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Q&A with David Heenan President & Co-Founder and Jordan Spivack CEO + Co-founder of Aces Health, Inc. providing an Automated Data Collection, Safety Monitoring and Analytics Platform for Clinical Trials

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CEOCFO: ***Mr. Heenan, what is the concept behind Aces Health Inc?***
Mr. Heenan: Aces Health stands for Automated Collection and Engagement System. It is the industry's first clinical trial automation platform. That means we automate subject and CRA engagements as well as automating the actual data collections of eCOA/ePRO and EDC, through over fifteen thousand different integrations, combining that with natural English processing and artificial intelligence.

"Patients are currently really inconvenienced and burdened by having to go into the trial sites… they have to go to the doctor's office for these blood draws for the trial. They have to really go in for unnecessary visits and turn in these paper forms that they are using, when we could do all of that by our mobile app. With an automated monitoring solution like Aces Health all of that can be done in real time, ensuring that not only the trial is staying on track and that the timeline and budget are being managed appropriately, but the patients are actually staying safe, which is the most important part! Obviously for the FDA, it is their priority and it is something we can help them to do."- Jordan Spivack

CEOCFO: ***What has been the challenge in creating an automated system?***
Mr. Heenan: Honestly, the biggest challenge for us is overcoming your legacy software in the industry, getting these big players to get used to the new reality of mobile technology and to not be afraid of the automation process, but to embrace it as a way to make their trials more efficient.

CEOCFO: ***What is the old method of collecting data? Would you give us some of the contrasts in how automation makes a difference?***
Mr. Heenan: In the beginning they used pencil and paper and would send subjects home with large notebooks and expect them to fill them out on a daily basis in real time and bring them back with accurate, complete data. That created several problems from patients self-reporting and from filling it out in hindsight rather than in real time or not coming back at all. Also, one of the biggest things was the burden that put on patients. It made them stay away from clinical trials or affected the retention in the clinical trials once they were in. Then a group of companies came along and essentially took those paper forms and put them on a computer screen, but it still required the manual entry of data. Then Aces comes along and we used over fifteen thousand integrations to fill out those forms automatically, minimizing the burden, both on the research subjects and the researchers themselves and reducing the amount of actual hands on work needed to just the very minimum. It allowed for higher retention, a higher success rate and to make it easier for people to get into trials.

CEOCFO: ***Is the patient then doing something on their cell phone or on their computer? Would you give us a couple of examples?***
Mr. Spivack: We make sure the patient is involved at every stop of the process, while making it as easy as possible for them to complete their responsibilities in the trials. As David alluded to, trial retention as a major problem for the industry; keeping patients actually in the trial to ensure that their data is sufficient for information that needs to go to the FDA or to make approvals and decisions about whether or not the drug is actually approved for market. Every step of the way, whether it is the patient's responsibility, keeping up with what they need to do on a day to day basis, for instance taking their medication, or it may be measurements they need to take outside of the office, such as their blood pressure, their blood glucose, their heart rate through tracking or even communication and just being able to ask questions. All that can be done using the Aces platform. This is kind of a radical paradigm shift from the current implementation of clinical trials. All that of that is collected separately, if you can even collect it at all. Patients are currently really inconvenienced and burdened by having to go into the trial sites. They take time out of their already busy, hectic lives, especially if they have some of these more serious diseases and they are going through a clinical trial, they have to go to the doctor's office for these blood draws for the trial. They have to really go in for unnecessary visits and turn in these paper forms that they are using, when we could do all of that by our mobile app. We do all of that automatically. We can make their lives easier, really, as they are going through the trials. Then of course, that translates to the coordinators and the study site staff as well, instead of having to manually reconcile these forms and check them for data accuracy, for risk monitors and marking sure the patients are going through the study. Right now, it takes a ton of resource hours to actually make sure that all that happens. With an automated monitoring solution like Aces Health all of that can be done in real time, ensuring that not only the trial is staying on track and that the timeline and budget are being managed appropriately, but the patients are actually staying safe, which is the most important part! Obviously for the FDA, it is their priority and it is something we can help them to do.

CEOCFO: ***How are you helping organizations overcome the fear that something will be missed with automation?***
Mr. Spivack: That is a great question! Fear is probably the right word as well! As I mentioned, that is one of our biggest struggles. We go into these meetings and they love the product, they know the need, but they do not really understand how to use it or what that means for the sales process to their clients. Therefore, a lot of this is through education. We have been fortunate enough to get some really innovative contracts with research universities in order to get that credibility, to get those customer references, to make them more comfortable. After that, we find the right person inside the organization with the right project in order to build that trust. We could give you a few examples of where we came in and did the minimum rollout of the product we have and rapidly expanded that contract because of the way we collect data and the inadequacy of the current systems to handle that data.

CEOCFO: ***Can an organization start with pieces; parts of what you are able to collect or would they be doing it all but it would just be for a small group? How do you start?***
Mr. Spivack: That is really an excellent question. We have made it a point to develop our solutions to be completely modular for exactly that reason. There are a number of advantages to doing it this way. Number one, obviously if an organization only wants to capture some parts of the patients experience digitally, but not all of it, they do not have to purchase the whole solution. They do not have to train their staff to use all of the functionality we can offer. They only have to invest in a subset of that financially and timewise. It also gives us a major advantage as we are going through the software validation cycles that are required for data capture in this industry. Obviously, it is highly regulated. We take patients' security and their data security extremely critically. As part of that validation process for any new code, any new module that fits into our system, testing is done to the fullest extent and allows our software to be one cohesive solution, but one cohesive solution that is comprised of many different interconnected parts. It allows us to do that more effectively.

