Tyler Kern 0:03
Welcome to the sunrise podcast powered by sunrise labs.

Hello, and welcome to making bright ideas work a podcast by sunrise labs. I'm your host today, Tyler Kern. Thank you so much for joining me for this episode. today's podcast is going to cover the topic of user centered design strategies for moving medical devices into the home and the pocket. And we're going to discuss why this is important what the term user centered approach means and what advantages this approach offers. Plus, we'll talk about what this means in the context of meeting FDA expectations. And I have two fantastic guests who are joining me for this conversation today. First and foremost, we have Alex Therrien. He is the director of user centered design at sunrise labs. Alex, thank you so much for joining me.

Alex Therrien 0:46
It's great to be here today, Tyler.

Tyler Kern 0:47
Absolutely. It's a it's fabulous to have you. And then also on the line, we have Kelly catelli. She is the principal Human Factors engineer for sunrise labs. Kelly, thank you for being here.

Kelly Catale 0:57
Well, thanks for having me. I'm excited to be here.

Tyler Kern 0:59
Well, I'm excited to get a chance to talk to you guys about this, because this is a really fascinating topic to me. And just as I've learned more about it, I've become more and more interested in the way that sunrise labs approaches this topic. So let's start off here. Why does this topic matter? Today?

Alex Therrien 1:14
It's been a long running trend for healthcare to be moving from the clinical spaces into more personal spaces like the home but it's it's been accelerating over the last, you know, call it 10 years on an exponential curve. And especially with the introduction of smartphones, it's actually moved into the pocket and onto the person. Kelly,

Tyler Kern 1:35
is there anything you want to add to to Alex's points, they're just on on why this topic is so relevant today.

Kelly Catale 1:40
FDA actually recently released some guidance and guidance to industry about providing the ability to expand capabilities for non invasive remote monitoring devices to help with bringing some of that technology into the home so that we can limit healthcare provider contact and potential exposure to COVID-19. So it is really prevalent in getting all the traction today, as opposed to previously even last year, that wasn't necessarily a driving force.

Tyler Kern 2:12
Hmm, absolutely. So we talked in the in the introduction that we were going to talk a little bit more about user centered approach. So can you define user centered approach? And what do you mean, when you use that term?

Alex Therrien 2:23
What it means is really trying to start from understanding needs of patients and needs of the end users as opposed to even starting with a technology or really a business strategy. If you can start from the standpoint of understanding where they're coming from as a patient or a user, you have empathy, you, you're able to start thinking in their shoes, you're going to actually be more successful at trying to

get them to understand what the value of your technology is, what the value is of your business strategy, and why it matters to them, and how it's going to help them to be successful in managing their health and possibly an ongoing chronic condition, we find that it's it's an important area to balance. As you know, the marketers and the strategic business people at our clients are really focused on where they can go next to be successful as a company, and our co workers in the technology space and what is possible. from a technology standpoint, this part helps to balance both of those major influences in the development of a product to make sure that it stays relevant, and it's likely to be adopted.

Kelly Catale 3:36
And in the past, technology has been the driving factor for projects. And it's important for us to keep in mind that our our frontier, our biggest frontier now is really surrounding the use of the product. Because we are getting to the point in our technology capabilities that we are refined enough that really the the biggest opportunities for improvement are the ways that our users interact with our products. So it's really important to consider that as what Alex was mentioning this, considering the patient and considering the end users of the products. At sunrise, we have a team of three disciplines. We have industrial designers who focus mainly on the hardware design and what you might consider to be sort of those, what do you call it, Alex, the concept sketches of the cool cars. I know in my mind, that's what I think of when you see car commercials and they have those sketches that look sleek and modern. That's what you could consider industrial design for cars. And there's that same level of care in the medical device realm as well. Then there's UX UI designers who work mainly in the software realm on designing screens and workflows and interaction models and strategy for interacting with the product. Then Human Factors engineering, which is mainly research based, and really characterizing the way that a user would interact and help shape the inputs to the design of the product. And our team really does a great job of coordinating and collaborating all three of these disciplines, which makes us unique in in our realm, because often you'll find houses that have one of these disciplines, and they're experts at one of them. And we can offer that collaborative approach that really brings the three into alignment and harmony, to create a user centered mindset to our design team, which includes all of the the mechanical engineers, electrical engineers, software engineers, as well, we bring that focus to the user, which is really key when we're talking about bringing technology into the home. And

