Patient Centricity In Clinical Trials

Tools to Connect and Engage

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About this Ebook

Patient centricity has become a popular buzzword in the clinical trial industry. With most clinical trials falling short of their goals, there is clearly room for significant fresh ideas, and applying patient centricity is a good one.

Patients have always been the key to studies, but the established model of bringing the patient into the process after the protocol has been written and all plans are in place is no longer sufficient. Patient centricity involves the patient playing a direct active role from the beginning, that is, protocol design.

> In this ebook, you will learn more about patient centricity, including how patient-centric tools are being applied in the clinical trial industry and what we can expect in the future.

The bottom line is this: A patient-centric focus will improve patient recruitment and engagement, reduce expenses, and potentially bring your product to market more quickly.

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Chapter 1

What Does Patient Centricity Really Mean?

> Patient centricity is officially defined as the process of designing a service or solution around the patient.

Sounds simple enough, right? For those of us in the clinical research space, it's not always as simple as it would seem. The cultural mindset has to realign with the end user in mind. In this case, the end user is the study participant.

Oftentimes we try to put ourselves in someone else's shoes, but frankly, until you've walked in those specific shoes, it's little more than educated speculation. The individuals we want to participate in our trials are all around us. All we have to do is create a forum to get direct feedback on:

- What would motivate them to participate in a trial
- What would prevent them from participating
- If interested in participating, what expectations they have

You don't have to ask your target audience every time for each new trial, but you do have to start asking often enough to allow you to build a solid, reliable foundation that will help you execute patient centricity with precision.

Every individual, company, and association in the clinical trial industry is already patient centric. The difference is the degree to which they implement activities to support the end game. The end game is bringing medications to market faster and doing this by creating or supporting studies validated by direct feedback from the end user. In this instance, the end user is the study participant.

We can remove the guesswork from the equation by engaging potential participants from the beginning and listening to what they have to say.

None of this focus on patient centricity is meant to downgrade the value of your own expertise in clinical trials. Our knowledge and experience is significant. Just let me add that it is easy (and sometimes tempting) to listen with a biased ear and selectively hear only what confirms our expectations or fits in with our plans. That can be intentional or unintentional. The art of listening includes keeping an open mind. The patient is a valuable resource. The business adage is true: feedback is a gift.

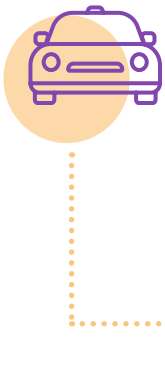
Chapter 2

Focus Groups for Protocol Design

Pharmaceutical, biotech, medical device, and private medical facilities have been conducting clinical trials for decades, and over the years, the "bar" for medical advancement has risen quickly.

The quest to advance medical intervention brings with it many challenges. One such challenge is to find individuals who meet protocol criteria. More importantly, the question should be asked: Is the study designed with that individual in mind?

With the current focus on patient centricity, coupled with technological advancements, it appears that engaging an individual to participate in a trial and maintain participation has been made the patient's responsibility. What can we do to make studies more attractive to those patients?



As an industry, we find ourselves in an evolution of how we design trials to gain interest and participation. In my experience, I see companies focusing on many end aspects of the study to provide support to study participants, such as stipend payments, transportation assistance, and other support items. These are important examples. But often these services are offered after study enrollment has started, limiting their ability to make a material impact, which can lead to longer term implications.

Conversely, I have had the honor of working with companies that are allowing enough time during the protocol design phase to utilize direct feedback, including focus groups and social listening. I will discuss social listening more in the next chapter.

