

Clinical Research Organizations in Bangladesh -A New Era of Opportunity

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Establishment of large pharmaceutical industries has increased since the liberation of Bangladesh. During the initial period, the industries aimed at meeting the in-country demand of products; however, with time and globalization, the industries started exploring opportunities for expanding their market outside of the country. Generally, the national industries were producing generic drugs and they usually have weak Research and Development activities. The situation is gradually changing and the industries are increasingly recognizing that without quality control to meet international standards, their efforts to export even the generic product will not be successful. This highlights the importance of establishing Clinical Research Organizations (CRO) in Bangladesh to develop capacity to conduct bioequivalence studies that meet international standards, more importantly FDA and European requirements. Additionally, some of the industries have started producing vaccines, which will necessitate development of further capacity of the pharmaceutical industry as well.

Why Bangladesh needs to establish local CROs?

Well, various clinical trials have been conducted in Bangladesh since late 1960s, particularly to assess efficacy of drugs that are already approved by western regulatory authorities. Over the last couple of decades, Bangladeshi health researchers are increasingly conducting phase-I animal experimentations and all phases of clinical trials in humans in strict compliance with GCP and GLP. However, large clinical trials, supported by multinational pharmaceuticals, are still monitored by external monitors/CRO, simply because local infrastructure is still inadequate. With little support, it is possible to establish efficient and credible CROs in the country, which would surely have high demand in Bangladesh and beyond.

Moreover, Bangladeshi Pharmaceuticals that export their products are relentlessly trying to expand their generic products into regulated markets either by contract manufacturing or ANDA (abbreviated new drug application) dossier submission. There thus is an opportunity to invest into the bioequivalence (BE) studies for Bangladeshi researchers in the coming years; having such an independent facility within the country would expedite their business venture in the global market in the most cost-effective manner.

Furthermore, Phase-I & II studies are being increasingly conducted in Bangladesh. Bangladesh could benefit from establishing local CROs for such studies, especially for products developed to address clinical problems that exist in the country, e.g. new TB and anti-malarial drugs. *FHI 360* commented – “We felt that with appropriate and adequate pre-clinical data that first in human studies should be possible and would both benefit the people of Bangladesh and local pharma. International pharma are considering Bangladesh as a location for first in human *Phase –I* studies and if that is not possible then there is the risk that the studies will go elsewhere including the follow-on *phases II-IV*”. Clearly, having local CROs would allow Bangladesh to take advantage of these opportunities and to develop a new market within the country.

The positive news is that the Government and the local institutions are slowly but surely realizing the opportunity and working together to materialize the prospect. In 2015, the Directorate of Drug Administration (DGDA) prepared "Guidelines for Good Clinical Practices (GCP) for Trials on Pharmaceutical Products in Bangladesh". In recent meeting they have informed to have received express of intention (EoI) to form CROs from three (3) institutions within Bangladesh, namely icddr,b, BSMMU and Khaja Yunus MC&H (Daily newspaper Bangla version: Prothom Alo 18th Feb 2016). This is a clear indication that DGDA (with the support of Ministry of Health and Family Welfare, GoB) is ready to offer such CROs to run within the country provided they fulfill all the criteria that DGDA have set.

Currently the local pharmaceuticals are relying on CROs of India, Singapore, Jordan etc. for their BE studies and as a result:

- There is no scope for technology transfer to Bangladesh;
- No development of local expertise in this important Pharmaceutical Sector;
- Considerable amount of foreign currency are being transferred out of country; and
- Results of BE studies are not deriving from the local populations.

The positive momentum with establishing local CROs will facilitate the clinical part of the process for the local pharmaceuticals and will help them to achieve cost efficiency through the local infrastructure. Outward transfer of foreign currency would minimize with the possibility of increase of inward flow of foreign currency. Additional local job market would be created which will further help the national economy. Moreover, for product registration purposes, results of BE studies conducted on local Bangladeshi population can be expected to be more useful than the results derived from other populations.

Finally, as a long term benefit, with local CROs being established, Bangladesh could become part of the global Phase III clinical trials supported by specialized hospitals in Dhaka city with huge patient load and experienced clinicians.

