Diagnostics Opportunities in India

– Guide for Finnish Companies

Finpro India
June 2013

Foreword

The total volume of the Indian *in vitro* diagnostics market is still relatively small today, only slightly larger than the total annual revenue of the Finnish IVD industry. It is, however, estimated to grow rapidly in the future. Now is the right time to explore this market opportunity.

The Indian IVD market potential consists of many different types of segments, just to mention the very urgent needs for affordable, easy-to-use solutions in low-resource settings, and the rapidly growing not so very price-sensitive market of 300-400 -million middle-class population. There is space in India for various types of technologies, products, and solutions. In many cases it is necessary to modify the product to make it suitable for local users. Often the best result is achieved by originally developing the solution for Indian needs. This is where collaborating with local players usually helps. Today, indeed, India should not be seen only as a very potential market or a place where one can manufacture products at a reasonable price. There are competitive innovation hubs in India and many more to come. Taken the complementary expertise of Finland and India there is good potential for jointly developing innovative, user–oriented total solutions for Indian needs. And not only for Indian needs; affordable, easy-to-use, high-quality solutions are wanted everywhere. Let's consider this option!

The spark for Tekes to start studying the Finnish potential for India collaboration in the diagnostics field came originally from the Indian Department of Biotechnology in the form of expression of interest. This started a process leading to a series of studies on Indian diagnostics ecosystem, visits by Tekes' experts and Finpro personnel to Indian diagnostics companies, universities and research institutes as well as organizations providing services for business development. Numerous interviews and desk studies have been made jointly by Tekes and Finpro to understand how the systems work. The information and knowledge cumulated through years 2008 to 2013 has been compiled in this guidebook. It is worth noting that during the present Indian "decade of innovation" evolution is swift in India, new institutes and initiatives are constantly being established. It is important to follow the developments. New opportunities continue to emerge.

This guidebook aims to answer the typical questions the Finnish companies have in their mind when considering starting businesses in India or collaborating with Indian organizations. The booklet describes key features of the Indian diagnostics ecosystem. Based on the gathered information we have summarized Finnish opportunities in a few application areas.

Understanding the opportunities, realizing the challenges, identifying the right partners and the ideal, perhaps even a rather narrow niche market, and knowing how to penetrate it are the keys to success in India. This guidebook hopefully helps Finnish companies understand and utilize this opportunity.

Finland's India Action Plan, prepared by the Ministry of Foreign Affairs in cooperation with other ministries and published in April 2013, encourages Finnish companies to explore India's growing business opportunities. It also gives recommendations for joint efforts of Finnish stakeholders. Establishment of the Indo-Finnish Diagnostics Research Centre in spring 2013 is a noteworthy event on the journey towards deeper Indo-Finnish partnering. We hope that this guidebook not only helps companies start India operations but also encourages Finnish companies, universities and research institutes to join forces for successful India cooperation.

We warmly thank all the visited organizations for their hospitality, and the interviewees for valuable and interesting discussions.

Helsinki, May 2013
Tekes - the Finnish Funding Agency for Technology and Innovation

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Incredible India

India, the largest democracy in the world; a country with varied cultures, practices and beliefs, a country surging ahead in the international scenario with its robust growth in economy and attracting investment across all the industries; has achieved all this because of its intrinsic strength and ability to grow within rather than be dependent on the exports.

1.1 Key characteristics of Indian economy

India has emerged as one of the most attractive business and investment destinations in the world today on account of its robust financial systems and capital markets as also open policy as regards foreign direct investment. In addition, the country enjoys immense demographic dividend with over 65 per cent population in the working age group of 15-45 years and a large and growing middle class resulting in strong domestic consumption. All these factors besides other strengths and advantages of Indian economy and industry contribute towards making India a trillion dollar economy – 10th largest in the world and 3rd largest in terms of GDP on Purchasing Power Parity (PPP) basis.

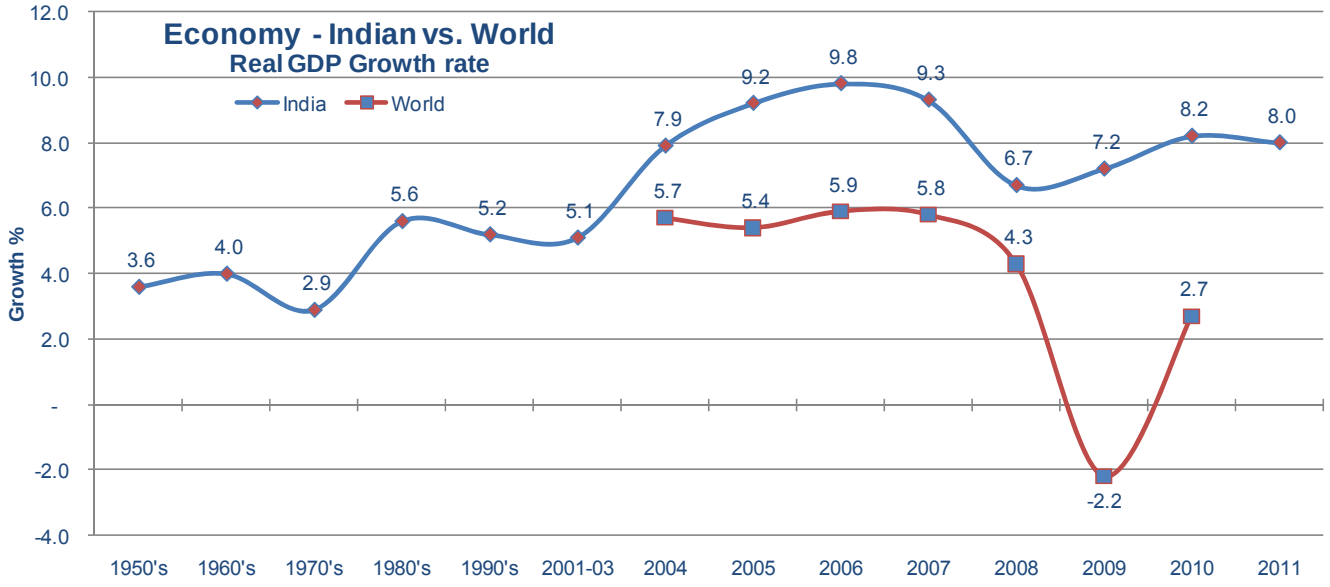


Figure 1: Strong growth fundamentals- India is a trillion dollar economy

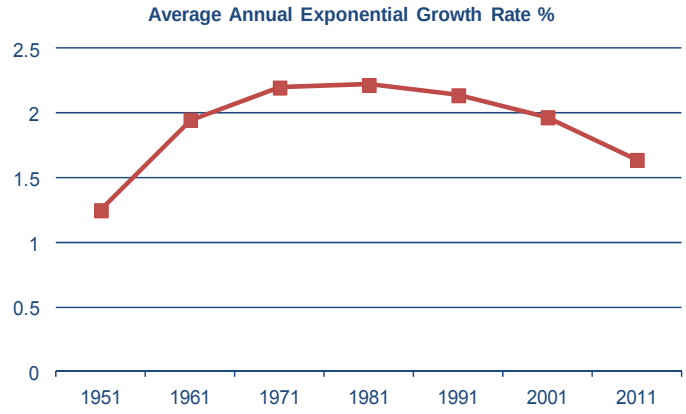


Figure 2: Sustained economic growth despite global slowdown

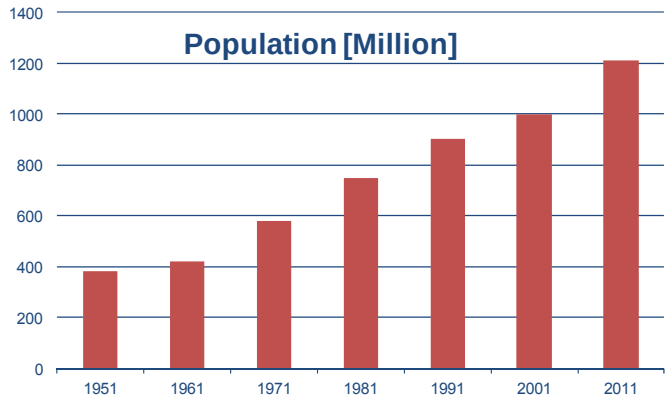


Figure 3: Reaping demographic dividend: young population, strong domestic consumption

Economic growth rate has been supported by the decreasing population growth rate over the years. As on 1st March 2011, India's population stood at 1.21 billion comprising of 624 million males [~52%] and 586 million females [~48%]. Nearly 8.3 billion [~69%] live in rural areas while 3.7 billion [~31%] live in urban areas, as per Census of India 2011. (*The Indian Census is the most credible source of information on Demography (Population characteristics), Economic Activity, Literacy and Education, Housing & Household Amenities, Urbanisation, Fertility and Mortality, Scheduled Castes and Scheduled Tribes, Language, Religion, Migration, Disability and many other socio-cultural and demographic data since 1872. Census 2011 will be the 15th National Census of the Country. This is the only source of primary data in the village, town and ward level, it provides valuable information for planning and formulation policies for Central and the State Governments and is widely used by National and International Agencies, Scholars, business people, industrialists, and many more.)*

Life expectancy was 49.7 during 1970's, this has increased to 63 years in 2000-04 and further improved to 63.5 years during 2002-06. There are inter-state, male-female and rural-urban differences in life expectancy at birth due to low literacy, differential income levels and socio-economic conditions and beliefs. (*Source: Annual Report to the People on Health, Ministry of Health & Family Welfare, Government of India)*

1.2 Indian healthcare overview

Healthcare is a State subject which follows a three tier system – Primary health centres catering to a group of villages, Secondary level comprises health centres located at district level whereas medical college hospitals constitute the tertiary level located in big cities. Besides, there are few advanced medical institutes of national importance having clinical, teaching and research facilities in multiple super-specialties. In addition to the Government run health system, same hierarchical healthcare services exist in private sector.

There is no national health insurance system, though the government, public sector and corporate organizations sponsor healthcare expenses of their employees and family. In recent years few insurance companies have ventured into health sector. In spite of well networked health care system, access to healthcare in rural areas is far from satisfactory. (*Source: Confederation of Indian Industry-CII)*

In the current scenario, 75% of the qualified consulting doctors practice in urban areas, 23% in semi-urban (towns) and only 2% in rural areas whereas the vast majority of population lives in the rural areas. Hospital beds per 1000 people are 0.10 in rural as compared to 2.2 in urban areas. Further, a vast proportion of North and North-eastern region of country lie in hilly terrain and some territory in remote islands making healthcare reach impossible to such far flung areas. (*Source: RGI-CGHR Million Death Study)*

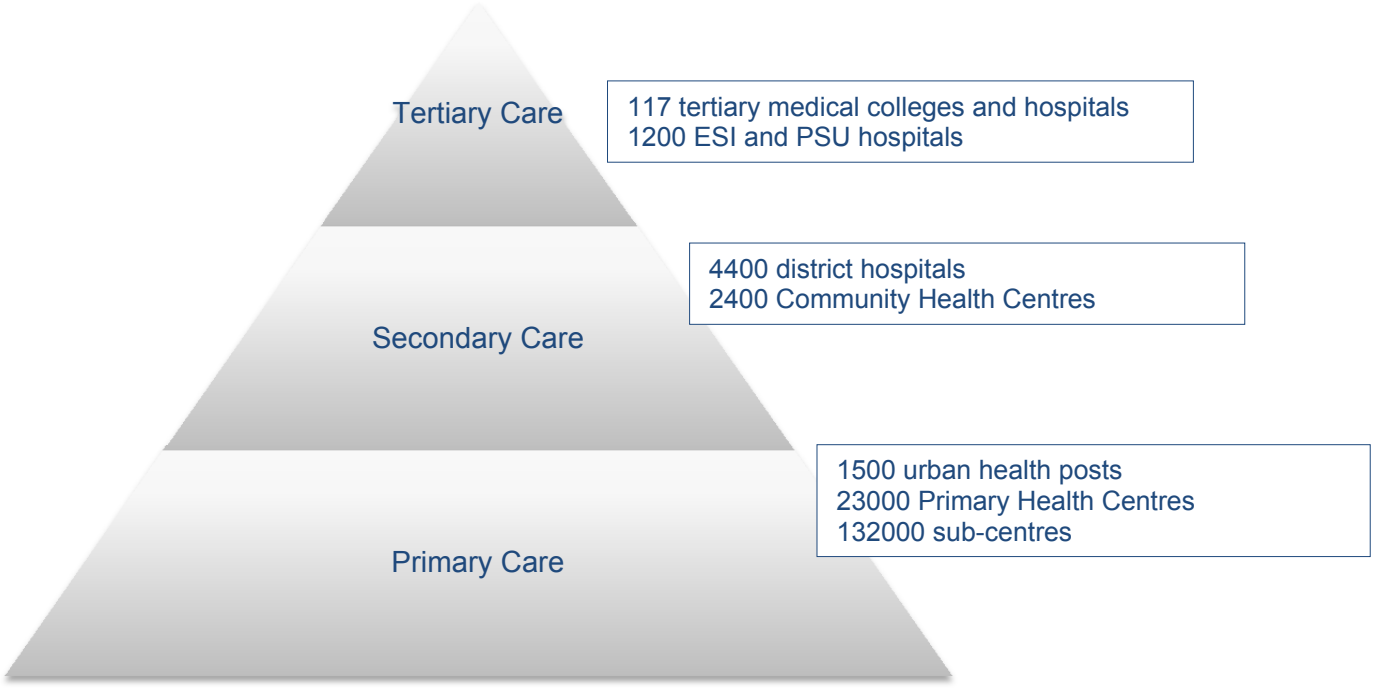


Figure 4: Healthcare Pyramid

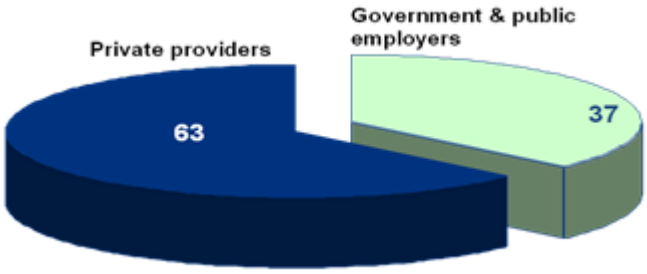


Figure 5: Primary Care

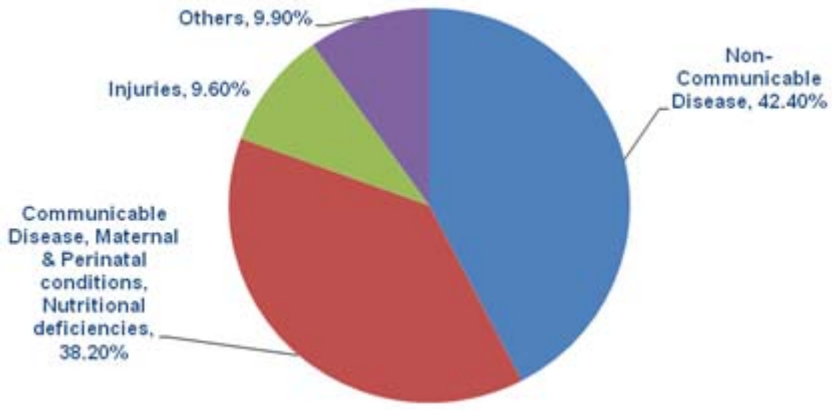


Figure 6: Distribution of deaths by major cause, India 2001 – 2003 (Source: Special Survey of Deaths, Registrar General of India)

