Interview: Berk Özdemir – CEO, Omega CRO – Turkey

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Omega CRO has evolved from its beginnings as a CRO contracted by local and multinational pharmaceutical companies into an organization leading clinical, epidemiological and observational studies of public interest across Turkey. CEO Berk

Özdemir discusses the highlights of these studies, including a giant EU 7th Framework project EU-GEI study on schizophrenia, and a longitudinal Cappadocia cohort study based on the famous Framingham study in the United States.

What would you say are the biggest strengths of Omega CRO at present, and which areas need some work?

This is my 14th year with Omega CRO, and my ninth year as general manager. Omega CRO founded in 1997 as the first Turkish CRO. Our biggest differentiating characteristic is that we are the only truly full service CRO in Turkey; other local CROs have limited services and often receive outsource services from us, while the global CROs have offices with limited services here in Turkey. We can take a study from the planning and protocol design phase, through document preparation and ethical and regulatory approval submissions, organize and monitor the study sites and investigators, and then manage the data, perform statistical analysis, copy-editing and writing medical manuscripts for publication. We also have the first clinical trial specific depot facilities for investigational and non-investigational medical products that serve since 2003.

Omega CRO is known to be an organization with great attention to detail and quality. Every big CRO or pharmaceutical company in Turkey employs Omega alumni, and there are CROs that were

founded by former colleagues. In the clinical trial area there are many colleagues and investigator who say they learned most of the things they know about clinical trials from Omega.

Omega has relationships with authorities in the MENA region, what is Omega's footprint in the region?

The founder of Omega CRO, Doctor Murat Hayran, was a clinician at Hacettepe University who wanted to do some clinical trials. He worked at university for a while but then he resigned and founded his own CRO. From the establishment of the company through the early 2000s, our focus as an organization was on pharmaceutical trials, ranging from phase II to phase IV, for both local and international clients. Starting in 2008, local companies began to struggle to invest in R&D due to the decrease in pharmaceutical prices. At the time, pharmaceutical clinical trials made up 95 percent of our business, and after seeing the research budgets of local pharmaceutical companies fall significantly, to the point that working with these clients was damaging our profitability, accordingly we decreased our collaboration with them.

This was one of the first steps in taking the CRO in a new direction, to reduce our dependence on the pharmaceutical industry in general and increase diversity and stability in our client portfolio. As such, we made relationships with the government, Ministry of Health, Scientific and Technological Research Council of Turkey (TUBITAK) and Coordinatorship of Scientific Research Projects of Universities that we had worked with. We collaborated with them in many projects. We also made relationships with the medical associations to get funding to conduct epidemiological studies in Turkey. This lead to Omega CRO conducting all of the prevalence studies in Turkey, on the field of psychiatry, rheumatology, urology, pulmonology, geriatrics, obstetrics, infectious diseases such as Crimean-Congo fever, gastroenterology such as hepatitis, cardiology such as hypertension, nephrology such as renal failure and salt consumption. Our salt consumption study was of key interest for the Ministry of Health (MoH), one that shaped their policy, because it showed that Turkey had the highest salt consumption per capita in the world at 16 grams per person per day. This study showed that one of the major sources of salt for Turkish people was bread, so the Ministry of Health actually intervened and told bakers to reduce the salt content of their bread, and as a result of this and other policies, salt consumption was reduced to 14 grams per person per day after three years.

After beginning to conduct this sort of epidemiological studies, we were able to reduce our pharmaceutical drug development trials business to 25 percent, without any trials from pharmaceutical companies that located in Turkey. We downsized the relevant departments, and increased the number of personnel we had in project development, data management, and

statistical analysis. As we developed expertise in the epidemiological area, as well as in the support areas for data management and such, we drew the attention of groups across the region who wanted to conduct their own epidemiological studies.

You are partnering with CROs, international and local, and servicing multinational pharma. Looking at your turnover, what percentage of your business to multinational clients account for?

At present, about half of our business is from medical associations, research funds and grants; this is a very good thing as we are less vulnerable to shifts pharmaceutical industry cycles and can contribute to our society through studies with a high impact on public health. About 20 percent of our business comes from international CROs like Icon, Ergomed, PSI, JSS, Fisher, and the rest is performing trials for the local affiliates of MNCs. We are Icon’s main vendor in Turkey. We provide regulatory submission, project management, site management, data management, IMP and nIMP storage and transferring services for Ergomed, PSI, JSS, Fisher.