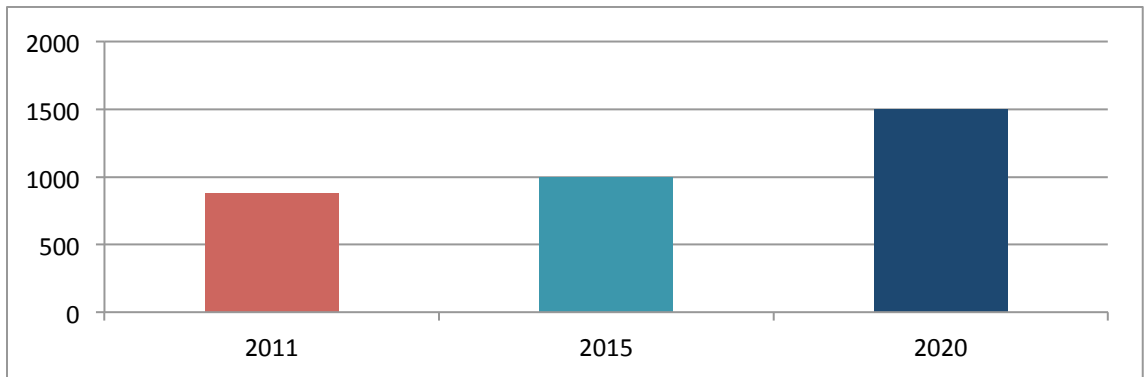
So, to explore this market for the benefit of the local pharmaceuticals and the country, what do we need?

It is submitted that there is no lack of experience in conducting all phases of clinical trials, including their management, and collaborative linkages with global CROs and multinational pharmaceuticals, but all that is required is good professional CROs in the Country. However, establishment of a high quality, full-suite clinical trial unit with associated facilities such as data management, supportive laboratory, trained staff and getting accreditation is not easy and requires considerable financial investments. Therefore, Bangladesh needs local and foreign investors to come forward to continue the momentum and steer it to the right direction. Common sense, market demand and the statistics given below clearly suggest that investment in this sector is likely to pay off. All we need now is a visionary who has the capacity and willingness to invest.

However, start ups are always tricky and building trust among the possible users will also take some time. So, potential investors need to know that return of investment will take longer time in compare to other business ventures, however, those with far vision and interested in developing national capacity need to come forward.

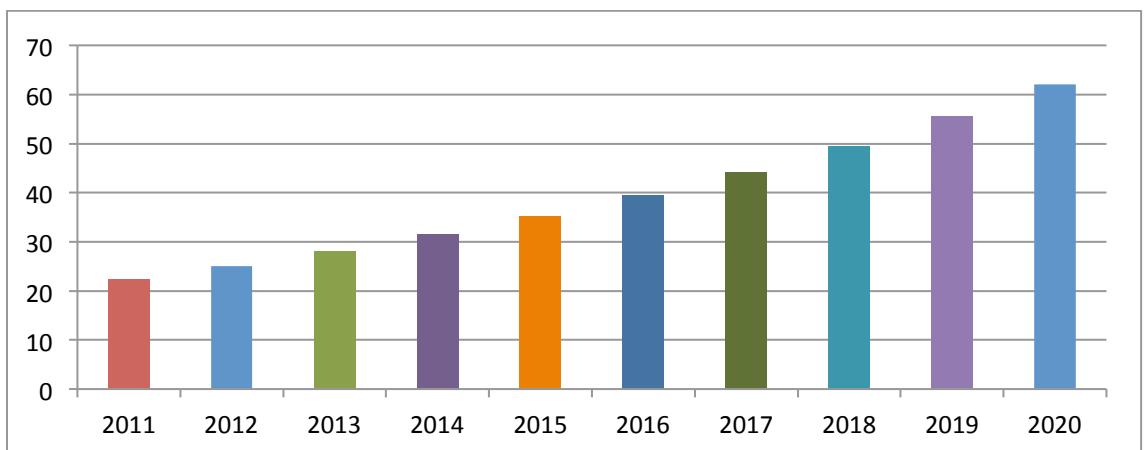
As a potential investor you must be thinking how big is the pie? Well, here are some data, you can do the math!!

- The **global pharmaceutical market** was valued at \$880 billion in 2011 and was expanded at 6% rate to reach close to \$1,100 billion in 2015. If these growth rates are maintained, the global pharmaceutical market could reach close to \$1.5 trillion by 2020.



