

## Novel ethnographic/contextual inquiry techniques for understanding connected device users in their native environment

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Pharmaceutical and medical device companies are embracing technology to increase patient engagement and improve adherence to costly and sometimes complex medication therapies. One solution includes developing drug delivery devices that connect to mobile medical applications (MMAs) to support patients in managing and tracking their medications. Developing an adherence system requires understanding users in their use environment, their challenges with taking medications, their health goals, and the behaviors to target for change. Device developers have long relied on in-person ethnography or in-person human factors studies in a research facility to gather these data. Unfortunately, this process is time-consuming, labor intensive, and costly. When considering a rare patient population, collecting data in person becomes even more complex. This work explores how collecting patient data using a remote ethnography platform addresses challenges with in-person studies early in the device development process, and shares a case example of the use of remote ethnography to better understand patients with cystic fibrosis (CF) to design and refine a medication adherence system prior to taking prototypes into in-person testing.

### INTRODUCTION

#### Current practices and limitations of traditional research methods

In-person research with patients, caregivers, and healthcare providers is a foundational tool for understanding medical device users, use cases, and use environments; it is a critical first step in the development of drug delivery devices, connected or “smart” devices, and surrounding behavioral health interventions, such as mobile medical applications (MMAs). To date, these studies typically take the form of in-person interviews or device handling studies (simulated use) in a research facility. While these techniques are inarguably useful, several limitations have been recognized with in-person approaches (Duh et al., 2006; Gardner, 2007; Hartson et al., 2003; Oztoprak & Erbug, 2008; Scholtz, 2001; Seffah & Habieb-Mammar, 2009; Tullis et al., 2002). These challenges are summarized in Table 1 and described in detail below.

First and most apparent, in-person studies are expensive and time-consuming to perform. Direct costs include reservation of a study facility, travel to and from the study facility, and video equipment rental among others. In terms of time commitment, studies are typically conducted over the course of several days, each in multiple locations, which requires that research teams allow time to travel between facilities. Second, several factors may limit participation from the study population of interest. In-person study facilities generally reside in concentrated metropolitan areas for ease of recruiting and to maximize use of the research facility, and necessarily exclude participants who do not live near (or cannot access) these facilities. Moreover, some patient populations may be unable or unwilling to travel to an in-person study facility due to their

condition, regardless of proximity. This ultimately limits the study sample, making true representation of the target population difficult. Third, in-person studies must be conducted at scheduled, pre-defined dates and times. This not only creates scheduling difficulties for both moderators and participants, but more importantly, requires that the research team gather all the necessary insights at a single point in time, typically no longer than an hour or two. This makes accurate data collection challenging if the research is focused on rare or infrequent events, such as disease exacerbations or monthly medication administrations, both of which are common with chronic, rare, or orphan diseases. Next, in certain disease areas, direct contact with participants (or participants with each other) during in-person studies poses an increased risk of infection. This is particularly important in patient populations with compromised immune systems (e.g. cystic fibrosis, cancer, HIV/AIDS, sickle cell disease, transplant recipients). Lastly, in-person research may introduce a number of well-documented biases, particularly observation bias and recollection bias (LeCompte & Goetz, 1982; Seffah & Habieb-Mammar, 2009). Studies are frequently conducted using cameras, recording equipment, one-way mirrors, and other techniques that are hard to disguise or hide from participants, and research can be perceived by respondents as intrusive. This intrusiveness is of special concern when dealing with chronic diseases or disease states that patients feel are embarrassing (e.g. HIV, ulcerative colitis, Crohn’s disease, hepatitis, Alzheimer’s disease). In-person research also relies on patient recollection of their experiences, rather than allowing researchers to observe these events directly in context. As a result, a participant’s recollection of their device use, medication administrations, or daily routines may be skewed towards events that happen frequently or have occurred most recently

(i.e. recency effect). Despite these limitations, reliance on in-person methods persists, and to date, there are few suitable substitutes to capture in-context device use. In-home ethnography has been employed as a way to minimize some of the

challenges associated with facility-based research, however, the cost, time to recruit and conduct, and invasive nature of this method is often prohibitive, particularly for mobile device evaluations (Kjeldskov & Graham, 2003).