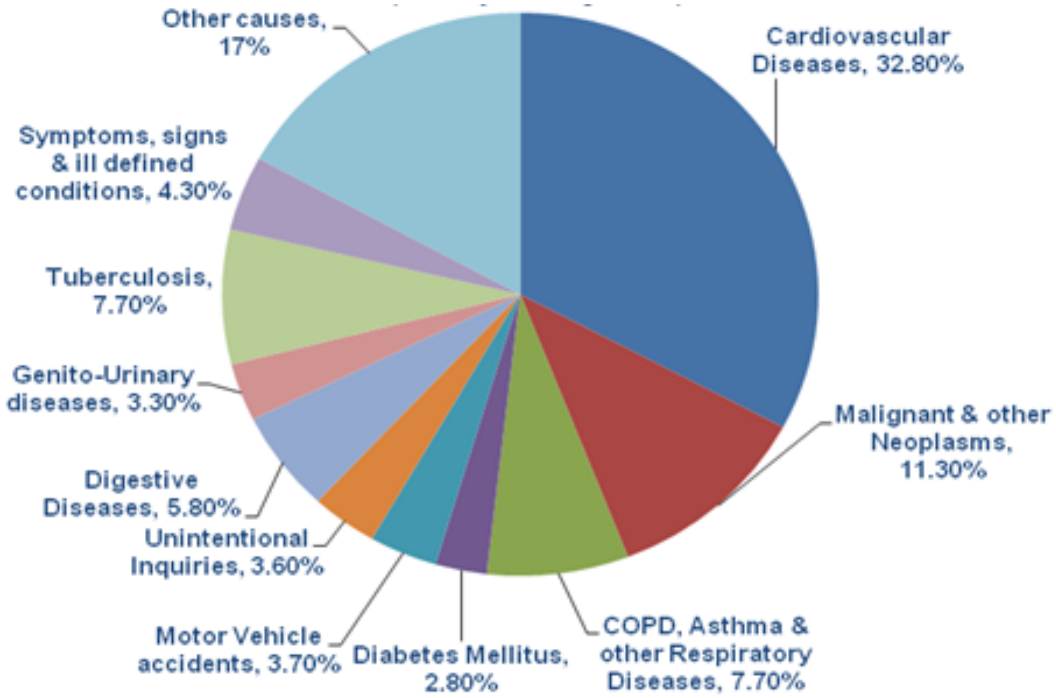


Figure 7: Causes of death in urban areas (25 – 69 yrs. of age as %) 2001 – 2003 - Cardiovascular diseases constitute the largest segment (Source: Special Survey of Deaths, Registrar General of India)

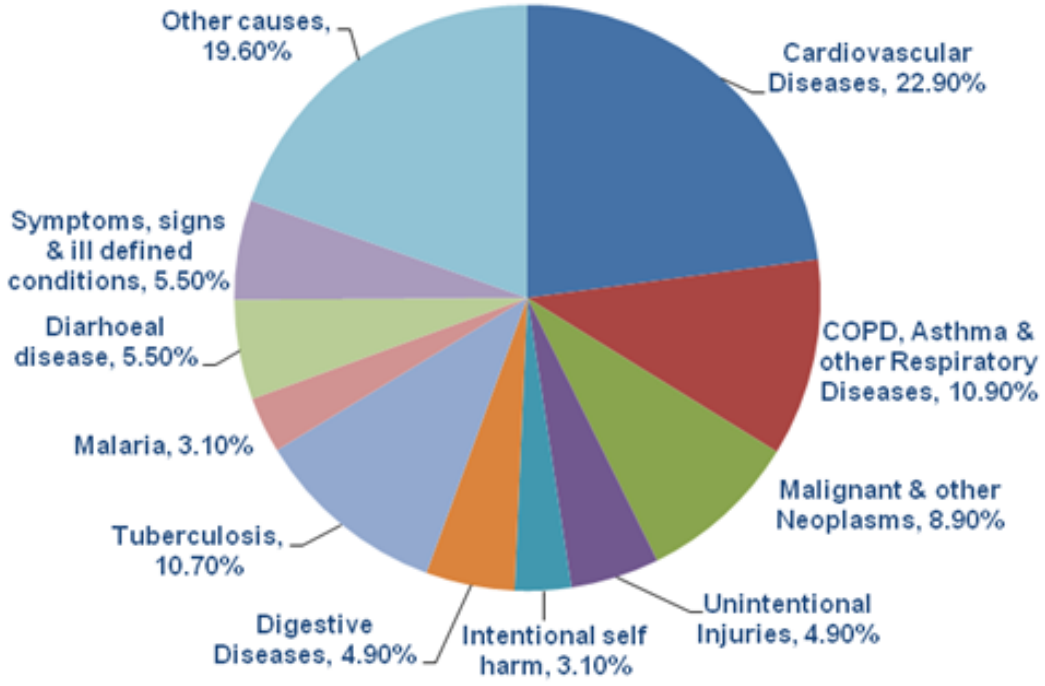


Figure 8: Causes of death in rural areas (25 – 69 yrs. of age as %) 2001 – 2003 - Cardiovascular diseases constitute the largest segment (Source: Special Survey of Deaths, Registrar General of India)

1.2.1 Healthcare financing

Proportion of insurance in healthcare financing in India is extremely low, even if it has been growing 25% annually during recent years. Approximately, less than 15% of the population is covered through prepayment.

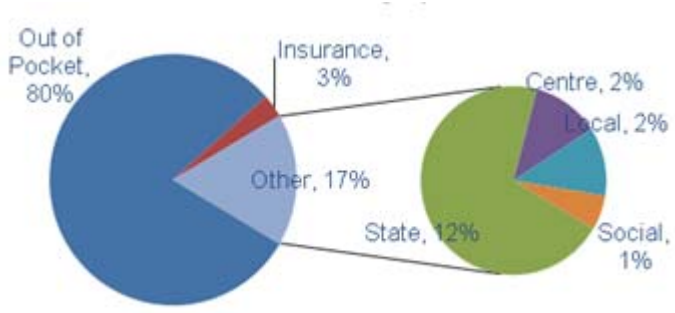


Figure 9: Out of-pocket spending is the biggest source of financing healthcare due to low insurance cover (Indian Healthcare financing by source 2010)

Out of that only 0.4% is from private health insurance. 3.4% comes from social insurance ESIS. Proportion of employer's spend is estimated at 5% and another 5% comes from community insurance schemes. In addition to this, government provides coverage through free access to its facilities. In 2000 around 4 million were covered and the target was to grow it into 12 million until 2006. However, there is a huge gap between rural and urban population covered by pre-payment. *(Source: Centrum Healthcare Sector October, 2010; KPMG analysis as in KPMG and ASSOCHAM, 2011, Emerging trends in Healthcare)*

There is free health care everywhere in India for Below Poverty Line (BPL) population offered in government hospitals as well as in most private hospitals. It seems that the BPL status is not questioned from patients and no identification proof is required. According to the Planning Commission of India, anyone earning INR 672.8 monthly or INR 22.42 per day in rural areas and INR 859.6 monthly or INR 28.35 per day in urban areas is above the poverty line (as defined in March 2012). Going by this methodology, the total number of people below the poverty line in the country is 354.6 million as against 407.2 million in 2004-05.

There are various modes of healthcare financing as listed below *(Source: Federation of Indian Chambers of Commerce and Industry-FICCI)*:

- **Social insurance** – Employer Social Insurance System (ESIS), is a mandated wage- based contribution from employees and employers.
- **Commercial health insurance** – There are 13 insurance companies in India, out of which 4 are governmental and 9 private insurance companies. Health insurance is a rapidly growing market in India. According to the estimates of Ernst & Young, the sector is likely to grow from USD 771 million to USD 3,8billion between 2006 and 2012. However, commercial health insurances are out of reach of the masses in India.
- **Employer based** – Both public and private sector provide health care for their employees.
- **Community health insurance (CHI) –** CHI is a not-for-profit insurance scheme aimed primarily at the informal sector. CHI schemes involve prepayment and large enough pooling of resources to cover the realized health care costs. Other terms used in reference to community health insurance are micro health insurance, local health insurance.

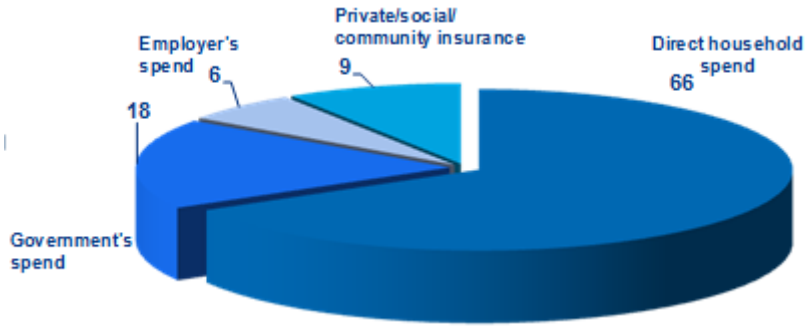


Figure 10: Modes of financing healthcare in India

Since the poorer section lacks resources to pay for health care, they are more likely to delay healthcare for as long as possible which often results in hospitalization at advanced stages of the disease, hence leading to increased expenditure. It has been estimated that at least 24 per cent of all Indians hospitalized fall below the poverty line because of hospitalization expenses; out-of-pocket spending on hospital treatment is estimated to bring another 2 per cent the proportion of the population below poverty line. Community health insurance aims to improve access to health care among the poor as well as protect the poor from indebtedness and impoverishment resulting from medical expenditure.

The Government pays a certain sum per person to the CHI pool. Schemes vary in the sense of what costs are covered, with some covering only the direct costs during necessary operation, some also indirect costs like medicines. 25 bodies are licensed as third party organizations (TPOs), which are allowed to administer CHI schemes. Membership is mainly voluntary even though in some communities, the community itself would pay the premium for its members and they in turn contribute during the year e.g. milk to the community. Coordinator of the CHI scheme can be a hospital, voluntary organization as insurer or voluntary organization acting as intermediary, purchasing services both from hospital and insurance company. Success factors of a CHI scheme seem to be effective and credible community based organization, affordable premium, large enough community and also a suitable pool of health care service providers, who commit to the prices agreed with the CHI trust.

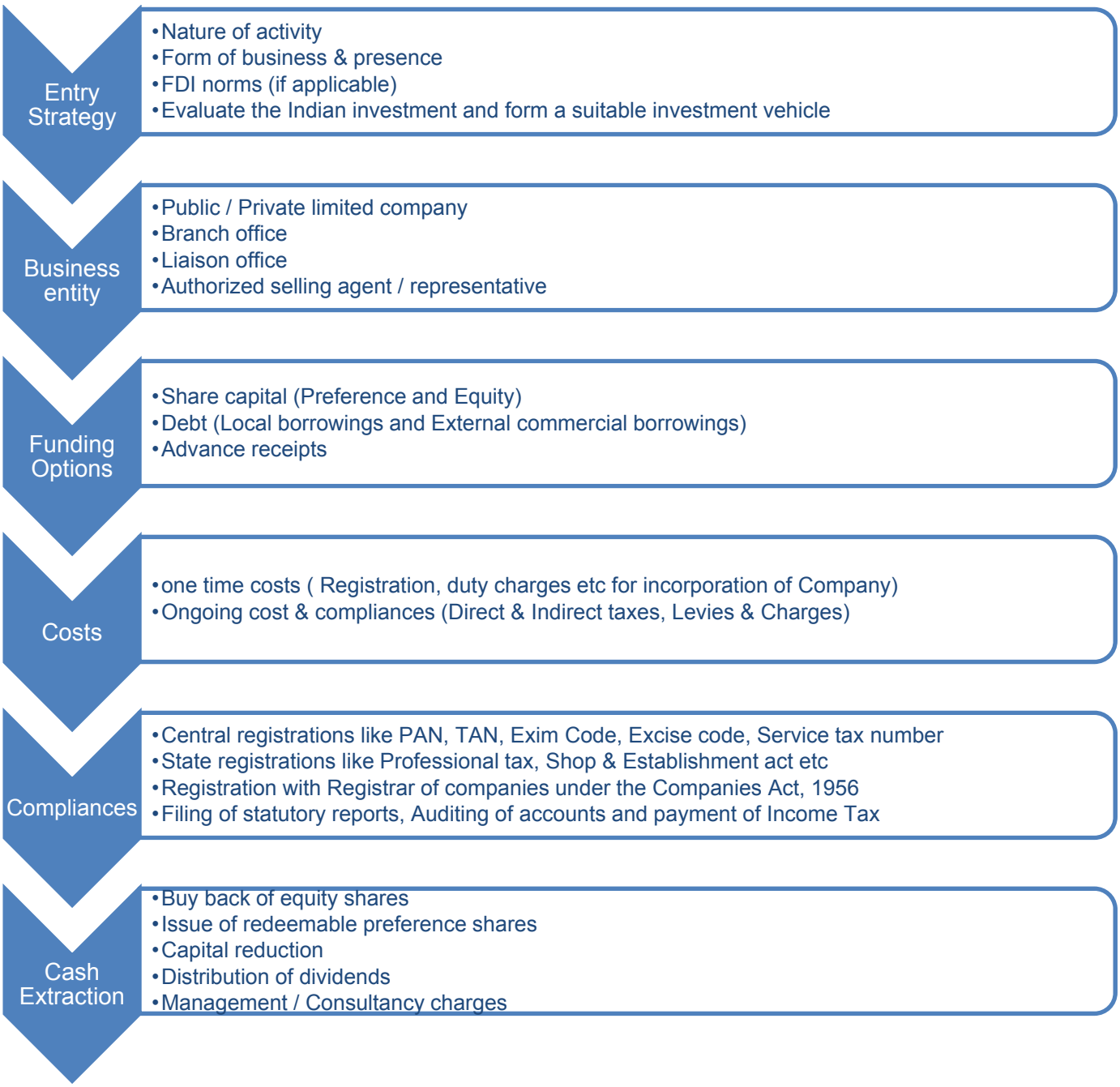
India is a very cost and price sensitive market, i.e. imported products are often too expensive. Healthcare spending of the common people is 65% of disposable income, as the healthcare insurance penetration is still in the initial stages. Lack of awareness of newer methods and tests among public healthcare personnel and lack of professionals per se are the supply side growth restraints.

1.2.2 Government incentives on diagnostics:

The Government of India has decided to increase health expenditure to 2.5 per cent of gross domestic product (GDP) by the end of the Twelfth Five Year Plan (2012-17), from the existing 1.4 per cent. FDI inflows into hospitals and diagnostic centres, and medical appliances stood at USD1.44 billion and USD0.6 billion respectively, during April 2000 - September 2012

- 100 per cent foreign direct investment (FDI) is permitted for all health related services under the automatic route
- Custom duty on life-saving equipment has been reduced to 5 per cent from 25 per cent and exempted from countervailing duty
- Import duty on medical equipment has been reduced to 7.5 per cent
- Hospitals with at least 100 beds are eligible for 150 per cent deduction for capital expenditure; other measures include exemption of service tax

India entry – key check points



- **Public / private limited company** – A registered company limited by shares issued to public or closely held, company can be a wholly owned subsidiary of the parent company, can do activities ranging from manufacturing to services and everything else needed to support the same
- **Branch office** – A branch office is a fully functional unit of the parent company, but under the rules and regulations of the resident country. They can directly bill the clients and also the agents.
- **Liaison office** – An office setup to keep track of the activities in the market and maintain relationships with key customer. Managed by a direct employee of the company. No direct billing can be done.

