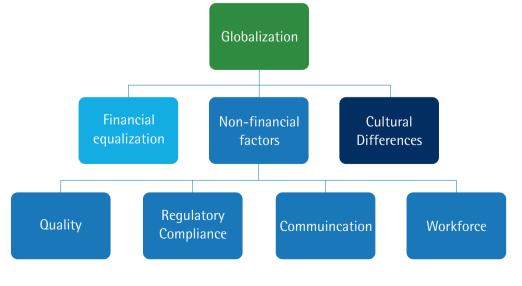# Pre-clinical Outsourcing into INDIA

It is a popular belief that if you can retain the interest of the reader in the first three sentences of the article, there is 87% chance that he/she will read the whole article. Well, if this is true, I think I have already utilized the first two sentences, but I promise if you bear with me for the next ten lines, you would not regret at the end. Let us start with some very interesting unknown facts about India, which I am sure even my fellow Indians would have barely heard.

52 — India tops the list in the entire world when compared with the average working hours by Millenials in a week – 52 hours/week. [Millenial careers: 2020 Vision –Forbes]

4 — India is ranked 4th in the number of doctorates in the world, after the US, Germany and the UK. [Millenial careers: 2020 Vision–Forbes]

1 — India is the world's biggest outsourcing destination in terms of financial attractiveness and business environment. [A T Kearney's 2016 Global Services Location Index (GSLI)]

2 — India is 2nd after the US, as a country with the highest number of English speaking population. [Wikipedia sensus]

3 — Every 3rd pill in the world is made in INDIA. [July 2017 –India Brand Equity Foundation]

50 — More than top 50 Indian pharmaceutical companies have a presence in the regulated markets – US, Canada, Western EU and Japan. [July 2017 –India Brand Equity Foundation]

The primary decision-making factors in the Pharmaceutical outsourcing revolve around three major globalization aspects:

- Globalization
  - Financial equalization
  - Non-financial factors
    - Quality
    - Regulatory Compliance
    - Communcation
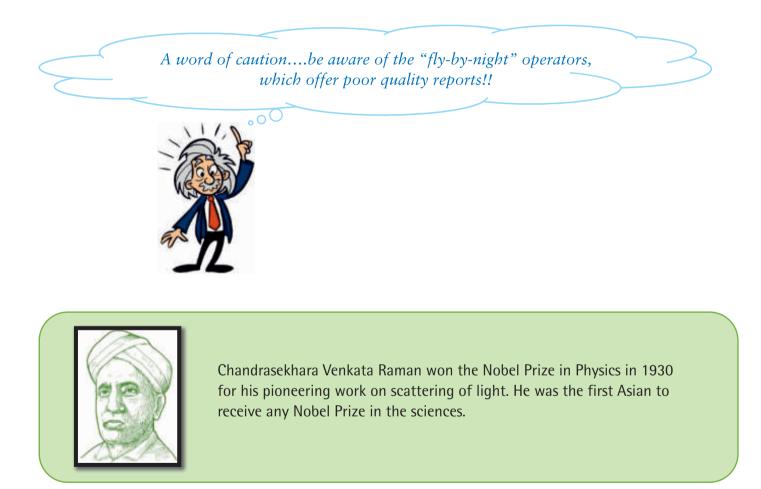   - Workforce
  - Cultural Differences

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Financial Equalization

It may sounds stereotypic, but yet it is inevitable to mention that India is the most economical option for outsourcing when it comes to preclinical or clinical studies. A NASSCOM report says that companies outsourcing their work to our country can save approximately 60% of their cost every year. The differences in wages in the US, UK, and India ranges to the tune of 50-60%, the currency arbitrage benefits of low cost of living in India translates into a great advantage for the global corporations.

For example, the average salary of an experienced GLP study director is ~$15,000 in India, while it is ~$70,000 in the United States. Yet, the standards of living are comparable, thanks to the buying power of the Indian currency!

I leave this thought to you since it is an individual or organizational preference to consider. I have met many outsourcing managers, who are yet to fathom the advantage of Multinational Indian CROs, whereas those who use such services continue to benefit a lot out of it.

A word of caution....be aware of the "fly-by-night" operators, which offer poor quality reports!!

