Wafaa Farhat Agoumi – Director General, ESISMP

[For Morocco] to become a major player in healthcare, investment in research and development is also needed

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Wafaa Farhat Agoumi serves as DG of the Health Engineering and Project Management Graduate School (ESISMP) in Casablanca, Morocco, as well as president of the African Association for Clinical Research (AARC). Agoumi gives an overview of her current work areas of focus, the evolution of clinical research in Morocco and Africa thus far, and her hopes for how it can be progressed by greater international collaboration.

Can you please briefly introduce yourself to our international audience?

I trained as a biologist and toxicologist and also have an Executive MBA in General Management from ESSEC. I worked in the pharmaceutical industry in France for 26 years, more specifically in drug development, namely clinical development, pharmacovigilance, and quality. In addition, I have been an Associate Professor at Montpellier University since 1999, when I created the Clinical research training programme at the Master degree level. I left my job in the pharmaceutical industry in December 2010 and kept my part-time university job in Montpellier. I moved to Morocco to set up the Ecole Supérieure d'Ingénierie de la Santé et de Managment de Projets (Health Engineering and Project Management Graduate School) in Casablanca, where I replicated the programme in 2011.

I continue to work with the industry as a regulatory affairs and protocol writing consultant in Europe and the Middle East. For instance, I worked on a regulatory framework with the Qatar Health Ministry, helping to set up clinical research audit procedures for clinical research units in Qatar.

Tell us about the birth of the *Association Africaine pour la Recherche Clinique* (African Association for Clinical Research (AARC)). When and how did the project take seed? What does the Association represent today and what are its missions?

Through my experience in the pharmaceutical industry, specifically relating to clinical development, I noticed that clinical research in Morocco had not been making progress for a while. This was partly due to regulatory barriers. The law was only introduced in 2015, but I had already brought in a first phase-two trial in the 1990s. We wanted Morocco to be a part of drug development because we have the skills here with well-trained doctors, pharmacists, and scientists.

I set up this training programme to enhance those skills and teach some clinical-research-specific skills. Unfortunately, the regulatory aspect slowed us down because the law did not exist.

We were working with a circular put in place in 2012, and only in 2015 was the law finally introduced. It was decided to improve on the implementing decree and provides a regulatory framework for the conception, execution and monitoring of clinical trials in Morocco. We could compare it to the French LoiHuriet, before clinical research in France was governed by European law.

Through this law, we established good clinical practices. It refers to several international standards which must be adhered to in order to do everything by the book.

The AARC was born from a round table with several manufacturing representatives (FMIIP [Moroccan Pharmaceutical Industry and Innovation Federation] members), academics and professionals who expressed an interest in drug development. We wanted it to be open to the rest of the African continent, which is why we called it the Association Africaine pour la Recherche Clinique. This allows us to build networks, act as a go-between between regulators and countries in terms of improving regulation. We want investors and manufacturers to show an interest in drug development in Africa, and we want to attract them.

At the same time, we need to improve awareness of clinical research on a national and continental levels. These jobs are not well known. We want to act as a point of contact for everyone; from manufacturers and regulators to professionals and academics, as well as the general public taking part in trials who may need to be reassured about consent, medical monitoring and risk.

With the Moroccan economy growing at a faster rate than those of its neighbours and greater inflows of investment following the recent investment charter, what opportunities do you see arising for the country in the healthcare space?

There has been a real political commitment since the pandemic uncovered a lot of problems in Moroccan healthcare. For instance, the roll-out of compulsory health insurance is a consequence of the pandemic, even if there was a vision prior to this event. Investment in healthcare is happening, for example there has been significant investment in vaccine production. We are not going to produce vaccines straight away but we are acquiring experience. We will have to see when production really takes off. Morocco would like to be a major player in Africa’s health security. We have also seen a lot of investment in private clinics. Furthermore, universities providing medical, pharmaceutical, and general healthcare sciences training are opening up.

But to become a major player in healthcare, investment in research and development is also needed.

Where are we up to in terms of research and development? What can you tell us about the clinical research landscape here in Morocco?

Honestly today there is not much and even trials we take part in are often international trials, very few originate directly from Morocco. They are usually Proof of Concept trials or minor trials concerning national trials. We do take part in several phase-two or phase-three and phase four trials, but it remains anecdotal in comparison to what we are capable of. Due to the regulatory constraints I have mentioned, there is no fluidity or regularity in clinical trial approvals. Some can be authorized within two weeks or a month, others can take six to eight months.