- **Authorized selling agent/representative** – Purely appointed for selling in respective regions/countries, they do the basic marketing and the parent company reimburses them any such related costs.

2.1 Need for localization

India represents an economic opportunity on a massive scale. Although India has not performed as expected in the first lap of the growth race against its giant Asian neighbour, China, there is a strong possibility that India may well move ahead.

India is a country of continental proportions, with vast regional diversity, issues and challenges like Europe. Consequently India should not be viewed as a single investment destination. To succeed in this market, businesses need to have an understanding of the environment, in the country as a whole and the various regions.

Foreign investors into India need to develop an 'India' strategy;

- Look at India as a long term strategic market
- Choose the right local partner
- Conceptualize India-specific products (value for money)
- Be hands-on, do not go only by 'market reports'
- Establish India-centric culture : consideration for local aspirations & sensitivities
- Co-ordinate between head office & Indian entity with clear communication channels, cross-cultural competencies, belief in local managerial competencies
- Understand the organizational structure and decision making process to avoid delays
- Develop India-specific strategy: Finnish business and HR practices may not necessarily work
- Optimally blend expatriate management with local talent
- Be visible: aggressive marketing and media presence are essential
- Closely engage with client/local partner at all times and constantly evolve offering to meet requirements
- Complement each other's strengths; establish R & D linkages with industry/ research institutes/ academia. Adopt suitable R & D cooperation model – in-house/ partly-outsourced/ fully outsourced

In short, foreign companies require an India-specific strategy with unique value propositions to address the varied needs of the country. There can be hurdles in the beginning, but these get resolved soon, overcome by opportunities offered by the market. Companies need to overcome their fear of entering India: India is diverse but good local knowledge; team and contacts are useful in making significant inroads into the market.

2.2 Regulatory processes for diagnostics

Central Drug Standard Control Organization (CDSCO) (http://cdsco.nic.in), Directorate General of Health Services is the authority responsible for laying down rules, standards and for approving import and manufacture of drugs, diagnostics, devices, and cosmetics.

Currently, two ministries are working on draft policy guidelines to establish medical devices regulatory authority in India to be named Central Drug Authority (CDA) and Medical Device Regulatory Authority of India.

The organization is led by Drug Controller General of India, who is responsible for approval of licenses of specified categories of drugs and diagnostics products.

Drugs Controller General of India
Phone: +91-11-23236975
Email: dci@nb.nic.in

Guidance document by CDSCO: Registration of Notified Diagnostics Kits in India

Under the Drug and Cosmetics Act (http://cdsco.nic.in/Drugs&CosmeticAct.pdf) , the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the State authorities while the Central Authorities are responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organisations and providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Drug Controller General of India is responsible for approval of licenses of specified categories of Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

Diagnostic kits are defined as notified or non-notified for regulatory purposes. The following IVD kits/ reagents are notified as “Drugs” under Drugs and Cosmetics Act 1940.

- *In-Vitro* Diagnostic Devices for HIV
- *In-Vitro* Diagnostic Devices for HBV
- *In-Vitro* Diagnostic Devices for HCV
- *In-Vitro* Blood grouping sera.

All IVD kits and reagents excluding those listed under the notified category would be covered under the category of non-notified IVD products.

Additional information on frequently asked questions can be found at - http://cdsco.nic.in/Final%20FAQS-IVD.pdf

2.2.1 Regulations related to imports

The following documents are required to be submitted in the following manner and order for the registration of the Notified Diagnostics Kits for import into India:

Applicants are requested to submit following documents in 2 separate files as follows:

1. Covering Letter – The covering letter should clearly specify the intent of the application (whether the application for the registration of the manufacturing site is being submitted for the first time, whether the application is for re-registration or is for the endorsement of additional products to an existing Registration Certificate) the list of documents that are being submitted (Index with page no’s) as well as any other important and relevant information may be provided in the covering letter. The covering letter should be duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory.
2. An Authorization letter in original issued by the Director/Company Secretary/Partner of the Indian Agent firm revealing the name & designation of the person authorized to sign legal documents such as Form 40, Power of Attorney etc. on behalf of the firm should be submitted at the time of submission of the application for registration. As per it should have validity period company’s

policies. Duly attested photocopies of the Authorization letter may be submitted at the time of submission of subsequent applications.

3. A duly filled Form 40 as per the Performa prescribed in the Drugs & Cosmetics Rules, signed & stamped by the Indian Agent along with name & designation.
4. The requisite fee as prescribed in the Drugs & Cosmetics Act & Rules viz. 1500 USD for the registration of the manufacturing premises and 1000 USD for a single Device and an additional fee at the rate of 1000 USD for each additional device proposed to be imported may be submitted at notified branches of Bank of Baroda (more details on CDSCO website).
5. Power of Attorney – The authorization by a manufacturer to his agent in India shall be documented by a Power of Attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate. Apostille Power of Attorney from Hague convention member countries is also acceptable. While submitting the Power of Attorney, the following points should be kept in mind:
6. It should be co-jointly signed and stamped by the manufacturer as well as the Indian Agent indicating the name & designation of the authorized signatories.
7. It should clearly list the names of all the proposed devices (including Model No's, if applicable) along with their specific Indication and/or intended use. Further, the names of the proposed devices should correlate with those mentioned in the Form 40 and Free Sale Certificate to be submitted.
8. The names & addresses of the manufacturer as well as the Indian Agent stated in the Power of Attorney should correlate with the Form 40.
    - It should be valid for the period of said Registration Certificate.
9. A) A duly filled Schedule D (I) along with the undertaking as per the Performa prescribed in the Drugs & Cosmetics Act & Rules, signed & stamped by the manufacturer indicating the name and designation of the authorized signatory is required to be submitted

    B) The requirements for Plant Master File
10. *A*) A duly filled Schedule D (II) as per the Performa prescribed in the Drugs & Cosmetics Act & Rules, signed & stamped by the manufacturer indicating the name and designation of the authorized signatory is required to be submitted

    B) The requirements for Device Master File
11. A duly attested (by gazetted officer)/notarized (in India) and valid copy of Wholesale License for sale or distribution of drugs under Drugs and Cosmetics Rules in Form 20B & 21B or its renewal in Form 21C issued by the State Drug Licensing Authority.
12. Or duly attested and valid copy of Manufacturing License issued by the State Drug Licensing Authority in case the Indian Manufacturer is importing the kits in bulk form for further processing.
13. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of Free Sale Certificate/Certificate to Foreign Government/ Certificate of Marketability for each kit issued by any of the GHTF member countries i.e. USA, Canada, Japan, Australia and European Union and from the National Regulatory Authority clearly stating that the proposed Kits/Reagents are freely sold in the country of origin.
    - Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of the manufacturing License/ Plant Registration certificate issued by the National Regulatory Authority of the country of origin, if any.
    - Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of ISO 13485 Certificate in respect of the manufacturing site (s).
    - Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of CE Full Quality Assurance Certificate in respect of the manufacturing site (s), if applicable.

- Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of CE Design Certificate in respect of the proposed Kit(s), if applicable.
- Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of Declaration of Conformity in respect of the proposed Kit(s).
- Performance Evaluation Report from National Institute of Biologicals, Noida, India in respect of Proposed Kit(s) of three Consecutive batches.
- The report of evaluation in details conducted by the National Control Authority of Country of origin.

14. Product Inserts (English version or Authenticated translated copy) and published articles (if any) for each Diagnostic kits/ Reagents proposed to be imported.
    - Specimen batch test report for at least consecutive three batches showing specification of each testing parameters from Manufacturer.
    - The detailed test report of all the components used/packed in the finished kit.
15. Original Colored Labels and pack size in respect of the proposed products.

Additional details can be found at CDSCO website.

The following documents are required to be submitted in the following manner and order for issue of the Import Licence of the Non-Notified diagnostic kits for import into India:

a. Covering Letter – The covering letter should clearly specify the intent of the application (whether the application for the Import Licence of the proposed kit is being submitted for the first time or the application is for renewal). The list of documents that are being submitted (Index with page no's) as well as any other important and relevant information may be provided in the covering letter. The covering letter should be duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory along with the name and address of the firm.

b. An Authorization letter in original issued by the Director/Company Secretary/Partner of the Indian Agent firm revealing the name & designation of the person authorized to sign (along with the name and address of the firm) legal documents such as Form 8 and Form 9 etc. on behalf of the firm should be submitted at the time of submission of the application for Import Licence. It should have validity period as per company's policies. Duly attested photocopies of the Authorization letter may be submitted at the time of submission of subsequent applications.

c. A duly filled Form 8 (Application for license of import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945) as per the Performa prescribed in the Drugs & Cosmetics Rules, signed & stamped by the Indian Agent along with name & designation of the authorized signatory indicating the Generic name, Brand name (if any) and intended use of each proposed kit.

d. A duly Apostle/Attested by Indian Embassy in the country of origin Form 9 as per the Performa prescribed in the Drugs & Cosmetics Rules, signed & stamped by the Manufacturer along with name & designation of the authorized signatory indicating the Generic name, Brand name(if any) and intended use of each proposed kit.

e. The Requisite Fee as prescribed in the Drugs & Cosmetics Act & Rules viz INR 1000 for One proposed kit and INR 100 for each additional kit to be imported may be submitted at notified branches of Bank of Baroda (details can be found on CDSCO website)

f. Duly Apostilled/notarized/attested from the Indian embassy (country of origin) valid copy of following:

g. Free sale certificate/ Exportability certificate in respect of the proposed Diagnostic kits/Reagents issued by National Regulatory Authority of the country of origin clearly stating that the proposed Kits/Reagents are freely sold in the country of origin.

h. Or if the proposed products are not sold freely in the country of origin, Free Sale Certificate/ Import licenses from National Regulatory Authority of other countries where the proposed products are being freely sold.

i. A duly attested (by gazetted officer)/notarized (in India) and valid copy of Wholesale License for sale or distribution of drugs under Drugs and Cosmetics Rules in Form 20B & 21B or its renewal in Form 21C issued by the State Drug Licensing Authority.

j. Or duly attested and valid copy of Manufacturing License issued by the State Drug Licensing Authority in case the Indian Manufacturer is importing the kits in bulk form for further processing.

k. A Valid copy of ISO 13485 Certificate Apostilled/notarized/Attested from the Indian embassy (country of origin) reflecting the name and the address of the manufacturing site.

l. Performance Evaluation Reports(Not test reports) of three consecutive batches of the proposed products conducted by National laboratory or accredited Laboratory in India needs to be submitted in respect of Kits/Reagents meant for screening of TB, Dengue, Malaria, Chikunguniya, Typhoid, Syphilis Test Kits, Blood glucose strips, Thyroid Markers and Cancer Markers. A copy of NABL certificate in respect of lab where in Performance evaluation carried out.

m. Product Inserts (English version or Authenticated translated copy) and published articles (if any) for each Diagnostic kits/ Reagents proposed to be imported.

n. Certificate of Analysis issued by the manufacturer in respect of the proposed products.

o. Original Colored Labels and pack size in respect of the proposed products.

p. Soft copy of product list along with specific intended use

q. For veterinary IVD Kits NOC from Department of Animal Husbandry, Ministry of Agriculture, Krishi Bhavan, New Delhi is required.

r. For Radio Immuno Assay Kits NOC from BARC, Mumbai is required.

Additional details can be found at CDSCO website.

2.2.2 Registration of diagnostic kits

Following steps may be adopted for Registration application for Notified IVD kits/reagents in India:

STEP 1. Pay the required Registration fee through TR-6 Challan (in triplicate) in Bank of Baroda, Kasturba Gandhi Marg, New Delhi.

A fee of one thousand and five hundred US dollars (or its equivalent in Indian rupees) shall be paid along with the application in Form 40 as registration fee for the manufacturing premises meant for manufacturing of Notified IVD kits/reagents intended for import into and use in India.

A fee of one thousand US dollars (or its equivalent in Indian rupees) shall be paid along with the application in Form 40 for the registration of a single Notified IVD kits/reagents meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional Notified IVD kits/reagents.

STEP 2. Compilation of Registration dossier as per the guidance documents available at the link: http://cdsco.nic.in/draft_guidance.htm

STEP 3. Submit Product Registration application at CDSCO (HQ), New Delhi

Notified IVD kits/reagents manufacturing site is not required to be inspected before grant of Registration Certificate in Form 41. However, if required, the applicant shall be liable for the payment of a fee of five

thousand US dollars (or its equivalent in Indian rupees) for expenditure as may be required for inspection or visit of the manufacturing premises.

The fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines". Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account "0210-Medical and Public Health, 04- Public Health, 104-Fee and Fines", and the original receipt of the said transfer shall be treated as an equivalent to the bank challan, subject to the approval by the Bank of Baroda that they have received the payment.

Applications for issue of grant of Registration Certificate/ Import License are prescreened as per checklist available under link: http://cdsco.nic.in/prescreening_checklist.htm. If the application is complete in all respects and information specified in Schedules D-I and D-II are in order, the licensing authority shall, within nine months from the date of receipt of an application, issue such Registration Certificate in Form 41.

Registration certificate in Form-41 for Notified IVD kits/reagents in India shall be valid for a period of three years from the date of its issue, unless, it is sooner suspended or cancelled.

An applicant can apply for both Registration Certificate (Form 41) and Import License (Form 10) together, provided Indian agent and importer remain same.

2.2.3 Manufacturing licence

The licensing procedure for *notified kits* is as follows:

Notified kits manufacturing

- Details of manufacturing facility & product dossier
- Joint inspection by State & Central Drugs Control Officials along with the experts
- Issue of Test Manufacturing Licence
- Evaluation at National Laboratory(NIB)
- Issue of license in form-28
- Testing of initial batches at National laboratory to verify the consistency of quality

Non-notified kits manufacturing

- License is issued by state drugs control department by following the GMP guideline and regular procedure in the particular state
- License in form-25 & 28

First the application is to be submitted to Drugs Controller General of India. After their approval, a test license is issued and the applicant is to send five test batches to National Biological Laboratory (located in Noida) or to The National Institute of Communicable Disease (NICD) (in New Delhi) for testing the quality consistency. If approved, manufacturing license can be applied from the central authorities. An audit will be conducted in the unit, after which the manufacturing license is granted. The process takes 3–6 months.

For non-notified devices neither test manufacturing license nor test batch evaluation is required. There is also no need for inspection by central authorities; the application is to be filed only with state drug offices.

Enforcement is a challenge, since the state authorities have limited control capabilities. Thus in practice quality control of diagnostics products is still highly insufficient, and there are large number of products of questionable quality in the market.

2.3 Customs duties and practices

Customs duty is levied on the import of goods into India. Total customs duty consists of the following:

- Basic customs duty: This is calculated at the effective rate applied to the landed value of the goods, which comprises of CIF value and the landing charges (1%).
- Additional Customs Duty (countervailing duty CVD): This is to counterbalance impact of excise duty on indigenous manufacture to ensure level playing field. It is payable at effective rate of excise duty. This is calculated on the landed value and the basic customs duty. However, on most of the consumer goods intended for retail sale, duty is calculated based on the maximum retail price (MRP) printed on their packs.
- Special Additional Duty (special CVD): Special CVD of 4% has been levied on all imports subject to Basic Customs Duty and Additional Duty of Customs (CVD) since March 1, 2006. Purpose of special CVD is to counter-balance VAT; sales tax etc. other local taxes.
- Education Cess (EC): This is levied at the rate of 3% on the aggregate of duties of customs.