Chandrasekhara Venkata Raman won the Nobel Prize in Physics in 1930 for his pioneering work on scattering of light. He was the first Asian to receive any Nobel Prize in the sciences.

It is obvious that one should not look at only short term financial factors, but should also look at long term benefits. Let us take a glimpse of the significance of other non-financial factors.

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Non-financial factors

Quality:

The facts that you read above might have given you some insight on the commitment to quality in India. The international accreditation program promoted to develop MAD council by the OECD initiative in 1989(*), which led to the European GLP authorities inspecting and issuing GLP compliance to the two largest Indian CROs of repute, JRF Global (Jai Research Foundation), and Advinus (Now known as Eurofins Advinus Ltd.) As per the data published on the 18th April 2017 by NGCMA (Indian GLP Monitoring authority), there are now 42 GLP accredited facilities. Thus, the outsourcing team should be aware of the approval of the facility by the NGCMA, before initiating the discussions.

Audit the lab, and meet the scientists, and the leaders.
Review the background control data and audit history.
Focus more on the quality processes and practice.

Prof. Har Gobind Khorana was an Indian-American biochemist who shared the 1968 Nobel Prize for Physiology or Medicine with Marshall W. Nirenberg and Robert W. Holley for research that helped to show how the order of nucleotides in nucleic acids, which carry the genetic code of the cell, control the cell's synthesis of proteins. In 1970, Khorana became the first to synthesize an artificial gene in a living cell.

(*) A further Council Act was adopted in 1989 to provide assurance that the data are indeed developed in compliance with the Principles of GLP. This Council Decision-Recommendation on Compliance with GLP establishes procedures for monitoring GLP compliance through government inspections and study audits as well as a framework for international liaison among monitoring and data-receiving authorities.

(http://www.oecd.org/chemicalsafety/testing/mutualacceptanceofdatamad.htm
https://legalinstruments.oecd.org/Instruments/ShowInstrumentView.aspx?InstrumentID=58&InstrumentPID=55&Lang=en&Book=False)
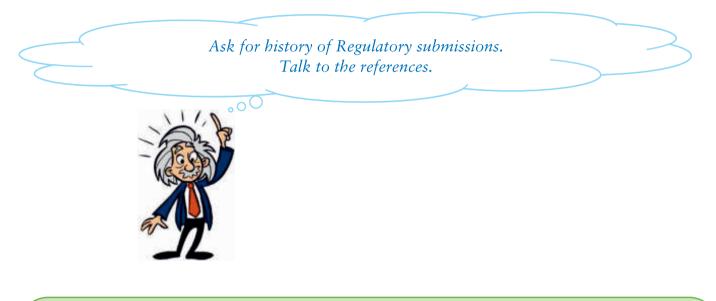
Non-financial factors

Regulatory Compliance:

Do I really have to tell you this? I am sure I don't. All of us know how to assess the compliance of the lab. India became a compliant member of OECD MAD council in 2012. The National GLP Compliance Monitoring Authority (NGCMA), commenced in 2002, has 15 full-time GLP inspectors, trained at several International platforms. They have taken severe actions of withholding the GLP status of a couple of labs, upon noticing non-compliance issues. This shows that they take their job very seriously.

For more than a decade, preclinical study data from Indian GLP labs have been submitted by several global companies to global regulators in the US, Canada, EU, the UK, and Japan. It is a different thing though that the Regulators will not audit the labs unless they find any critical issue in the study reports.

Ask for history of Regulatory submissions.
Talk to the references.

Prof. Satyendra Nath Bose was an Indian physicist specializing in quantum mechanics. He is most remembered for his role played in the class of particles 'bosons', which were named after him by Paul Dirac to commemorate his work in the field. His paper called "Planck's Law and the Hypothesis of Light Quanta" was translated by Albert Einstein, and was published in Zeitschrift für Physik under Bose's name, in 1924. This formed the basis of the Bose-Einstein Statistics.

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Non-financial factors

Communication:

With thousands of dialects, more than 200 identifiable mother tongues, and 22 major languages, India is almost equally diverse as Europe and Africa taken together! Even two adjacent states could not understand each other's language. In such scenario, English is a common language, apart from Hindi. Unlike other Asian countries, India has made it mandatory to keep English as a compulsory language in schools. All Universities have English as the only language for scientific and technical education. All the corporate companies, and now even many of the Govt offices have made English as an official communication language. Thanks to the ancestors of my British friends...! I really mean it! ☺

Over 90% of Indian villages have mobile phone connectivity. Reliance Jio, a popular telecom-internet service provider, has created a world record by gaining 16 million subscribers in a month! Unlike the west, people never put their mobile phones on voicemails, meaning, they would always attend to the work calls, no matter where they are – on vacation, or during festivals!

