Go Beyond South Africa:

North Africa (Francophonic Countries) Being the Next Generation Clinical Trial Destination in Africa

Abstract

Africa is the world's second largest continent with population of more than 1 Billion. 24% of the global disease burden is accounted in Africa, while infectious diseases like HIV/AIDS and Tuberculosis still remained as a major problem. There is also an increasing demand for drugs treating Non-Communicable Diseases like Cardiovascular, Respiratory disorders, Cancer and Diabetes. In 2012, African Pharmaceutical market revenue was USD 18 Billion and growing with a CAGR of 10.6%, expected to reach USD 30 Billion by 2016. 7 established countries in both Sub-Saharan and North African countries (**South Africa, Nigeria, Kenya, Egypt, Morocco, Algeria and Tunisia**) are contributing more than 80% of the market in Africa. Large pharma can diversify their business and product portfolio and find the path to market in Africa by conducting local R&D studies and more number of local clinical trials. Currently more than 45% of the whole continent's clinical trials are being conducted in South Africa and hence the need for the next generation clinical trial destination for a pharma company.

Problem Statement

The major challenges faced by a pharma company to find the path to market in Africa are

- Regulatory timelines for registering a product takes an average of 2-3 years in the continent due to lack of availability of protocol standards and poor governance structure. This will increase cost and risk for a pharma company
- Limited opportunity for public reimbursements
- Weak infrastructure in cold chain distribution
- Limited knowledge among physicians on diseases, unmet medical needs and Pharmacovigilance

Public reimbursement could be made better by Pharma giants entering into the local pharma market and concentrate on innovative drugs for unmet medical needs such as Malaria, Tuberculosis, HIV and other antibiotics across African countries and conduct local R&D and clinical trials that include phase 1-4 and other observational studies . Pharma giants can also consider technology transfer by partnering with local drug manufacturers and research centers to diversify their business portfolio.

This series of whitepaper will focus on alternative clinical trial destinations that also have potential to grow as big pharma markets in future. Focus of this whitepaper would be on North Africa (Morocco, Tunisia and Algeria).

Industry to be impacted

Pharmaceutical	Food, Beverage & Tobacco	Metal, Mining & Minerals	Chemicals
Oil & Gas	Personal Products	Bank & Financial Services	Hi-tech

Category to be impacted

Marketing of Drugs	Safety Data Assessment	**Clinical Trials**	Packaging
Post Marketing	Grains	Edible Oil	Grains

Key Focus

Sourcing Opportunity	Supplier Intelligence	Technology	Substitute Opportunity
Supply chain Risk	Input Cost	Price Outlook	Sustainability

Introduction

- **Industry**: Pharmaceutical and Biopharmaceutical R&D
- **Category**: Clinical Development Services (Emerging markets)
- **Area of focus**: Current Category Procurement Challenges and Sourcing Options for Clinical Development Services.

Introduction

Currently more than 45% of the clinical trials in Africa are being conducted in South Africa, whereas it is contributing 22% of the Africa's pharma market. This implies pharma giants have to diversify their clinical trial footprint in Africa and go beyond South Africa.

North African countries Morocco, Tunisia, Algeria, Egypt, Libya and Sudan are currently nurturing their abilities in clinical research by preparing themselves with developed healthcare infrastructure, skilled employees, Biostatistics and Data management expertise, to attract large pharma and ease their clinical research activities in their countries. Having closer proximity to European countries Portugal, Spain, Austria, Italy and Greece, and being francophonic enables North African countries to work closely with the European pharma companies as well. They are more influenced and adopted Clinical Trial guidelines from EMA, which will not compromise with the quality parameters for clinical research.

Morocco, Tunisia and Algeria's pharma market is established and combined revenue is 30% more than South Africa's Pharma revenue and promising greater potential for clinical trials. To study more on the clinical research scenario in these countries, Beroe had interviews with the top management of regional CROs in Morocco, Tunisia and Algeria.

Morocco

As per BMI, Morocco Pharmaceuticals and Healthcare Report, Q3, 2013, the pharmaceutical drug market in Morocco is estimated to be USD 1.35 Billion and expected to reach USD 2.07 Billion, by 2017. In 2012, the prescription drug market is USD 928 Million, out of this, generic drugs contribute to 25% and branded drugs are around 45%. By 2017, Generic drug market is expected to increase to 32% and eventually patented drugs decrease to 40%.

70% of the pharmaceutical drugs manufactured in Morocco are supplied for the domestic market. According to W H O, drugs manufactured in Morocco are as good in quality as the drugs manufactured in European countries. Sanofi, GSK and Pfizer have got their manufacturing units in Morocco, sustaining the domestic drug market. Hence there are more local clinical trials that have been happening in Morocco.

Clinical Trial Scenario:
During 2001-2004, 245 local clinical trials were conducted and in 2004, ethics committee was formed. First Global Clinical trial was conducted in 2007 and 15-20 global clinical trials are conducted during 2007-2010. Government (by then) has suspended clinical trials in Morocco and reauthorized by the current Government 2012. A Moroccan regulatory/competent board is influenced by the European/French regulatory laws and follows the same. Currently, clinical trials in different therapeutic areas are happening in the country but early phase clinical trials are not allowed. CROs in Morocco are working on a Bio Ethical Bill to implement early phase studies which is expected to be made and implemented by 2014. Presently, 65% of the clinical trials happening in Morocco are in Phase-III.