Due to these additions – besides the basic customs duty – final duty is much higher than the basic customs duty. Diagnostics kits and reagents attract a basic customs duty of 10 % and total customs duty of 31.70 %, which is based on following calculation, using product with value of INR 100 as example.

Table 1: Customs duty calculations

				INR
A	Assessable Value (CIF Value +1% Landing Charges)*			**100**
B	Basic Customs Duty (BCD)	10% of A	0,10	10,00
C	AV (Assessable value)+ BCD (Basic Customs Duty)	A+B		110,00
D	Additional Duty (C.V.D) - 14%	14% of C	0,14	15,40
E	Education Cess - 3% on C.V.D	3% of D	0,03	0,46
F	AV + BCD + CVD + Edu. Cess	C+D+E		125,86
G	Less: Assessable Value	-A		
H	Import duty	F-G		25,86
I	Education Cess - 3% on Import duty	3% of H	0,03	0,78
J	**Import Duty**	H+I		**26,64**
K	Special CVD on (A+J) - 4% of the import duty	4% of A+ J	0,04	5,07
L	**Total import Duty**	J+K		**31,70**
	*unit in kg			

The shipment for diagnostic products arriving on the Indian port should be accompanied with:

- Batch release certificate for the specific lot sent
- Shelf-life certificate stating that the products shipped have more than 60% shelf-life at the time of landing in India
- Certificate of Analysis for the lot supplied.

The product carton, in turn, should have following information:

- Name & address of the manufacturer
- Name & address of the importer
- Import license number
- Date of manufacture
- Date of expiry

2.4 Taxation

India's tax structure is well developed and tax levy is divided between Central and State governments. The Central government levies direct taxes like income tax, wealth tax and corporate tax; and indirect taxes like customs duty excise duty, central sales tax and service tax. The taxes that come under state would be professional tax, state sales tax along with local taxes like entry tax or Octroi. Now the state sales tax has been replaced by VAT all across the country.

The Indian tax year is from 1st April of the current year to 31st March of the subsequent year. All corporates are required to file ROI, even in the event of loss for the entity. If non-resident corporate conducts business in India, they should also file a ROI in India on the specified date. Corporate tax liability need to the estimated and settled as advance tax in four instalments on 15th of June, September, December and March. Late filing of ROI/ delay in payment in taxes attracts penal interest at prefixed rates. They are imposed on the balance of unpaid tax due or underpayment of the advance tax due.

For payment of income tax and other direct taxes the company has to obtain Permanent Account Number (PAN), which is a ten character unique number allotted to a company by the Income Tax Department. It also has Tax Deduction and Collection Account Number (TAN), which, in turn, is a 10 digit alpha numeric number required to be obtained by all companies and persons who are deducting or collecting tax.

2.4.1 Direct taxation

2.4.1.1 Corporate income tax

The Income Tax Act, 1961, governs the levy of income tax. The policy regarding income taxation in India is decided by Ministry of Finance, Government of India. The highest administrative authority for income tax is the Central Board of Direct Taxes, which administers the Act.

Corporate tax rates are different for domestic and foreign companies. Domestic companies are those incorporated in India. Foreign companies having Liaison/representative offices, project offices, unincorporated joint ventures and branch offices are treated as foreign companies.

Taxation rates for Assessment Year 2010–2011 are as follows:

For domestic companies: (incorporated under the companies act, 1956**)**

- Income tax: 30% of the net income
- Surcharge: 7.5% of the income tax
- Education cess: 3% of the income tax + surcharge
- Net effect: 33.99%

For foreign companies: (liaison office, branch/es, project office**)**

- Income tax: 40% of the net income
- Surcharge: 2.5% of the income tax
- Education cess: 3% of the income tax + surcharge
- Net effect: 42.23%

Surcharge and Education cess are calculated in the same manner for all taxes. The surcharge of 7.5% is always applied on the tax paid by companies with gross turnover exceeding INR 10 million (€172,414).

The taxable income is called “Total Income” which is computed after adding certain disallowances, such as loss on sale of asset and miscellaneous expenditure written off, and reducing certain allowances/benefits from the book profits. Depreciation is allowed separately at following rates for computing taxable income:

- Factory Building: 10%
- Furniture & Fittings: 10%
- Plant & Machinery (general): 15%
- Computers: 60%
- Motorcar, other than those used in a business of running them on hire: 15%
- Intangible assets (such as know-how, patents, copyrights, trademarks, licenses, franchises or any other business or commercial rights of similar nature): 25%
- For certain priority items, such as energy saving devices and pollution control equipment, depreciation is allowed at higher rates.

In case of a new asset, depreciation for the full year is allowed only if the asset is put to use for 180 days or more during the fiscal year, otherwise depreciation is allowed only at half the prescribed rate. Additional depreciation of 20% of actual cost of new plant and machinery is allowed in the year in which a new manufacturing industrial undertaking is set up or in the year of expansion of an existing manufacturing industrial undertaking. In the latest budget the Government presented some fiscal incentives towards R&D activities: weighted deduction for expenditure in-house or scientific research enhanced from 150% to 200%. It is allowed for approved Indian organizations engaged in scientific research and development work.

2.4.1.2 Minimum alternate tax

MAT is levied at 18% of the adjusted book profits, if the payable income tax (inclusive of surcharge and education cess) according to the normal provisions is less than 10% of the profits. A surcharge of 10% is applicable for domestic companies if the adjusted book profits exceed INR 10 million (€ 10,000,000). In addition, the taxable income is subject to the 3% Education Cess. This results in total rate of 19.93 %.

Dividend distribution tax

Dividend distribution tax (DDT) at the rate of 15% (plus education cess) is levied on those companies declaring dividend. This is resulting in an effective taxation rate of 16.609% for a company on its distributed profits. The dividend tax is payable also when subsidiary pays dividends to the parent company. DDT has been criticized since it basically means double taxation on the profits. Despite the criticisms, the tax continues to exist.

In the budget 2010–11 no changes were made to DDT rate considerably except the removal of surcharge. However, as from April 1st 2008 onwards a domestic parent company – provided it is not a subsidiary of another company – can pay the DDT on net dividend, i.e. dividend declared less dividend received from its immediate step down subsidiary.

2.4.1.3 Transfer pricing

Comprehensive transfer pricing regulations (TPRs) were introduced from 1st April 2001. The objective was to prevent MNCs from manipulating prices in intra-group transactions, e.g. by transferring their profits out of India. Indian transfer pricing provisions are generally in line with the transfer pricing guidelines for MNCs and tax administrators under the OECD guidelines.

Under TPR, any international transaction between two or more associated enterprises must be at arm's length price (ALP). The determination of arm's length price for international transaction is subject to "safe harbour" rules. The CBDT is empowered to draft this and it indicates the circumstances under which tax authorities accept a transfer price declared by a taxpayer. These regulations also apply to cost-sharing arrangements. TPRs require the application of the most appropriate among all prescribed methods. The following methods have been prescribed:

- Comparable uncontrolled price method
- Resale price method
- Cost plus method
- Profit split method
- Transactional and net margin method

However, TPRs don't mandate a hierarchy of methods. They require taxpayers entering international transactions to maintain prescribed documents and information and also obtain and furnish an accountant's report, which included prescribed details relating to the international transaction being carried out, to the tax authorities.

The prescribed documents include details of the ownership structure, description of the functions performed, risk undertaken, assets used by the partied to the relevant transaction, etc. Failure to maintain the documentation required by TPRs or to furnish the report of a chartered accountant result in imposition of a penalty.

As per TPRs, enterprises are considered to be associated if there is direct/indirect participation in the management, control or capital of an enterprise or by the same persons in both enterprises. Some important provisions which trigger an associated enterprise relationship would include:

- Direct/Indirect shareholding giving rise to 26% or more of voting power
- Dependence on source of raw materials/ consumables as well as on customers in the case of manufactured/ processed goods, price and other conditions being influenced by the contracting party
- Authority to appoint more than 50% of board of directors or one or more of executive directors or members of the governing board of the other enterprise
- Dependence on borrowing, i.e. advancing loans amounting to not less than 51% of the total assets of the enterprise of providing a guarantee amounting to not less than 10% of the total borrowings

2.4.1.4 Other direct taxes

Fringe benefit tax

Fringe benefit tax was introduced in 2005; it has recently been abolished by the Finance act, 2009

Wealth tax

Wealth Tax is charged on each company for every assessment year in respect of net wealth of the corresponding valuation date, at the rate of 1% of the amount by which the net wealth exceeds INR 3 million (approx. € 50,000). Net wealth is to be computed in the following manner

- Aggregating the value all specified non-productive assets
- Deducting debts form the above sum that have been specifically secured by or incurred in relation to such assets.

Wealth tax is not deductible for central income tax purposes.

Withholding tax

When making certain payments to non-residents and non-residential companies Indian companies are required to deduct withholding tax. As per Section 40(a)(i) read with Section 195 of the of the Indian Income Tax Act, the entire expenses, relating to any payments to Non-Residents without deduction and deposit of the relevant withholding tax are to be disallowed in the computation of its taxable income

Capital gains tax

Profit or gains arising from the transfer of a capital asset during the previous year is taxable as Capital Gains under section45 (1) of the Income Tax Act. The taxability of capital gains is in the year of transfer of the capital asset[1].

Capital assets are classified as Long Term or Short Term with reference to the period of holding of the assets till it is transferred. The classification is made on the following basis:

Table 2: Classification of capital assets

Nature of Asset	Short Term Capital Asset	Long Term Capital Asset
Shares in a company or any other security listed in a recognized stock exchange in India or a unit of a Unit Trust of India or a unit of a mutual fund specified under section 10(23D).	Held for not more than 12 months.	Held for more than 12 months.
Assets other than assets mentioned in above	Held for not more than 36 months.	Held for more than 36 months.

Subject to certain exceptions, capital gain is computed in the following manner:
Capital Gain = (Full value of consideration received or accrued on transfer of capital asset) - (Cost of acquisition of capital assets + Cost of improvement of capital assets + Expenditure incurred wholly and exclusively in connection with the transfer of capital asset such as stamp duty, registration charges, legal fees, brokerage etc.) The cost inflation index is notified by the Central Government for every year.

Long term capital gains from equities are not taxed. However, short term capital gain from equities held for less than one year, is taxed at 15% plus surcharge and education cess (increased from 10% to 15% after

[1] Capital asset means property of any kind held by the assessee except stock in trade, consumable stores or raw materials held for the purpose of business.

Budget 2008– 09). This rate is applicable only for transactions that attract Securities Transaction Tax (STT).

Other short term capital gains (arising from house, buildings, real estate, bank deposits etc.) are taxed in the same manner as income under other heads. Barring certain exceptions, other long term capital gains are taxed at the flat rate of 20%.

All the following taxes explained below are applicable in case of purchase of machinery, ancillary products and services for the purpose of generating / transmitting / distribution of electricity.

2.4.2 Indirect taxation

Excise duty is a tax applicable to all the manufactured goods within India and is payable by the manufacturer. The Central Excise Act, 1944 and the Central Excise Tariff Act, 1985, govern excise duties. An article attracting excise duty must be both movable and marketable – they should be in a position to be taken to the market and sold.

Basic Excise duty (also termed as cenvat) is usually is payable on assessable value on ad valorem basis. Generally this is understood as the price mentioned in bill or invoice. However, in some cases it is based on the maximum retail price, fixed tariff value etc. Subject to specified conditions, there is export of finished goods and import of input materials, without payment of excise duty.

The basic general rate for excise duty is about 10%. Education cess at the rate of 3 % is payable of the basic duty. Thus the effective rate is 10.32%.

2.4.2.1 Value added tax (VAT)/ central sales tax (CST)

By 1st April 2008 all the Indian states have adopted Value Added Tax (VAT). All business transactions carried on within a State by individuals, partnerships, companies etc. will be covered by VAT. Since the VAT Act applies only to sales within a State, the following sales are not governed by the VAT Act:

Sale in the course of inter-State trade or commerce which shall continue to be liable to tax under the Central Sales Tax Act, 1956;

Sale which takes place outside the State; Sales in the course of export or import.

VAT has 4 slabs of taxes 0%, 1%, 4% and 12.5%. Out of these 4 and 12.5 are the most common ones. Dealers can deduct the amount of tax paid by him for purchase from the tax collected on sales, thereby paying just the balance amount to the Government. VAT paid on inputs purchased and used in the manufacture of goods – also those for exports – will be refunded.

Interstate sales continue to be liable to CST, which is imposed by the central government and administered by the state governments. There rate of CST has been reduced, subject to the provision of prescribed declaration forms. The applicable VAT rate in the relevant state applies in the event the prescribed declaration has not been provided. Declaration forms are only issued when the goods are procured for

i. Resale
ii. Manufacture or processing of goods for sale
iii. Telecommunications network
iv. Mining
v. The generation or distribution of electricity or any other form or power

VAT has removed some of the weaknesses in the former Union excise duties (at the central level) and sales taxes (at the state level). However, many companies are complaining that due to disadvantageous indirect tax system India is still not an attractive destination for manufacturing. Some relief for complicated indirect tax structure is expected in couple of years: India is set to undergo a major tax reform over the next couple of years, as the government and state authorities have agreed to enforce a dual Goods and Services Tax (GST) from April 2011-12. This move will ensure that producers are not subjected to double taxation in this area. Producer will get a set-off against all the taxes he pays on inputs at actual rates. At the moment the goods and services tax model and its roadmap is being finalized by the empowered committee established under the Government of India.

2.4.2.2 Service tax

Service tax is a tax levied on certain identified taxable services provided in India by specified service providers. It is rendered at the rate of 10% of the gross value of taxable services. In addition an education cess at 3% is also levied on the service tax resulting in an effective rate of 10.3 %. The rate of service tax continues at 10%. The Government has broadened the service tax base by introducing eight new categories of services and has expanded the scope of certain existing services.

2.4.2.3 Octroi & entry tax

Octroi is the tax levied on import or conveying of any goods in the municipal area of any town or city. Octroi has been largely abolished, and it is levied only in cities within the state of Maharashtra. Also Maharashtra is planning to abolish this duty within the coming years. The range of Octroi ranges from 4 to 5% of the invoice amount. Octroi rates vary from municipality to municipality and are on invoice value of the product.

For e.g. In Maharashtra Octroi is levied on the value of goods at the following rates:

Table 3: Octroi rates in Maharashtra

Mumbai – 5.5%	Thane – 4.5%
Ulhasnagar – 4%	Kalyan – 4%
Nashik – 4%	Pune – 5%
Pune – 4%	Solapur – 4%
Kolhapur – 4%	Sangli – 4%
Miraj – 4%	Nagpur – 3%
Nagpur – 3%	Aurangabad – 4%

Several states (except Maharashtra) are collecting Entry Tax or other equivalent tax (e.g. in Haryana this is called Local Area Development Tax) on entry of goods within the State limits. The rate of entry tax is usually between 2% and 4%.

2.4.3 Electricity duty

Electricity duty is levied by state governments on electricity supplied to consumer. Total exemption for electricity duty for captive power plants is for 5 years; for SEZ / EOU / STP is for 10 years; new industrial project located under specific areas for 15 years. In case the GENCO supplies electricity to the TRANSCOM & DISCOM, there would be tax implications.

