How Data Capture Technology Can Accelerate Clinical Trial Conduct

Welcome to the PharmaVOICE Webcast Network. In this episode, I meet with Jonathan Andrus, Chief Business Officer, Clinical Ink. We talk about numerous aspects of clinical trial data collection including EDC, DDC and BYOD. There is also a related white paper on BYOD.

I'm Dan Limbach, your host and producer of the PharmaVOICE Webcast Network.

Dan: Welcome to the webcast program, Jonathan.

Jonathan: Thanks Dan. It's great to be with you again as always.

Dan: Well, it's my pleasure. Well, we've certainly had an unprecedented year due to COVID. How have the needs of clinical trial data collection changed over the past year?

Jonathan: It's a great question and I think as I reflect back over my – this is actually my 25th year in industry and I look back over all the different years and think about all the change that we've seen and I think no more so over the past 12 or so months have I seen the amount of change at least happening at the rapid stage that it is. I think one of the things that really resonates with me is kind of the word flexibility and pivot I think are some words that come mind when I think about this past year and how sponsors have really been challenged to continue on with their clinical trials. Whether they're doing COVID-related studies or just other therapeutic areas of focus of these companies where they want to continue to keep the critical research going and do so in a way that is going to be able to recruit and especially retain patients and come up with flexible solutions that are going to enable them to be able to do that. And never before have I seen that more important over these past 12 months.

I think as companies have taken a look at their schedule of assessments, their time and event schedules and really looked hard at how are we collecting data, how can we do it differently, what might we be able to do to be able to encourage participation in clinical trials such that patients participants are not fearful of coming into a medical facility, fearful of leaving their home to participate in the study and to do other things and how can they meet patients where they are, meet them where they are and involve them in clinical research, not make an additional burden on folks. Many people are struggling with a number of things from being distanced from their families, working from home and just people are struggling in general.

I mean I think it goes without saying myself having one more virtual meeting, one more virtual activity, less and less human interaction and it's draining, it's straining and I think sponsor companies, CROs have really had to look hard and pivot, pivot quickly in order to react to the

needs of the clinical trial and in order to keep research, critical research going forward across so many different needy-needy therapeutic areas where patients are desperate for new therapies and new solutions for them as they're battling various chronic illnesses and diseases.

Dan: Well, I hear you. I've got about 18 years in this industry and this has been unprecedented in terms of pivots and just adjustments across the board. So we'll see how it all plays out.

Jonathan: I think one example just to kind of hit off of what you said about pivots. One of the kind of case study, if I may just share briefly, is we had a customer that came to us, had two phase 2 and two phase 3 studies where they were quickly losing patients to follow up. They weren't able to come back in for visits. This was in the CNS space. They were able to work with us and quickly redeploy a number of the assessments that patients were having to do on site and actually deploy them to a bring your own device model where patients could actually interact and interface with the solution from their home, carry on with the clinical research. We were able to quickly pivot for that company, deploy those 10 different assessments across those phase 2 and phase 3 studies and literally in the span of 10 business days and had that study deployed for them and have patients using their own phones and their own devices to be able to collect that data for that particular set of studies. Again, I think it just goes to show you that companies are willing and able now to get creative and flexible with really deploying unique solutions in order to meet their patients where they are.

Sorry, I just thought I would interject that as a side note related to this and kind of the flexibility and pivot aspect of what we were talking about.

Dan: Oh, I appreciate it. I love those examples. Let's talk about efficiency and accuracy. Jonathan, what are the operational issues that influence the industry's ability to accomplish cost effective studies with reliable results?

Jonathan: What I've seen and this is something that early Clinical Ink has been building and deploying now for well over 10 years at this point. These operational issues I think transcend even what we've seen in these past 12 or so months since the pandemic and really it comes down to getting data that are delayed or lagging. Historically, a lot of the customers, a lot of our sponsor organizations have used traditional electronic data capture models and then using those EDC models they still rely heavily on a paper-based approach where data are initially captured in some other format and then later transcribed. And really what that has created is oftentimes incomplete or incorrect data, e.g., transcription errors or the mis-entry of information, incorrect flow of data as they try to enter data well after the fact of the patient being there and collecting that information. So a lot of times there's just a lag time between the actual patient visit and when the data are actually entered into the system and that directly impacts data quality, data consistency and data availability for customers to be able to get early insights into what's going on with their clinical trials.

