

## **8. Fostering Indian Clinical Trials Industry**

### **8.1 Clinical Trials Opportunity**

India has significant valid population to participate in clinical trials and the country also has proven capabilities in medical skills, hospital beds and IT capability. This offers an opportunity to capture the market share in global clinical R&D market such as clinical trials, data management, testing, etc. By building the above key blocks in the drug discovery value chain, India can reach the status of integrated provider in chemistry and biology services. The country can learn skills while earning, at least in certain parts of drug discovery process. (Refer Appendix VII for status of Clinical trials in India.). This could enable the country to attract drug discovery firms to conduct research in India with spin-off benefits in making India as an R&D hub in the long term.

Costs of clinical trials in India are around one-tenth of their levels in the U.S. and it is estimated that they could be worth US\$300 million to India by 2010. Major drug producers that are already conducting trials in India include Pfizer, estimated to have some 20 ongoing clinical trials; GSK, with seven trials; Eli Lilly, with 17 trials; plus AstraZeneca and Novartis as well as Chiltern. Leading contract research organizations (CROs) such as Quintiles, SFBC International and ICON Clinical Research have extensive operations in India.

Currently, India is experiencing a growing number of collaborations between Indian and foreign firms in the domestic market, especially involving the biotechnology sector, in a wide variety of areas such as collaborative R&D including drug discovery and clinical trials.

R&D often gravitates to countries with large domestic markets for the resulting products.<sup>13</sup> In this case, India's GDP growth has not been as high as China's, hence it cannot offset China's advantage on pure spending power. However, India will continue to have a significant advantage over the next few years, due to its proficiency in back office work, etc.<sup>14</sup> Component break-up of R&D are presented in Table 23 & Chart 22 below.

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<sup>13</sup> Diana Farrell, Noshir Kaka, and Sascha Starze, "Ensuring India's Off-shoring Future", 2005 Special Edition, *McKinsey Quarterly*, available at [www.mckinsey.com](http://www.mckinsey.com).

<sup>14</sup> *Id.*

| <b>Sl. No.</b> | <b>Item</b>          | <b>%</b>     |
|----------------|----------------------|--------------|
| <b>1.</b>      | Clinical Development | <b>38.2%</b> |
| 1a.            | Phase - 1            | 18%          |
| 1b.            | Phase – II & III     | 67%          |
| 1c.            | Phase – IV           | 16%          |
| <b>2.</b>      | Discovery            | <b>26.9%</b> |
| <b>3.</b>      | Non-Clinical         | <b>19.5%</b> |
| <b>4.</b>      | Regulatory           | <b>4.1%</b>  |
| <b>5.</b>      | Others               | <b>11.3%</b> |

*Source: Zinnov Analysis*

## 8.2 Challenges and Potential Solutions

Scarcity of specialist clinical pharmacologists, clinical investigators is most critical issue facing Indian clinical trial industry.

### Enhancing Availability of Clinical Investigators/Researchers

**India should attract Indian scientists to set-up service centres in India and provide Venture Capital funds on some prioritization basis.**

**Efforts should be made to coordinate with medical colleges and pharmacy colleges to enhance focus and seats in clinical pharmacology.**

**A study may be organised for examining the opportunity to set up a discipline for clinical research or a special training to become clinical investigators.**

To carry out clinical trials successfully, Indian firms need expensive infrastructure facilities such as hospitals with modern imaging technologies, facilities like world class Biochemistry Laboratories, X-ray Units, CT/MRI scans and round-the-clock availability of specialists. Unlike a manufacturing industry which has more flexibility in choosing the locations, clinical services providers require space and infrastructure at a convenient location close to general population. Hence, in addition to infrastructure, considerable real estate costs become a burden. India needs to attract large medical hospitals and institutions to enter this arena. These hospitals and institutions understand the equipment and can create space. By declaring commercial clinical research, bioequivalence studies research, etc., as an R&D investment eligible for tax incentives, the country can draw these institutions to set up these incremental activities. Pharmexcil could engage in information dissemination activities to the potential institutions.

**Enhancing Capacity for Clinical Trials, Animal Toxicity/BE centres**

**Standardised project reports on building service centers should be developed and current medical institutions and hospitals should be motivated to evaluate setting up of such infrastructure.**

**Clinical trials, bioequivalence studies, various toxicity study centers contributing in drug discovery work could be unambiguously termed as R&D investment eligible for tax holidays and weighted deduction.**

**Drug discovery firms cannot do all work in house and they need to outsource some of work like testing, etc., to third parties. Such outsourcing portion by a government approved R&D facility should be considered for weighted deduction. In the absence of this, each firm has a miniature service center for its own purpose and the sector can not develop and skills required can not be institutionalized.**

India, in order to successfully undertake clinical trials needs to employ a greater number of proficient Institutional Review Boards (IRBs), having professional competence in addition to knowledge of international and national regulations, applicable laws and standards of professional conduct and practice.

**Government Body Should Facilitate Learning and Legislation with Respect to IRBs**

**A course familiarizing Institutional Review Boards (IRBs) could be designed and the information should be communicated to eminent eligible people retiring from various service sectors. By attracting them to understand the opportunity and familiarizing them with the subject, the country can enhance pool of available experts to help these boards.**

**Incentives to CRO**

**The incentives mentioned in the draft National Pharmaceuticals Policy of 2006 such as exemption of service tax for direct investment in the field of clinical development and data management, exemption from import duty, improved regulatory infrastructure and some form of protection for undisclosed test data, etc., ought to be acted upon.**

Clinical trial samples imports and exports are currently heavily regulated. Each clinical trial specimen samples exports require approvals from DGFT, DCGI, etc. International clinical trials will need certain

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portion of specimens to be tested in certain central laboratories as a procedure of validation of trials. The current approval system requires several weeks of lead time, which is not conducive for commercial business. In addition, consignment to consignment approval system is causing avoidable time delays. Lot of clinical trials involve new drugs and often they will be in the chemical name. Importation of these samples for clinical trials activity with chemical names, etc., has dimensions different from conventional imports of drugs.

