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Co-Founder Of 'Anti-CRO' Talks Building Better Clinical Trials

by Elizabeth Orr

Medtech Insight interviewed Meri Beckwith, co-founder of "anti-CRO" clinical research organization Lindus Health, about his company's efforts to make clinical trials more efficient and reliable.

London-based clinical research organization Lindus Health wants to be "the anti-CRO." The company argues that clinical trials are the biggest bottleneck to advances in health care, in part because CROs often serve their own financial interest over what's best for companies or patients. It uses a new financial model in offering services such as trial design, patient recruitment, clinical data capture, monitoring and project management.

Medtech Insight caught up with Lindus co-founder Meri Beckwith at last week's Next Generation Dx summit in Washington, DC, where Beckwith gave a presentation on patient recruitment for infectious disease studies. He spoke to us about the role of technology in clinical trials, problems he sees in current trial practice, and Lindus' upcoming projects.

Q How do you balance the cost of improved technology for clinical trials with the goal of making trials as accessible as possible?

A The way I thought about it was, the value of a clinical trial per participant is in the tens of thousands of dollars. So if someone drops out, the cost and lost time and money to replace them was tens of thousands of dollars.

I spoke to an older lady [in a trial] who had mobility issues. And she was like, 'I have to come in once a week to the hospital. I don't want to get sick. I'm out.' And sure, a system costs money, but that's one person. You can so quickly make it back if you just

prevent people leaving the trial like that.

But the way a typical CRO would run a trial is, they don't have any technology themselves. They need to go to a third party. Whereas what we do is we just have all the technology ourselves. It's really quick to set up. It's already built. There's effectively no cost. And so we are incentivized to do whatever it takes to make the trial as beneficial for the patients as possible and prevent stories like that lady leaving the trial.

MERI BECKWITH, CO-FOUNDER OF LINDUS HEALTH *Source: Medtech Insight*

You spoke about seasonality for clinical trials. Obviously, everybody's trying to study the flu during flu season. How do you get your trial to stand out among ten other flu trials?

Firstly, just by making it extremely easy to participate. I think there's another underrated point around communication. I sign up for a lot of clinical trials [and] I'm just always shocked by how dense the medical language is. I think people forget that this has to be really easily legible to someone who doesn't have a medical background. I'm not a doctor, but I obviously know probably more than the average person, and I struggle to understand what the trial is about, what it's testing. So I think that communication piece of just putting things in really simple, plain English already makes you stand out. It's a low bar.

And then also you have flu trials. Still, 99% of people with flu don't enroll in a clinical trial. So it's broadening your access and meeting patients where they are. We go with digital first, finding patients via things like social media, via primary care, rather than just relying on a few higher-end clinical trial sites, and then proactively finding patients before they get sick so you can enroll them straight away. All of those things,

you're effectively finding patients that no one else would think to find.

We will post in small- or medium-sized Facebook groups, often where people are just asking for advice from doctors and nurses, and we also just run ads directed at people who have influenza.

"Just getting the basics right, making the trial as easy as possible for a participant to say yes to, paying them properly for their time and inconvenience, goes a really long way" – Meri Beckwith

Q **I'm sure community groups get solicitations all the time to help find clinical trial participants. What do you do to appeal to them?**

A We're actually surprised. It's not as common as you'd think, and we've used community groups a lot for quite specific communities like rare disease patients. A lot of these patients are just desperate, understandably, for treatment, and so they're very, very active. They're very, very willing to take part.

Just getting the basics right, making the trial as easy as possible for a participant to say yes to, paying them properly for their time and inconvenience, goes a really long way. And it's stuff that a lot of people just don't do even now, which is crazy. And I think these community groups pay attention to that, and they will ask, 'Okay, are you paying people? What are the risks?' And just making sure you have a very clear answer goes a long way.

We just published some research with Oxford University, where we interviewed a lot of people from ethnic minority backgrounds and diverse lower-income communities. And the thing that comes across as the biggest motivator for them to take part in clinical trials is payment, which is understandable because if you work a shift job, you have to take a day off to go take part in a trial. You're losing income, right?

> We have conversations with pharma in particular all the time where they just don't get it. They're like, 'Oh, we don't want to pay people to take part in a trial because we don't want to induce them.' And I'm like, 'Well, guess what? You're only going to get privileged people who can afford to take a day off or don't work.' And they just don't understand it.

