability to triangulate the data provided the company with interesting insights regarding the efficacy of the treatment as compared to perceptions of the treatment.

The UX findings influenced the design of the device, the instructions for use, and the patient support resources. They also were used as input to the design of subsequent clinical trial protocols.

**Rewards**

This research was rewarding in several ways. First, the longitudinal aspect (three interviews over time with each patient-caregiver pair) allowed us to form relationships with the participants. We got to know them personally which allowed for deeper empathy. This was felt most keenly with participants who were eager to share how the disease impacted their lives, fears, and hopes for the future. For those of us trained to behave professionally and neutrally during UX research, this was a shift in mentality and approach: it was okay to sympathize, share some of our own vulnerabilities, and use facial expressions, voice, and body language to show that understanding and enable deeper conversations.

By conducting UX research as part of a clinical trial, the client's product design team also developed empathy for their users in ways they never would have from the clinical data alone.

Finally, it was extremely rewarding to see meaningful improvements in quality of life for some of the patients and caregivers as a result of the new treatment. The research team shared these successes with each other, and the wins helped to balance the more difficult aspects of the research.

**Lessons Learned**

For those who are contemplating conducting UX research as part of a clinical trial, we recommend the following:

- Remain organized and detail-oriented. For example, preparing checklists with step-by-step instructions for scheduling participants, research protocols, and required paperwork, are essential to the success of the team's effort.
- Consider having a kickoff meeting between the clinical trial team and the UX team to ensure that

each understands the nuances of the other's methods and requirements.

- Remain aware of the confidentiality requirements required as part of a clinical trial.
- Due to confidentiality requirements, engage a live notetaker when it is not possible to use transcription services.
- Incorporate extra time for weekly meetings and communication to ensure all team members execute participant communication, paperwork, and interviews in a consistent and timely manner.
- When planning the UX research, consider the extra time required for scanning and uploading documents.
- Be aware of additional forms that may be required by the clinical study protocol. Anticipate that all hard copies may need to be kept and stored.
- During the interviews, exercise empathy for participants and caregivers. When facing a chronic condition, patients and caregivers truly value sharing their stories.

**Conclusion**

Medical device manufacturers should consider including UX research as part of their clinical trials for home-based therapies whenever possible. Important insights can be gained regarding the patient's and caregiver's journeys that are not possible to obtain otherwise. The ability to compare the perceived effectiveness of the treatment with the clinical endpoints can help guide the design of the treatment regimen.