Electricity duty; varies widely from state to state (from 2% to 17% of the consumption units); creates additional burden for the industrial consumers.

For example: There is a tax levy under Tamil Nadu Tax and Consumption or Sale of Electricity Act, 2003. But if the power generated is sold to TNEB only, then this levy is not there on such sales. Recently state of Punjab has passed an order through which an electricity duty of 5% was imposed on electricity traded outside the state of Punjab.

2.4.4 General sales tax (GST)

The indirect tax regime in India is going to be replaced by a comprehensive dual GST; concurrently levied by the central and the state. The base of GST would be comprehensive, including virtually all goods and services, with minimum exemptions.

The structure would follow the destination principle, i.e. imports would be included in the tax base, while exports would be nil. For inter-state transaction in India, the state of destination can levy the tax opposed to that of origin.

GST is said to replace most of the indirect taxes currently being levied both at the centre and state level.

Table 4: Taxes levied by Centre and States

Central Taxes	State taxes
Central Excise duty (including additional excise duties)	VAT / Sales tax (incl. CST & Purchase tax)
Service tax	Entertainment tax (other than levies by local bodies)
Additional Customs duty	Entry tax (not in lieu of Octroi)
Cesses & Surcharges	Luxury tax
	Taxes on lottery, betting and gambling
	State Cesses & Surcharges

There is a consideration given to replacing other taxes like stamp duty, taxes on vehicles, taxes on goods and passengers, taxes and duties on electricity and Octroi as well.

Full input credit system would operate in parallel for central and state GST. Tax paid on procurement of goods and services will be available for credit against that payable on the supply of goods or services. Cross utilization of input tax credit for between central and state GST would not be permitted. Many of the design features of the GST are yet to be finalized and are being discussed by centre and states. The GST was early planned to be rolled out in 2010FY, but now it's expected to be in force from 2012FY.

2.3.2 Other taxes & cess

2.4.4.1 Stamp duty

Stamp duty is paid for a transaction executed by way of a document or instrument under the provisions of the India Stamp Act or the state acts. Duty is generally dependent on the state where the agreement is executed. It is applicable on purchase of land and various other transactions line lease, conveyance, mortgage, partitions, transfers, etc. The duty is calculated on an ad valorem basis, depending on the nature of the instrument and the state where it is executed. Stamp duty can be paid by using stamp paper,

adhesive stamps or by franking. Further in can be levied at a flat rate on a certain document, irrespective of the amount involved.

2.4.4.2 Profession tax

This tax is a state levy on professions, trades, a calling or employment in a state. Thus every person who is engaged in any of the activities mentioned above is liable to pay profession tax. Profession tax is not levied in all states currently. The employer is liable to pay the requisite amount of profession tax on such salaries or wages, irrespective of whether it has been deducted from the salaries paid.

2.4.4.3 Securities transaction tax (STT)

This is a tax levied on all transactions done on the stock exchanges. It's applicable on purchase or sale of equity shares, derivatives, equity oriented funds and equity oriented mutual funds.

Table 5: Securities Transaction Tax rates

Transaction	Rates %	Payable by
purchase/ sale of equity shares, units of equity-oriented mutual funds (delivery-based)	0.125%	purchaser & seller
sale of equity shares, units of equity-oriented mutual funds (non-delivery based)	0.025%	Seller
sale of an option in securities	0.017%	Seller
sale of an option in securities, where an option is exercised	0.125%	Purchaser
sale of futures in securities	0.017%	Seller
sale of units of equity-oriented funds to a mutual fund	0.250%	Seller

2.4.4.4 Luxury tax

Luxury tax is a state levy on specified luxuries and facilities, services, enjoyments, utilities, etc. Certain examples are hotels, clubs and even cigarettes.

2.4.4.5 Entertainment tax

Entertainment tax is paid by the entertainment industry. It applicable on large scale entertainment shows, private/sponsored festivals, movie tickets, amusement parks, horse racing, golf etc. The entertainment tax department based in New Delhi is looking after the affairs with respect to this taxation.

2.4.4.6 Property tax

The owner of a property (largely real estate) is liable to pay property tax. The amount of tax is estimated on the value or the property being taxed on ad valorem basis at applicable rates. It is levied by the local municipal authorities in India.

2.4.5 Tax deducted at source

Under the Indian Income Tax Act 1961, there are often a number of requirements for tax deduction at source for payments made for various outside contractors for services, payments for rent etc. Tax deduction at source means the tax required to be paid by the recipient of income, is deducted by the person paying the income to him. Thus, the tax is deducted at the source of income itself. The income tax act enjoins on the payer of such income to deduct the given percentage of income as income tax and pay the balance amount to the recipient of such income. The tax so deducted at source by the payer is to be deposited in the income tax department account.

The income from for instance following sources is subjected to tax deduction at source:

- Salary and all other positive incomes under any head on income
- Interest on securities
- Interest other than interest on securities
- Payments to contractors and sub-contractors
- Any interest other than interest on securities payable to non-residents, not being a company or to a foreign company
- Payment on account of repurchase of Units by Mutual Fund
- Payment for Commission or brokerage
- Payment of rent
- Payment of fees for professional or technical services
- Income from Units purchased in foreign currency or long-term capital gain arising from the transfer of such Units purchased in foreign currency
- Payment of any income to non-residents in respect of interest or dividend on bonds and shares.

Some of the important TDS rates are shown in a table below:

Table 6: Rates of tax deducted at source

Payment	TDS (with surcharge[2] and cess)
Payment to Contractors	**1.0%**
Payment to Sub-Contractor	**1.0%**
On Rent for Plant & Machinery – **On Rent for Land & building –**	**2%** **10%**
Payment for Professional Fees / Technical Services / Commission / Brokerage	**11.33%**
Payment of Interest – • **To an individual** • **To a company**	 **10%** **20%**

2.4.6 Expatriate taxation

The liability to tax under the Income Tax (IT) Act depends upon the residential status of the individual, irrespective of his/her nationality or domicile. Thus for income taxation purposes it makes no difference whether the person is from Finland or Singapore.

[2] *Surcharge applicable when income exceeds INR 1 million*

For tax purposes, an individual may be *resident, non-resident or not-ordinarily resident (NOR).* An individual is said to be *resident* in India in a tax year (1st April to 31st March next) if he/she is present:

1. In India for a period or periods amounting to 182 days or more in a tax year; or
2. In India for an aggregate period of 60 days or more in the tax year and has been in India for an aggregate period of 365 days or more in the four tax years preceding that particular tax year.

Individuals fulfilling neither of these conditions are *non-residents*.
An individual is said to be *not-ordinarily resident* in India in any tax year if such person is:

1. An individual who has been non-resident in India nine out of ten tax years preceding that tax year; or
2. Who has during the seven tax years preceding that tax year, been in India for a period or periods aggregating to 729 days or less.

A resident is taxed on worldwide income in India. However, they are entitled to claim credit for foreign taxes pad under Double Tax Avoidance Agreement (DTAA). The provisions under DTAA between Finland and India are discussed later in this report.

A non-resident is taxed only on income received or that arises or is deemed to arise in India.

A person *not-ordinarily resident* is taxed like a non-resident but is also liable to tax on income accruing abroad if it is from business controlled in or a profession set up in India.

In effect, a newcomer to India remains not-ordinarily resident for the first nine years of residence in India.

What is then taxable: All types of remuneration received or receivable by the expat from the employer for the services rendered, including the benefits-in-kind (i.e. perquisites) are subject to tax, wherever received, whether in India or abroad. Where an employer bears the tax liability, the expat's taxable income is determined by grossing it up with the tax paid by the employer so that the tax on the grossed-up income is equal to the tax paid by the employer.

In most other aspects, expatriates are on the same footing as Indians. Peak tax rate is 30%.

2.5 Intellectual property rights (IPR)

Intellectual property rights (IPR) are one concern area of Finnish companies, when thinking of R&D cooperation in India. Many companies that are established in India prefer to keep all R&D in their own hands, rather investing into own personnel. Intellectual property is mainly protected through patents. There are also combinations of various modes of IPR such as patents, designs, trademarks and copyrights.

Modes of protecting intellectual property under patents are

- Processes
- Products
- Apparatus, tools and machinery
- Inventions, capable of industrial application

India has been a member of WTO since 2003, and the legislations relating to the protection of intellectual property rights was amended to comply with the TRIPS Agreement. Further amendments to the Patents

Act, 1970 were made in 2005. Indian patent law is now fully compatible with the TRIPS Agreement. With the amendments made in 2005, both process and product patent protection is now available in all fields of technology. The law has provision both for pre-grant and post-grant opposition in the Patent Office. The term of patent protection is now 20 years for all inventions.

- Governed by Patent Act, 1970 and Patent Rules, 2003 (as amended)
- India follows a first-to-file system
- India also allows 'Pre grant Opposition', unlike Europe where only 'Post grant opposition exists'
- In compliance with TRIPS obligation
- Product patent allowed from 2005
- Judicious borrowing of Patent Jurisprudence from EU/UK

2.5.1 Indian patent law

All fields of technology and diagnostic kits are patentable. Following categories are not regarded as inventions and thus not patentable:

- Section 3(b)- Contrary to public order and morality
- Section 3(c) – discovery of living things
- Section 3(d) – new forms of a known substance
- Section 3(e) – composition-mere admixture
- Section 3(i) – method of treatment of animals and humans
- Section 3(j) – plants, animals and parts thereof and Essentially Biological Processes
- Section 3(k) – computer programs per se

Patenting process has 12 stages:

1. Identification of patent opportunity during project progress. Is the invention novel, b) non-obvious in view of what is already know
2. Prior art search
3. Filing of patent application in India with provisional specification before any public disclosure of the invention.
4. Consider matter for international filing.
5. Generate further examples to support the invention.
6. Filing of complete specification 12 months after provisional specification (extension to 15 months possible with late fee only in India)
7. Technical examination by Patent Office.
8. Acceptance of patent and publication in the Gazette.
9. Opposition by competitor, if any.
10. Grant and sealing of patent.
11. Maintenance of patent by payment of renewal fees.
12. Enforcement / revocation (possible litigation, if any)

Applications for patents have to be submitted to the Controller General of Patents, Designs, Trademarks and Geographical Indications. The patent rights accrue from the date of publication of the patent application, which is within one month after completion of 18 months of its filing or at an earlier date, if requested by the applicant. On average, it takes 2–2.5 years to grant a patent. The long procedure is mainly due to lack of qualified people conducting examinations (industry picks up the best people) and insufficient IT infrastructure in patent offices. The applicant has no right to start infringement proceedings until the patent has been granted.

Provisions exist in various laws for dealing with counterfeiters and those who engage in the manufacture and marketing of pirated goods. Persons found guilty are tried under the relevant legislations governing the offences. Further, the Court may also order that the goods which are found to be infringing shall be seized, forfeited or destroyed. The Customs Act empowers the Central Government to prohibit or restrict import or export of goods in order to protect trademarks, copyrights and patents. The Central Government has also issued a notification prohibiting import of goods in violation of the Trade Marks Act.

The enforcement of the law is the concern of the State Governments. Most of the States have set up Intellectual Property Rights Cells to look into the complaints of violation and infringement of IPR. The primary responsibility for investigating complaints of manufacture of pirated goods rests with the State police within whose jurisdiction the manufacturing unit is situated. The police, in case of violations, initiate proceedings against the guilty. The Central Government, in turn, has set up an Inter-Ministerial Coordination Committee on Intellectual Property Rights Enforcement Issues to have a focused approach in the matter.

Unfortunately the enforcement machinery is still weak. Courts are overloaded with cases, and it can take years before the matter can be handled Thus the violators of IPR often remain unpunished.

2.5.2 Royalty practices

Practices for the share of royalties between the funding organization and the research institute vary. However, it is a common practice that IPR is agreed with a written contract. As an example of IPR agreements with Indian funding organizations are DBT and ICMR. In DBT funded projects ownership structure is 50% DBT and 50% institute. In ICMR funded projects ownership is 100% ICMR and share of royalties can be 60/40 or 70/30.

2.6 Operational costs

The following are certain illustrations of the various business related costs in India. These are tentative and can vary according to the region and type of services availed.

Table 7: Expenses figures

Living (*Figures in Euros*)		**Rental**	
House Rent	200 -1000 /month	Bungalow office	~300 – 500 /100 sq.mt
Car	5,500 – 12,000 one time	Commercial office	~500 – 700 /100 sq.mt
Taxi	7-15 for local use, approx. 30 for 8 hours	Factory Setup	~150k /5000 sq.mt
Domestic Flights	40-120 / flight		
Restaurant	2-10 /person /meal		
General Grocery	90-150 /person /month		
Manpower		**Taxes**	
R&D Head	Mostly US returned. On salary slightly lesser or same as what he/she got in US	Personal Income Tax	Slab systems of 10%, 20% & 30%, based on Income levels
R&D fresher	5500 – 8000 /year, based on candidate & college	Corporate Tax	32%
Area Sales Manager	18000 – 25000 /year	Service Tax	12%
Experienced person [3-4 year]	~10000 /year	Value Added Tax	State Specific
Entry level sales	4000 – 5000 /year, including incentives	Import Duty	~19.56% [as per international classification & WTO Harmonization]
CRO / Research person [~5 years]	1500 /month	Excise duty	8%
Commercial person	1500 – 2000 /month	Direct Tax Code	Under discussion
Secretary [~2 years]	3500 /year	**Others**	
Peon	~100 /month	Bank FD Interest	~9%
Company		Inflation	~8 – 11%
Starting time	30 – 45 days	Business loan	~12-20%
Closure/ Winding up	~180-365 days [Depends on the kind of business]	Labour/Pension laws	Min 20 employees

2.7 Cultural aspects

India is a complex country with varieties of cultures and beliefs and that is what defines the people. People from different socio-economic strata, educational background and religion may behave differently. The points discussed are some behavioural aspects and in no-way depict exactly the way how an Indian would always behave. Educated Indians are adapted to various societies and ways & means of westerners. They understand the importance of time. They can even be quite assertive, aggressive and direct, quite contradictory to what is generally perceived.

Some cultural adjustments would be required, but still business sentiments and logic (avoiding risks and uncertainties or high risk – high return) pays off, as they do elsewhere.

Foreign investors should have at least a preliminary overview of the India specific strategy, ready with them, while conversing with a potential a partner or an associate. The overview should consists of the following

- A long term perspective of the proposed investment along with a good regional business model
- Conceptualized India specific products/ product lines/services
- Keep in mind the value for money concept
- Utilize an optimal mix of expatriate and local talent in the management
- Define a clear communication channel between HQ & Indian entity
- Have a consideration for local aspirations & sensitiveness while establishing the corporate culture

The investor should also pay attention to / consider the following

- Be hands on – don't always go the "*report*" way
- Personal interaction – with customers and employees is very critical
- Hierarchy still exists – chain of command, protocol etc. are strictly followed (esp. government departments and similar organizations)
- Delays are a common phenomena (example: approvals from Government departments)
- Do factor in last minute delays in project plans/ schedules
- Complex & high bureaucratic decision making is slow and requires follow-up and perseverance (includes documentation, chain of permissions etc)
- To tackle these utilize the skills of the local management and have it delegated to them

Some interesting situations

"*Can't say no*"

Behind a hesitation to say "no" to a given task, there is a willingness to try; presumption of the unrealistic nature of the job, possibility of causing disappointment or offense could be some other related reasons. To tackle this it is good to have an environment safe/comfortable where one can say "no" and fear no repercussions

"*Criticism vs Self-esteem*"

Criticism needs to be done constructively, such that it doesn't damage one's self-esteem, especially in front of known people, colleagues or public

"*Aggressiveness*"

Over aggressiveness and related behaviour can be interpreted as a sign of disrespect and can even affect further communication and interaction.