CROs in Morocco:
When the clinical trials have suspended in Morocco during 2010, only few local CROs have sustained with the regulatory reformations and continued their services by outsourcing Biometric and Biostatistics services for European companies. Large pharma companies engaging with the CROs for outsourcing clinical trials should make sure that the CRO have investigating centers and Certifications/Authorizations from USFDA and EMA.

"Stratance Health is one among them, having an experience in outsourcing clinical trials for European clients and also got expertise in

Biometrics, Biostatistics, Data Management, Monitoring (on site / Centralized) and Regulatory services."

Factors favoring clinical trials in Morocco:

– Casablanca, the eighth largest city and seventh largest population in the continent is in Morocco. It has got a stable ethnicity and considered as a good source for patient pool with willingness to participate in clinical trials
– The cost per patient for clinical trials would be 30-40% of the cost that incurs in developed markets like US and Europe
– Accessibility to Biology and life science graduates from School of Medical Sciences and Biology are rich. Moroccan CROs recruit, train and depute them as CRAs. CRA turnaround rates are low. Regional CROs in Morocco have potential to outsource CRAs for European countries for clinical monitoring in near future as they are fluent in French, English and other European languages

Tunisia

In 2012, Pharma market revenue is around USD 900 Million. Top Pharma companies like MSD, Roche, AZ have their units in Tunisia manufacturing local drugs. Currently 135 clinical trials are happening in Tunisia

"Out of 12 clinical studies kicked off in the last 3 years, 6 of them are conducted by Poseidon Pharma. Company engages with other firms for Medical / scientific writing services and also provides Patient Assisted programs, Healthcare market research etc. to sustain in the clinical trial industry."

Clinical Trial Scenario:

The first clinical trial was conducted in late 1990s. GCP guidelines for clinical trials were framed by Ministry of Public Health during 2000 and the same is being followed. Currently 172 clinical trials are being conducted in Tunisia. Out of which 12 clinical studies are kicked off in the last 3 years. Ministry of Health (MoH) is the regulatory authority. Tunisia has a favorable regulatory environment for clinical trials with shortest timeline for approvals, from scratch to site, it takes 3 months approximately. 1 month for ethics committee approval, 4-6 weeks for MoH approval and another 3-4 weeks for site identification and study initiation. Phase 3 and 4 clinical trials are allowed for most of the pathologies and phase 2 is allowed when no effective treatment is available. But BA/BE and Early phase studies are not allowed to be conducted currently. CROs in Tunisia are proposing an amendment for new clinical trial guideline for allowing BA/BE and Phase-1 studies and it is expected to be approved in next 2-3 years. CROs in Tunisia have expertise in Biostatistics and provide Post Marketing services to Saudi, UAE and Turkey. The number of clinical trials is expected to be doubled in next 2 years

Factors favoring clinical trials in Tunisia:

– Tunisia has a high scientific medical standard with adequate accessibility to patients and hospitals with better healthcare system
– People living in Tunisia are Caucasian with heterogenic diversities. Literacy rate is around 90% with 17% of them graduating in life sciences are the major source for Clinical trial Associates and Coordinators
– More than 75% of the investigators for GCP monitoring are graduated from European universities and hence the quality standard are high
– Good relationship between physicians and patients, unavailability and unaffordability of medicine are the factors driving higher patient retention rates close to 90%
– Splendid telecommunication services
– Conducting Clinical trials in Tunisia will be 50-60% of the cost that incurs in Europe and USA

Algeria

Algeria is the 10th largest country in the world with population of 37 million and it is the second largest francophonic country in the world. In 2012, pharma market size in Algeria was USD 3.21 Billion and expected to be USD 3.53 Billion by 2013. Top pharma companies like GSK has manufacturing sites in Algeria partnering with Laboratoire Pharmaceutique

Algerien (LPA) focusing on new antibiotics. Novo Nordisk is collaborating with MoH by means of a bilateral relationship between Denmark and Algeria.

"Clinical Group is the active regional CRO conducting global clinical trials in all the therapeutic areas. They are recruiting Algerians graduated and working in European countries as CRAs."

Clinical Trial Scenario:

First scientific research was conducted in 1985 and first clinical research was registered in 2006. Ministry of Health (MoH) is the regulatory/competent authority in the country. Algerian GCP regulation was approved in 2009 and it is adopted clearly from the International GCP. Regulatory approval is a sequential process with time lines of 4-5 months approximately. 4-6 weeks for Ethics committee approval and 2-3 months for MoH approval. Patient documents should be recorded in both French and Arabic languages. Currently, most of the clinical trials conducted in Algeria are focused on Oncology, Hematology, Cardiology and Metabolism therapeutic areas. Phase 1 and BA/BE studies are allowed to be conducted in MoH certified research laboratories. Global CROs cannot work directly in the country but can engage with local CRO who have MoH certification.