Global Pharmaceuticals Market Projection (\$ US Million)

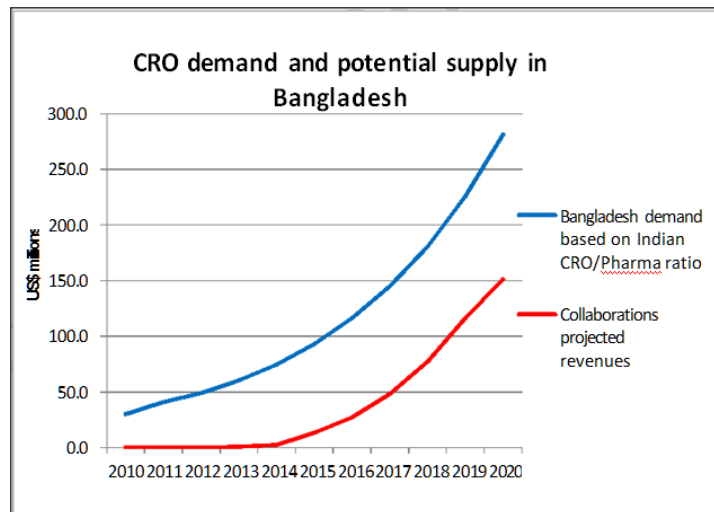
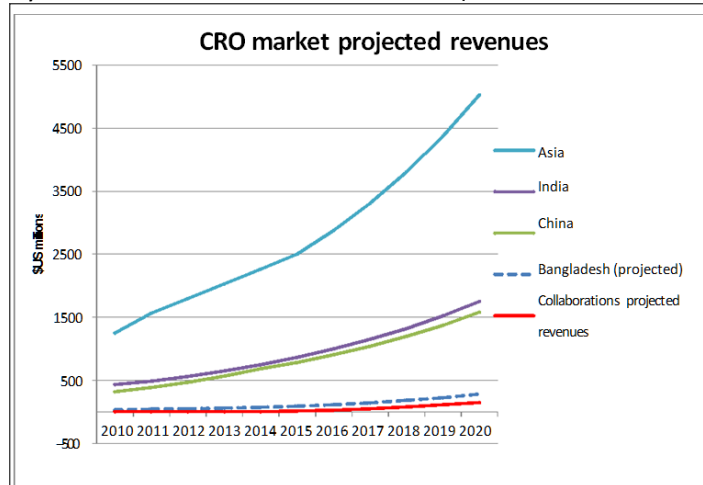
- The **global CRO market** is valued at approximately \$20 billion today. Growth rates projected over the next few years by a number of different research firms are in the range of 10-15% annually. If these growth rates are maintained, the global CRO market at 12% growth rate can reach \$62 billion by 2020.



Global CRO Market Projection (\$ US Million)

- The **Asian-Pacific CRO** market is valued at approximately \$2.5 billion and it is expected to reach \$5 billion in 2020.
- The **Indian CRO** market is valued at approximately \$100 million and it is expected to reach \$1700 million in 2020.
- The **China CRO** market is valued at approximately \$850 million and it is expected to reach \$1550 million in 2020.

- **Bangladesh's GDP** was about \$180 billion in 2015. It is projected to grow at 6-7% annually in constant terms in the next few years.
- **Bangladesh's pharmaceutical industry** was valued at about \$1.5 billion in 2013. According to leading Managing Directors in this industry in Bangladesh, pharmaceuticals can be expected to grow at more than 3 times the rate of GDP growth. Based on IMF World Economic Outlook GDP projections and a GDP/Pharmaceutical ratio of 3.3 percent, we can project an average annual pharmaceutical industry growth rate of approximately 23% for the next 10 years, with revenues reaching \$4 billion by end of 2016 and \$9 billion in 2020 (in constant 2011 US dollars).



Since Bangladesh does not have any **Contract Research Organization (CRO)** as of today, purely based on the ratio of global pharmaceuticals to CROs, we can estimate that the potential CRO market demand in Bangladesh (domestic demand as well as demand of foreign pharmaceutical companies operating in Bangladesh) is approximately \$100 million in 2016 and could reach to \$300 million in 2020.

This projection is merely based on global pharma to CRO ratio and not on any market survey, but as an investor one can do the market survey and then decide. Nevertheless, it does look promising, isn't it?