Alex Therrien 5:52
I really liked the way that you you describe that, as I think about it, it's really around that tight integration model between the folks shaping the user experience of, of interfaces, you know, in the digital realm, and the hardware focused user experience in the industrial design realm. And really the the intelligence gathering and the user requirements, user needs definition from the Human Factors engineering side of our team. And when they all work together and have a strong cross functional understanding of each other. That's really where the magic of what the user centered team at sunrise brings to the table. And we're really excited about how we're, we're interoperating there, because it makes sure that all of those disciplines are considered as we're going through it's it's a holistic approach. It's a it's a thoughtful systems based approach ensures that there's a lot less gaps between these disciplines where things can kind of fall in and be less than the the great experience that we're trying to shape for our end users.

Tyler Kern 7:03
Excellent, excellent. Let's kind of talk me through the advantages and what you've seen when it comes to using the user centered approach.

Alex Therrien 7:11
Really, it comes down to two big buckets. For us. There's there's business success, by helping our clients to understand how to reach patients and improve patient adoption and patient adherence. If we can help patients be successful with managing their healthcare and defined health improvements, through the use of design, patient experience, and through, you know, being more user centered and

understanding their experiences, we're going to be helping the patients and be successful, which in turn helps the payers to justify why this new therapy might be out there. The other part is the regulatory success, the FDA has some pretty specific expectations about how we're managing patient risk or user risk with the medical devices that we produce. And if we're not understanding the context of use, if we're not really invested in trying to help improve those areas where we're risk might occur from the misuse of a device from the misunderstanding of the device, we're not going to be successful. And as people move into this new accelerated frontier of personalized medicine, there's a lot of opportunity, because there's a lot less control of those personal health spaces.

Kelly Catale 8:29
So Alex, you mentioned business success. And I think this is really critical for any product, what we see the success as is patient adherence. And its adherence to using the product in the way that you expect it to be used as a medical device developer. And our job as device developers is to introduce or maybe modify a behavior in a patient's existing lifestyle, they live a certain way, they have certain patterns and routines. And this new product might be a disruption in some way. And if your patients don't stick with their therapy, then they won't have the outcome that they desire, and that you desire as the developer. And if they aren't having that that improved health outcome, then payers don't want to reimburse for your product because they see it as ineffective. And that's really a critical systems level of thinking for the whole the holistic problem that you're trying to solve, right. So we're not just thinking about, let's shove this product into a patient's face and tell them they need to use it and it's going to make their life better. Because if it doesn't meet them where they are, then it's effectively a brick that they can't use. So we see it as this this entire approach to be critical for business success, because at the end of the day, you want people to be delighted by the use of your product and Want to keep coming back to use it, especially when you're talking about improving medical conditions that ultimately improve the well being of your patient?

Alex Therrien 10:09
I love that you talked about that rational kind of way of thinking about it, if if I'm showing you that this is good for you, why aren't you just taking it? And that's actually a kind of an interesting transition for us to kind of think about empathy. You know, if we talk about, you know, business success, there's, there's really three areas of what helps us get there, you know, one is empathy. And it's making sure that we have the patient in mind, we've kind of touched on that already. systems thinking is, is the next part starting to think about the whole continuum of the way healthcare is being delivered? And, you know, its influences on adoption, and, you know, patients and success? And really, is it designed? Well, you know, if it's not well executed, the patient who adopts it is going to end up ejecting out because they're frustrated by the experience, it's not helping them to get there. You know, it's these three pillars within, you know, business success that we try and focus on as a cross functional team to make sure that, you know, from a human factors engineering standpoint, we're getting the best understanding of the patient journey, and the best understanding of how the users and healthcare practitioners are operating in the space, to build that understanding that empathy. And then to draw that out into a fuller picture of the system's thinking about how all these components of the overall health care system, everything from, you know, the immediate focus of the patient, all the way out to you know, how is how is this coming through into the pharmacy? How is this coming through the doctor's office? How is this getting to the end patient so that we can make sure that we're eliminating friction within the system, and then executing it well, and all aspects of the team, the designers that the human factors, researchers are all critical, each step of these these three parts of the process?

