Sule Mene – Founder and CEO, MENE Health Group, Turkey

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Sule Mene, co-founder, president and CEO of Mene Health Group, shares with PharmaBoardroom the journey of her company starting as the first government-approved CRO of Turkey, its parallel growth alongside the increasingly prominent clinical trial environment of the country, evolution to becoming a value chain group of companies in clinical research and how she plans to lead the company into the global market by leveraging its unrivalled, holistic service offering.

The number of ongoing clinical trials in Turkey has more than doubled between 2011 and 2016, thereby placing Turkey in the top three countries to have the fastest rate of increase in clinical trial registrations. How do you explain this eye-catching development?

This growth can be attributed to the improved regulatory framework for clinical trials in Turkey. The Ministry of Health (MoH) and the Turkish Medicines and Medical Devices Agency (TiTCK) understand the importance of having clinical trials done in Turkey, and guidelines, forms, and processes have been made clear and concise. There is no longer the sense of mystery that we faced in the past regarding the starting and approval timelines. The process was streamlined to improve both the speed and quality of trials in the country, which has made a significant difference. In the grand scheme of things, this new system is similar to the one being used in the

European ecosystem and the sponsors of trials have logically recognized the value of Turkey in this sector.

What are the strengths and advantages of Turkey for conducting clinical trials?

One of the unique strengths of Turkey is the country's patient population and the high prevalence of certain diseases. For example, due to the fact that Turkey has a high rate of consanguineous marriage *[declining, but still revolving slightly over 20 percent overall – Ed]*, many inherited and recessively transmitted rare diseases are significantly more prevalent in our country than in the US and Europe.

The second advantage is that Turkey has been participating in clinical trials for over 30 years. There is a high level of research discipline and adherence to Good Clinical Practice (GCP). Investigators take a very active role during the studies – conducting audits to ensure standards are upheld. An impressive feat in Turkey moreover is the absence of fraud; of course, errors can be made and information can be mistaken but we do not experience intentional fraud.

Turkey also has a well-established hospital infrastructure that is perpetually developing. In the past, only university hospitals could conduct clinical trials. However, in recent years, the MoH has allowed top-ranked healthcare institutions to participate as well. This has opened up the available wealth of resources in Turkey dramatically.

Another aspect to consider is the booming development of the country's health tourism industry *[the MoH expects between 850,000 and one million visitors for medical tourism in 2018 and around two million by 2023 – ed],* as Turkish hospitals, medical equipment, and professional quality are well recognized in the region and beyond. These factors have driven the industry in recent time and sponsors increasingly want to come to Turkey for trials because they can also gather insights from medical tourism patients.

Phase III-IV studies typically constitute most of the clinical trials conducted in pharmaemerging countries. Is the Turkish ecosystem mature enough for phase I-II trials?

Over the past few years, the number of phase II trials conducted in Turkey has increased substantially. There is a desire to participate in phase I trials as well, but only specific institutions

have been given the approval to do so up to now. The limitation does not exist in the ability to carry out the trials, but rather in the current regulatory framework: if the MoH would entitle a large number of top institutions in the country to conduct phase I trials, I have no doubt we will witness a similar surge as for Phase II-III-IV trials. In addition to this, Turkey has developed state-of-the-art private hospital networks in the past 20 years which initially was helpful to drive healthcare tourism to Turkey; moreover, they paved the way for the intellectually developed hospitals and staff to seek for diversification in conducting further clinical research in neighbouring countries, as well. This is definitely going to transform some of the private hospitals that have clinical research understanding into clinical research excellency centres

Still on the regulatory side, do you see any other rooms for improvements to prioritize?

The MoH needs to remain aligned with the EU, which is currently working on a single assessment and approval system for new medicines. In this context, the Turkish agency should work closely alongside its European counterparts to ensure we are included in the same registry system and are not excluded from the harmonization efforts bolstered by our neighbours.

Having been in the industry for over 25 years, how have you seen the relationship between clients and clinical research organizations (CRO) evolving?

Several years ago, the client-CRO relationship focus was on fulfilling a service by completing singular tasks. However, this has transformed into a mutual partnership in a way. In this regard, Mene Health Group is sharing services with its clients and we collaborate during studies from start to finish. They are very open with their goals of projects and we are working more closely than ever before.

With this change, there is a higher expectation of delivery and output in all roles. Research is getting more expensive and all sponsors are consolidating budgets to achieve quality results in a shorter period of time. We have also seen that the pharma industry is increasingly reluctant to spend resources on creating in-house R&D capacities, and the latter has become more comfortable with outsourcing services to clinical research organizations despite past hesitation. Today clinical trial sponsors fully rely on CROs to facilitate, optimize, and accelerate the advancement of R&D projects, but the context was completely different ten years ago when we had to sell the concept of working with a CRO on top of selling ourselves as a preferred partner. Mene Health Group evolved

beyond being a CRO and created a holistic value chain with its clinical trials, specific warehouse and transportation, and site coordination activities

In 2002 you decided to take a leap of faith and leave the corporate world to set up your own company. Can you introduce Mene Health Group to our international readers and share some of the milestones you have achieved in recent years?

