

Breakthrough Analytical Tools for Drug Development and Clinical Trials: Combining Market Research with Industry Knowledge



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- Dr. Ross Weaver, PharmD, MBA

CEOCFO: *Dr. Weaver, what was the vision when you founded Clinical SCORE?*

Dr. Weaver: The vision of the company was to help pharmaceutical companies to accelerate their clinical trials. Our premise was that the goal of getting trials done and the challenges that most companies have are fairly common. The way we saw it is that it is a forecasting problem; how many patients are getting in verses how many did you want to get in. When we have done forecasting to uncover issues before, the first thing do is try to figure out, in a detailed way, what are the problems, what are the reasons for it and what can be done to address it. What we saw was a gap in the market where organizations jumped from where there was a problem and went right into trying to solve it instead of sorting out very specifically, what the issues were.

CEOCFO: *How has that played out today? What are you providing?*

Dr. Weaver: We have recently expanded our product offerings, so now our business is at a totally different level. We offer high value innovative services in a few different areas. It is all about the pharmaceutical industry. However, in the clinical area we have refined it so that we have a specific tool that we use a normative data base and standard questionnaire and with that we can very quickly and efficiently identify where their challenges. We are the only people doing this type of work in the industry. However, we have also found that that same mindset works in some other areas. We tend to be working in the less traditional “blue ocean” marketing areas. We are the only company that is addressing the pharmaceutical industry’s needs for our type of services. It is part of our novel business approach to interview patients who were in the clinical trials after the trials were done. As a result of this, we gain insight about the value of the product, the onset of it and other information that no one else has. This in an example of our high value, truly innovative services. No one else delivers this to the industry.

CEOCFO: *What are you doing that the industry has not thought of before?*

Dr. Weaver: We are doing everything that this industry hasn’t thought of yet! Our biggest breakthrough right now is directly interviewing patients who were in sponsored clinical trials. When we talk to people across the industry, they want to immediately know: “Why is no one else in that area?” It is because the people who would best know how to do this are very nervous about clinical trials and those who know about clinical trials do not know how to do the interviews well. We happen to be able to flourish in this space, based on our combined industry experience from over the years, and our willingness to step out on that expertise and truly deliver this unique value proposition.

CEOCFO: *Would you give us an example of what you are asking in an interview or what you are trying to elicit and how you are able to get that out of people?*

Dr. Weaver: I will give you a concrete example: We recently did a project for a company in the respiratory area. They had an internal view of the compound and one of the things that the sponsor expected was a rapid onset of action, because

the science indicated that patients would have an improvement in FEV-1 quickly, for example, which is a major amount of lung function. What we found was that it *actually took a couple of months* for patients to be able to perceive the benefit. However, once onset occurred, in the patients' own words, it was life changing! The company truly did not know it was that beneficial. What they found was that it would take longer for onset to occur, so they had to develop programs that would get patients from when started to stay on the medication for a couple of months. They had no plans to do that until we uncovered this through the interviews. They also did not know the value of the product, when it really works, of how impactful and beneficial it was. As you could imagine, if you were on one of those brand teams, how exciting and how pleasing it is to be working on something that adds so much value to people.

CEO CFO: *Would you tell us about the different products and services you offer?*

Dr. Weaver: The product we just talked about, which is the one focused on interviewing the patients who were receiving the drug in the trials is called CTI, or Clinical Trial Insights. Another product is in Medical Affairs, where we interview key opinion leaders and identify what they are looking for from their medical science liaisons; these physicians and pharmacists who work for drug companies that see them, what they are looking for and how well they deliver it. That product is called Partner of Choice. Finally, what we have is an umbrella product for across the clinical area, delving into a company's whole portfolio of trials to identify where there are issues relating to their CRO, including their compensation terms, payment terms and so on. This is called Attune Analytics.

CEO CFO: *Would some of your clients make use of each of the products or are they typically segmented?*

Dr. Weaver: That is a good question, Lynn. The answer is not generally. We have three separate, segmented audiences within the company and they really do not overlap with each other.

CEO CFO: *How are you reaching the different groups that should know about Clinical SCORE?*

Dr. Weaver: Our Marketing Director does outreach through both social media and digital. We have attended trade shows, giving dynamic, impactful presentations. We have contributed articles to every major industry publication, and we enjoy consistent interaction from being routinely published in these top mediums. We also direct internal sales activities that work on reaching out to the folks that engage with our content. Those are the main ways that we maintain and develop our industry position.