**Table 1: Limitations of facility-based, in-person research**

Limitation	Implications
Cost and time requirements	Studies are expensive and time-intensive to complete. In-person study costs include facility rental, refreshments, audio-visual equipment rental, and travel for both researchers and participants. In-person studies typically require spending two or more days in each of two or more cities to realize recruiting quotas.
Recruiting constraints	In-person requirements may produce a geographically and potentially demographically limited study sample that may not truly represent the study sample of interest.
Forced single point of contact	Insights from participants must be obtained during a single encounter. As a result, rare or infrequent events are difficult to capture.
Infection risk	Vulnerable patient populations may be completely excluded from research or require that special precautions be taken to reduce risk.
Observation bias	Participants' behavior may be influenced by the act of being directly observed, and results may not be representative of true use conditions.
Recollection bias	The accuracy or completeness of what participants recall from their experiences may differ significantly from what truly occurred in the moment.

**Connected systems and the growing demand for nimble research techniques**

The limitations of traditional user research techniques have become more apparent as drug delivery devices have evolved into “connected” or “smart” systems (i.e. an internet-enabled device plus another system component, such as an MMA). Medical device development has traditionally followed a lengthy, waterfall, phase-gate process, partly due to existing design control regulations, the desire to reduce risk in a stepwise manner throughout development, and the need to obtain robust usability data throughout development. Conversely, software development typically employs “Agile” or “sprint” development methodologies, where intentionally-rapid iteration cycles are used to refine and add functionality (Sy, 2007). The advent of MMAs and other software components that must be developed in conjunction with drug delivery devices has created a mismatch in these development timelines. Considering these challenges, there is a need for a human factors and usability testing tool that can overcome the barriers associated with in-person testing, while still providing usability inputs to support design development with confidence and rigor.

**Mobile devices as viable and familiar research tools**

Mobile devices, including smartphones and tablets, offer viable, readily-available tools for capturing in-context ethnography and product use. According to a 2015 study by the Pew Research Center, nearly two-thirds (64%) of Americans own a smartphone (Smith et al., 2015). The same study found that smartphone ownership and usage is widespread regardless of age, ethnicity, socioeconomic status, or geography. In addition to prevalence, smartphones offer a medium for unprecedented connectivity. Mobile device users are accustomed to sharing the details of their lives through the many outlets at their fingertips (photos, videos, social media, etc.). People regularly broadcast what they are eating, who they are

with, and what they are doing, all in context of their daily lives. Consumer product companies have taken advantage of this trend, and have begun to use remote usability techniques to study mobile application users in their natural context (Alharbi & Mayhew, 2015; Bastien, 2010; Burzacca & Pater-nò, 2013; Chalil Madathil & Greenstein, 2011; De Guzman, 2016; Rodriguez & Resnick, 2010). However, remote research techniques have not yet been employed in a systematic manner to study physical medical devices or their associated MMAs in a regulated environment.

**Remote research as an alternative to traditional methods**

This paper outlines a method for conducting remote research that provides unfiltered, in-context usability and behavioral data at a pace that supports the speed of Agile Development, without sacrificing the rigor historically associated with waterfall or phase-gate implementations. This approach utilized clinicians on the research team to better understand the complexity and nuance of managing a chronic disease, and the implications those factors have on developing a solution for the target patient population. In this paper, we will discuss the application of this method to study the use of a connected adherence solution in patients with cystic fibrosis (CF). This study offered a unique opportunity to test the hypothesis that remote research is a viable alternative to in-person research early in device development, as conducting traditional in-person ethnography in this population is particularly challenging. First, CF is a rare disease that affects only 30,000 individuals nationwide, making recruiting a geographically diverse sample of patients able to travel to an in-person study site very difficult and costly. Second, patients with CF are at high-risk for potentially fatal cross-infection if they interact in the same facility, or if bacteria from one patient is transferred to the home of another (Floto et al., 2016), creating the need to employ additional protocols to protect patients who participate. Third, therapy for CF involves a highly complex medication

regimen with different routes of administration and frequencies, nutrition management, and physical lung clearance techniques, all of which occur at varying times throughout a patient's daily routine. Finally, patients with CF are at constant risk of unpredictable disease exacerbation, which makes scheduling a specific date and time for facility research very challenging.