### **Simplifying approval procedures for Clinical Trials Export/Import Materials**

**Established/accredited CROs should be permitted to take one time clearance for import/export of clinical trial materials if the parties to the contract are the same avoiding repeated clearances from various agencies. Based on risk profiling approval from single agency should be considered as time element is most crucial in obtaining and executing of contracts.**

**Companies engaged in stability testing will have to test large number of samples and import duty on these consignments will kill the business. An approval from DCGI declaring that such samples for research on a case to case basis can cause the waiver. It is not practical to procure licenses in a timely manner to import them for testing in the expected time frame. Analytical testing like stability testing etc are good opportunities despite our handicap of distance and transportation. Government may draft necessary legislation keeping the new dimensions and opportunities in the pharmaceutical business. Extensive decentralisation and online approvals are essential. Self approval facility should be given for established corporates based on some risk profiling and audits.**

Contract research organizations in chemistry service need scale to attract interest of the buyers and such organizations are capital intensive with long payback period. By leaving the segment to follow its natural course, the industry may not develop in the desired direction. For example, biotechnology industry is characterized by thousands of firms with average size of employees less than fifty. Often university professors, scientists, etc., start these firms and develop some targets. Such targets after screening get licensed to big pharmaceutical companies for development and commercialization.

At current interest rates and real estate costs, setting up such facilities, establishing credibility and sourcing business demotivates either established organizations or new start ups to get into this area. However for India's strategic purposes, this component is very vital.

Contract research of large scale should be taken up by some existing firms with financial muscle. Commercial R&D firms have to be independent firms to avail tax advantages. Hence, these large companies cannot avail tax holiday in this area by setting up a division or subsidiary. Completely independent companies often face capital sourcing problems. The services from these independent

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companies will attract service tax incidence. Further, outsourcing to these firms by the parent company research department make them lose weighted deduction advantage. Hence spin offs from major companies to boost this sector is unlikely. Spin offs from companies will help focus and specialize in those areas which can go for economies of scale and global business sourcing.

### **Service Tax Exemptions for pharmaceutical R&D**

**R&D services may be exempted from service tax net for national priority sectors. Providing drugs for Indian citizens is a big priority for nation and this sector could be waived from the net.**

### **VC Funding for CROs to Promote Value Chain in Drug Discovery**

**Prioritised Venture Capital based funding should be provided to set up large contract research organizations.**

Large scale stability testing, Animal toxicity testing services is a very attractive opportunity for India. For example, every drug needs stability data over a long period of time. Corporates outsource such activity. The CRO has to be reliable and should conduct stability studies for the agreed period and retain the records for several years. Large scale stability studies center will have economies of scale like any IT organization. The skill set required is standard and the process is mechanical. However, the cost of setting up such centers is capital intensive. India should consciously draw varieties of R&D activity pieces into the country. Outsourcing of API synthesis, API production, formulation development, formulation manufacturing, analytical testing, stability testing, animal toxicology centers, etc. are various pieces involved.

Pharmexcil/government departments should meet up corporates and push for setting up of large scale stability centers which does work for multiple organizations. This will be a conscious step in building economies of scale in an otherwise fragmented industry. Also, such step will help SMEs to avoid huge capital expenditure involved in maintaining stability.

Samples imported for stability studies should not carry any import duty. These samples get analysed and there will be no re-export to set off the duties. In the global analytical market there is no room to bear the country's import duties. As the market is new, our current laws need to be fine tuned to accommodate these areas. State DCIs may be empowered to give permissions of duty free imports of stability samples from foreign clients.

Analytical testing is a very important piece in the building of contract services industry. Analytical testing industry is dependent on both availability of chemists and capital investments in analytical instruments.

## **Strategy for Increasing Exports of Pharmaceutical Products**

Our country is a good candidate country to obtain a good market share in the global market. However, the proximity to market is an important dimension in the sourcing of business. In spite of the disadvantage, lot of analytical testing, method development, method validation and other services can move to our country.

However, import of samples for analysis requires speedier arrival of samples, the reference drugs, etc. In the current system of every thing needing approval from DCGI such as reference drugs, import of samples etc., the business is experiencing abortion in the womb itself.

### **Decentralisation of Approval System**

**There is a need to decentralize the approval system (e.g., State DCI approval) of T licenses for already approved drugs in India. Automatic approval may be given for new drugs for “invitro testing work” or if the testing is not in humans (e.g., State DCI). The bottlenecks in importation of blood samples for analysis have to be removed fast. Risk profiling should be done and reputed clients and reputed service centers in India should be given exemptions with obligation to submit annual reports.**

Most countries require some highly standardised documentation like COPP, FSC, etc. If a company has fifty products registered in fifty countries, the firm will have to get almost 2,500 certificates from DCI offices. Although it is simple, it is avoidable waste of time. Such certificates should be available on line for substantial exporters. A fresh guideline and procedure should be issued by Government removing unnecessary approvals and procedures. Testing services is a time bound activity and competes with established players. We have inherent disadvantage of distance and shipping costs. In addition, if there are too many procedural delays and requirements, a significant opportunity is lost. In addition, the opportunity to become a global hub for pharmaceuticals require successful large scale infrastructure in various links that build the chain.

**Such certificates should be available on line for substantial exporters. Or a drug control office employee empowered to sign such documents should be posted at where there is a huge requirement of procedural documents.**