CEOCFO: ***Would you walk us through a typical engagement?***
Mr. Heenan: Yes, I will use a research university. Initially, we were doing a "bring-your-own-device electronic patient reported outcome only" project with them. Therefore, the patients would enroll in a trial, download the application and they would be automated, such as the surveys and questionnaires at the appropriate time through the length of the trials. Then a survey will be available in real time to a researcher and aggregated as they come in. This particular trial was set to be put on a hold by the FDA, because the FDA wanted to take temperature daily as part of adverse event reporting. This would have been particularly burdensome, both for the patients due to their therapeutic area and also because this was a government grant funded trial and they just did not have the funding to man the phone all the time to collect that data. Therefore, we overcame that by integrating with a Bluetooth enabled Nokia thermometer, the Thermo, and having preset thresholds in our automation engine: depending on the input from those thermometers, alerts or reports would be made for unacceptable rising temperatures in order to overcome that obstacle put forth by the FDA. Within twenty four hours the clinical trial was approved by the FDA after updating the protocol with that method. Then, in this particular university, their proprietary data repository was not set up to handle real time data and it certainly was not set up to act on real time data

and automated alerts. Therefore, the contract was extended once again in order to use Aces as the centralized data repository for this multi centered trial. That is typical of our “land and expand” strategy. That is also typical of our vision for that fully vertically integrated clinical trial automation engine.

CEOCFO: ***What is your marketing strategy today? Are you reaching out to different organizations?***
Mr. Heenan: We have a twofold strategy right now, really. The one is that we have been very successful in getting invited to be speakers at different conferences, which is generating a bunch of inbound leads. We also hire strategically in order to flex the network of our employees from the industry and that is the other source of our inbound leads. To date, we have done minimal outbound marketing or advertising and as things are going we might not need to!

CEOCFO: ***Are you seeking partnership investment funding as you grow?***
Mr. Heenan: Yes. In fact a big part of our plotted strategy is to develop partnerships with complimentary platforms and also devices. This is where we get our fifteen thousand integrations which makes us the most interoperable clinical trial system on the market to date, which is a huge value proposition. Therefore, we are constantly looking for those partnerships and would love anyone that is interested in working with us to reach out and let us know! We are very open. Second, of course we are interested in fundraising, but are not in need and are diligently and patiently looking for the appropriate strategic partners to really take us to the next level and expand globally. We do believe that we should not only be competing, but overtaking the Veevas and the Medidatas of the world. We think they have become less innovative than the industry demands, and with the acceleration of breakthroughs in modern medicine you have got to have this real time, cloud-based system. You have to leverage the best tools to get the best outcomes.

CEOCFO: ***What do people miss? Are there certain modules that are not getting the attention you would expect? Are there certain aspects of what you do that either are not resonating or people do not understand that surprises you?***
Mr. Spivack: Yes, that is a good question! To be honest, I think the thing that people miss is what they have been missing for the last twenty years in this industry, which is innovation and disruption in general. David came from the CDC. Myself, I came from healthcare on the member management side; building software for health plans. Neither one of us had extensive experience in clinical research. We arrived here through some other partners and through our work. However, it is really just the level of monolithic infrastructure that we have seen from the industry, the unwillingness to embrace technology that could help them on an everyday basis, that’s probably the part that has been most surprising. I will say that much of this is changing where we are starting to see industry mentalities evolving. We are starting to see them realize the benefits of technology. Much of what we do is really that educational process as we are going through sales of how digital can be the next frontier for clinical development, how we can really save money for sponsors and CROs. Therefore, I would not necessarily say there is one piece or another. I would say it is more of an overall industry trend that is really finally starting to emerge and players like Aces are proud to be a part of it.
Mr. Heenan: Just to put a final point on that, I think we are in a situation right now where the industry is missing the forest for the trees. They do not see the big picture of the synergistic value of full vertical integration, so they get locked in or keyed in on a particular feature set that they think is really cool and could use. That is exactly what happened with that research university. “Okay, we want to be certain they are great”, and as we get in there they see that combining all of this stuff into one ecosystem just makes so much more sense than the way they are doing it now. The average clinical research associate has twelve different logins per clinical trial and they are probably on three or four clinical trials. It is just ludicrous!

CEOCFO: ***Why is Aces Health Inc important, not only from a business perspective, but also a health perspective?***
Mr. Spivack: Aces is important because we are solving so many problems in the industry. We see ourselves as a connector. We see ourselves as, to use a cliché, the missing link between a number of different types of systems, whether manual or digital, that exist on the market today. It is probably key in healthcare and in clinical research everywhere. Systems are built using separate or outdated legacy APIs (Application Program Interfaces), but that is like early HL7 compared to FIHR. Systems are built using proprietary data models that cannot communicate with each other. That means that patients do not have access to their own record from different hospital systems. In clinical research; the average drug takes 15 years and 2.5 billion dollars to go to market because the systems that they are using require twelve different log ins for a single clinical research associate. When you look at these problems, it is no wonder that drug development is so expensive. You look at how just the drug development, the therapeutics, and medical devices have been slowed down, not just on the regulation side but on the industry side-- the R&D has slowed down by all of these issues. Think about how many lifesaving medications and treatments are not going to market because of the bureaucracy and the technical red tape you see in these organizations. Though we really set out to build Aces as that center point; that end to end system that would enable fluidity in the system and that would truly make all of these processes in trials easier. That is a goal we have been building to ever since.