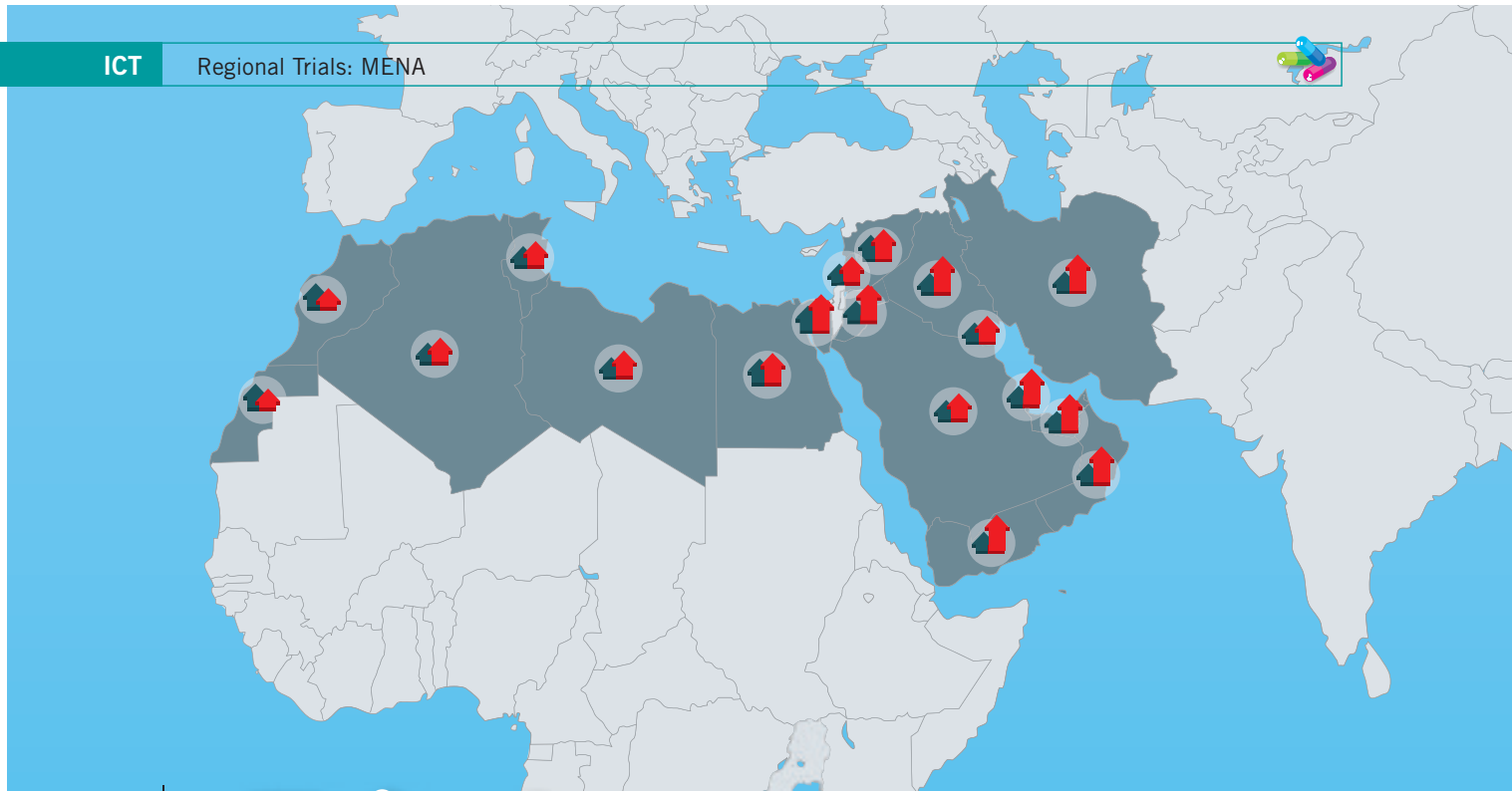

Riches on the Horizon

Chiheb Guerfel at Poseidon Pharma Services discusses the development of clinical trials in the Middle East and North Africa, and highlights the benefits of conducting research in this region

In our constantly changing modern world, the Middle East and North Africa (MENA) region has been at the forefront of the news for a variety of crucial reasons – especially over the last year. With these events radically changing people's lives throughout the area, the concept of 'a right to healthcare', as well as government responses to aspirations of better health, will not remain as it was. More specifically, health providers are facing new demands for a global standard in state-of-the-art medicine – a level of quality which western clinical research adheres to every single day.

Pharmaceutical research in North Africa still fails to generate the level of interest it should from health authorities. Although the region has efficient CROs, a wealth of potential CRAs, a good network of investigators and modern, furnished and fully equipped hospitals, local clinical research is still some distance from achieving the profile it would like among government health policy makers, health economists and resource allocators in the region, as well as among everyday medical practitioners.