Tyler Kern 12:02
What types of tools and methods do you use to ensure that you are successfully grasping exactly the point of view that a consumer is going to have once they utilize the product? Does that make sense? How can you fully get inside the the mind and the behaviors of a particular individual to ensure that this really does kind of fit that that model that you've held up for patient adherence? Does that make sense?

Kelly Catale 12:28
Definitely one of the key tools that we use for learning more about our patients, and their lifestyle is actually what we call primary research. And it includes interviews, and potentially observations, so we would interview our end users. So we might go and work with a research house to recruit a set of patients who have the condition or who are representative users of the product that we're hoping to develop. And we'll sit down and talk with them, we'll ask them, what, what do you do normally, during the day, what is your life? Like? What products do you already use? What's your familiarity with mobile devices? How comfortable are you with them? There's all kinds of questions we can ask to really get our sense of how can we meet them where they are? Where, where are they? Where do we have to meet them. And the key is to really understand, okay, we're working with, especially when we're talking about bringing medical device technology into the home, we're working with people who might not have the same level of education or training as a user in the clinical environment, who has really specific training for using a certain product or understanding the science behind it, or the physiology in the treatment. We will also do research, through literature searches and other ways, maybe conferences or whatnot to understand our users and the condition that we're hoping to address. So there might be comorbidities or parallel symptoms with patients who have certain diseases that are typically common. And so we need to make sure that no, say we're talking about MS patients, then multiple sclerosis, that is, there is typically associated mental cognitive issues where it might be harder to think through higher level decision making processes. And so we don't want to put something in front of a user who has a mess that requires them to make really complex decisions, because then we're introducing a potential point of failure. So we use I would say primary research, to interview and maybe observe people using existing products on Understand any workarounds they might have, or any feedback they might have on things that they already currently use. And then we might use research in more of a literature search way to understand the disease state or condition more fully, so that we can grasp what limitations or abilities we will have to meet when we design the product.

Alex Therrien 15:24
And I'd like to add into that, because I think so much of what Kelly's talking about is this immersion process is trying to learn about how the patients that we're trying to serve or the end users that we're trying to help, how they view the world and what their, what their realities are, like, we can't see the world through their eyes, it's their unique individuals, but we can try and learn from them about how they see how they see things. And it's, it's funny how the small things are really important. So as you as you're building empathy, type two diabetes is a space that I've worked in for a little bit. And, you know, if you think about it, there's a lot of pressure and shame that can be applied to people who are in that, that, you know, a chronic condition, you know, where healthcare practitioners doing their best to try and intervene, may have used, you know, carrot and stick threat and, and, you know, and SUV kind of approaches to trying to get people to adopt new exercise or diet regimes that may help to delay or avoid the onset of such a chronic condition. But it doesn't always work. And if you think about it, you know, constantly being reminded of your your health condition, every time you do a basic lifelong activity like eating, that's got to take a lot out of you on a daily basis. Yeah, having to manage, you know, every time you need to sit down. And at a point in your life, where you want to be relating to people, you know, a meal is sort of a common communal event where you get to, you know, engage with people, it's typically a distressing kind of environment, you're having to think about, like, I have to take a blood glucose reading, I have to time my insulin delivery for when my food arrives, so that I have the uptake of my medication at the right time. All of that is just forcing them to be, you know, if I was to use, you know, Alex, as a person versus Alex, as a, you know, or a diabetes patient named Alex, those are two very different ways of looking at the world. And one has me probably getting emotional reserves edit back end, because I'm a person who is just active in the world, they have, you know, communal relationships. The other one is I'm constantly being reminded my health condition. And it's sapping my resolve and weakens whatever emotional reserves, I have to be successful adapting to behaviors. Really, patients want to feel like a person, they don't want to be defined by their health condition. And, you know, anything that we can do to help support that is really what is going to lead us to be successful.

Tyler Kern 18:08
When you take these these various data points that you guys have pointed out that you use that you combine, when you're you're using and utilizing the user centered approach. It really also drives home the need for those three areas like what you talked about when it came to industrial designers, UX UI designers, and then human factor engineers just to be able to take all of those data points and put them together into something that that makes sense for the user and really fits what their needs are.