So those are a lot of the issues that still influence the current industry's ability to help achieve that cost effective study,. And by embracing this direct capture type approach where you're not transcribing data, it really does enable remote monitoring, remote activities to be done, again, especially in this COVID pandemic type world where the ability to keep an eye on data, to monitor data, to ensure its accuracy is so critically important for clinical trial work.

Dan: Indeed. Well now I'd like to pivot and focus on the sponsor's needs for a bit. What type of flexibility are sponsors looking for in clinical trials?

Jonathan: I think right off the bat, and again I don't mean to be glib in my response, but it's all about having options. Whether or not your clinical trial depending on your therapeutic area and the types of assessments that you need to do, maybe your study still does require a lot of site-based visits, but maybe you could do some type of combination or a hybrid type approach where you're utilizing both site and home-based visits. So being able to utilize a traveling nurse or a traveling coordinator type model where nurses and coordinators can travel out to where the patients are, meet them where they are. Whether that's a patient population that maybe is immunocompromised or maybe don't have great mobility and so therefore, meeting those patients where they are, collecting the data, keeping them engaged in that study is really important.

We have some customers right now they're doing all home-based visits. For example, in rare disease and types of areas like that, that becomes absolutely critical if you're a caregiver for a loved one having someone come and conduct research, maybe get that patient involved in some cutting edge and groundbreaking research, but doing it within the comfort of their own home is so so important and having solutions and tools to enable that, I think, really are what sponsors are looking for.

I think beyond that it's enabling – and I talked about this before about allowing patients to use their own devices, their own smartphones and mobile devices, but in some cases a patient may not have one or may not be comfortable using that.

Also being able to have the flexibility of offering provision devices and a combination of all of that is absolutely the types of flexibility that sponsors are really looking for with regard to that. Which then drives the monitoring flexibility. Sponsors are really looking for how can they also keep their clinical research professionals that are involved in conducting and monitoring these studies safe most importantly and then also having access and view into the data as early as possible. So having remote monitoring flexibility to be able to see data in your real time, to be able to assess that data and get queries and other data issues identified early on.

I think fourthly, a unified reporting environment which is really allowing not only sponsors, but also sites to be able to keep an eye on data from a variety of the different sources that are being collected from within the clinical trial, all coming together in a unified manner so they can see what's going on from a lab data standpoint, from patient diary data, patient questionnaire data, you name it, all those data coming together so that both sites and sponsors can see and understand how compliant are patients, how compliant are sites, what's going on with that data so that they can proactively follow up with them before issues get out of hand that they can really be much more proactive in the management of the clinical trial.

And then I think finally, really to obtain this kind of flexibility a number of companies are now really looking hard at a direct data capture strategy and how imperative that is. Again, as I talked about before, this is something Clinical Ink, we are the leaders in direct data capture e-source. We've been doing this the longest and now well over 10 years and I think companies are now coming around to understanding this, especially in the world that we find ourselves living in, how absolutely imperative this is to add that additional level of flexibility from a sponsor standpoint.

Dan: I couldn't agree more. There's been certainly a lot of buzz and activity around hybrid trials and decentralized trials and having the right tools obviously and technology is extremely important. So now I'd like to dig into some comparisons of two approaches to data capture. Jonathan, what are the differences between e-source, direct data capture and EDC? Are there any regulatory concerns with DDC?

Jonathan: Sure Dan, thanks for that. I won't spend too much time on EDC because I think if anyone has worked in the industry for more than a month they probably are very much familiar with electronic data capture, which is really the ability to get data into electronic format from some other source. It's essentially a transcription-based solution that allows for the entry of those data into electronic case report forms. What really pivots from EDC to direct data capture or DDC is that at the time of the patient encounter and notice I used the word encounter, not necessarily visit because that encounter could be through a Zoom healthcare meeting, Doxy.me, a televisit type encounter. It could be an encounter within the patient's home. It could be an encounter at the research site, but regardless of the modality by which your meeting with that patient it's the entry of the patient or participant data directly into the platform into the direct data capture solution without any transcription and that gives again, research professionals involved in the running of the study access to both data and documents in real time.