This study sought to determine if a remote research approach could address the limitations of traditional research techniques and produce more insightful results earlier in development. The research team hypothesized that: 1) users' comfort with using their smart phones to describe and capture their daily lives would result in an unfiltered view into their current practices, reaching more patients, more cost-effectively, in less time; 2) enabling patients to interact with the moderator, engineers, and clinicians over several days would produce more detailed ethnographic data; 3) the approach would allow the research team to define and test many elements of an MMA remotely early in development; 4) remote testing would enable keeping pace with the rapid "sprint" nature of Agile Development, and keep MMA development teams progressing; 5) having clinicians with relevant experience on the research team would provide unique insights that may have been missed by non-clinicians.

## METHODS

To test the above hypotheses, a three-phased approach was used: 1) understand users in context; 2) generate and test initial concepts; and 3) refine these concepts into a viable prototype intended to be tested in-person.

Recruitment for each phase targeted adults with CF who had busy lifestyles to understand the most complex use scenarios. The first phase of testing, understanding users and their use environments, recruited participants based on the following three criteria: 1) confirmed diagnosis of cystic fibrosis; 2) age 18-34; and 3) lifestyle described as one of the following at the time of study initiation: attended college full-time, worked full-time outside the home, worked from home either part-time or full-time due to their disease (not as a result of other factors, e.g. caring for children), or stayed at home and cared for at least one child under the age of six. Subsequent phases of testing, including concept development and concept refinement, utilized the same recruiting criteria stated above. The initial study helped researchers define this user population in terms of three useful personas for understanding patient mindset and behaviors based on locus of control and motivations for managing their disease. Subsequent studies helped to refine those personas and the associated user needs.

To understand users in context, the research team employed a proprietary remote ethnographic research tool to facilitate capturing various types of feedback. Participants were mailed an in-home study kit to support making "show and tell" videos and photos on their smart phones via a mobile research app. They were guided through a multi-day exploration of their use environment, daily routines, medication regimens, and administration practices. Researchers engaged pa-

tients through a secure, online portal to ask probing or clarifying follow-up questions.

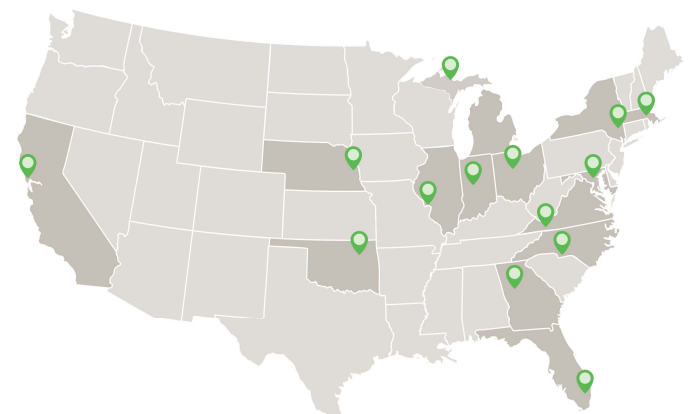
The second phase of testing was designed to generate and test initial MMA ideas and concepts. Researchers engaged the participants from the first study phase via a secure online study portal, conducting live one-hour interviews. Participants watched a short presentation describing how their medical devices would connect to an MMA and were shown sketches of what the app features might look like. The moderator probed on participants' reactions to the concepts, capturing the usefulness and value of potential features.

The third study phase focused on refining the MMA product concept and consisted of engaging all new participants during live one-hour interviews conducted via a secure online study portal. Participants were shown wire-frames of some key MMA screens, further refined from the second remote user study. The moderator guided participants through each app screen, probing for understanding, expectations, and areas of confusion.

Clinicians were present during each phase of testing for support in developing and refining the concept. Their role consisted of interpreting therapeutic regimens, interacting with participants to build trust and credibility, educating the research team on how various data is measured and presented to patients (e.g. lung function), and designing study language to clarify areas of patient confusion.

## RESULTS

The three studies described above were completed over the course of three months, which included recruitment, analysis, and report generation for each study. Patients were recruited from a national pool, rather than a regional pool, resulting in a diverse study sample that cut across several geographic regions and patient demographics (Figure 1).



