Arianne Clinical Research Algeria â?? Cellia Habita, President and CEO

05.01.2015

Tags:

clinical trials, CRO

The global CEO of Arianne, who herself happens to be American-Algerian, outlines why, in an era of clinical research globalisation, the country has all the right fundamentals in place to establish itself as a leader in conducting clinical trials and how the Algerian genetic code is well suited for testing Western orientated pharmaceutical products.

What initially brought Arianne to the MENA region and Algeria in particular?

We are headquartered in the US with an emphasis on providing both clinical and regulatory services worldwide. We cover 25 countries across the globe. The Middle East and North Africa (MENA) is actually a rather underrepresented region with less than one percent of all global ongoing clinical trials. American CROs are not established in the region and have mostly ignored this region possibly due to geopolitical factors. It is nevertheless well-known that specific countries such as South Africa and Algeria represent sizable markets for the pharma industry. The same can be said of the MENA region as a whole with important pharma markets developing in Saudi Arabia, the UAE and Egypt. We felt it was important for us to be present here as a differentiator within the CRO market, but also because of a growing willingness within the research world to incorporate countries such Algeria in their studies. These demands will only continue to increase since the MENA market is one of the few growing pharmaceutical markets and with the current saturation of clinical research in North America, Western Europe and even CEE (Central and Eastern Europe). We were keen to be at the forefront of that. I myself was also born here, so have an additional incentive to be contributing to a place that is dear to me.

How then would you describe your market offering in Algeria?

Algeria very much represents the latest addition to our portfolio, but we intend to make it the centerpiece of operations in this part of the world. We arrived here with a strong clinical operations expertise particularly in interventional clinical trials. If you examine the regional map and trace the

evolution of clinical studies, you will find that the first trials conducted were in general observational studies. But this is now slowly changing with more and more interventional studies underway. Companies are more comfortable working in the region, and are finding out that local investigators can provide quality data and are very keen to participate in clinical research, particularly in the case of Algeria. We feel we can contribute in this field because knowing that more than 80% of our studies are interventional we can bring that extra know-how into Algeria and the neighboring countries. When we speak to local investigators they are tremendously excited about working with us because it offers them an opportunity to gain exposure to clinical research and to develop new investigational products from the latest and the best of what R&D has to offer. In terms of therapeutic areas, we have expertise and an excellent track record in cancer and diabetes research, amongst other indications which also happen to represent some of the largest market segments for pharmaceutical product development in the region. All of this makes us a great fit and natural participant in the market. We bring something new in terms of our knowledge and crucially possess the capabilities to properly support local investigators by affording them practical know-how and exposure.

Who do you see as your prospective client base in Algeria?

Our model prior to coming to this region has historically been to focus on biotech companies in the US, Europe and some major Asian pharma players. That was initially our niche, but since setting up across the MENA region, things have changed for us and we now are primarily working with pharmaceutical companies when it comes to MENA. Having said that, we continue to aggressively market the region for biotech companies while remaining cognizant of the potential to be derived from a high presence of pharmaceutical companies that have been attracted by the vast untapped patient populations., In addition, it is often critical for these groups to conduct studies within the countries they plan to market their products as it often facilitates their interactions with the regulator agencies and the registration of their products locally. For the last 18 months, we have been raising awareness for the region and more specifically, Algeria, by hosting events for clinical outsourcing to attract more Sponsors pharma and biotechs. Once they arrive, we should be seen as obvious partners. Raising awareness and an understanding about the Algerian market is important especially from an American perspective since the MENA region remains something of a black box of unknown quality. Thatâ??s why we do our best to spread the word as to what the country has to offer and reassure potential Sponsors about the quality of the data collected here.

To what extent can Algeria practically establish itself as a new destination for bioequivalence studies?