The impact of the two main types of research (investigator-initiated and sponsor-initiated studies) is still minimal in North Africa due to a lack of political and legislative willpower to integrate the studies into the expansion of the healthcare and health services sectors. Indeed, there are several questions that need to be asked about activities in this field, including:

- Why is investigator-driven research – which is essential to evidence-based medicine – lagging behind in the MENA region compared to Europe, the US and other regions?
- Why are the region's talented and enthusiastic doctors, who have knowledge in epidemiology, public health, biostatistics and pharmacology, unemployed in their home countries yet often hired in under a week when they move abroad?
- Why is progress lacking, despite every important physical component of the research process being available?

A WEALTH OF OPPORTUNITY

Evidence-based medicine is the most attractive, efficient, reproducible and profitable way of curing people. Health authorities should therefore strive to facilitate legislation that will create more research opportunities, and should widen the application of the law to preclinical, early phase and post-marketing studies. This will undoubtedly benefit patients, medical knowledge in general, and of course

the pharmaceutical and biotech industry protagonists. In Tunisia, for example, a redefinition by health authorities of the regulations governing the clinical research process is about to be published, and is expected to have immediate repercussions on the number of new trials, CRO activity and research involvement.

Despite the lack of interest from local health authorities, sponsors are highly interested in the region due to the large number of drug-naïve patients with diabetes, metabolic diseases and hypertension, as well as a range of cancers and neurological diseases. This is due to characteristics unique to the population in the region, including the age pyramid, extremely rapid lifestyle changes, high consanguity rates and a mix of ethnic backgrounds, amongst other factors.

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BIG PHARMA'S CONCERNS

Like any change in direction, this initial move towards MENA is accompanied by unfounded anxiety from Big Pharma. Concerns include inadequate sample populations, non-conformity, a lack of data accuracy and a lack of harmony with western standards in trial handling and data management, as well as incidents of non-compliance that have happened in the past. Today, clinical research in the region is considered by investigators and academics to be a comprehensive process – a view supported by CROs and the small number of 'courageous' sponsors who are already satisfied with the region's abilities to conduct clinical trials.

In fact, although awareness of clinical research among the general public is still minimal, several Phase 2, 3 and 4 trials have occurred over the past decade with excellent enrolment and retention rates. This is in part due to the cultural aspect of the patient/doctor relationship, which in MENA is approaching paternalistic, making the process of obtaining informed consent easier, but sometimes delicate.

Guidance from advisory boards, generalised promotion of GCP teaching, and enhancement of the relationship between institutional review boards, sponsors and investigators, are all required elements when running a high-quality trial, and in turn will all contribute to an improved profile for the region's research programmes.

Reimbursement and market access have a bright future, and are gaining interest from government, health authorities and multinationals, who are taking seriously the rapidly increasing number of patients diagnosed with emerging chronic diseases, and the tremendous burden this represents for communities in the region and beyond. The media have begun to report extensively on this burden, and it is gaining an increasing presence in the yearly national health insurance funds bill, as well as in government resource allocation schemes. But on the other hand, clinical research is still lacking the same level of interest due to confidentiality considerations and no discernable culture of research participation in communities.

CONCLUSION

As many indicators show, the future of clinical research could lie in the MENA region. Together with authorities and CROs, pharma multinationals should overcome the discrepancy in standards at all costs, in order to get the best out of the region's research programmes. A crucial ingredient for this process is bilateral cooperation within several institutional frameworks, including the EU, WHO and so on. If implemented, this will also strengthen academic medical research; in addition, pharma and biotech startups can acquire more knowledge of the core capabilities of local scientists, investigators, CROs and sites by performing swift, relevant feasibility studies.

Furthermore, CROs have the crucial role of sustaining and supporting multinational pharmaceutical companies' medical departments and the investigators required for a study. They must also ensure that, on behalf of both patients and authorities, trials are conducted in an ethical manner. This will be the main focus of a symposium about clinical research in the Tunisia Health Expo, which takes place in March.

The internet and new technologies in general have contributed to extensive changes in the social and political landscape in the region. Now is the time to overcome the gap in clinical research and healthcare between MENA and traditional regions with regard to clinical development and eHealth projects such as compliance monitoring, more efficient and extended use of ePRO, and patient assistance programmes.

About the author

Chiheb Guerfel has more than eight years of clinical practice experience in Europe and North Africa in the fields of occupational medicine, remote medicine and community-based health. During this time he implemented several epidemiological projects for a wide range of sponsors, including academia, the pharma industry and health programmes for the oil industry, and occupied a number of positions in the local pharma industry. In 2007 Chiheb set up a pharma business support regional company, providing monitoring and clinical research services, as well as biostatistics and market research solutions. At Poseidon Pharma Services, he is involved in widening local and regional interest in clinical research and pushing towards excellence in GCPs among the medical public.
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