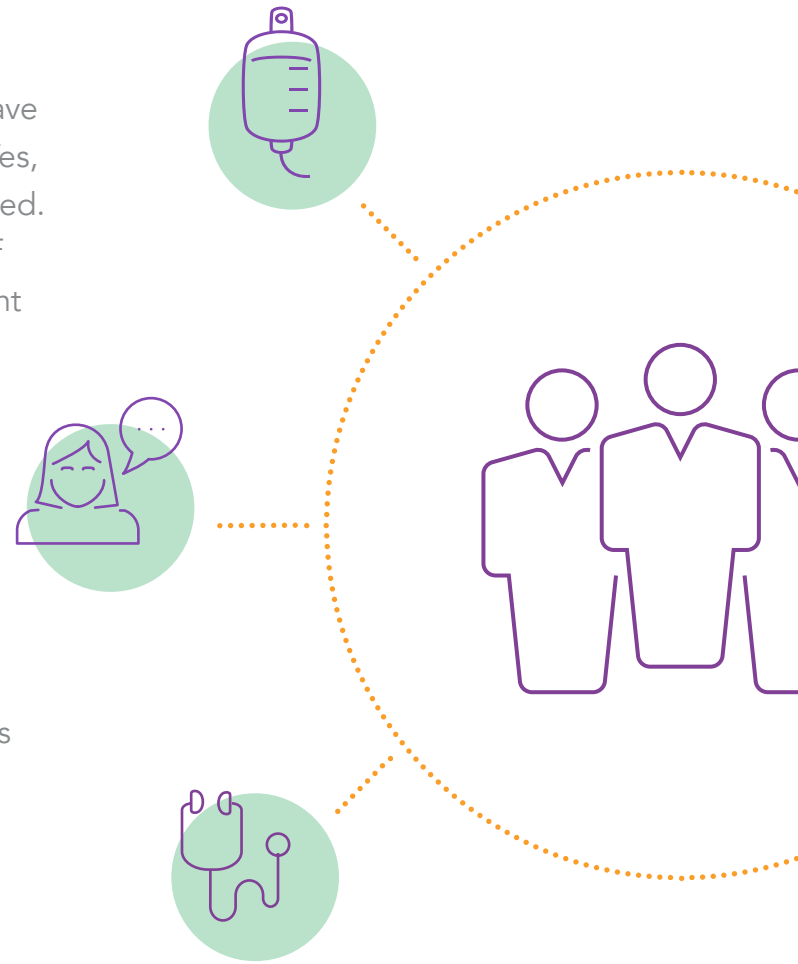
Focus groups have long been used by marketers and politicians. The informal, guided panel discussion among customers (or potential customers) and voters can be a cost-effective means of gathering information.

In clinical trials, focus groups and social listening can be used to gain direct insight about how a target audience views trials, including:

- The design of the trial
- What is attractive about participating
- What is holding them back from participating
- The level of support and guidance they expect upon participating
- How a study can fit in with their lifestyle

> **Conducting this level of upfront inquiry can shave months off of enrollment.**

You're probably saying to yourself, "I don't have enough time to build in this upfront work!" Yes, you are busy and likely very often overwhelmed. But just imagine: if you built in two months of upfront work, you could reduce the enrollment timeline. For example, in the "what is holding them back" question in the bullet points above, your focus group might tell you there are too many blood draws, or that the number of study clinic visits over a given period of time will force them to miss too much work. Modifying the protocol to accommodate such concerns can make the study more attractive to potential participants and lead to more of them willing to enroll.



Do you need to hire a marketing company or a focus group practitioner to recruit your focus group and facilitate the event? No, though it can make things easier. (Richard Krueger of the University of Minnesota put together a good online resource for conducting focus groups. You can find it here: *http://www.eiu.edu/ihec/Krueger-FocusGroupInterviews.pdf*).

If you hire an outside company or a professional to moderate your focus group, you will need to set aside time to bring them up to speed on the study and what you want to learn. The moderator role is a critical one. Remember, that person's role is to ask questions and gently lead the discussion to gain useful information. He or she is not there to promote the company or the study, and must remain neutral.

When conducted and analyzed effectively, focus group information gives you the right formula for writing the protocol and supporting the study sites, which can save you significant enrollment time and dollars. Who wouldn't want that?

Chapter 3

Social Listening

Getting feedback from potential clinical trial participants has long been part of research programs undertaken in our industry. The typical modus operandi, as covered in the previous chapter, is to seek out the information from a particular group of people through such means as focus groups. These methods are effective and should be used. But as our industry embraces the true sense of patient centricity, we are expanding the methods we use to gain direct feedback.

Next time you're getting ready to develop a protocol or seek input on an enrollment support plan, an excellent channel for direct feedback is social listening. It uses existing and readily accessible technology to our benefit.

> **Social listening is the strategic monitoring and tracking of conversations on social media, blogs, message boards, and consumer review sites around the globe.**

This quiet listening technique allows us to experience the raw voice and opinion of the target audience firsthand. It's a superb and direct way to learn such things as:

- How members of our target group truly feel about their disease
- What they are willing to do to seek treatment that improves their health
- The questions they are asking about trials and what information they are looking for

Social listening doesn't require a lot of time, plus it can actually speed up our research and remove much of the bias. But it does require an internet/social media savvy person to find the right sources and implement a strategy that will gather the data and put it to use.

