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Data Assessment Tools and Services for Clinical Trials

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CEOCFO: *Mr. Malamis, what is the approach at CRO Analytics™?*
Mr. Malamis: Our approach is to, for the first time, directly measure the quality of outsourced and in-sourced clinical research. Despite the critically important role research and clinical trial performance have on the industry, they have never been directly assessed from a quality perspective. To date, they have been measured using operational metrics, which obviously are very important, but are typically measures of time and quantity, not quality. Performance has never been assessed directly from a quality perspective. Therefore, that is what we are doing.

CEOCFO: *Would you please further explain what that means in specifics as opposed to in the abstract?*
Mr. Malamis: The first thing to understand is that quality, in a service industry, is a construct of experience and expectations. Therefore, if I describe a restaurant to you and I tell you that these are the things that I think about this restaurant, you are going to go to that restaurant with a set of expectations. Then when asked to assess the quality of that restaurant you are automatically going to factor in those expectations, along with your experience, in order to assess the quality. Obviously, that is very different than product quality, which is much more of a tangible item. Therefore, the trick with service quality assessment is to use a set of statistically validated tools; we call them "assessments" that can, in a very rigorous fashion, measure that construct. Meaning, accurately measure the experience and the expectations of that experience in order to assess the quality.

CEOCFO: *How do you measure the expectation part?*
Mr. Malamis: All of our findings, to date, have been published and will continue to be published in peer review journals like *Applied Clinical Trials*. To accomplish this we spent a number of years developing a set of validated data collection instruments. The first set was aimed at Phase II through IV clinical trials.

The way we achieved this was by interviewing hundreds of people in the industry to first determine what the basic structure of the research should look like. The feedback indicated that the structure should look at the different stages of clinical trials and should take into account all of the stakeholders. If you think of a three hundred and sixty degree balanced score card approach, we want the views of the trial sponsor, the CRO, investigative sites, patients, etc. as it is a collaborative effort.

Once we had the basic structure of stages and stakeholders we focused on creating data collection instruments – surveys – that could be used in that paradigm. Ultimately, we want the views of the investigative sites and of the patient in assessing the quality of trials. To achieve this, we asked stakeholder representatives, at each stage, what they think constitutes a high quality clinical trial and what do you have to do correctly in order to have a high quality clinical trial? As you might imagine, we received hundreds of responses. So, we kept asking the same questions until we did not get any new responses.

Those responses constituted the first draft of each assessment, which were then used to have stakeholders evaluate specific trials they have been involved in. Concurrently, we did the same thing with an overall quality assessment. By having that latter assessment, you can then statistically determine what the key drivers of quality were at each stage and eliminate those that are not statistically meaningful. After a few cycles of this, we had a streamlined, efficient, valid, and reliable set of assessments.

This methodology is nothing new, in fact it is a very standard methodology. We took service quality measurements and statistical validation methodology, both which have been very well established in the literature and we simply applied them to the clinical trial setting. That is the process for developing these tools. That process was headed up by Dr. Michael Howley, who is an associate clinical professor at Drexel University with a focus on services marketing.

CEOCFO: ***Are people looking for a better way or is it more that they are happy to find that CRO Analytics has much more depth than standard?***
Mr. Malamis: I think both. The reality is that the industry is frustrated, for several reasons. The primary reason being that they have used; and I used even as former head of CRO, operational metrics as a stand in for directly measuring quality. For example, you may have a car that operates at a certain range, speed and gas performance, but there are probably twenty other cars out there that do that. Therefore, those are the only metrics that you knew. You would have no way of assessing the quality of those cars. You have a hotel with a bed and a desk and a bathroom and a TV. I can tell you that here is the square footage and you could have four rooms exactly the same. One could be at the Ritz Carlton and one could be at Motel Six; two completely different levels of quality, for instance. Therefore, quality is not inherent in the tangible operational of metrics.

The problem is that operational metrics are so easy to measure because they are there. You do not have to go looking for them. Therefore, for years now the industry has used them to measure quality. However, they are beginning to get extremely frustrated because they are seeing not improvement in performance. When I say no improvement in performance, I mean specifically with regard to the ability to meet timelines and budgets on clinical trials. Research is routinely on the industry's ability to meet those parameters and it is routinely found that there has been no improvement.