What are you hoping the country will gain from this new drug regulator being created?

Regarding clinical trials, I hope the agency will harmonize the process and take the lead. It would be a good idea for it to play a coordinating role, for example providing a point of contact for manufacturers needing authorizations. Of course, the CNDP (National Commission for Personal Data Protection Monitoring) and ethics committees are independent from the agency, but it could still act as a coordinator.

The Moroccan government’s ambition is to move towards innovation. Do you think they are aware of this need to go further in clinical research? Is the dialogue open?

Even if they want to help innovation, we still need clinical research. The dialogue is open and I think both manufacturers and regulators are aware. The AARC recently organized a conference which gave us an opportunity to discuss these issues with them. The medicines directorate (DMP)’s representative even offered their support to manufacturers.

However, many do not know the DMP is willing to meet and support them, perhaps because of the way people interact through digitalized platforms. They do not communicate enough on the advancements.

Who are the main players you interact with in Morocco and Africa to further this topic?

We do this through conventions, conferences, and seminars where all parties are invited: manufacturers, ethics committees, DMP and CNDP representatives. In the last few years, the FMIIP, LEMM, the association of multinational pharma companies in Morocco, and AARC have organized regular seminars in order to make people aware of the challenges facing manufacturers and researchers.

Do you have current partnerships which have borne fruit?

Personally, I do not have any. I have been contacted by multinationals before, because of the Russia-Ukraine war. They want to implement several trials in Morocco for stability, because all trials taking place in Russia or Ukraine were affected by access issues, if they were not stopped altogether. This is an important opportunity for the area. I am no longer a player in the industry, I'm a teacher who can only offer advice, but I contacted the DMP to let them know these players who want to engage with Morocco need support.

The government is making education a priority but keeping the educated workforce in Morocco is a major challenge. What can you tell us about education, what skills need developing? What opportunities do you see arising there?

When I came back to Morocco, I really wanted to expand the clinical research workforce. I believe we can still grow even if we are not a research and development country. Just taking part in drug development on an international level could be very interesting. We could also develop data management platforms. Only one Moroccan drug has been developed so far (Olipen), others being generics or resulting in collaborations with other countries. I have always wanted to develop these collaborations, it's important to become involved.

Data managers, biostatisticians, clinical trial coordinators and clinical research assistants: these jobs are especially important and sought-after. Unfortunately, even at my school, many students choose to specialize in drug design and production or in the environment rather than in clinical research. Very few choose clinical research because they think there are few opportunities. Yet they are all hired at the end of their internship. And even those who work in clinical research and are hired by laboratories or CROs such as IQVIA or MCT Pharma leave for France or Canada after a year or two. For them, the job offers are more attractive and more numerous.

The government says it will invest in healthcare, security, and education. With regards to health, they have rolled out health insurance cover, but in terms of education, what is being done in Morocco?

There have been several measures to improve the education system.

French and English were reintroduced in primary schools to improve school leavers' proficiency. Additionally, the former Higher Education Minister implemented a Bachelor system to introduce language and soft skills to the bachelor degree, which was lengthened to four years. Subsequently, the new Higher Education Minister brought it back to three years in line with the Bologna Process. He has also introduced better foreign language learning and power skills across all six semesters, starting in September 2023. Work is therefore in progress.

In reference to education and clinical research, what are your hopes for the next few years in Morocco? What would you like to see happen?

My hopes are not just limited to Morocco, but cover Africa as whole. We must work with other countries because clinical research is global. I would like to see international-standard clinical investigation centers open up. It is not difficult, we do have the means and the skills, we just need political will to coordinate, harmonize and go forward at the same pace as other countries. Turkey and Egypt have advanced quickly and significantly in terms of clinical research thanks to political will.

I hope this new agency will provide the necessary coordination to attract investors, they need speed. We are a stable, multicultural country (which is interesting in terms of pathologies and ethnological differences), we now have an interesting regulatory framework, but it's not enough. We need political affirmation so that the administration can speed up the pace of authorizations and follow-up.

They should work with the AMA (African Medicines Agency) which was created last year. The AMA is willing to work with the EMA (European Medicines Agency) so I hope we can break down some barriers and have an African agency capable of regulating all aspects, from clinical trial approvals to marketing authorizations, to grow and also retain the workforce in Africa.

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