**Figure 1: Recruitment geography.**

Participant location spanned fourteen U.S. states and ranged from metropolitan to rural regions. Many of these areas are not in proximity to in-person research facilities.

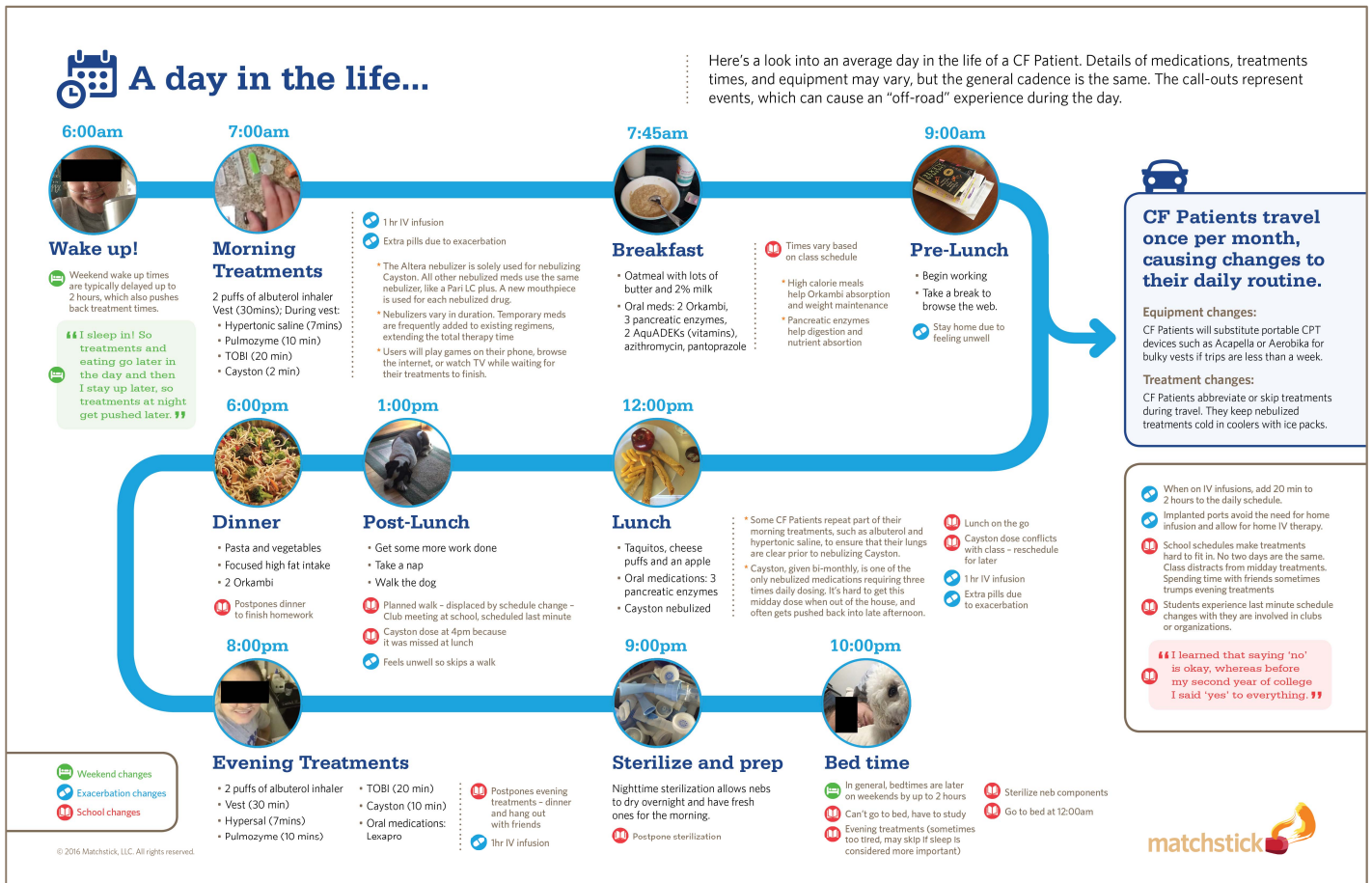
**Phase 1: Understand users, use environment, needs, and use scenarios**

The first phase of study was conducted completely asynchronously using the remote research platform mentioned above. Patients could complete their study materials on their own schedule over a two-week period. Flexibility was particularly critical in this patient population, as medication administration practices and schedules differed significantly between participants. For example, CF patients typically divide their treatments into segments by time of day and according to their meal schedules (e.g. some medications are taken in the morning and others must be taken with food). Similarly, patients may cycle through several antibiotic regimens, which can vary from monthly on-off periods to doses given three times a week. The remote research platform facilitated capturing these administrations, observing daily routines, and comparing practices across patients, enabling designers to organize the MMA to fit into their current practices (Figure 2).