Biosimilar and bioequivalence studies are already taking place in some Middle Eastern countries such as in Jordan and Lebanon. Egypt is also pushing hard to establish itself as a preferred destination. Algeria is already conducting bioequivalence studies, not as much as Jordan, but has the capacity to do more and be a player in this arena. Algeria has a tremendous potential for conducting all types of clinical trials particularly interventional studies within a global setting. The country has a well-educated workforce especially when it comes to Investigators and their staff. Algeriaâ??s hospitals in the regions are also comparable with those in Southern and Eastern European countries so the appropriate infrastructure is definitely there. You could say they represent a good match and a real competitive alternative.

It is also very important to note that Algeria possesses a predominantly Caucasian population which means they are genetically very similar to western populations. This confers a significant advantage. Conducting clinical trials in India and China brings the benefit of being able to develop a product that can reach out to a 2.2 billion local population, but not something that is necessarily suitable for Western markets because their genetic makeup for some disorders may not be representative of North American and Western patients. The latter represent at this point in time the largest

consumers. Genetically Algerians are much closer to western patients. There is a real opening for leveraging this part of the world and integrating the data with US and European studies without risking the sorts of differences that could ultimately compromise the performance of the product when sold on Western markets or require additional clinical studies to better represent the targeted patient population.

During this era of globalization of clinical research, what would you say are the other key selling points for Algeria?

The main appeal is the large untapped population. We are talking, just in Algeria, about 40 million people, many of whom are â??naÃ¯veâ? when it comes to prior pharmaceutical treatment and their correct usage. The whole MENA region represents close to 600 million inhabitants, not a number to be neglected. Add to that the fact that they are well-educated with a high level of adult literacy, with government actively working on improving the quality of care, of research and the regulatory environment. Look back 10-15 years ago, how the newly joined central and Eastern European countries to the EU were when it came to clinical research. They had a very limited exposure and experience. Today, no global study passes on that region, and it must be noted that it is a saturated region when it comes to clinical trials. Plus they do not represent the market share MENA represents for pharmaceutical companies. There is always a snowball effect. What started off as quite small and insignificant, rapidly matured into booming industries. Imagine, then the potential of Algeria with its much larger starting base when compared to countries such as the Ex-Jugoslav republic or certain ex-Soviet countries.

In this game, the key is to have a fast timetable to market and speedy patient enrolment. How does Algeria fare on these fronts?

Algeria has surprisingly attractive timelines for regulatory approval. A comparison with other regulatory agencies around the world is indicative of this. In Brazil, for example, you can expect a 12 month wait; elsewhere 9 and 6 months for China and Eastern Europe, respectively. In Algeria, by contrast, the whole process is complete within only 3 months. Ethical committees in Algeria are also centralized which is helpful because it means submitting all your sites to a single center. The local regulatory system is sequential, and once ethical approval is granted, submissions can be made to the Ministry of Health. Approvals are usually granted within 2 months, but of course could be longer if queries arise.

Even in the USA, though the FDA itself might respond after 30 days to an IND, tt may take longer to get the study up and running. For example, working with large academic centers which have their own IRBs, it often may take up to 6 months before authorizing the study within their institution.

The Lebanese model is the fastest and one of the oldest frameworks in the MENA region and is notable for allowing Phase I clinical trials. For timeframes in the Maghreb, you can think of three months, and in the Gulf there is much more of a differentiation between observational and interventional with each country reliant upon its own specific system. North Africa holds the advantage in being much more homogenous â?? both in terms of its populations and its regulatory frameworks.

As a relative newcomer to the clinical research scene, what has Algeria still to learn if it is to establish itself as a heavyweight destination for clinical studies?

Itâ??s really about the rule of numbers. You have to do 10,000 hours of something to really become good at it. The more local Investigators gain exposure and practice in conducting studies, the more competent they will become at it. It is something relatively new here and thatâ??s why it is very important for the country to be participating in international trials. Same for the regulatory agencies,

the EMA, 15 years ago, did not have all the directives and guidelines it has today. It takes time and it is based on experience and exposure.