Sometimes you may have to bear with a strange accent or English dialect, but it would not be incomprehensible!

Arrange a video-call and check the communication facility with lab.
Identify a good speaker as focal contact point.

Dr. Subrahmanyan Chandrashekhar was awarded the 1983 Nobel Prize for Physics for his mathematical theory of black holes. The Chandrasekhar limit is named after him.

Workforce and IT infrastructure

India and China alone have contributed to the tune of 84% of all international student enrolment between years 2000-01 and 2010-11. This shows the commitment of people towards desire of higher education and training. A very few Indian CROs would take this very seriously, and send their workforce for several International training workshops, courses and scientific symposia.

India is ranked 4th in number of PhD graduates. Most of the Indian companies work 6 days a week and culturally Indians are open to spend extra hours at work if required. This gives a lot of advantage to western clients as the scientists are open for teleconferences to match time zones of the west.

As per the Global Developer Population and Demographic Study 2017, India will overtake the United States in terms of the highest number of software developers. Technically, it might already have overtaken if we consider the Indian developers working in the US! As per the Global Cybersecurity Index (GCI) 2017, published by the International Telecommunication Union (United Nations), India falls within the green zones, and has all the necessary technical, organizational, legal and capacity measures to monitor the cyber security. There are several such facts & figures, but do I really need to prove this point?

Check how many International conferences are attended?
Ask for education and turnover ratio of manpower.
Check how long the leaders have stayed within the company?

Considered as the Father of India's space programme, Vikram Sarabhai was instrumental in the setting up of the Indian Space Research Organization (ISRO), which is one of the top 5 Space Research Organizations in the world.

One of the greatest space scientists, and former president of India, Dr. A P J Abdul Kalam, played pivotal roles in India's space, missile, and nuclear programs and had served Indian Govt. in many positions.

His books – "Wings of Fire" and "India 2020" are must read books.

Cultural Differences

After all good points, here come some cautions while you work with Indian professionals on a daily basis for monitoring your projects. Just to simplify, let me compare some cultural differences between Indian and Western culture. No offense to any particular culture, but these are qualitative parameters, which are generally observed but not necessarily inculcated in every individual.

Cultural / Professional parameter	Western	Indian
Say NO	Denies if he/she thinks it cannot be done. No need to waste time of either parties.	Will avoid saying NO. Will try to do pushing the limits.
Time commitment – Both cultures have different mindset, and none of them are wrong.	Commits 6 days, if he/she thinks he/she would deliver in 4 days. Keeps buffer time considering the worst case scenario; Most likely delivers in 4 days.	Commits 3 days, if he/she thinks it may take 4 days. Gives challenging commitment and tries to achieve; Sometimes may take 4 days.
Will be done	Says this only when he is 100% sure.	Says when he is ~90% sure, but tries the level best; mostly completes it.
Business focus	Master of one – A Specialist	Jack of all – A Generalist. Can be converted to specialist if situation demands.
Work is driven by	Process driven. No chaos. Completes systematically.	Process + Rush at deadline. Performs better under chaos.
Everyday work	Management by Objective	Management by Control
Business Transactions	ONLY contractual terms matter	TRUST matters more
Importance	Transaction > Relation	Relation > Transaction

There were few rare instances of quality issues by two or three fly-by-night operators, which were considered as severe offenses, and appropriate punitive measures were taken by Govt agencies, but media would always portray these rare incidences as frequent, which happen everywhere. If one performs all due diligence and visits the lab before taking any decision, such incidences may not arise. Needless to say, in absence of such due dilligence, this may even happen in western labs.

It is just one point-of-view based on obvious facts, figures, and experience. Someone may have had different experiences. Please feel free to share your experiences (Good or Bad)….!

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Acknowledgment:

About The Author

Samir Pandya, MBA, B. Pharma is a Business Development Professional having experience of more than 10 years in CRO industry.

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