The remote, asynchronous nature of the research technique produced several benefits. First, as expected, it eliminated any potential infection risk – no patient in the study

experienced an exacerbation of their disease due to participation. Second, it allowed the research team to gather numerous data types to better inform development by employing multiple research modalities simultaneously, including online bulletin board discussions, individual discussions between moderators and participants, shared video journals, photos, and projective exercises.

In addition, the nature of the study helped minimize several of the common biases of traditional in-person techniques. Rather than relying on memories of their experiences, participants provided first-person views of their lives through photos and videos. This not only provided rich, concrete, contextual data that was free from recollection bias, but the use of visuals compared to descriptions also minimized any potential self-censoring or observation bias. As a result, the research team could view the participants' use environment as they themselves see it, uncovering insights that would be difficult to capture using traditional methods. For example, patient photos and videos revealed unique patient practices around nebulizer use and shed light on the vast breadth of treatments CF patients are faced with (Figure 3). With internal clinician input on the implications of this treatment regimen and



**Figure 2: Patient journey maps**

Remote ethnography enabled the research team to capture the events that occurred during participants' daily lives, and make estimates for the broader patient population. This included treatments, meals, and deviations from typical routines that occurred because of infrequent events, such as at home IV infusions related to exacerbations. Differences among participants were also observed and noted.

knowledge of participants' comorbid conditions, the decision was made to design the MMA for the total disease burden compared to one medication, as originally intended. Contextual data generated by the platform combined with attitudinal and behavioral questions also enabled the research team to develop distinct user personas, providing a better ability to assess use environments, user needs, use steps associated with current therapy regimen, and identify potential use errors to design a system for facilitating medication adherence (Figure 4).

### **Phase 2: Generate ideas and test**

The second phase of the study utilized live, remote interviews with the same participants from Phase 1 to further probe and clarify their initial feedback. This phase introduced ideas for an adherence app solution, and enabled fast iteration of concept and overall system design. Low fidelity sketches enabled researchers to test potential concepts and have patients fill in the details of why they would use them. The results helped define which app and system features were most valuable to CF patients and which were valued least. In addition, it helped the team understand deviations from normal routine, what exacerbations look like, and how routines and medication regimens change during exacerbations and travel. This phase also enabled researchers to strengthen persona definitions and determine which personas would most want to use and benefit from the adherence system.

### **Phase 3: Refine product concept**

Phase 3 used live remote interviews with a fresh participant set to refine the adherence concept tested in Phase 2. The team tested a higher-fidelity, wire-frame version of the app and obtained system-level feedback on basic flows and functions of the concept. The team gauged understanding of basic flows and functions of features within the app, and clarified wording and visual representations of how data should be presented. This input resulted in the development team creating a minimum viable product (MVP) for testing in an in-person environment.

## **DISCUSSION**

This paper details a remote research approach used to capture in-context usability and behavioral data to inform the development of a connected medical device and MMA. The solution was designed for patients with CF, a vulnerable population whose complex disease makes participation in traditional in-person research studies largely infeasible. Compared to traditional approaches, the methods employed in this study allowed the research team to observe participants in their true use environments using multiple research modalities, while successfully completing the three studies securely, rapidly, and cost-effectively. Moreover, the flexible, comfortable, and participant-guided nature of the approach helped minimize biases common to in-person research, producing rich, first-person views of use environments and user practices.