"It is a very practical application that delivers actionable data that can ultimately make a difference in people's lives. It may seem a long way from assessing study startup or the study in Phase II to saving a person's life, but if you are getting a product to market one month or six months sooner, there are people's lives that are impacted by that."- Peter Malamis

Billions of dollars have been spent in the last fifteen years on new generations of clinical research software -- Clinical Trial Management Systems, electronic data collections, electronic patient reported outcomes and signal systems; all that spending and no meaningful improvement. There has to be something missing in that puzzle.

At CRO Analytics, we think that to measure quality you have to measure quality. Therefore, we like to think that we are not replacing anything. We are not displacing anything. We are a missing piece of the puzzle in terms of the improvement. When we get a chance to sit down and talk to people on the sponsor side and CRO side, they understand our mission and they love it. That is because, not only is it something new -- there are many new things out there -- but it clicks with them. They are saying, "Yes! That is what we have been missing! We have all these operational metrics, but we do not know what they mean." We can help them understand what they mean.

CEOCFO: ***Is the product generally available today or are you still in the development phase?***
Mr. Malamis: Our product, Performer™, is fully available. It is an up and running, functioning system. Performer was used in our collaboration with *Applied Clinical Trials* on the first ever industry wide assessment of outsourcing quality, which was published in January. If you want to see the tool that was used in that research, which was just one component of our platform, you can go to www.trialquality.com, register and see the actual assessments. We are trying to be very transparent. We have published our methodology and all of our assessments are up on that website to look at. In addition to the data collection capability that you can see on that website, the administrative capability is up and functioning, as is the standard reporting capabilities.

CEOCFO: ***What might someone see as a result of using your tool?***
Mr. Malamis: That is a very important question. The software is constructed so that it is utilized during the actual conduct of the trial. It starts at the end of the contracting process where the contracting process is assessed and it goes through study startup, which is the next assessment, study conduct and study close out. Each of those assessments can be completed by trial personnel. We are looking for witnesses to performance. That is how you assess quality during those different stages of the trial.

The results are immediately reported on the reporting function. Immediately, users will be able to see how your trial is doing, relative to what our research has determined to be the key drivers of quality at each stage. To get more specific; we know, for example, that the project managers regulatory and GCP knowledge, is the single greatest driver of quality at

the study startup stage. Therefore, that is going to be assessed. However, we also know that there are a myriad of other functions and professional skill sets; things like responsiveness and timeliness and problem solving, that come into play.

Let us say that you are in a study startup and, not unusually, experiencing delays. What you would normally do first is look to see if the problem lies with your sites or your patients or recruiting. Depending on the severity of the problem, you could spend weeks on determining the exact issue. That is because it could be anything or a combination of several issues. It could be the project manager's knowledge or their ability to communicate or problem solve. It could be the investigator meeting. It could be the protocol. It could be the CRA performance, or the availability of the documents from the site; it could be any number of different things. What CRO Analytics does, is give you the ability to compress that root cause analysis from weeks to minutes and immediately begin to zero in on what the potential problem is. So rather than spending in a global trial, weeks surveying different regions and talking to different people and trying to understand whose perspective is the most balanced and the most insightful and what are the potential problems, you have that at your fingertips right away.

We think there is a very direct correlation between the use of our data and the efficiency with which those kinds of issues can be dealt with at the trial level. Therefore, it is a very trial specific benefit. However, we are also able to assess the strengths and weaknesses of all of your functional areas and of all of your outsourcing relationships because we can also track by all of the sub vendors, not just the primary CRO. For that reason, Performer is a very powerful tool that can be used at the trial level, at the functional level and even at corporate level, to assist in alliance governance activities. We tried to make it so that it is granular and meaningful and therefore, very usable.

CEOCFO: ***There are many new ideas, new products and new concepts in all of healthcare. How do you break through the noise and get the attention of the appropriate people?***
Mr. Malamis: These are very good questions! We recognized that going in and felt like we had kind of a double challenge. We not only had the challenge of being a new company and a new product but also being a new product category. Currently, there is really nothing that does what we do. There is very good work that is done by other groups in the area of consensus metrics operational metrics and customer satisfaction. However, no one is directly measuring quality. Therefore, not only are we new and no one has heard of us, but no one has really used the technique or tool like the one that we developed.

