Interview: Douglas Peddicord â?? Executive Director, ACRO (Association of Clinical Research Organizations), USA

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Douglas Peddicord, executive director of ACRO, introduces ACROâ??s mission, the evolution of the CRO space in the US and globally, and how the latest political developments are affecting the association and its members.

Can you begin by introducing ACRO and its mission?

ACRO was established in 2002 and founded by, and still largely consists of, large global full service CROs. ACRO is open to all CROs, but it is actually the global CROs that have always participated in the association. In our space, it is the larger companies that are interested into devoting resources to government affairs, whereas many of the smaller companies are much more focused only on their own growth and business success.

In our experience it takes a company of a certain size to really think about legislative and regulatory policy and how to influence the legislative, regulatory and business environment. We at ACRO have always focused on advocating for our members, as well as for our whole sector; our interest is an environment that is positive for clinical research around the world.

All of our member companies are global and, broadly speaking, the distribution of their work and revenues reflects the clinical research industry as well as the pharma industry as a whole, with roughly 50 percent in the US, 30 percent in Europe, and 20 percent in Asia Pacific and the rest of the

world. The association primarily focuses on US and Europe; we would like to dedicate more resources for Asia Pacific and the rest of the world in the way that our member companies have done, but it would not be practical for us to do so.

What shifts have you seen in past 15 years since your arrival to lead ACRO, in the way the CRO space have evolved?

The largest evolution over the last 15 years has been the move from being seen primarily as service providers to being seen as capable of being strategic partners. What that has meant is that there has been a move from functional service provider to full service partner.

On the part of sponsors, the shift has been from solely outsourcing pieces of a clinical development project, whether a data or a laboratory piece, to outsourcing entire projects. Our global companies have the capabilities and the infrastructure to run really large global projects. Another emerging trend is the increasing emergence of smaller biotech firms. Big Pharma, for whom we do a great deal of work, has the clinical development infrastructure to insource that work if they choose to. They have moved towards outsourcing because it is more efficient and it smooths out the variable resources that the boom and bust of drug development causes. For Big Pharma, we CROs are a way to gain efficiency and offload some of the variability and resource needs.

For smaller pharma companies and for biotechs, we are the infrastructure that they simply do not have. Therefore, if a Big Pharma company wants to insource their project entirely and run it all, they obviously can do so. However, if a 15-person biotech company that has one biologic in development, when they get to the point of development they are most likely going to look at a CRO for all of those resources as it does not make a lot of sense to build those resources for themselves.

Thematically, there have been two major shifts. One is the move from service provider to strategic partner, the other is being adaptable in responding to a drug development market that is changing, that has not only large pharma companies, but now increasingly has small pharma and small biotech and this is what our members have looked to respond to.

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Catering to these trends mean that CROs have to have the financial capabilities and infrastructure to be able to respond to different types of demand at any given time- how do they go about?

To reiterate, we have gone from only providing services to actually being deeply engaged in the entre development process including things like research design and regulatory affairs. Additionally, the number of MD PhDs who are in CROs has risen dramatically over the last 15 years.

How is having these two very different sets of clients affecting the operations of your member companies?

There is more and more outsourcing, not only of the clinical development phase, We are also seeing increased outsourcing of early stage drug discovery work on one end, and at the other, post-approval commercialization work. In many ways, that represents the entire life cycle of drug discovery, development and commercialization. Some of our companies are engaging not only in the development phase, which was always their sweet spot, but are increasingly engaged in early stage drug discovery, as well as later stage of commercialization. In some ways, these CROs are actually now looking like some of their Pharma customers, with similar sorts of engagement.

As some communication channels between the pharma industry, and stakeholders are being reduced, the dialogue between CRO and those stakeholders is rather opened. In some cases, CROs they even have contracts with government, and do a large deal of data collection- which will have an impact over the outcome-based pricing debate. Would you say that CROs hold an advantage?

Yes, certainly in the US, the move towards outcome-based pricing is going to significantly increase both post-approval studies, as well as the use of clinical data from a variety of sources.

Many of our members have a long history of acquiring data from a variety of sources. Quintiles IMS is one example of a company that has, over a long period of time, built a database not only of clinical trials, but of things like clinical care work and pharmacy prescribing. In that sense, the CRO sector is more prepared to use real world data, meaning everything that is not clinical trials. We are, in many ways, simply more equipped than our customers to capture real world data, whether through registries, patient reported outcomes, or data accessed through electronic health records.

Our customers have been focused, as they should have been, on data that supports the approval of their drug. Over time, we have focused on lots of related data so in that sense we are well positioned to move in the direction to which both the public and regulator wants to move: regulators are increasingly seeking that same sort of outcomes data that is going to be used more and more in pricing decisions. For CROs, which in general are not patent holders, we do not have the kind of pricing pressures or have to worry about the ultimate product costs that pharma has to.

Being the holder of data related to patients and to drug pipelines, with such a large spectrum of customers can pose certain ethical business issues. What is your members approach to this matter?

We work for the industry and to some extent, some of our companies are consulting now to payers as well.

We, CROs, have always been in a kind of middle man position. We run clinical development on products which, in the end we do not own or set prices for and this has always been the case. We have long been in that kind of reasonably neutral third-party position.

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Since the very beginning of the industry, our ethic has been that CROs cannot be incentivized for positive results. We run studies and we cannot engage in a contractual relationship that says we get paid more if the study is successful. That is in many ways the kind of ethical bedrock. Yes, we get paid for providing the service but not the outcome. Our sponsors bear both the burden of failures as well as the potential enormous incentives of successes; we do not quite have that.