> **The social listening tool doesn't end after the protocol is finished and patients have been recruited. Once your trial is up and running, you can monitor activity of participants for feedback regarding their opinions about how they are doing in the trial and how their study visits are going.**

Facebook presently has 2.2 billion active users. Twitter has 330 million. The online group is a massive one, though it is not useful for all studies. The elderly, or for example, those with cognitive impairment, are less likely to be talking online. However, these are good examples of social listening opportunities to get information from caregivers, who are a critical element of many clinical studies.

If you find yourself concerned that social listening is an invasive form of snooping, I understand. But keep in mind that I am not advocating hacking into Facebook or Twitter accounts or posing as someone you aren't to gain trust and information. The people who use these sites set the levels of privacy they desire and are comfortable with. Your social listening purpose, which is to help them, is a sound one.

So log on to the internet and harness the power of social media. People are talking! The wise clinical trial professional invests in taking time to listen.

Chapter 4

Keep Patients Engaged: Is There an App for That?

With patient attrition rates in clinical trials on the rise, retention strategies and tools must be constantly refreshed, refined, and even reinvented. Truly patient-centric approaches to aid retention are called for. How about a tool that puts the study right in the patient's hands – specifically, on their phone?

For an international Alzheimer's disease study, we were challenged to facilitate engagement and support for study participants as well as their caregivers. Working with the sponsor, we decided to create a convenient and robust study app with pertinent study information and much more. The goal: keep the patient and caregivers engaged, connected, and in compliance.

App features included:

- Quick and easy access to pertinent study information
- Visit reminders customized per patient and per visit with time, date, and location as well as procedures and how to prepare for the visit
- Alzheimer's disease information
- Healthy living tips
- Push notifications integrated with the patient's smartphone calendar
- One-touch site contact
- Stipend payments

Since this was an Alzheimer's study, more emphasis was given toward the caregivers, who were closely involved with the study and required to accompany the patients to their visits. Caregivers were 40-50 years of age with a higher level of use and understanding about smartphone applications than the patients.

The app and corresponding website were rolled out in local languages to sites in more than 25 countries. Patients and caregivers clearly appreciated this tool, and it was an immediate success. **Utilization quickly reached 60 percent**, and the **retention rate reached 78 percent**, well above the sponsor's goal of 70 percent.

Newzoo's 2017 Global Market Report lists the top 50 countries by population owning a smartphone. United Arab Emirates is number one at 80.6 percent. United States is seventh at 69.3 percent, and the United Kingdom at 68.6 percent. Fiftieth on the list is Bangladesh at 5.2 percent. As you can see in the case of Bangladesh this is a tool that will not work everywhere, and of course, patients and caregivers were not required to have or use smartphones for this study. For that population, traditional tools were developed, such as printed materials, to provide the information they needed.

As clinical studies are moving toward a full patient centricity experience, including virtual studies (topic of the next chapter), utilizing a study app is a great step in the right direction of bringing this experience to the forefront.

> Clinical study apps are an excellent tool, one welcomed by participants, to help increase patient engagement and compliance.

Chapter 5

Virtual Clinical Studies

Over the last several decades, the clinical research industry has been faced with the challenge of meeting enrollment goals on time. Eighty percent of trials fall short of their goals. Moreover, the industry is further challenged with maintaining trial participation by patients once they are enrolled. Attrition rates average about 40 percent.

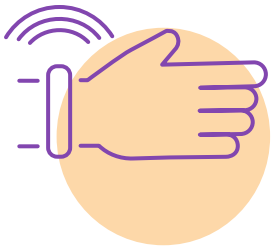
There are many reasons why our industry struggles with these metrics. At the top of the list are study design, patient burden, and accessibility. What is the answer to mitigate these challenges? Virtual clinical studies.

As we move through the 21st century, technological advances, such as wearable sensors to collect data through a mobile device and transmit it to sites in real time, allow us to bring the trial to a patient. Patients communicate with study staff members remotely, and receive their study drugs and supplies through the mail. The patient may now have the opportunity to participate from home versus coming to the trial, or in this case, the research center.