Kelly Catale 18:35
And I want to piggyback on something that we've mentioned a couple times. So we use the phrase device and we say the system. And I think there is an important distinction that needs to be made, which is the system, a lot of people think, oh, the system is the product, right? So we have you know, if we're talking about a monitoring device, then you might have some subsystems, some, you know, software, maybe some hardware, electrical components, and the interface, maybe it's a touchscreen or whatnot. And then people say that's the system. And when we take a user centered approach, we actually have to consider everything that the user interacts with. And this is another piece of that systems thinking, which every piece of the user interacts with, also includes potential packaging. So if the product comes in a package, what can a labeling are you putting on it? How is it conveying the intent of the product? Does it come with instructions? Does it come with training? That's a really, really important piece when it comes to designing a product for home use. We mentioned earlier about how users of medical products historically have had significant training, you know, doctors nurses, they're well prepared to administer treatment to monitor patients. conditions and understand what the data that's coming out of the product is actually telling them. Now, when we bring products into the home, we really have to understand that lay people, as we call them lay people, there are people who could have training, they might not have training, they might have a degree, a college degree, they might have only fit, or you might have finished sixth grade, right? We don't know. And we have to meet them at whatever level of education and background that they have. And training can be a really important part of the system as a whole that can make or break a product. And we've seen that there have been some really creative ways to design training, we've seen online training is a really big trend now where you might offer a video to help your users understand your product, and use it effectively alongside the video, you might have training embedded within your system. Or you might even offer some augmented reality, that can actually help deliver training through maybe a smartphone, if you already have a product in your hands that you use every day, why not integrate some way to offer a more realistic experience with interacting with the product. And I know that that's something that's an a frontier that is really waiting to be explored a bit more. And we see this as you know, learning opportunities are really important for interacting with the product, and the system as a whole. So taking that systems level approach does consider all of those components that impact the use of the product, I think it's important to keep that in mind. Because oftentimes, there's this heavy, heavy focus on let's you know, characterize risk for using the system and what can go wrong. But often the training comes at the end, right? It's, it's a Oh, no, we need to develop, you know, some sort of plan for training or some instructions for using it because we need to prove that we have instructions, right, it's usually an expectation that you'll have something to inform your users. So we keep that in mind. Throughout the the product development process as well,

Alex Therrien 22:18
technology and mechanisms and software are so much more predictable. It isn't to say that they're they aren't complicated on their own, but they're they're predictable, in a lot of ways and the human beings, you know, there there is an approach that people will figure is rational. And then there's a lot of times what you'll see out there in the marketplace, what goes on with, with the use of medical devices, and it's completely unpredictable. So when you get down to training, it can be often confusing and baffling to some of our counterparts that it's it's easier to focus on the knowns. And right, we really do believe that there's such an opportunity for our clients to have better outcomes related to training and related to, you know, the intent if if they're able to bring that into the product. And you know, as Kelly was suggesting, there's some great opportunities for starting to embed that into the into the interface in the way that you've made it core to the product. You know, augmented reality is an element of a

system, there's great ways to simulate the experience of a product safely. And with the kind of coaching that a device medical device developer would want to have their patients go through, and you can kind of curate the way that they're learning. And it follows good adult learning principles, you know, that that kind of experiential learning where you can play an experiment and, you know, have sort of a safe sandbox in which to do it. You know, we're very big advocates for thinking non traditionally about, you know, how and if instructions for use is presented. I'm sorry, I almost went three letter acronym there. And, you know, the the ability to think about training in a more predictable fashion

Tyler Kern 24:04
in that initial question, when we talked about the advantages that that user centered design approach offered, you mentioned business success to patient adherence, but also regulatory success through meeting FDA expectations. So let's talk through that FDA aspect as well. So what does it mean to take a user centered approach to meeting FDA expectations?