"*Be tactful*"

Disagreement need not always be expressed with a straightforward NO! The turndown can be conveyed in a toned down gentle manner and the difficulty would be understood. Remember that its *friendly and constructive* bargaining.

"*Its not money & business always*"

Indians want to recognize the value in any business engagement, in addition to the monetary benefits. Even important business meetings in Indian will not begin without a gush of small talk, inquiries about family, weather, etc.

Indian respect people who value their family and at times family would gain priority over work too.

Delays in appointment are accepted, but it's not commonly practiced.

Statistics, empirical data, power point presentations and reports may not be the only basis for decision making; there is faith, intuition and gut feel to guide.

Innovation ecosystem

The Indian Government has declared 2010-2020 as the 'Decade of Innovation' recognizing the importance of innovation in driving economic growth, employment and competitiveness. The Government has created a public-private partnership (PPP) fund of US$ 985.80 million so as to involve the private sector in R&D, especially in the fields of vaccines, drugs and pharmaceuticals, super computing, solar energy and electronic hardware. Despite the trend in increasing R & D spend; India's aggregate domestic spending on R&D has remained less than 1% of the GDP.

Bio-Pharma and pharmaceuticals have emerged as strong areas for R & D within the healthcare sector. Main segments within Bio-Pharma are: Vaccines – DPT with Hepatitis B, Hepatitis A, Polio etc.; Therapeutics – TB, HIV, Cholera, Dengue, Typhoid and Cancer. Within Pharmaceuticals, main segments by manufacturing: API's – 25% of market and Formulations – 75% market; by therapeutic areas: Chronic (28% market): Cardiovascular, CNS, Oncology, Diabetes, Obesity; Acute: Anti-infectives, Gastro, Respiratory, Analgesic, Vitamins. In recent years, the focus of Indian Pharma Industry has shifted from generics to new drug delivery systems and new molecules/drugs with increased international collaboration.

The diagnostics segment, too, has witnessed increased 'frugal' innovation activity so as to meet low resource constraints of the Indian market. Solutions for the local market need to be low-cost, less time consuming, point-of-care and easy to transport given the decentralized nature of healthcare delivery. A case in point is the development of Low Cost Point of Care (POC) Device for Detection of Blood Glucose by BITS-Pilani (Hyderabad campus) that will cost less than INR 2 per blood sample and require 1000 times lesser blood than what glucose meters use currently. The blood glucose count shows up in 10 seconds. Another example is Forus Health's '3nethra' a low-cost, portable, intelligent, non-invasive, non-mydriatic eye pre-screening device that can detect 5 major ailments constituting 90% of blindness- Diabetic retinopathy, cataract, glaucoma, cornea problems and refractive errors. Bangalore-based Bigtec Labs is at an advanced stage in the realization of a Micro Electro-Mechanical Systems (MEMS) based nucleic acid amplification platform (supported by the New Millennium India Technology Leadership Initiative from CSIR, Government of India) that can be extended to diagnose several diseases. Such a system can be tailored to accept whole blood samples or samples with minimal processing, extending the diagnosis capability to remote locations with minimal facilities. Results are available in a few minutes, making it an ideal platform for Doctor's Office Disease Monitoring. Though funding for diagnostics R &D in India has remained lower than other segments, the expansion of public and private health insurance is expected to result in the demand for speedy, accurate and cost-effective diagnostics to cater to local needs.

3.1 Research and corporate cooperation status

Although traditionally industry-academia links have been considered weak in India, the growing emphasis on applied research has resulted in stronger links between the two and substantial increase in two-way collaboration. Many scientists are interested in projects with company involvement, and some of the newest research institutes have active company cooperation as one of their strategic principles.

The Indian entrepreneurship ecosystem is beginning to take shape in India – an increasing number of educational institutions are setting up incubation centres and a larger number of graduates are willing to start ventures on their own, instead of joining a well-established company according to the Indian Angel Network. The Government, on its part, has begun to recognize the importance of early-stage entrepreneurship and has initiated actions towards this end. According to industry and experts' estimates, nearly USD 10 billion was invested in 2011 in about 500 Private Equity deals across all sectors, which is almost 10 per cent higher than in 2010. The Indian Department of Science & Technology (www.dst.gov.in) and Department of Biotechnology (http://dbtindia.nic.in) play a key role in research funding and are constantly developing new schemes for innovation funding.

The figure below depicts the various stages of funding of R & D:

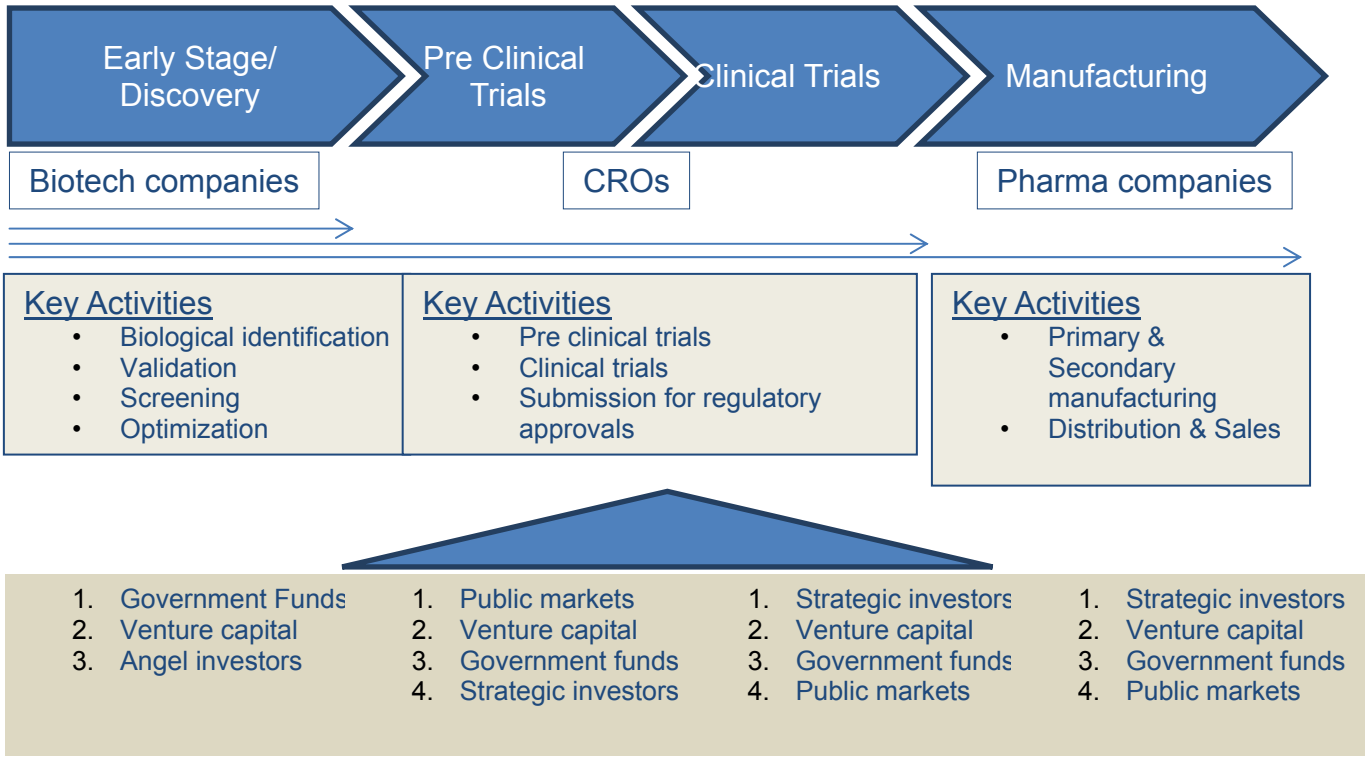


Figure 11: Stage wise funding of R&D

3.2 R&D ecosystem & hotspots

There are numerous Indian research organizations and universities which undertake research work on diagnostics. However, very few institutes have put remarkable efforts to develop it systematically. In general, diagnostics has not received the attention it requires. It is noteworthy that India is investing a lot in the development of new universities and research institutes. The aim is not only to foster knowledge creation but also to increase innovation capacity for urgent needs of the society. Application-oriented institutes and research units addressing affordable healthcare solutions are being established. Continued follow-up of the innovation ecosystem is thus necessary.

Some of the research institutions and universities that are working with diagnostics are presented in Table 8 on next page..

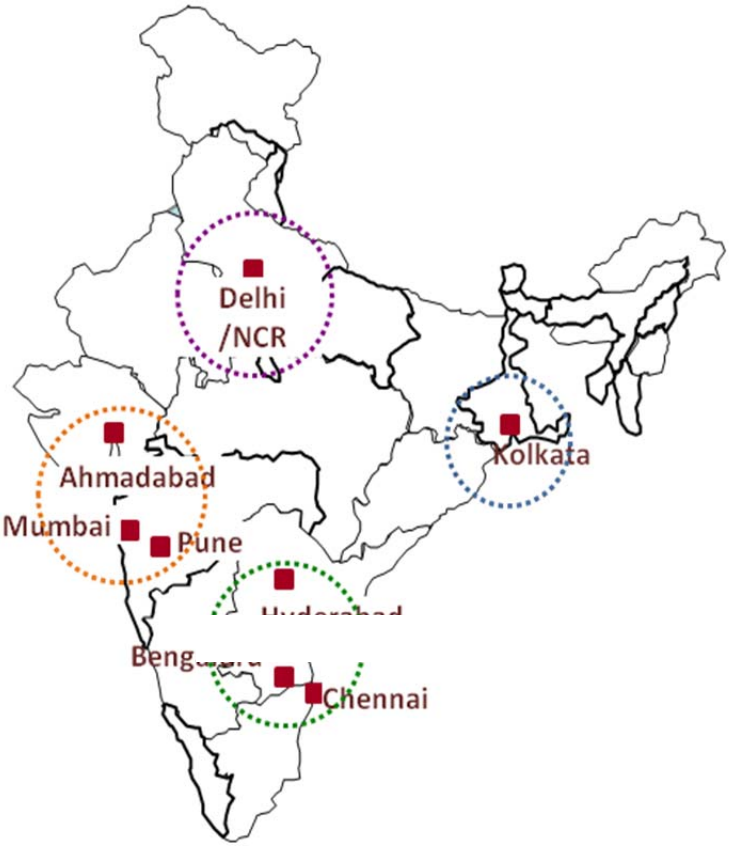


Figure 12: Major R&D hotsposts in India

Table 8: R & D universities and institutes by Region

Zone	Cities	Actors
North	Delhi /NCR	THSTI, ICGEB, University of Delhi South Campus, AIIMS, IITD (+ FITT), NII, NIMR
	Chandigarh	Institute of Microbial Technology
East	Kolkata	IIT Kharagpur
	Bhubaneswar	ILS
West	Mumbai	IITB, TIFR, NIRRH, ACTREC
	Pune	NCL, NARI, NIV, NCCS, TRDDC
	Ahmedabad	NID, IIMA
South	Hyderabad	CCMB, CDFD
	Bengaluru	c-Camp, NCBS, IISc, IBAB, JNCASR
	Chennai	IITM, NiRT, BCG Vaccine Laboratory, Anna University
	Vellore	CMC+ CSCR, VIT + Technology Business Incubator
	Trivandrum	RGCB, NIIST

Table 9: Activities of R & D universities and institutes

Organization	Activities (in Diagnostics)	Other remarks/conclusions
NORTH		
All Indian Institute for Medical Sciences (AIIMS) Delhi www.aiims.edu	AIIMS has its own hospital, does clinical trials, evaluation studies, research activities in epidemic diseases, etc and it has also done some research work in diagnostics. AIIMS is a member of the National Biodesign Alliance.	AIIMS has developed a PCR (polymerase chain reaction) test for the diagnosis of tuberculosis, and plague; and highly sensitive and specific ELISA for detecting HIV antibodies.
Indian Institute of Technology Delhi (IITD), Delhi www.iitd.ac.in	IIT Delhi has active research in biotechnology as well as in various technologies for diagnostic solutions. IITD is a member of the National Biodesign Alliance, and has a multidisciplinary approach.	IIT Delhi has research activities e.g. on cancer cells and diabetic's diagnostic device development. They are under process of developing rapid tests for food contamination. IIT Delhi projects are funded by e.g. DBT. IIT would be interested in intellectual property creation with a Finnish counterpart in the field of knowledge of biomedical and electronics engineering for product development of compatible sizes for commercialization.
University of Delhi South Campus http://web1.south.du.ac.in/	UDSC is a large multidisciplinary University with many departments. Department of Biochemistry carries out both basic and applied research in different areas of human diseases with its focus on macromolecular delivery, vaccine development and diagnostics. Specific thrust areas include, among others, studies on gene regulation and pathogenesis of Mycobacterium tuberculosis, identification and validation of new drug targets against TB, development of vaccine against TB, production of monoclonal antibodies using hybridoma technology for a variety of applications, phage display based identification of immunodominant epitopes for disease identification such as AIDS, hepatitis and tuberculosis; drug delivery and targeted delivery of DNA vaccines.	Research collaboration with Finland on TB diagnostics
National Institute of Malaria Research (NIMR)	NIMR is one of the institutes of the Indian Council of Medical Research (an autonomous body under	The major areas of research carried out over the years are on mosquito fauna surveys, development of genetic and

http://www.mrcindia.org/	Department of Health Research, Ministry of Health & Family Welfare, Govt. of India). The primary task of the Institute is to find short term as well as long term solutions to the problems of malaria through basic, applied and operational field research. The Institute also plays a key role in man power resource development through trainings/workshops and transfer of technology.	molecular markers for important malaria vectors and parasites, cytotaxonomic studies identifying major vectors as species complexes and laboratory and field studies to examine the biological variations among sibling species, development of molecular identification techniques for sibling species, monitoring of insecticide resistance through space and time, preparation of action plans, etc. have yielded valuable information. Field evaluation of new insecticides, biolarvicides, insecticide-impregnated bed nets, drugs and parasite diagnostic kits have provided new armament to malaria control. Many of these have found place in national malaria control programme. NIMR has a network of well developed laboratories at Delhi carrying out research on all aspects of malaria along with 10 field laboratories in malarious areas, which serve as testing ground for new technologies and help in the transfer of technologies.
Translational Health Science and Technology Institute (THSTI) http://www.thsti.res.in	THSTI is an autonomous institute of Department of Biotechnology, Government of India that seeks to establish collaborations with research institutions and hospitals around India, making this a national undertaking. The goal is by multidisciplinary research to provide affordable technologies and solutions that address global healthcare challenges	Partner in the Indo-Finnish Diagnostics Research Centre. More information on THSTI page on 57 and Indo-Finnish Diagnostics Research Centre on page 61.
International Centre for Genetic Engineering and Biotechnology (ICGEB), Delhi www.icgeb.res.in	ICGEB is focused on developing technologies for developing country needs. The Centre employs currently 36 PhDs. They are strong in developing and producing bio molecules. ICGEB is a member of the National Biodesign Alliance	ICGEB has lot of experience in international collaboration. However, Finland is the only country for diagnostics cooperation. ICGEB has collaboration with University of Turku and VTT. Joint projects that focus on development of affordable diagnostics methods for e.g. infectious disease and blood bank testing have been funded by DBT and Tekes (or Academy of Finland).
National Institute of Immunology (NII) Delhi www.nii.res.in	NII is an autonomous institution supported by the DBT. The Institute is committed to advanced research addressing the basic mechanisms	NII research activities include among others pathogenesis of HIV and Typhoid.