In the USA, the number of CROs founded by people leaving pharma companies has increased. Can this also pose a problem to the reputation of the segment?

There are around 1,000 CROs in the US, but the 11 companies that are in ACRO represent about 70 percent of revenues. The barriers to entry of setting up a three-person consultancy are not very high. However, the sponsors of clinical development projects, especially in larger pharma, are very much aware that the infrastructure, reputation, and long-term stability of their providers are essential. These drug development project will take a dozen years, seven or eight years in clinical trial phases.

Certainly, larger companies will look at small and new entrants into the field and will make a decision based on a couple of things: including whether that entrant has unique or important niche capabilities that the sponsor cannot find otherwise, but also look at whether that company will still be around in 10 years when the sponsor wants to go to the FDA with an approval package.

There remain a lot of opportunities in the field, but we are also seeing an awful lot of roll up of resources and M&A activity; we may be coming to the end of this particular cycle. I donâ??t see the likelihood of a handful of companies representing 70 percent of revenues changing.

Shall we expect to see more mergers and acquisition like that of IMS and Quintiles in the near future? What are the current trends?

Without looking at that specific merger, clearly what are seeing is the enormous emergence of technology and technology platforms, that facilitate the data aspect of the development process in terms of both collection and aggregation. Things that used to essentially be manual are increasingly done using technology. There is a range of how our large clinical research member companies have moved in relation to technology platforms. Some have invested a lot in in-house resources, others have taken a â??buy not buildâ?? approach and there has been the emergence of companies in the data/technology space, some of which have become part of a CRO and others are selling to CROs.

The members of ACRO have traditionally been CROs that represent full-service global companies. However, in the last couple of years we have had several companies join the association that look rather different than those â??traditionalâ?? CROs. We now have Bioclinica as well as Medidata: two companies that are very much engaged in the clinical research process but are as much technology providers as they are more traditional project managers and clinical researchers.

In terms of evolution, our industry has experienced M&A activity and consolidation, but is now also a lot closer to technology companies. For example, Oracle Health Sciences is very much engaged in parts of the research space. It is interesting to see both aspects of this; on the one hand there is a lot of consolidation and on the other hand there is kind of boundary permeability on the outside in which companies like Oracle and IBM are very much engaged.

What are the most important things you see happening in the next years?

In terms of the current US administration, what the FDA Commission Dr. Gottlieb is hoping for in the next three and a half years is, as his predecessors have hoped, to find ways to encourage the development of more treatments in a way that is faster and less expensive. The FDA has two mandates, one is to protect the public, and the other is to ensure that the public has a supply of products that are intended to improve their health. He is supposed to be doing both of those â?? protecting against ineffective or dangerous products and encouraging the development of effective and safe products.

I think he wants to get to ways of doing development that are faster and more efficient. He clearly has a big interest in the clinical trial phase of development, and he has spoken about things like innovative trial design, adaptive trials, in silico trails, as well as modeling and simulations to reduce the numbers of patients that it takes to execute the trial. With the availability of genetic information, we are clearly moving towards the potential for the development of personalized medicine, which will mean smaller trials but also many more trials. For our industry, I think that this is a â??come out in the washâ?? kind of proposition; we will certainly see smaller projects as you are looking at a much more targeted population but there will be many more of those projects because instead of developing drugs which are 60 percent effective across a very large populations we are looking to split that population into ten subpopulations then develop 10 products which hopefully will get to have 75 percent efficiency. We are looking to increase the response rate of people who actually take

the drug in the end. That has the potential to be revolutionary in a lot of ways, certainly for individuals who take the resulting products.

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We as CROs are well positioned, because we have the capacity to run lots and lots of projects. Some of our challenges will remain as they are now, especially related to things like patient recruitment. There are not enough physicians participating in clinical trials and not enough patients participating in clinical trials. What we are developing is a better and better ability to use data to find the right patients.

It has been a fascinating industry to watch over this 15 years. The growth rate of the CRO industry is around 6.8 percent annually, which compares favorably to the pharma industry. This is certainly what is driving the M&A activity as well as venture capital investing; it is a well-positioned and positively positioned market right now.

Large pharma is outsourcing more clinical development and now also beginning to outsource not only the clinical development but also some of the early clinical drug discovery as well as late phase commercialization. Additionally, there are more and more small pharma and biotech companies coming into being; the advantage for us is that over time we have more customers.

What we need to do is figure out exactly how to exactly use the emerging technologies, whether wearable devices or data analytic technologies, to match that growing customer base.

To finish there is a huge debate around the repeal of the Affordable Healthcare Act in the Senate; does ACRO take any position on it, how might this impact your member companiesâ?? operations?

We have not taken any position on it and, in terms of health insurance issues, our members are primarily affected as big employer. The issue of the affordability of insurance or how expensive health insurance is in the United States is a business issue for any company with 20,000 employees. From a clinical research perspective, the availability of insurance is related very much to whether or not an individual is part of the healthcare system, and we happen to get patients for clinical trials because they are part of the healthcare system.

In that sense, obviously, if the number of people that have health insurance declines precipitously, it is likely to mean over time that there will be fewer people who are likely to be engaged in clinical trials because they are not in the healthcare system. There is a small counterargument in that sometimes clinical trials become the only access to the healthcare system for uninsured people. In lots of ways this is not a very good argument. You want people to be engaged in clinical research for a variety of reasons that range from altruism to seeking more effective treatments, but you do not want them to be engaged in clinical research as the only way to get to healthcare.

We are downstream of the ACA debate and have not taken a position on the legislation per se but in the same way you need a healthy pharma industry, you also need people to have access to the products that come out of that pharma industry, and at least in the US it certainly helps to have insurance to have access to drugs.

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