Kelly Catale 24:24
So from a regulatory standpoint, we consider FDA and any other regulatory body that our clients are going to meet, seeking approval from as the first customer. So we consider them to be the first line of the interaction within your product and they may now be using it for actual treatment or monitoring that they need to understand just as any of your future customers are actually using your product, how the product is used and what the intent of your system is. Is it safe and effective? That's the real key question that gets asked when you're seeking approval. And from our eyes, taking a user centered approach means having a strategy that really addresses your users and anticipates the project and also product risks that you will be facing when using the product or that the end users will be facing.

Alex Therrien 25:25
I love where you started there. That's it's it's a really great point that they're our first client and our customer, I should say. And it's funny, because if you think about it, from a big picture standpoint, we've we've talked a bit about this the success in the court of the business successes, are the patient's going to be seeing an improvement in their health care condition, like are they going to be able to notice that that's something we all want? Are the payers going to be able to measure that? Is it just a 1% improvement in the overall population health that they monitor, and, you know, try and manage financially against that? Or is it you know, 10 2030 40% improvement in the overall population health, a dramatically successful product is what all of those influencers on the successful medical device want to see out of what is being brought to market. If you think about it, the FDA is asking a lot of the same questions, they just have to anchor it in in safe and effective use, they want to see a lot of the things that they asked us to do or just good design practice. Think about the context of use, think about and get to know it, don't just treat it generically really embed and build the empathy of what the patient experiences so that you can anticipate how there might be a problem. Just thinking of a user population as a single monolithic group, as opposed to a variety of people with a variety of education, a variety of economic circumstances, a variety of cultural influences, all of those things matter. And it's going to help you to speak intelligently about where risk lives within your system, and lead the conversation with the agency. So they can see that you have really done the time to get to know where your products going to be used, anticipated that in the design of it and mitigated the risk from a use related circumstance. A good point on this is I've worked on peritoneal dialysis devices in my past, which is a fancy way of saying you know, a bionic kidney that you use at home. And you work on this, it's it's, you know, a pump that delivers fluid into the body, it's warmed. And you think about the risks associated with that it by hitting the right button, and by hitting the right numbers to enter this to run my therapy, am I hooking everything up correctly? Right? Am I keeping hygiene, right? Who would have thought that you have to worry about a cat? Yeah, if it's a warm, soft, fluid bag sitting on top of the heater bed, it turns out, you know, by looking into what's going on over years of use of this product in the home, your pets like to go and fall asleep on something warm and soft like that, and it can create a risk of infection, it can create a risk of damage to the dialysis bag. You know, there's there's a lot of issues that could come out of that. And that's not something that you're going to find out just

from going well, it's a high school educated, you know, General person who does, you know, these kinds of things with the device, and it's in a somewhat well lit home, you know, the basics of what you could understand about where that's going on, you have to spend some time there to figure out cat damage and is, you know, a high risk item? Actually, it turns out it is is that a high frequency? Well, a lot of people in the United States at least own pets. Sure, you know, and these are, these are considerations that you know, have surprised me at different points in my career, but they certainly are irrelevant, and they matter. And I you know, I share that one just to be silly, but you know, there's a lot more depth in there than a lot of a lot of people can assume.

Kelly Catale 29:08
And to take it back to your original question. Tyler, asking about a user centered approach from meeting FDA expectations. You know, we we believe that just as any product needs to meet the user where they are, every project has their own has its own trajectory as well and has its own level of investment and effort into human factors engineering. And we mentioned the three disciplines to our user centered design team, when it comes to regulatory documentation and proof of safe and effective use the Human Factors engineering side as is really the most prevalent from that end for providing evidence. And we have seen that not every project needs this This full blown Human Factors engineering effort. And so taking an approach of understanding, where would we advise our clients to focus their effort? How do we develop a strategy that is clear and allows the freedom to to innovate, while also making sure that you're you're creating a system that is safe and effective for your end users? And so we've actually seen several projects where the role was to our role was to advise on what kind of changes if you have a system already on the market, and you want to have a generation to have your system? Okay, well, what can you change, without triggering the need for a significant body of work or body of evidence to prove that all those changes from a human factor standpoint, don't impact the safety and effectiveness of use. So we've had some, you know, great discussions with FDA on defining a plan and a strategy to make sure that the approach from a human factor standpoint is robust and comprehensive enough, while also allowing the freedom to focus budget and, and really energy from the development teams standpoint, in the areas that matter most,

Alex Therrien 31:18
it really does help when you have that that kind of upfront strategy and plan that you've developed in partnership with, with our clients, that we can make the process quite a bit more predictable, in terms of where we're focused, where we we have to tailor our efforts and where we invest the most. And, you know, Kelly is spot on with, you know, being strategic with the application of human factors, you know, some of our clients don't really understand that you don't have to do a full blown Human Factors evaluation with research with end users, if you skill, the product such that you're not changing the interface in a way that is going to impact the safe and effective use of it, you can eliminate that scope from the project, as opposed to, you know, advice on how to design the product better to make sure that you're not triggering, you know, risk in in the execution of it.

