Interview with Mehmet Yusuf, Managing Director, ALTİS Medical Research Turkey

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Mr Yusuf, Pharmaceutical Executive's readers are keen to discover, through our reports, prominent industry personalities, and they like to hear their stories. Having been instrumental in the formation of the CRO Association, SAKDER, and as GM of Altis, can you tell us a little bit more about yourself?

I have an education in medicine which I successfully completed in 1983. Following my compulsory military service, I subsequently pursued a further education in biomedical engineering, completed in 1990. In parallel to my studies, I started my career at a local pharmaceuticals company, C-Phar, for about 4 years. Following that, I continued my career development at Hoffmann-La Roche as a Medical Coordinator, for about ten years.

Stepping out of the corporate sphere, I founded Altis CRO in 2001; a business within the scope of clinical trials. In addition to this, I have been instructing at Bo?aziçi University in the Biomedical engineering institute. In my most recent entrepreneurial endeavour involved establishing the first the first Turkish data management and biostatistics company data management company, in 2010, together with my colleague, Prof. Dr. Mustafa ?enocak, – head of medical informatics at Istanbul University.

Altis is among the pioneering CRO's in Turkey and has recently celebrated its 10th year anniversary. In that time, what have been among Altis's key milestones and achievements?

When I founded the company, I had limited financial capacity. Therefore, we have learned to focus on gradual yet concrete growth since the beginning and that is what we have been emphasising on

for the past ten years. While I am open to other venues as well, this is the vision that I aim to sustain for Altis.

Last year, during our tenth year anniversary, we had the chance to take a retrospective look at our achievements. It became apparent to me that what we have been doing most consistently over the years, despite some financial setbacks, was top class solid clinical research. This is largely due to the fact that the local market fluctuates considerably and does not allow for sizable profit margins, unlike in other countries. This particular branch of the industry is very profitable, but not in Turkey. The key here is to acquire internationally sponsored trials, of which we have a few. Naturally, we are constantly seeking to expand our client base, but for the time being most of our clients are local.

Between 2008/9 Turkey adopted the EU directive on implementing GCP guidelines. How has this affected the industry and your business?

Turkey may have officially put this statement into legislation recently, however, the fundamental idea existed since 1993 as a draft bill, and was introduced as the first ICH GCP as a final document in 1996. Turkey had its own clinical trial regulation in 1992 which had come into effect in 1993. It was very much in line with the then published in ICH GCP and in some few instances it surpassed its level of standards. Around late 1990's, CADRIAC countries (The Collaboration Agreement of Drug Regulatory Authorities in European Union Associated Countries; a collaboration of 12 countries including Turkey) who was in accession plans for the EU, had an aim to apply EU regulations even before they went into negotiations with EU officials. At that time, I was helping Turkish government officials in that commission to satisfy the set standards. That is to say that Turkey had adopted this perspective early on since 1993. Therefore, in the latest legislations in recent years, the EU directive was indeed adopted as a written legal basis statement. However, I think that this was only a matter of putting things into their place, since the idea was there and it enforced all the time since the late 1990's. That is, the same principles were already in effect and in the legislation.

Therefore, in response to your question, not much has effectively changed since adopting the directive, in those terms.

What role is the government playing in the development of the Clinical Research sector in Turkey? Are
they doing enough?

In terms of goodwill, I think the government, or at least the technocrats with whom we communicate with most, have excellent will and vision. That is, they have the correct mind-set, so to say, to educate themselves. It is often the case that when they assume their roles, they know little with respect to the drivers of clinical research growth. The health technocrats are willing to listen to the

market participants and learn quickly. In fact, in the last two or three administrations they have all had the same idea and worked in the same direction, to develop the clinical research market.

As to whether they are doing enough, it is my understanding that politics is an entirely different game with different priorities. Apparently, due to the experimental nature of the industry, the advancing of clinical trials within the political arena is a difficult subject that rarely merits good political credit. Nonetheless, I think the technocrats are doing their best and it is moving slowly, but surely. For instance, in 2008 – 2010, the clinical trials industry was in a tight spot and we really needed clinical trials law. However, I personally did not think that that would transpire since it coincided with an election period, denoting far removed priorities. To my pleasant surprise, however, the Ministry of Health worked extremely hard towards achieving this goal and actually passed the law before the elections. I think that is really more than one can expect because I am aware that they can have different priorities and so I think they are doing a fantastic job.

What makes Turkey an attractive market for Clinical trials, in terms of pool of patient's available, qualification of researchers, hospital infrastructures, and service providers?