Mene Research was the first MoH approved CRO in Turkey and experienced initial success. In the meantime, we swiftly understood the importance of providing a complete set of services for investigational medicinal products (IMP): for example, all the documentation and preparation can be done perfectly, but if the IMP is not stored or transferred properly, there is a problem. As a result, we incorporated Depot Meridian, the drug storage arm of the group, the first clinical trial specific warehouse to be accredited by the Turkish Ministry of Health (MoH). Depot Meridian offers stand-alone storage services for clinical trial drugs while assisting in making import license applications to the MoH, gaining customs clearance for importing and exporting drugs. At first, we only handled the IMPs of the studies we conducted, but we rapidly increased our scope of action given the strong demand we met.

With the increase of temperature-sensitive biotechnology products, handling IMPs has become even more challenging, while an increasing emphasis is put on cold chain management from a regulatory standpoint. Although the IMPs can be stored in the right conditions in a warehouse there is a difficulty of delivering them to the sites, especially if you consider the extreme temperatures that can affect a country like Turkey. As a result, we built another department focusing only on the temperature-controlled transfer of IMPs, Meridian CSL, which is responsible for distribution and collection of clinical supplies, transportation of temperature-sensitive products in controlled vehicles or passive shippers, management of destruction services, as well as document management and biological sample retrieval for storage.

Currently, we are handling more than 200 projects in Turkey, and this number keeps on improving year after year. As the ecosystem of clinical trials changes, we have an advantage because we are well established and have a long history in the sector.

MENE SMO is the site management organization (SMO) for clinical trials. MENE SMO provides site management organisation solutions for clinical trials of novel drugs and treatments. MENE SMO’s team of clinical research coordinators (CRCs) specialize in supporting clinical operations, project management, and quality assurance activities under directions from the principal investigator (PI).

With such a strong foothold in the Turkish market, how is Mene Group expanding its services to become a noteworthy global player?

Mene Health Group covers a long value chain. We are not only concerned with one aspect of clinical trials, but instead, cover the entire base from start to finish – the selection of a site, data collection, supply chain management, and more. Our scope of service is concentrated on clinical trials exclusively, including both pharmaceuticals and medical products, and no other CROs in the world can match the depth and width of our service offering. We have the expertise and know-how to offer an all-in-one package which we can reproduce across the globe.

Expanding overseas, Mene Health Group opened an arm in the US focused on medical device studies and recently established operations in Europe, the Balkans and Asia. Even our colleagues from other countries are asking to launch joint ventures. We are also in the processes of planning to enter two additional countries in Europe. In 2018, there are many economic difficulties both in Turkey and globally, but we will not be stopped by this challenge. On the contrary, we continue to grow and in the next few years, we plan on being present in five countries across three continents.

The latest achievement of Mene Research is being a founding partner of a global alliance called ACROSS Global Alliance, headquartered in Singapore. ACROSS Global is a strategic alliance of clinical research organizations (CRO) that extends across the world. Twelve CRO members across 95 countries provide sponsors with access to more than 1,500 study sites and almost endless numbers of potential clinical trial subjects. ACROSS' more than 1,300 employees are fully dedicated to the highest standards of conducting cost-effective clinical trials across the globe. The well-balanced combination of local knowledge, globally experienced professionals and the latest technology allows our clients to conduct faster, cost-effective studies without sacrificing quality. Whether for small or mid-size Pharma and Biotech, the ACROSS Global Alliance makes global studies seamless.

Mene SMO also signed an exclusive strategic partnering agreement with Swiss company Chrondel to be a licensee of Chrondel services in Turkey. Chrondel is a global site management organization for the clinical research industry. Chrondel's training experience, research expertise and robust IT infrastructure will enable Mene SMO to partner globally with research sites, investigators and hospital management to leverage site performance, efficiency, quality and activities.

During our journey of a product life cycle, starting from the discovery of the new molecules, we had the chances to observe the baby steps of many different innovative life sciences companies that

also enabled us to learn in depth of clinical research in every aspect. Today we believe the future of healthcare will mostly rely on life sciences start-up companies, and we have created a business model to support these companies and have a revenue stream to grow bigger and support many more companies. We call this new business model Mene Ventures BV, a company established in the Netherlands for angel investment to life sciences.

Looking a bit farther into the future, where do you see Mene Health Group by 2023?

In 2020, 30 percent of pharmaceutical products will be biologicals – 80 percent by 2050. This means the treatment necessary to handle the products will be very important. Our work in clinical trials is putting us ahead of the curve. We would like to use this change to implement bigger projects with prestigious products, and we see the most innovative biotech products as our future market.

At a minimum, we want Mene Health Group to have reached at least 10 to 12 countries in the world and have a presence on all the continents. Currently, we are working with a management company to establish a site organization department. This plan is not only for Turkey – we will eventually build into Europe as well. Over the last few years, we have to put all our energy into the strategy and planning, and very soon we will begin to see the developments.

What would be your final message to our international readers?

It is important to remember that Turkey has been participating in clinical research for more than 30 years. In the past, Turkey faced many difficulties and boundaries; however, we have overcome these hurdles with huge success. I believe this has made the Turkish ecosystem much stronger. The medical professionals in the country are every eager to do the research, the motivation to play an ever-increasing role on the global R&D map is particularly strong, and I have no doubt we will continue to climb up the innovation ladder in the coming years. It is always a big advantage to have a solid R&D framework, the government is aware of this and is giving full support to nurture this environment.

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