Tyler Kern 32:15
Absolutely. And is that is there an element of this of the FDA approval process, where you know, as you strive to meet their expectations, that there is a clear story that you're trying to tell about the product where you can show, hey, this is what it is, this is how it works. And that sort of thing is storytelling kind of part of this,

Kelly Catale 32:35
it's arguably one of the most important parts of the human factors engineering effort, or project. The final report that you submit to FDA that contains all of your evidence throughout the the Human Factors engineering program is intended to be a effectively a story of how your product progresses, throughout its its development lifetime, if you will. So the storytelling aspect is it's kind of funny, I think of it as you know, okay, we as human factors, engineers, need to help advise and help drive clear and effective user interfaces. So the design of the product, and then we have to use those same exact skills to help develop a clear and effective story to tell to the FDA. So we're using a lot of those, you

know, parallel skills in our storytelling abilities to deliver a report, that helps me clear that, yes, the design has progressed, it has evolved in a way that shows that we've, we've learned, we understand our users, we've gathered feedback, and we've made really well informed decisions that help eliminate risk, or mitigate risk as much as we can. And with FDA being a very risk driven organization, they want that proof, right? They they want to know, do you understand all of the context of use? And have you addressed it in a way that you feel confident is is actually going to solve the problems that you see? And we've actually found from a storytelling perspective that the most realistic stories are the ones that make FDA feel most confident. So we've seen clients really sort of cringe at the thought of putting things in their their report that admit to initial weaknesses in the product, right. So okay, we designed to this first iteration of the product. And we went in and showed it to users and holy moly, it failed hard, and we had so many users in our testing, and it was a disaster. And then when you go to put your report together at the end, and naturally you found these fine you've addressed them, right? I mean, you've, you've addressed them. And realistically, you've gone back and actually tested it to show that you've, you have actually solved whatever problems you've observed. And then it's better. Right? You have to show that that progression.

Alex Therrien 35:15
And you know, it creates a sense of believability to it too, right. You know, if I showed up tomorrow, and I said, Today, I got up, and for the first time ever, I ran a marathon with no training and oh, man, I was amazing. I came in at like, 30 I think tomorrow, I'm gonna cut another, you know, 20 minutes off my time. It's gonna be amazing. Sure, you might kind of be a little skeptical. Great. Versus, man. I thought I was gonna get up today and run 20 miles I got, you know, like, half a mile and man, I was winded, I, it's hot. I was having trouble. Like, I got a lot of training ahead of me. Those are two very different, different stories with different levels of believability.

Tyler Kern 35:55
100% 100%. No, that is absolutely true. That is absolutely true. Well, Alex and Kelly, thank you so much for joining me today here on the podcast and explaining so much about the user centered design strategy for moving medical devices into the home and the pocket. I think this has been incredibly informative and giving people a really good framework with which to understand you know, how you utilize the user, the user centered approach, and what that looks like in practice and how that works also with meeting FDA expectations, and so I think you guys have done an incredible job explaining this today.

Kelly Catale 36:29
Thank you very much.

Tyler Kern 36:30
Absolutely. Absolutely. And everybody, thank you so much for tuning into this episode of making bright ideas work, a podcast by sunrise labs. We appreciate you listening very much. Of course, if you enjoyed what you heard today, make sure you go subscribe on Apple podcasts or Spotify, and you'll be able to listen to previous episodes of the show as well as get the latest episode downloaded directly there on your device. And you'll stay up to date with everything going on with sunrise labs. As I mentioned before, we'll be back soon with more episodes. But until then, I've been your host today Tyler Kern. Thanks for listening