	involved in body's defence, host-pathogen interactions and related areas. NII has 42 faculties each of them having their own laboratories. NII has core research actives in 1. Immunity and Infection 2. Reproduction and development 3. Molecular design 4. Gene regulation NII is a member of the National Biodesign Alliance	
Institute of Microbial Technology (IMTECH) Chandigarh www.imtech.res.in	One of the 38 national laboratories of the Council of Scientific & Industrial Research (CSIR). It seeks to be a fore-runner in the area of Biotechnology.	The scientists of IMTECH are focused on basic and application-oriented research for microbial and biotechnology.
EAST		
Indian Institute of Technology, Kharagpur (IITK) http://www.iitk.ac.in/	It offers under-graduate, post-graduate and doctoral programs in engineering. IITK has 19 departments, research areas vary from biotechnology and materials science to management.	
Institute of Life Sciences Bhubaneswar www.ils.res.in	Institute of Life Sciences has active research activities in 1. Infectious disease biology 2. Gene function & regulation Transitional research & technology development	ILS has developed nano-particulate drug delivery systems for cancer therapy (breast & prostrate). They are also working on the other areas for therapy development for leukaemia, vaccine development for malarial disease and test of human immunology with the pathogens (like vibrio cholerae and bacteria). Their projects are funded by ICMR (Indian Council of Medical Research), European commission, and Indo-German joint initiatives for specific research projects
WEST		
Advanced Centre for Treatment, Research and Education in Cancer (ACTREC) Navi Mumbai www.actrec.gov.in	R&D satellite of the TATA Memorial Centre. Cancer diagnostics, especially high-end. Focusing on cancer of children, breast cancer, brain tumours and bone marrow transfer. Sister organization Tata Memorial Hospital serves as good client base, so testing can be done in-house and ACTREC is also well aware of all problems, questions and latest technologies.	As special case there are immuno-supressed patients, whose immunosystem is compromised because of cancer treatments. ACTREC has state of the art animal testing facility with PET, CT, SPEC, and is going to purchase IMR for animals.

Tata Institute of Fundamental Research (TIFR) Mumbai www.tifr.res.in	The focus of TIFR is on basic research in physics, chemistry, biology, mathematics, computer science and science education. TIFR works under the Department of Atomic Energy.	They are also working in the field of Molecular Biology and Biological sciences.
National Institute for Research in Reproductive Health (NIRRH) Mumbai www.nirrh.res.in	NIRRH is a research institute of the Indian Council of Medical Research (ICMR). It is affiliated to the University of Mumbai that offers degrees to the M.Sc. and Ph.D. students in Biotechnology, Life Sciences, Biochemistry and Applied Biology.	The focus is on improving the reproductive health of people through research, education and health care services.
Indian Institute of Management Ahmedabad, IIMA, Ahmedabad http://www.iimahd.ernet.in/	IIMA has consistently been ranked as the number one management school in the country year after year in the last several years. In its latest ranking, The Economist has ranked IIMA at 56 among the top 100 international B-schools in the world that offer full time MBA. The Financial Times (FT) has ranked the two-year post graduate programme in management (PGP) of IIMA in the top ten programmes in the category of Masters Programmes in Management that do not require work experience as pre-requisite for admission. FT reported that this was the first time that any Indian B-school was not only included in the survey but also achieved such high ranking. The Financial Times has also ranked the one-year post graduate programme in management for executives (PGPX) among the top MBA programmes globally. The two post graduate programme in management with specialization in agri-sector (PGP-ABM) is ranked at number one among comparable programmes globally by Eduniversal.	The faculty is the principal driver of change through their direct involvement in every aspect of the Institute: academics, governance, research, and consultancy. They combine the very highest standards of teaching and mentoring with diverse backgrounds as eminent entrepreneurs, policy makers, researchers, theoreticians and consultants. The rich diversity of their backgrounds install in the students a continuous desire to achieve excellence. Faculty members serve on executive committees and policy formulation boards of a rich variety of organizations in both private and public domains. These include corporations, financial institutions, cooperative societies, NGOs, academic institutions and international agencies such as FAO, World Bank, and WTO. Such active involvement generates precious cross-fertilization and ensures that all academic programmes are kept up to date.

National Institute of Design, Ahmedabad www.nid.edu	Cooperation opportunities exist in product design / re-development as student project. This can be an opportunity for Finnish companies for product R&D / re-design for Indian market. The institute is also recognised as a scientific e and industrial research organisation by the Department of Science and Technology, Government of India	The mandate for NID is to offer world-class design education and to promote design awareness and application towards improving the quality of life. Upgrading the design of products and systems of everyday use with an aim to bring in indigenous design solutions by focusing on affordable design for the masses
National Chemical Laboratory (NCL), Pune www.ncl-india.org	NCL is a research, development and consulting organisation with a focus on chemistry and chemical engineering. NCL focuses research activities in 1. Catalysis 2. Biochemical Science 3. Organic Chemistry 4. Polymer Science 5. Physical and Materials Chemistry Chemical Engineering Science	Interest in interdisciplinary research and diagnostic applications. Has also a business incubator, the Venture Center, located within the NCL Innovation Park, for nurturing technology and knowledge-based enterprises.
National Centre for Cell Sciences (NCCS), Pune http://www.nccs.res.in/	The National Centre for Cell Sciences, Pune (NCCS) was established as a National Repository of Animal Cell Culture with a mandate of basic research, teaching & training, and as a national repository for cell lines/ hybridomas etc. It also conducts manpower development in animal tissue culture through training programmes/workshops and extends infrastructural facilities to researchers and institutions in biochemical sciences.	The centre focuses on basic research in the areas of Cell Biology, Cancer Biology, Infectious diseases, Immunology, Molecular Biology, Proteomics, Genomics, Diabetes and Tissue Engineering that leads to enhancement in understanding the events at molecular level.
Tata Research Development and Design Centre (TRDDC), Pune http://www.tcs-trddc.com/	The Tata Research Development and Design Centre (TRDDC) was established in 1981 as a division of Tata Consultancy Services Limited (TCS), India's largest IT services organization. TRDDC is today one of India's premier research and development centres; it is also the largest R&D facility among the network of Innovation Laboratories at TCS. TRDDC offers a collaborative and open innovation environment for engaging with industry partners and clients in	TRDDC is home to three R&D laboratories: Process Engineering, Software Engineering and Systems Research. The R&D work at TRDDC leads to the creation of tools and processes that simplify the development, maintenance and management of large IT and engineering systems. In addition, several of their projects are directed at improving the environment, healthcare and education. Active among others in material sciences incl. production of nanoparticles and drug delivery systems, as well as low-cost water purification

	various domains, academia, strategic technology partners, startups, standards organizations, among others.	systems. The Bio Sciences R&D unit is active in bioinformatics, metagenomics, genome informatics, next generation sequencing, algorithms for biological data, disease informatics and systems biology. Various collaboration opportunities with Finnish organisations.
National Institute of Virology(NIV), Pune www.icmr.nic.in/pinstitute/niv.htm	One of the major Institutes of the Indian Council of Medical Research (ICMR). NIV research activities cover all major viral diseases.	NIV is recognized as the WHO (world health organization) regional collaborating centre for reference and research on Arboviruses, and national reference centre for Hepatitis and influenza. Collaboration with companies, e.g Serum Institute of India and Cadila Pharmaceuticals.
National AIDS Research Institute (NARI) Pune www.nari-icmr.res.in	Mission is to establish research initiatives that have an interface with intervention and policy development to prevent and control the spread of the HIV/AIDS epidemic. Focuses on various aspects of research on HIV and AIDS, e.g. research on candidate vaccines, diagnostics and drugs. Clinical research and therapeutic trials.	
SOUTH		
Centre for DNA Fingerprinting and Diagnostics (CDFD) Hyderabad www.cdfd.org.in	Autonomous organization funded by DBT. Genetic diagnostic laboratory offers diagnosis of genetic diseases (cytogenetic, biochemical and molecular) as well as prenatal diagnosis for chromosomal abnormalities, single gene disorders and inborn errors of metabolism. DNA fingerprinting service. Patient counselling. Research on molecular pathophysiology and mapping of genetic disorders.	Basic research., not currently active in diagnostic kit development

Centre for Cellular and Molecular Biology (CCMB) Hyderabad www.ccmb.res.in	One of the constituent laboratories of CSIR. Research activities of CCMB cover many areas of modern biomedical and molecular biology research, e.g. 1. Genomics 2. Bioinformatics 3. Molecular biology 4. Genetics and evolution 5. Biochemistry & Biophysics 6. Infectious diseases 7. Cell Biology & Development Biotechnology and Biomedicine	Good research facilities. Application-oriented research in several fields like diagnostics, drug discovery (e.g. Alzheimer's', Hepatitis B, colon cancer, leukaemia, atherosclerosis, Diabetes T1&2) and plant biology.
Institute of Bioinformatics and Applied Biotechnology (IBAB) www.ibab.ac.in	IBAB receives continuing strong support from the Government of Karnataka. In addition, it has received grant support from the Government of India's Department of Science and Technology (DST), Department of Biotechnology (DBT) and the Department of IT (DIT). As a founder member of the National Entrepreneurship Network (NEN), the institute is now expanding its efforts in this realm. IBAB was set up so as to: • Become a globally recognised institution of higher learning in bioinformatics and biotechnology. • Undertake short-term training programmes especially executive training programmes to upgrade the skills of professionals in related industries. • Provide incubation and other services to entrepreneurs and potential entrepreneurs. • Carry out research and development.	Research activities at IBAB involve both computational and experimental approaches. Collaborative and contract research projects with companies are also considered. In addition, IBAB promotes entrepreneurship in bioinformatics and biotechnology
Indian Institute of Science (IISc) Bangalore www.iisc.ernet.in	IISc research areas vary from biological to mechanical sciences. IISc Division of Biological Sciences has research activities in infectious diseases, drug and molecular design, and gene targetting, genetic disorders and genetic diversity.	Mainly basic research, some industry collaborations. Diagnostic activities are mainly for cardiovascular and diabetics. IISc would be interested in co-operation in this field.

National Centre for Biological Sciences (NCBS) Bangalore www.ncbs.res.in	NCBS is part of the Tata Institute of Fundamental Research. The mandate of NCBS is fundamental research in the frontier areas of biology. Their research interests range from the study of single molecules to ecology and evolution. Together with the newly established Institute for Stem Cell Biology and Regenerative Medicine (inStem) and with Centre for Cellular and Molecular Platforms (C-CAMP) NCBS forms the Bangalore Biocluster, an innovative synergistic institutional model for cutting-edge scientific research and technology development.	
Centre for Cellular and Molecular Platforms (C-CAMP), Bangalore www.ccamp.res.in	C-CAMP offers high-end platform technologies and services related to confocal and fluorescence microscopy, flow cytometry, molecular characterization and proteomics, next generation sequencing/genomics, protein technology core, etc	Centre for Cellular and Molecular Platforms (C-CAMP), located in Bangalore is a Dept. of Biotechnology (Govt. of India) initiative, and is envisioned to be a major platform technology, industry-interaction and incubator unit.
Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR) Bangalore www.jncasr.ac.in	JNCASR is a multidisciplinary institute that grants Master's and Ph.D. degrees. Funded by DST.	Research focuses on Science and Engineering in broad areas ranging from Materials to Genetics.
Indian Institute of Technology Madras (IITM), Chennai www.iitm.ac.in	One of the oldest IITs. IIT Madras offers undergraduate, postgraduate and research degrees across 15 disciplines in Engineering, Sciences, Humanities and Management. Basic research in several areas of biotechnology like medical and industrial biotech and bioprocess engineering; stem cell research, cardiovascular complications of diabetes, recombinant antibodies etc.	Department of Electrical Engineering has developed several socially relevant products for rural areas, incl. remote medical diagnostics. Industrial consultancy through the Center For Industrial Consultancy and Sponsored Research (ICSR).
Healthcare Technology Innovation Centre (HTIC), IITM http://htic.iitm.ac.in/	Health Technology Innovation Centre (HTIC) is a newly established DBT-funded R&D centre at IITM. HTIC aims to develop affordable med-tech	Current activities in ophthalmology, neonatal health, intensive care units (ICU), ultrasound imaging, interventional oncology, cardiovascular disease risk monitoring. Aim to set up a med-tech

	solutions for pressing needs in India and other developing countries. They have developed some interesting prototype solutions for rural health care in industry cooperation.	incubator at IITM Research Park. Interested in cooperation with Finland; options include academic collaboration, R&D services or joint product development with industry, technology evaluation, researcher exchange etc. Long-term strategic cooperation favoured.
The Center for Social Innovation and Entrepreneurship (CSIE) at IITM http://csie.iitm.ac.in/	CSIE at IITM was founded in 2010 with a focus on teaching and research related to social enterprise in India. It aims to bring together the innovation and entrepreneurship aspects of IITM by creating knowledge and understanding that will be of relevance to the problems of poor in India.Cooperation with Villgro, Innovations Foundation, a social business incubator, based in Chennai. Villgro supports adoption and diffusion of innovative technology through rural India. Main interest in energy, environment, water and such aspects, affordable healthcare solutions may be interesting, too.	Collaboration opportunities linked to student projects.
Anna University Chennai www.annauniv.edu	Centre for Biotechnology of Anna university, funded by DBT, DST, ICMR and Bill & Melinda Gates foundation. Has active research on: 1. Molecular Immuno-technology 2. Immuno-technology 3. Bio-organic and computational biology 4. Protein Biotechnology 5. Molecular Biology 6. Genetic Engineering and Molecular Biology 7. Bioprocess Engineering 8. Bioprocess Technology and Automation 9. Tissue Culture and Drug Discovery Applied research, holistic view on diagnostics (biomolecules and testing platforms), close cooperation with industry, several commercialised products. Major research activities are conducted on infectious diseases, esp. diarrhea and parasites; vaccines,	Centre of Biotechnology has developed several commercialised diagnostic tests, including rapid diagnostic systems for food pathogen detection. Interested in R&D collaboration. International co-operation includes a MoU with DESY (Deutsches Elektronen-Synchrotron), European union projects and Indo-Swiss project for Intellectual property and technology exchange.

	drug formulation, bioprocess engineering etc.	
National Institute for Research in Tuberculosis (NiRT) Chennai www.trc-chennai.org	The NiRT / Tuberculosis Research Centre (TRC), a permanent institute under the Indian Council of Medical Research (ICMR), is an internationally recognized institution for Tuberculosis (TB) research. Functions include clinical trials for TB drugs and vaccines, epidemiology of TB, national programmes for TB prevention and treatment. Some basic research. Training of microbiologists, training programme for microscopy and culture (Univ. of Madras)	It is a Supranational Reference Laboratory and a WHO Collaborating Centre for TB Research and Training. Collaboration opportunities include clinical evaluation of new products, access to patient material. Interested in novel technologies, esp. detection of multi-resistant TB.
Christian Medical College (CMC) Vellore www.cmch-vellore.edu	Focuses on education and research in science of medicine and nursing. Close connection to a very large hospital and comprehensive laboratory services at the same campus. Research areas cover all aspects of medical research. CMC is the member of the National Biodesign Alliance.	Various collaboration opportunities from research to technology evaluation. Interest e.g. in virology and diabetes.
Centre for Stem Cell Research (CSCR), CMC, Vellore www.cscr.in	CSCR is a unit of inStem, Bangalore. Aim is to use stem cell science to better understand human diseases and ultimately develop cell based therapies from some of them. Currently works mainly with adult stem cells. Aims to develop cellular and animal models and carry out human clinical trialsTwith stem cells.	It is collaboration between Christian Medical College, Vellore and Department of Biotechnology, Ministry of Science and Technology, Government of India.
Vellore Institute of Technology (VIT), Vellore www.vit.ac.in	Research activities span over diverse disciplines like rapid prototyping, manufacturing, product design, biomedical research, and optoelectronics. Centre for Biotechnology focuses on e.g. animal diseases diagnostics, bioprocess and metabolic engineering. Centre for Micro ElectroMechanical Systems develops MEMS for medical applications.	Technology Business Incubator is a joint initiative by VIT University and Department of Science and Technology, Government of India. It aims to assist technology start-up businesses to incubate their technology venture.