CEO CFO: *Are people surprised to find out what you can do and are they ever skeptical?*

Dr. Weaver: Yes and yes! Yes, they are surprised and yes, they are skeptical; both with good reasons. It is an industry that has been around a long time. Why would something so novel not be readily available, people wonder. However, what has happened with CTI is that the industry has moved from focusing almost solely on the physician to now much more focus on the patient. Patient centricity has become very popular in the industry. Therefore, interviewing the patients who receive the drugs during the trials has become something that people are now willing to consider that they were not willing to consider a few years ago.

CEO CFO: *When pharmaceutical companies realize what you can do for them, does cost matter or is somewhat secondary?*

Dr. Weaver: Your question is exactly the right way to look at it. It is the credibility that is the issue more than the price itself. If in fact they believe in what we can do and deliver; if they find what we are saying is credible, then price is not the barrier. It is that credibility. The Sponsor Companies' position is: Can you really do what you are saying you will do? Will you really deliver what you are saying you will be able to deliver? The answer is an astounding yes, given our repeat engagements and ability to penetrate across organizations once we have an interaction.

CEO CFO: *Where does regulatory come in, if at all, in what you are doing?*

Mr. Weaver: It is more of what is called compliance than regulatory. Regulatory is not that substantial an issue in anything we do. What they want to make sure of is that we are; A, ethical. Nobody ever argues about the ethics when we describe what we do. B, does it meet all the legal requirements, so it is a little bit regulatory, but it is really more legal. Then C; is it appropriate and within these various groups, authorized? Therefore, occasionally we have to go to organizations within hospitals called IRBs, whose goal is to make sure that patients are not being abused in clinical trials, that the patients are being protected, and rightly so. Therefore, they see what we do and typically exempt what we do without even needing an IRB, because we are just talking to patients. We are not doing any intervention with them. Therefore, for regulatory we typically have to go through legal, make sure it is HIPAA compliant and all of those kinds of hurdles. Once they hear what we do and how we do it, we get through those hurdles dissipate.

CEOCFO: When you are assessing a company's strategic approach what might you find that is surprising to the company?

Dr. Weaver: I can give you another concrete example in a different area. Within our Medical Affairs product, Partner of Choice, these are the opinion leaders in the field that we are interviewing and getting insights from. One of the things that we encounter from people is a "deer-in-the-headlights" look, and then they realize that that makes complete sense that you can could segment these opinion leaders by what they are wanting from companies. By that I mean that some of these opinion leaders really want to have an interaction with the company of a very scientific interchange. Other ones are looking for more assistance to get involved in clinical trials, to be supporting the company and helping the company complete clinical trials. Meanwhile, some of them just want the science and do not want anything to do with the trials or advisory boards or anything like that. Other ones are just the opposite. All they want are the advisory boards and clinical trials, and they are not really interested in the interaction. They feel like they have enough otherwise. Often there is mix of this. There is a lot of confusion and some companies really have not thought about things that way. It's a new perspective to be asking if they are they meeting their needs and then allows them to evaluate what should they do to improve their service offerings to those different segments."

CEOCFO: Do you anticipate a point in time when using your services would be fairly routine for companies in the industry, just part of the normal course of business?

Dr. Weaver: Yes, and we are getting there with all of them! We have a specific company that has now made our CTI product a "brand standard" to accompany all their clinical trials. They made an operational decision that every Phase II molecule that has substantial value; they are going to purchase a CTI engagement. Within another organization, for Medical Affairs, every therapeutic area of the company, has used our services for Partner of Choice. Others, looking across their portfolio, are looking at putting that into place as part of their routine. Therefore, in all of the three areas I would say yes, it is the case and we are consistently building on that.

CEOCFO: What is next for Clinical SCORE? What might be different a year from now?

Dr. Weaver: We are very much in growth mode. We are only three years old. Therefore, our "right now" is to reach within the companies that we are interacting with and our clients and offer our services more readily and widely utilized within those companies. For certain other ones, it is more about gaining new clients and broadening the base of clients. Then, for each of our services, we continue to improve our product offering. We are offering enhancements to Partner of Choice moving into KPIs for clinical trials. We are improving on delivering our value proposition across the whole portfolio. For interviewing the patients in the clinical trials; historically we did it after the trial was done. Now, we can do it during certain types of trials. Therefore, we are continuing to improve our services everywhere.

CEOCFO: Why is Clinical SCORE an important company, not only for the health industry, but for the general public? How are you making a difference?

Dr. Weaver: Within in the health industry, we all want to deliver the improvements that, at the end of the day, will be what gives us longer and better lives. We are helping the industry be more efficient and ultimately more effective. At the end of the day, you don't know what you don't know. We work to highlight areas for improvement that can assist the drug development industry to keep moving forward.