As you surely know, Turkey boasts an immense number of beds, as well as an equally large number of people treated for various kinds of diseases. The annual turnover of patients visiting hospitals is also great, at about 80 million; exceeding the size of the population. Moreover, the number of potential researchers for clinical trials is also significant. This includes doctors in universities, teaching hospitals and people in specialty training. This leaves you with a massive pool of talent and patients for this sector which is already a very powerful argument.

The third point is, as I said, that the Turkish clinical trials industry already has a mature legislative system since the early 1990's. I would agree that it does take some time before legislation is internalised and put into practice, but I think that we are past that already since mid-2000.

In summary, there is mature legislation, mature clinical practise, with ample amounts of facilities, top level researchers and a large number and variety of patients. Also, the labour is relatively inexpensive. What more can you ask for?

Indeed. The pharmaceutical market has been adversely affected not only by the economic crisis, but also due reduced government spending and protectionist style policies. Some say Turkey is still attractive in relative terms compared to Europe. What is your position with regard to this challenging context?

Earlier, I mentioned that it is difficult to stay afloat in Turkey with local studies alone. In terms of the size of the clinical trials market here, I would estimate that the share of locally sourced studies is probably less than 25%. Therefore, the adverse effects you mentioned have affected only a small share of the total clinical trials market. The remaining 75% has probably not been affected by this.

In fact, it is likely that the foreign dimension of the market has received increased attention as a result of the shrinking local market.

In terms of being preferable to EU service providers, I could not agree more with the statement. There is a huge potential has not yet been fully realised. I think the position of Turkey today is comparable to that in rest of Eastern Europe 20 years ago. Certainly, there will be a saturation point sometime in the future, but we are not there yet and I believe that Turkey is a preferable market at this time.

Altis offers a wide range of CRO services from phase I-IV CT's to clinical research training. What are your most sought after services today?

The best known and most prestigious service that we are providing are the clinical trial training services. We are doing this almost exclusively for Roche and it is being very highly regarded. Next to that, I would say our phase trials are next in terms of popularity.

I should point out however, that phase I studies were extremely difficult in Turkey. This has recently changed with the introduction of a new law last year. Until that amendment, we adapted to those challenges by forming a strategic alliance with a Jordanian CRO that was exclusively involved in phase I studies. They carried out our phase I studies for us, while we carried out their higher phase trials for them; a mutually beneficial situation for us and our customers.

How do you evaluate the company's current strengths?

As I mentioned earlier, when we took a look back on our ten years of service, it was evident to us and our clients that we had never disappointed. Although we did experience some challenging times, we never let anyone down and we never turned our back on hardship. Put differently, we have a solid commitment to our clients, always deliver on our promises and almost always exceed their expectations.

I do believe we serve and provide for our clients through the highest levels of dedication and standards, likely more than anyone else. We do this not at the expense of the data or quality of work, rather it is about being proactive and delivering immediately. With our customer environment, it is not only expected but also appreciated.

Last but not least, we at Altis maintain a solid and close relationship with the government officials. I believe this is very important in our industry to stay ahead of the pack and be able to react efficiently and effectively to the rapidly changing dynamics of the clinical trials industry.

What are the must have of a Clinical Research Organization to succeed in Turkey and be the partner of choice for the industry?

Turkey is really a strange bird, no pun intended. I think that it is paramount to be flexible with local Turkish customers. Having worked with many international partners, this is often more true in Turkey than in anywhere else. Customers tend to be highly demanding and require things to be done by yesterday. Of course, that is tough.

Also, in dealing with the government, it is very important to have a solid relationship with people there and this requires a significant amount of relationship building and interpersonal skills. Last but not least, you should always deliver.

What growth objectives or strategies have you defined for Altis over the medium term?

Overall, we are pursuing a strategy of steady organic growth of our operations. Looking ahead, we intend to expand and establish offices in New Jersey and Delhi. We have opted for New Jersey for the simple reason that it is probably the heart of the pharmaceutical industry in the United States. I believe it makes sense as I have seen many small CRO's like ours be successful in international business by maintaining offices there.

Delhi, on the other hand, has a double reason. First, it is also the heart of a very lively clinical trials environment. It has an impressively excellent pool of educated mathematicians and statisticians and it boasts a booming economy with inexpensive labour. In addition to this, I have a solid business network there that can accelerate the development of our business.

In short, I hope to grow Altis into a humble worldwide CRO that can cater to each individual clients needs in a unique and flexible manner. I think this is the way forward and this is how we will make a difference.

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