We have been working with Drug Information Association (DIA) to set up the first DIA Maghreb which will take place in Algiers in February 2015. The aim will be to discuss a range of thematic topics including biosimilar development, clinical trials and intellectual property. By fostering this two-way exchange, we hope to make it easier for all parties within the country to tap into what it going on in the clinical research world globally and for outsiders to gain familiarity with the characteristics of the Algerian market.

Outsiders sometimes ask about the reliability of the country regulatory framework and wonder about the integrity of the data coming from clinical trials in Algeria. In reality Algeria has much stronger regulations in place to protect IP than the rest of the region and also compares very favorably to countries like India and China. The quality of the data is also respectable despite the much smaller volume of studies that have been completed to date. The Maghreb region, as a whole, complies with ICH guidelines and Algeria is no exception.

The country is on the right track and there are no specific major shortfalls. This is a work in progress that will take time. Right now, there are probably 200 trials, 80 to 90% of which are observational. We believe that in a country like Algeria, with the right policies and training, this number could surpass 2000 trials per year, bringing in millions of dollars in new investment and linking Algerian clinicians to the global research community.

The government has committed to making Algeria a center of excellence for biotechnology by 2020. How far along the line are we to making this a reality and what specific contribution does ARIANNE expect to make?

The very first meeting in June 2011 was an eye-opener for all sides. Creating a program of such a scope and complexity requires well thought ideas, extensive exchanges and communications from all sides before a strong implementation. In this case there are many government and institutional parties involved within Algeria but also the local innovative pharma industry. But with the signature of the MOU in San Diego this past June during BIO, things are starting to take shape. Despite some delays, things will start to happen in 2015. And again, it is unfair to expect such a vision to be an overnight process.

If you analyze the growth trajectory of the top performing Asian healthcare industries, they basically started off with local production of raw materials and generic manufacturing. Over time they transitioned their capabilities to undertaking more and more complex forms and now we see new biotechs and innovation coming from that part of the world. This certainly did not happen automatically overnight. Today, I would diagnose Algeria as being at the generic phase. The next step is for local biotech firms to develop and these most likely would be grounded upon international partnerships. There is a process, a sequence of events that cannot be short circuited. The standard development path, however, is to build up a highly specialized, highly trained workforce that can contribute to the booming and growing local infrastructure so that, when the moment comes to launch into biotech, the foundations are already there.

ARIANNE was present at the signing of the MOU and we believe we can contribute in helping the local growth â?? we all have a potential role to play. I know from first-hand experience that leading U.S. and European-based innovative companies are very committed to working with Algerian policy-makers to realize the goals of the Vision 2020 report, which was endorsed by the government in 2012 as their road map for the future. That report was formulated via input from more than 25 Algerian officials, and offers various recommendations, including in the regulatory and educational

areas. Algeria is the only country in Africa today that has this kind of detailed vision, strategy and policy-road map as a platform for dialogue with the industry.

When we next interview you in 4 to 5 yearsâ?? time, what will have changed?

Over the next five years you will see a very different clinical research profile developing across Algeria. More and more companies are opening their doors including service providers such as ARIANNE and this is a trend that is set to continue. The types of international vendors that we work with are increasingly keen to leverage Algeria so there will be much more activity in that domain. Moreover, the governmentâ??s vision for Algeria 2020 will move forward along and will lead to high level projects and programs that will only showcase Algeria as an R&D Hub in both the region and the world.

Algeria is fast becoming a country that will be hard to ignore. The innovative medicines industry invests globally tens of billions of dollars each year in R&D, and Algeria is one of only country in Africa today that has signed an MOU with the industry setting out a framework to discuss proposals that would propel the sector in Algeria. Algeria needs to capitalize on this â??first moverâ?• advantage that it has over its MEA rivals.

In terms of ARIANNEâ??s own growth, our ambition is to become renowned as experts in this part of the world. We already cover pockets across the African continent â?? from North to South Africa â?? but over the next few years we intend to firmly establish ourselves as the go-to American CRO for Africa and MENA.

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