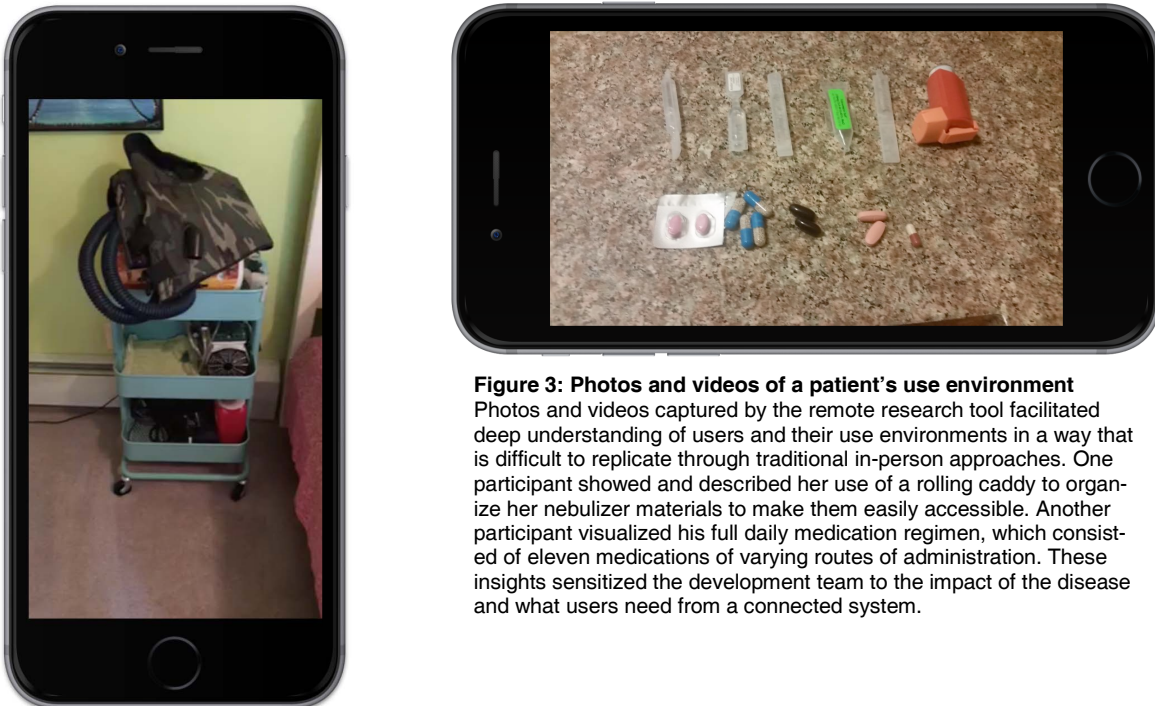
In addition to providing insightful data that is difficult to capture with traditional approaches, remote research helped to retire risk before development transitioned to in-person handling studies. In this study, the outputs of remote research were used to define and refine an MMA interface well in advance of traditional in-person user testing. The nimbleness of the remote approach also enabled the development team to capture feedback as patients provided it and rapidly iterate on the system's design features. Moreover, user feedback on the potential value of the suggested features and how they would use them enabled the design team to prioritize development efforts and refine the presentation for the next round of formative testing. When the research ultimately progressed to in-person handling studies, the development team had the context and necessary insight to refine the design features already defined through remote research. The result was a user-vetted, interactive, and clinically accurate working prototype.

Finally, this work sheds light on the value that clinicians bring to healthcare-related user research. In this study, clinicians on the research team informed the development team as to issues associated with the unique CF patient population and their therapies. They advised on how to present data regarding lung function, group medications for therapy sessions, and capture the variability attributed to nebulizer use, in a way that would make the most sense to patients. In addition, clinicians helped clarify areas of confusion for patients, where information presented did not fit with their mental models of how they handle their therapies.