This is more than a convenience. It lessens the geographic challenges of studies by allowing participation of patients who live in rural areas or far from study sites, or are homebound or less mobile, such as the elderly. The patient pool just got bigger.

Companies like Pfizer (REMOTE 2011 study in patients with overactive bladder) and Sanofi (VERKKO 2015 study in diabetic patients) have blazed the trail by being among the first pharma companies to execute virtual clinical trials.

There are still scenarios that have to be calculated into the study design to mitigate enrollment challenges. From Pfizer's REMOTE trial, we learned that one challenge is the lack of trust among an older, less tech-familiar population that has to provide informed consent through an app.



Conversely, we've seen good results from some virtual trials that focus on the use of a device (like the wireless glucose meter in the VERKKO study) versus evaluating medication impact, which was the focus of the REMOTE study.

> **Virtual clinical studies may be best used as a complement to traditional clinical studies, since not all study designs will be conducive to the virtual clinical trials.**

For example, studies that require a doctor or nurse to conduct exams, or direct monitoring in the hospital or repeated MRIs, will likely never have a virtual option.

This is an area still in its infancy, but it is growing. While the silver bullet to overcome challenges in patient enrollment and engagement still doesn't exist, there are exciting opportunities and a definite future for virtual clinical studies.

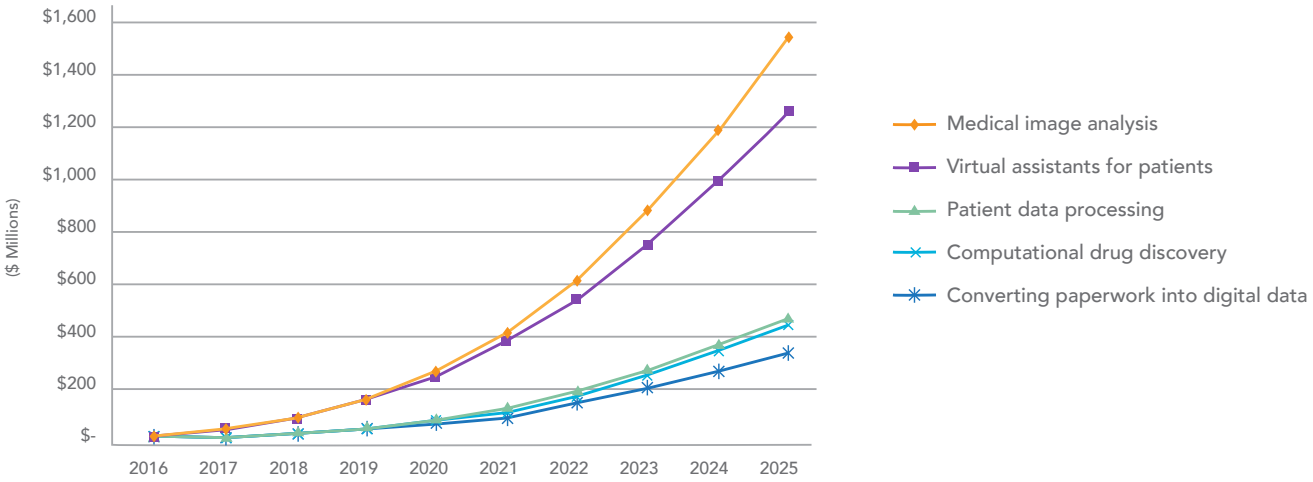
Chapter 6

Peering into the Future: The Role of Artificial Intelligence

Technology is developing at breakneck speed, and machines are becoming smarter and cleverer. Artificial intelligence (AI), machines that can learn and reason on their own, is sweeping across almost all industries and is creating new ones. AI is here to stay.

The market intelligence firm Tractica predicts health care revenue from AI will reach $19.3 billion worldwide by 2025.