Consequently, we felt most importantly; and I am fortunate to have investors and a board that agrees wholeheartedly with this; that the most important thing was to establish our scientific rigor via publications and presentations and conferences, so that people would, in a sense, be introduced conceptually to the idea of a proper quality measurement. Dr. Howley, who if you have not seen him present is one of the best presenters out there, will have spoken at nineteen conferences between the DIA (Drug Information Association) meeting in 2014 and DIA this year, where we have two presentations. At none of these conferences have we paid to sponsor our speech. We do not do that. We do not pay to be a sponsor of a conference and then be able to speak at it, like so many folks do. The reception has been great!

In addition to that, as I said, we are committed to publishing all of our results. There are several publications already of our applied clinical trials, our general methodology and our findings overall on the study of quality in clinical trials and in study startups specifically. We are going to continue to publish as long as we have new data. We thought that the very first thing to do is establish credibility. That is because without it, no amount of awareness in the world would really matter. If you think about it, you are dealing with an industry that makes its living off of submitting data to the FDA and other organizations. Therefore, we felt like our data should be at least as rigorous and defensible as the data that they use to submit their products. Hence, that is the tack that we take.

That is a long answer, in sum, it is establish credibility, conduct pilot programs; one which we are in the middle of right now with a hand full of sponsors and CROs and is going to be fully subscribed pretty quickly, I think, and really roll out in a measured way. If you look at other software launches, for example, those big fancy booths and marketing campaigns and sales forces and all things that might be appropriate for those products; we did not think that was appropriate here. However, it is a new methodology and so people have to understand it. We have to understand it. We are still learning exactly where the greatest value will be seen by the users.

CEOCFO: ***What have you learned that has caused some changes or tweaks?***
Mr. Malamis: The first thing we have learned is that frustration exists in this industry. This expressed frustration has reinforced our belief that we are going down the right road and that we have something to offer that is different and will improve the way clinical trials measured. I think that is important. We have been working on this for quite some time.

When were finally able to get out there and talk to people about it and show people, we were gratified to see that they were not just interested in it because it was something new, but that because they thought it was substantive and meaningful.

However, I think more to the point of your question; we learned that it is a big commitment to bite off on a process that really assesses, holistically, the entire clinical trial. There is really nothing else that does that. Therefore, if you think about it, the people who have to provide the assessments that we have to have filled out; they span the length and the breadth of any research organization. Those people might never even know each other. The people in contracting, the people in closeout and the people at the head of functional areas or in the field, might never even meet each other. They could pass each other on the street and not know who they were. That is definitely a challenge for us.

The way that we address that is by allowing people to begin with any of the stage assessments that they want. In other words, we enable pilot participants to start with as few as one of the stages up to all of them. I would say that that is probably the second most important thing that we have learned.

The third most important thing that I think is worth citing is that there is data fatigue, system overload and software overload. If you are a site you are using all kinds of different digital systems, potentially. Even if you are a sponsor, you have inherited legacy systems as you have acquired products or companies or upgraded your own. We tried to make our software as user friendly and as easy as possible. We actually started with the design process and then turned it over to the programmer. In other words, we graphically designed all of our screens and then we asked the programmer to complete them. Therefore, the system looks very clean and very simple. If you open it up it to complete an assessment it looks no more complicated than a standard survey. What is behind it is much more complicated. However, when you are administering it or completing the assessments or even looking at the reports, we try to make it as user friendly and clean and crisp as possible.

CEOCFO: ***Why pay attention to CRO Analytics today?***
Mr. Malamis: Because we offer a substantive, meaningful new approach to saving money and speeding therapies to patients. It is a very practical application that delivers actionable data that can ultimately make a difference in people's lives. It may seem a long way from assessing study startup or the study in Phase II to saving a person's life, but if you are getting a product to market one month or six months sooner, there are people's lives that are impacted by that. It is real, it is scientifically rigorous. It is well grounded in methodology. Therefore, it can absolutely be a piece of the puzzle to improving clinical trial performance. We are not claiming that we are going to change the fundamental nature of clinical research or anything like that. We are claiming that here is something that can make a meaningful difference and the value associated with it is well worth the level of effort. That is why I would say that you should pay attention to us.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

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