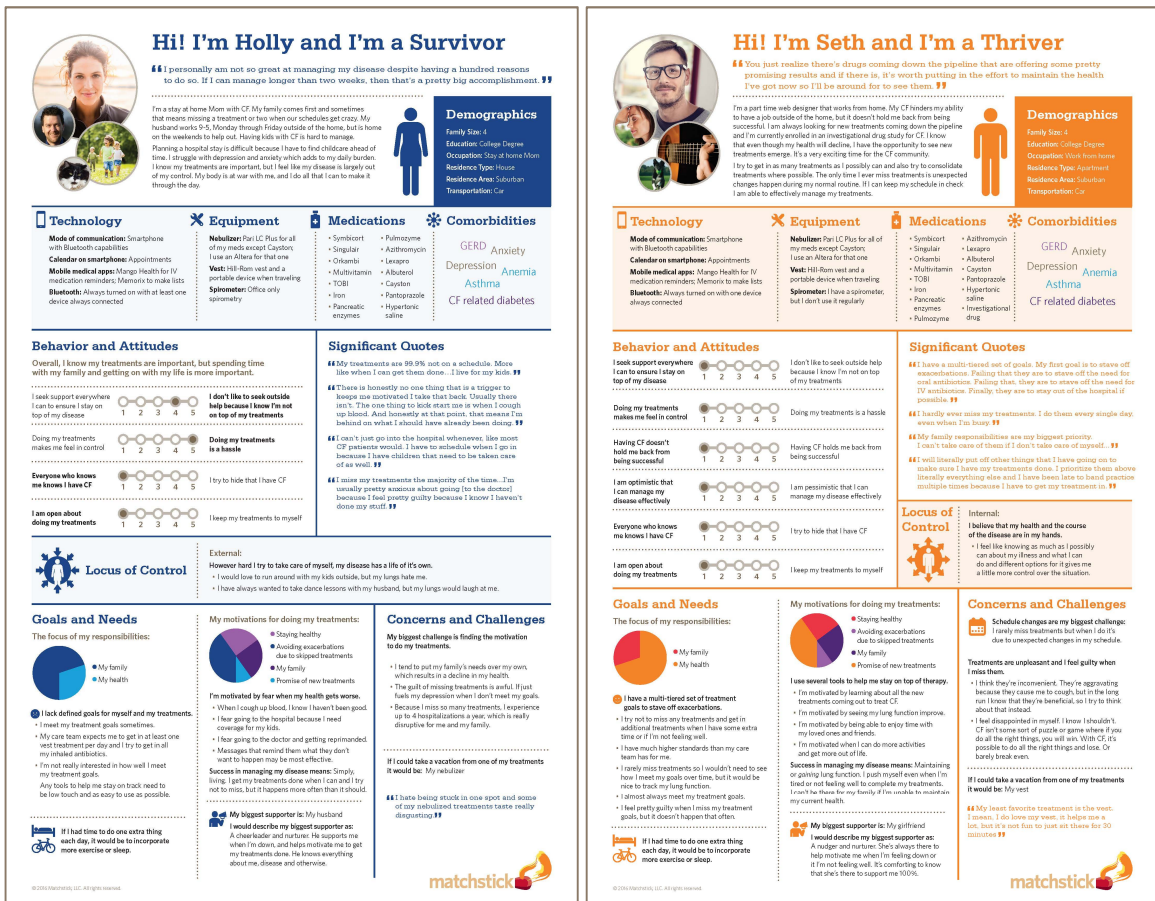
Despite this study's strengths, there are limitations to remote research that must be acknowledged. As evident in this study's time course, in-person handling studies are better-suited for testing more costly, higher-fidelity prototypes that require direct moderator guidance. Similarly, summative validation studies in which users complete pre-defined tasks require the controlled environment of in-person facilities. Still, the results of this study suggest that remote research can be used synergistically with in-person techniques to collect different types of human factors and usability data.

In conclusion, this study supports the notion that remote research offers a viable alternative to traditional in-person research methods during early concept development. Using the methodology employed in this study, the research team captured unfiltered views into participants' daily lives and rapid feedback of product concepts, resulting in a better understanding of the user, his/her use environment, and insightful design iterations of a connected adherence solution for patients with CF. The success of a remote research approach to study participants with this rare disease suggests that a similar methodology could be applied to other user populations.

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**Figure 3: Photos and videos of a patient's use environment**  
 Photos and videos captured by the remote research tool facilitated deep understanding of users and their use environments in a way that is difficult to replicate through traditional in-person approaches. One participant showed and described her use of a rolling caddy to organize her nebulizer materials to make them easily accessible. Another participant visualized his full daily medication regimen, which consisted of eleven medications of varying routes of administration. These insights sensitized the development team to the impact of the disease and what users need from a connected system.



**Figure 4: Patient personas**  
 The research team developed user personas based on behavior and internal motivation that helped define user needs and determine which patient types would benefit most from a connected adherence system. *Note: photos are stock photos, not actual patients.*

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