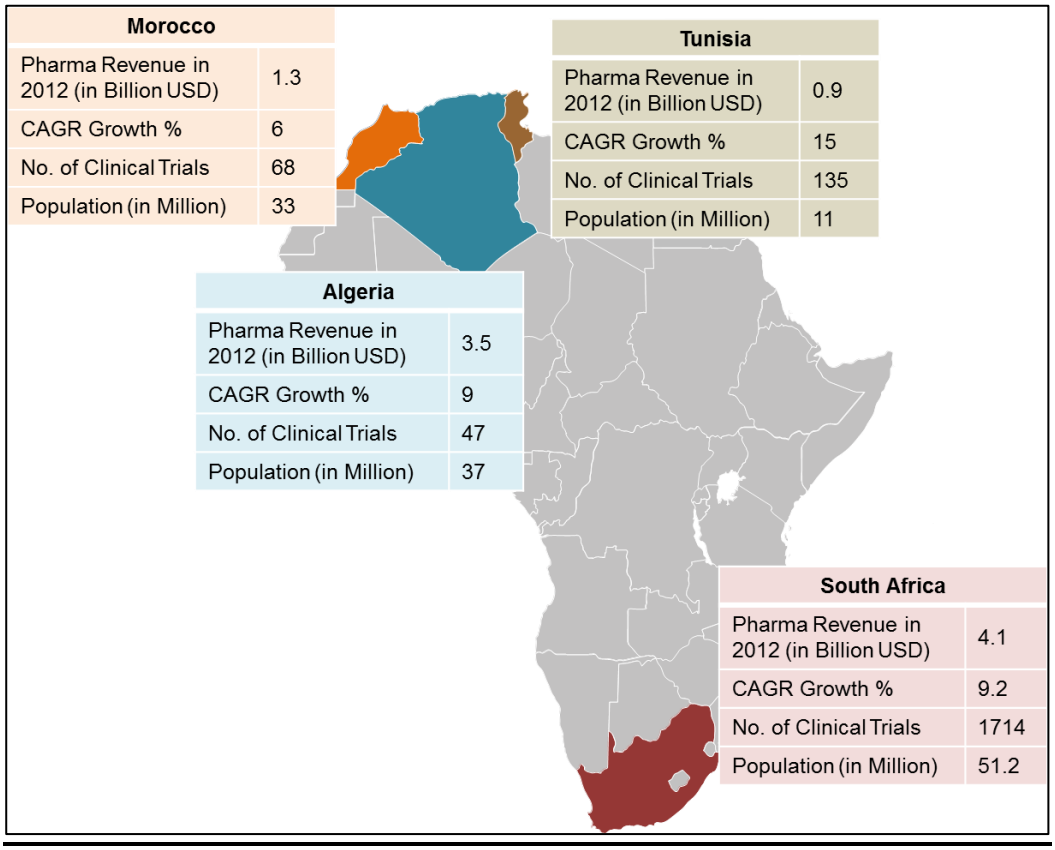
Factors favoring clinical trials in Algeria:

- Hospitals in major cities of Algeria have better infrastructure and equipment for conducting clinical trials
- Patient recruitment rate in Algeria is 10 times faster than in other developed countries
- Cost of clinical trials would be 40-50% lesser than in developed countries
- CROs adhering to GCP-ICH guidelines
- Clinical Research Associates and Coordinators are graduated from neighboring European countries like France and hence they tend to maintain good quality standards
- Good Market access for novel drugs post clinical trial successful completion

Conclusion:

- Francophonic Morocco, Tunisia and Algeria are also the potential pharma markets with growing demand for new drugs and medical awareness among physicians and patients.
- These are also emerging as next generation clinical trial destination with their growing population, developing infrastructure, availability of skilled personnel and flexible regulatory guidelines with shorter timelines.
- Cost of clinical trials per patient is 40-50% lesser than in developed countries and hence it is the major factor to be considered.
- It would be optimal for Pharma companies to consider these regions in their 'Africa Clinical Research Strategy'.

Figure-1: Showing Pharma Market and Clinical trials in North African regions



Industry Speaks

	Regional Supplier: Global CROs are not allowed to operate their clinical research activities directly in Algeria, Tunisia and Morocco, and they have to partner with a regional CRO in that country. Large pharma have to ensure whether the CRO or research center is certified by that country's regulatory body (MoH) before they engage for conducting clinical trials. ***CEO, Local CRO Services provider, Algeria***
	Consultant: Clinical Research in North African countries are reframing its regulations, infrastructure and service capabilities along with the Middle East countries and together promoting their markets as MENA (Middle East and North Africa) regions. They have better accessibility to mostly accepted European regulations and guidelines. Adhering to EMA guidelines would promise better quality of Clinical research in North African countries. ***Dr. Chiheb Guerfel, CEO, Poseidon Pharma CRO, Tunisia***
	Academic/Research Centers: North African countries have good expertise in Biostatistics as there is an institute of Biostatistics studies graduating students every year. Biometrics and Biostatistics services are being outsourced very frequently for European pharma companies ***Managing Partner of services provider, Morocco***

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