Q **Are there any kickback or policy concerns around paying patients?**

A Before you launch any clinical trial where you're paying patients, it's all heavily scrutinized by the [institutional review board] or the ethics committee. So in theory, you will never be allowed to offer a payment that strays into kickback territory, because they will stop you. But there's a pretty big difference between not paying someone at all and paying [a kickback]. We usually aim for about $50 per hour, which pays properly for someone's time and the inconvenience, but it's hard to argue that was enough to be a kickback.

Q **Can you tell me a little bit about how Lindus helps companies planning clinical trials?**

A We just run the whole trial. Patient recruitment is almost the easy part. You might hear that the biggest problem in clinical trials is patient recruitment, [but I think] the problem is that the whole trial design just makes it hard for patients to participate.

There's really dumb stuff. Like we see a lot of clinical trial protocols where either the trial schedule or the eligibility criteria just seem to have been written in a vacuum. So they haven't spoken to patients, they haven't spoken to clinicians to really understand how care pathways work in this condition. And unknowingly, they've excluded all their population.

I'll give you a recent example. A hypertension trial needed people who were hypertensive, but if you had been prescribed certain anti-hypertensive meds you were excluded – without realizing it's a frontline therapy. So that's 95% population gone, and there was no real clinical reason for that. Finding patients is the easy part, but making sure they have a smooth journey and the actual trial retains them has been the hard part. So like 90% of our effort goes to overseeing the sites, managing the sites, collecting all the data, monitoring the data, all that stuff after the patient recruitment.

Q **What do you see as the next advances for technology in clinical trial management?**

A There's so much stuff. Generative AI is having an impact. It's making a bunch of processes 10% more efficient at the moment, which is still a pretty big deal. I just think clinical trial technology is still at least a decade behind even health technology, which is itself a decade behind. There's really basic stuff, like a lot of sites still use paper, and it just creates huge inefficiencies because it needs to be separately monitored using a double data entry. So getting people off paper, that's already a huge win.

Then there's a load of stuff that we've started doing around centralized real-time monitoring, like monitoring clinical trial data as it comes in. It's very poorly adopted throughout the industry, because you need to have all the data in one consistent format, which is something we can do because we're providing the database and managing all the sites. But we're seeing huge impacts because if a piece of data is wrong, we can spot it in real time and often follow up with the site while the participant is still there. We can see things like adverse events. So if participants had a safety issue, we can pick it up much faster than waiting for someone to go out and inspect paper records. We're really just scratching the surface of the benefits that's having, and I'm really excited about what we can do with centralized real-time monitoring over the next five years.

Q **What projects are you most excited about right now for your company?**

A We just launched a really exciting new study in ovarian cancer with a company called Cleo Diagnostics. I think they're really cool because ovarian cancer is obviously very underserved and it's particularly difficult to detect at stage one and stage two, which is when the crucial window is for treatment. Clio has new technology, which increased sensitivity at those early stages. So we're launching a 1,600 patient study across the US to enroll patients with stage one and stage two ovarian cancer to get the samples to show that that's efficacious. And the early data from some of their other work is really positive.

Clinical research is daunting, and it can be expensive, but it doesn't need to be hard if you're working with a partner where there are aligned incentives, where you're finding wins for the developer, the CRO and the patient. – Meri Beckwith

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Q **You already talked about some of the mistakes you see from people coming in to start a trial. But is there anything else that you think manufacturers maybe don't realize but should?**

A I would say if we're talking about a regulatory trial, particularly with the FDA, there's no excuse not to do a pre-submission. It's just a fantastic way of hugely de-risking your clinical trial timelines.

Another big mistake people make is they're too soft on the CROs who are running their clinical trials. We just see situations where the CRO is getting away with what's basically fraud, doing things like massively overcharging for services, terrible cost control, and then just passing the cost on to manufacturers. Really, being incredibly lazy with how they design clinical trials, making it hard for patients to participate, bloating clinical trial designs intentionally, doing things that they know will lead to slower enrollment, because that's how they make more money. I get really upset about this because this impacts the lives of patients who are in the clinical trial as

> well.
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> Manufacturers should be demanding more from their CRO partners in terms of, how can we design this trial better? How can we align so the CRO is not being paid for failure? Clinical research is daunting, and it can be expensive, but it doesn't need to be hard if you're working with a partner where there are aligned incentives, where you're finding wins for the developer, the CRO and the patient.