The other important thing with direct data capture is that you're also running real time edits, logic validations as the data are being entered. And so those data are being questioned and queried at the time of when they're being collected and not weeks and months after the fact which often happens in an EDC type situation. The other distinction is any direct data capture system worth its value needs to be able to work offline and many probably listening to this

podcast would say this is 2021, what are you talking about, why is that really necessary for a system to be able to function without being connected to the internet. And what we have seen, especially over the past 12 months, is that we're seeing such a variety of different ways in which people are interacting with a solution where we have visits occurring at home as I've talked about before.

We also have a couple of studies going on right now where they're collecting data in long-term care facilities. So again, these locations may not have the best Wi-Fi or the Wi-Fi might be spotty at times and so having the ability to work offline and collect those data both in long-term care, at home and other remote locations is really important so that you have the same function, the same capabilities as you would whether or not the solution was connected to the internet or not. The other part is that all of these things, all of the above things that I just talked about then enables the remote monitoring of those activities as well, so that allows the CRAs, the clinical project managers, the centralized data reviewers to be able to look at those data, monitor them, remotely verify them.

And I think the other part sometimes people throw up is well, what did the regulators think about it. I have concerns about whether or not FDA or MHRA or EMA or fill in the blank regulatory Ministry of Health ask concerns about it and I would just go on to say that there are certainly FDA references around the use of e-source. EMA published an e-source best practices points to consider type document back in the summer of 2019 and I would encourage listeners to look at that. It's the EMA reflection paper on the use of e-source and make sure that any vendor that you're looking at to embrace and an e-source direct data capture approach does follow those. So any concerns that there might be around from a regulatory acceptance standpoint, you know we've been involved in countless submissions related to that. Our systems have been involved in inspectional activities going on at research sites innumerable times and no issues have been raised to us concerning the use of these solutions for the capture of that.

Dan: Well, that's certainly good to know. So finally Jonathan, you mentioned that sponsors are looking for ways to better engage participants. How does BYOD support that initiative?

Jonathan: So from a bring your own device standpoint, if Dan, you like me, I live with my smartphone, with my mobile device, much to the chagrin of my family. There's rare a time where I am not connected to it 24 hours a day, 7 days a week. I think that's probably true of many of us. If you were to leave to head out to go to the supermarket or to go wherever it might – out to dinner and you didn't have your smartphone with you, you're mostly going to turn around and go back and get that device. So our philosophy and one again from a leadership standpoint we are the leaders in a bring your own device solution perspective is that smartphones are really central to most people's lives, participants included involved in clinical research.

So utilizing those devices within your clinical trial for a better participant-centric solution is really the right model to go. And what's interesting is if you look percentage-wise last report, 81% of Americans have their own smartphones and it's equally as high in other parts of the world, Western Europe throughout certain parts of Asia as well. But not all, it certainly have the amount of smartphone proliferation that we see here and some of the areas that I talked about, so also being able to have a provision option coupled with a BYOD approach is still important and I would say generally speaking with a lot of like the sponsors that we're working with, we still do have a small, an increasingly small percentage of provision phones that we include with each of our studies to account for those that might need a phone in order to stay involved with the study.

The other part I think is that there's none a doubt that as far as deployment compliance, retention and higher data quality is or all come as a result of utilizing a bring your own device approach. We can deploy studies very rapidly. You have no hardware aspects to it because patients are simply going out, grabbing the app from the app store and off they go and they're ready to work whether on diary data or engagement data or questionnaires, whatever it might be and it does. It's been proven to drive better compliance because I'm getting reminder messages directly on my phone to do a certain task or to complete a diary and it just drives that compliance and ultimately better data quality and better eye towards what's going on within your study.

Dan: Well, it certainly is true that smartphones and to a lesser extent tablets are so tethered to the individual now because they're intertwined with so many aspects of our daily lives, so why not utilize this technology for data capture and clinical research. Jonathan, I want to thank you for sharing your thought leadership and expertise with us today.

Jonathan: You are most welcome. Always a pleasure to meet with you Dan. Thanks.

And that does it for this episode. For more information about Clinical Ink, visit clinicalink.com. And don't forget to check out our other podcasts, white papers, webinars, videos, virtual panels and more at pharmavoice.com.

Until next time, I'm Dan Limbach.