What are some of the most notable epidemiological studies that you are conducting?

We have done some projects for the European Union. The biggest one is relevant to schizophrenia and its total budget is EUR 15 million. About 30 partners from around the world are participating in this project, which is called EU-GEI. Participants are Ankara University and our company from Turkey. This study was the first and the biggest of its kind in Turkey at this scale. TUBITAK requested us to make presentations on how Turkey can attract more projects of this type.

However, our flagship project is a long term core-study in Cappadocia, in the Avanos and Gülşehir; districts of city of Nevşehir. This study is long-term cardiovascular epidemiological study similar to the well-known Framingham study in the United States, which closely monitors health statistics of representative population. Dr. Hayran wanted to do a study of this type in Turkey, and we were able to start one in 2013 with the support of the Turkish Internal Medicine Association. The sample size between these two districts is larger than Framingham at 5 209 adult, as Avanos and Gülşehir have populations of 13 500 and 12 000 people respectively. Having two districts included in the study also differentiates this study from the Framingham model, as it allows the possibility of intervening in one population while using the other as a control. For example, we introduced an influenza vaccination education program in one district, and saw the vaccination rate increase significantly relative to the control. The MoH has been a big supporter of this project as it offers a good evidence base to develop new health policy, and in some cases can serve as a pilot province for such policies. Overall, we are very excited to be conducting this study, and have already

learned a lot about health issues in the Turkish community and non-communicable diseases.

What are some of the key challenges that global pharma and multinational CROs pose local Turkish CROs?

In general, medical companies do their works by outsources, but then they decide to do their work in-house. On the other hand staff turnover rate is higher in medical companies. Medical company staffs change their positions approximately in 2-3 years. This means that the responsible person change and she/he hand over her/his responsibilities to another person. This negatively affects the study related procedures sometimes. Beside, in many pharmaceutical companies, decision to work with which CRO is taken by Purchasing Department instead of Medical Department. In this case, they prefer to give work to CRO that offered more affordable budget instead of considering their quality. This leads to studies being conducted with poor quality.

Another problem is local CROs train their employees from ground level, but the global CROs are able to offer salaries twice as high as local CROs. And, they are able to attract many of experienced employees from the local CROs, draining the local CROs of their experienced employees.

In Turkey, there are some very good projects underway in line with the Vision 2023 goals, and the MoH recently hosted a workshop in Izmir on how to attract more clinical trials. Also, on behalf of the CRO association SAKDER, I am a member of Technical Committee Of Drug Industry established by Ministry of Science, Industry and Technology. This committee is discussing methods of how we can increase the pharmaceutical market as a whole, and what we can do to encourage the development of a Turkish drugs or medical devices.

How can the Ministry of Health and government help the industry to attract more trials?

The Turkish clinical trial area has changed a lot since Omega CRO was founded. At the beginning we didn’t have a solid regulatory framework, then we had solid regulations but the timelines became too slow, and now we have optimal regulation with optimal timelines. However, the current situation is still not very competitive, it is difficult for us to substantially increase the number of global trials we can attract. In our discussions with the MoH and investigators, the main barrier we have identified at present is the investigator payments, which is not very satisfactory. These payments are made through a revolving fund, and roughly 40 percent of the money in the fund goes to investigators. However, this 40 percent must also cover any payments to site coordinators to assist with the study, as we do not have site nurses in Turkey as in other countries. Unfortunately, increasing the payments to investigators would fall under the responsibility of a government economic council, and while the MoH understands the value of clinical trials and has

tried to advocate for increased payments, the financial authorities aren’t particularly open to understanding the reasoning for increasing payments.

Looking to the future, what is your vision for the next three to five years and what will be the story you tell us then?

In five years there will only be a few local CROs, and all the biggest CROs on the market, and perhaps a few freelancers. Omega CRO will be one of these local CROs and will survive, because we understood the changing dynamics of pharmaceutical industry/clinical trials and we adapted our client portfolio and our departments accordingly. We will continue to have a strong impact on Turkish public health through our epidemiological studies, and look forward to the results of the first decade of our core study in Cappadocia in 2023, and will continue to offer a full spectrum of CRO services at the highest standards of quality in the region. I would like to mention Dr. Murat Hayran on this occasion. He is our founder and unfortunately he died in 2013. We try to work follow his lead and we try to develop Omega CRO to memory of him.

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