Top Five Healthcare Artificial Intelligence Use Cases Revenue, World Markets: 2016-2025



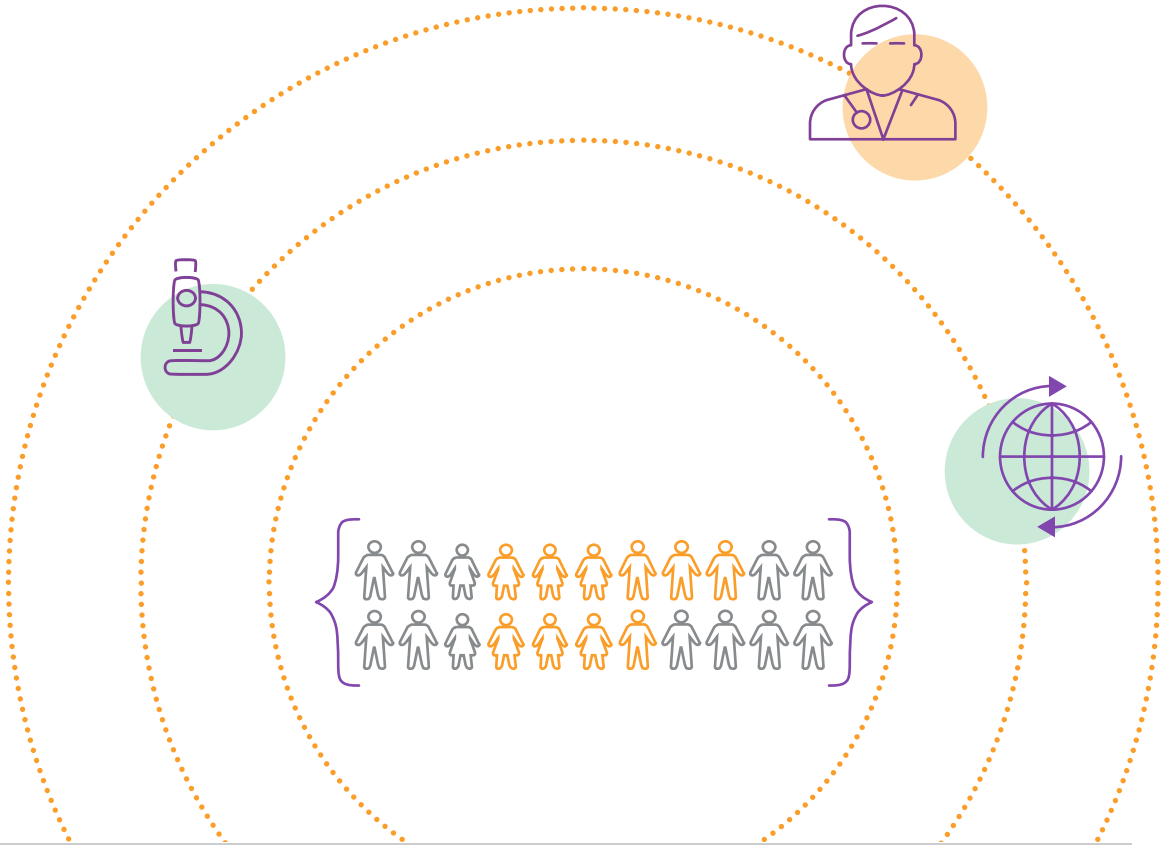
Source: Tractica.com

That's big – and many more predictions have been made about the future of AI, some very dire. In 2014, the renowned physicist Stephen Hawking made headlines when he told the BBC that AI could lead to the end of the human race. Let's all stay tuned for that!

> I'm much more optimistic. AI has proved itself as amazingly efficient at swiftly analyzing the data it is given.

AI is ready to step in to help with clinical trials, and it shows promise with such tasks as reviewing medical records and identifying potential participants. AI's abilities will lead to dramatic reductions in the trial timeline.

Contemplating the full scope of AI's role in the future of clinical trials is an interesting exercise. I find myself wondering if AI will advance to such a degree that it will have a complete understanding of the human body and all diseases and that we will no longer need human participants in studies. AI would know the disease and easily predict the compound and dose needed for ideal treatment. And perhaps vice versa: AI could review any compound and unveil its best uses in disease treatment, previously unknown.



About the Author

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Melynda is a 23-year clinical research veteran with expertise that spans protocol planning, recruitment, retention, global regulations, emerging markets, and more. Melynda is a 2008 inductee into *PharmaVoice* magazine's 100 Most Inspiring People in the Life Sciences. She has written extensively for clinical trade publications and blogs at *ImperialCRS.com/blog*. She is author of the ebook *Tricks of the Trade: Recruitment and Retention Planning for Different Study Types* and is co-author of the ebook *Your Patients Are Here: Where to Recruit & How to Retain Highly Engaged Patients*. Find these and her other books at *ImperialCRS.com/resources/ebooks*.


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