National Institute for Interdisciplinary Science and Technology (NIIST), Thiruvananthapuram http://www.niist.res.in/english/	NIIST is mainly engaged in R&D programmes in areas related to Agro-processing, Chemical Sciences, Materials Science and Technology, Biotechnology, Process Engineering and Environmental Technology. Today, the Division of Biotechnology focuses also on health and genomics.	The National Institute for Interdisciplinary Science and Technology (NIIST), Thiruvananthapuram, is a constituent Laboratory of the Council of Scientific and Industrial Research (CSIR).
Rajiv Gandhi Centre for Biotechnology (RGCB) Thiruvananthapuram www.rgcb.res.in	Basic and applied programs in human disease, animal disease and plant disease, Cancer Research Program, Cardiovascular Biology Program, Infectious Disease Biology including emerging & re-emerging viral diseases, Neurobiology, Environment & disease, Reproductive biology and infertility, genetics of disease and the use of chemical biology in disease research.	RGCB began in 1990 amongst humble surroundings as a small charitable society called the Centre for Development of Education, Science and Technology (C-DEST). Two new business development ventures with industry partners, one for development of molecular diagnostics and the other for software development in clinical informatics & bioinformatics have been established.
BCG Vaccine Laboratory http://mohfw.nic.in/WriteReadData/l892s/9336897656BCG%20Vaccine-chennai.pdf	The BCG Vaccine Laboratory, Chennai is a sub-ordinate office of the Directorate General of Health Services (DGHS) under the Ministry of Health and Family Welfare of the Government of India, possessing International Accreditation (ISO 9001:2000) issued by BVQI (Bureau Veritas Quality International)	The activities of this Laboratory are: 1. Manufacture of Freeze Dried BCG Vaccine for the control of Childhood Tuberculosis and Tuberculous Meningitis in children and supply to Expanded Programme of Immunization (EPI) of the Government of India and to other needy medical faculties/ Hospitals: 2. Manufacture and supply of Freeze Dried BCG Therapeutic (40mg) for cancer Chemotherapy especially Carcinoma of Urinary Bladder all over the country. 3. To act as National Quality Control Laboratory for BCG Vaccine.

3.3 Incubation and business development services

The major needs of Finnish companies, based on interviews of 24 companies, with regard to incubation and business development services have been summarised in the Figure below.

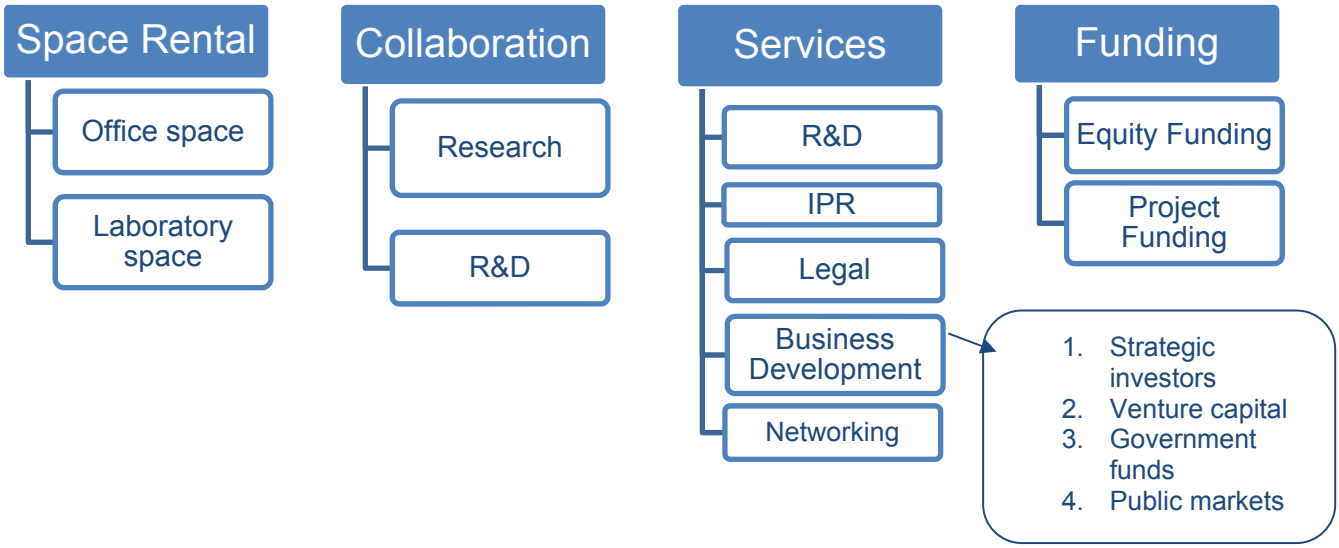


Figure 13: Service needs of Finnish companies

Most Indian bio- sector incubators today offer only laboratory space, while services covering all aspects of business development are rarely found. One reason is that many incubators are in the initial stage and have thus not finalized their service offering and pricing. It is noteworthy, though, that many new business incubators with a more holistic view are currently being developed by public and private organisations, hopefully leading to a much better situation in near future.

3.3.1 Service providers

The following are the main business development and incubation service providers in the life science sector in India. There are constantly new actors established and the old ones are developing their service offering.

3.3.1.1 Biotech Consortium India Ltd. (BCIL) [http://www.bcil.nic.in]

BCIL is promoted by the Department of Biotechnology, Government of India and has been actively involved in technology transfer, project consultancy, fund syndication, information dissemination, and manpower training & placement related to biotechnology over the last decade and half. BCIL facilitates commercialization of biotechnology by establishing linkages among the various stake holders including industry , R&D institutions, government, financial institutions and international agencies and providing access to technologies ; creating awareness about business opportunities, IPR protection, regulatory and bio safety requirements; preparing feasibility and detailed project reports; arranging financial support and manpower training and placement . Services provided by BCIL are:

- Technology transfer
- Project consultancy
- Certification services
- Information services

- Bio safety
- Biotech Industrial Training Programme
- Project management

3.3.1.2 Centre for Innovation Incubation and Entrepreneurship @ IIMA [http://www.ciieindia.org]

Centre for Innovation Incubation and Entrepreneurship (CIIE) at Indian Institute of Management Ahmedabad (IIM Ahmedabad) fosters innovation driven entrepreneurship in India through incubation, investment and training. CIIE is a government funded Incubator centre, operational since 2007, not sector specific but has persons focusing on main sectors like life sciences/health care, ICT and cleantech. It provides mainly business development. Incubatees are technology focussed start-ups, which have innovation in technology or in business model. CIIE currently has around 45 start-up incubatees. The respective alumni network also acts as mentors for start-up companies.

For own incubatees CIIE provides sparring in strategies, pitching etc.; networking events; basic funding from various sources (govt, grants, private sources including VC's. Incubatees do not necessarily need to be located within IIMA/ CIIE premises. Out of current 48 incubatees, a small number (5) are focused on medical devices and healthcare/medicine access.

3.3.1.3 Translational Health Science and Technology Institute (THSTI) [http://www.thsti.res.in]

THSTI is an autonomous institute of Department of Biotechnology, Government of India that seeks to establish collaborations with research institutions and hospitals around India, making this a national undertaking. The goal is by multidisciplinary research to provide affordable technologies and solutions that address global healthcare challenges.

3.3.1.4 Centre for Cellular and Molecular Platforms (C-CAMP) [http://www.ccamp.res.in]

Centre for Cellular and Molecular Platforms (C-CAMP), located in Bangalore at the campus of National Centre for Biological Sciences is a Dept. of Biotechnology (Govt. of India) initiative, and is envisioned to be a major platform technology, industry-interaction and incubator unit. C-CAMP is engaged in two major types of research and development work: development of novel technologies and tools and development of novel modalities for the existing tools and technologies.

C-CAMP offers high-end platform technologies and services related to the following platforms:

- **Confocal and Fluorescence Microscopy**: The facility houses state-of-the-art imaging equipment to allow researchers to observe nano-scale architecture and phenomena in living systems.
- **Flow Cytometry**: The Flow Cytometry facility houses state-of-the-art imaging equipment to allow researchers to observe nano-scale architecture and phenomena in living systems
- **Molecular Characterisation and Proteomics**: a mass spectrometry (MS) facility has been formed at NCBS with an aim to provide researchers state-of-the-art techniques to characterize biomolecules with an emphasis on proteins and peptides.
- **Next Generation Sequencing/Genomics**: The Bangalore BioCluster (C-CAMP, NCBS, and INSTEM) have launched the NGS facility to provide genomics service to scientists, to train researchers, and work on national and international genomic projects.

- **Protein Technology Core**: The Protein Technology Core facility (PTC) at C-CAMP offers assistance/expertise to structural and other biologists with cloning, protein expression and purification services. In addition, C-CAMP is setting up Cell-Free Technology (*In-vitro* translations) based on prokaryotic and eukaryotic systems.
- **High Throughput Screening**: The screening facility at NCBS has housed two high-throughput screens thus far, an RNAi screen and a chemical screen. The successful implementation and completion of these projects has enabled the screening facility to become a potential platform for high throughput studies of different biological processes, given the availability of the Human genome shRNA library and the Drosophila RNAi library (dsRNA templates for the entire fly genome) at the facility.
- **Fly Facility**: The NCBS-fly facility managed by Centre for Cellular and Molecular Platforms (C-CAMP) offers a world class microinjection service for the generation of transgenic lines, Screening Platforms, Drosophila strain development and also maintains a large number of mutant strains and transgenic lines.
- **Intellectual Property Management Office (IPMO) and Technology Transfer Office (TTO)**: At C-CAMP, the IPMO and TTO have been established to allow researchers in life sciences from the Bangalore Bio Cluster (BBC) to realize the commercial potential of their exciting inventions and innovative research. The IPMO and TTO work with BBC researchers and scientists pan-India to protect their IP and commercialise new technologies in collaboration with and through legal, industrial and commercial partners.
- **Innovation Accelerator**: C-CAMP provides both scientific and business expertise to entrepreneurs, with novel ideas who may need assistance taking the firm from scratch/infancy to an IPO.

3.3.1.5 Foundation for Innovative New Diagnostics (FIND) [http://www.finddiagnostics.org/]

Launched in 2003 with an initial five-year grant from the Bill and Melinda Gates Foundation, FIND is a non-profit foundation for developing and implementing new affordable, easy to use and cutting-edge diagnostics for poverty related-diseases. Headquartered in Geneva, Switzerland, FIND has offices in Kampala (Uganda) and New Delhi (India). Current disease programmes include tuberculosis, malaria and human African trypanosomiasis (HAT), also known as sleeping sickness.

FIND supports the R&D of promising reagents or platforms and oversees their evaluation and demonstration in both laboratory and field trials. FIND also undertakes laboratory strengthening and scale up projects to facilitate the rapid uptake of new tools in disease endemic countries. FIND collaborates with public health authorities in developing countries to demonstrate the feasibility and programmatic impact of new technologies on patients and disease control programmes. FIND brings together public health organizations, diagnostic companies, funders etc., and sustains effective partnerships between them. The design, development, manufacture, evaluation and demonstration of diagnostic tools are achieved entirely through its partner organizations.

FIND's operating model is centered on a strong project management system. Each project portfolio is managed as a separate business unit with product lines, well-defined targets and timing at every stage of the R&D process. FIND has developed a commercial model based on a segmented intellectual property (IP) policy that overcomes the usual barriers to product availability and motivates some of the very best biotechnology companies to innovate in high tech diagnostics. It also ensures affordability and access for the public health sectors in developing countries. Industry partners assign all rights to FIND for royalty-free use of their technology in the public and private non-profit sectors in high endemic countries, while the industry partner retains distribution rights for developed countries and the private sector in developing

countries. This enables the partner to recover R&D costs and to create the returns needed to develop new technologies.

Collaboration opportunities include R&D and testing in Indian market, and sales channel to public health care. New technologies are screened in Switzerland.

3.3.1.6 i2India

[http://www.i2indiaventures.com]

i2india is an early stage seed-funding/Technology Commercialization and Incubation firm based out of Bangalore. I2india was created on foundational investments by Imperial Innovations Plc UK (The technology transfer arm of Imperial College, London), CMG Partners UK (led by successful Indian entrepreneur Chris Mathias) and various leading Indian industry leaders and experts such as Tata Sons.

i2india offers the following services:

- Innovation transfer across geographies: I2india partners with global innovators to help them de-risk the entire process of introducing new technologies/products to tap India's vast but fragmented and challenging market space.
- Market Research: Pro-active diligence to identify India's greatest challenges in the fields of healthcare, energy and cleantech, Innovative education, and engineering and healthcare. Immediate areas of interest in healthcare sector include e.g. micro-array - and image-based diagnostics.
- Joint Ventures with local presence: i2india is aimed to create, fund and staff a new venture in India and incubate it during its early stages, providing support through market penetration and follow-on fund-raise.
- Efficient marketing & distribution strategy: I2india has developed a network of partners who provide cost-efficient and broad-base distribution for new products.
- Prototyping / field-testing: i2india runs an innovation center and partners with various test laboratories in metro and rural settings.
- Product localization: i2india conducts primary end-user research to right-size product features/pricing. They have local product design and development partners.
- Local manufacturing: i2india has relationships with small, independent as well as large industry partners such as Thermax, Tatas, Ranbaxy, GVK Bio, Merck etc.
- Leadership team recruitment: i2india has built a network of EiRs (Entrepreneur in Residence) in India as well as Indian and UK mentors to enable strong execution.
- Innovation feedback: Ideas for new blockbusters in relatively un-addressed market segments.

3.3.1.7 Institute of Bioinformatics and Applied Biotechnology (IBAB)

[http://www.ibab.ac.in]

IBAB receives continuing strong support from the Government of Karnataka. In addition, it has received grant support from the Government of India's Department of Science and Technology (DST), Department of Biotechnology (DBT) and the Department of IT (DIT). As a founder member of the National Entrepreneurship Network (NEN), the institute is now expanding its efforts in this realm.

IBAB was set up so as to:

- Become a globally recognised institution of higher learning in bioinformatics and biotechnology.

- Undertake short-term training programmes especially executive training programmes to upgrade the skills of professionals in related industries.
- Provide incubation and other services to entrepreneurs and potential entrepreneurs.
- Carry out research and development.

Research activities at IBAB involve both computational and experimental approaches. Collaborative and contract research projects with companies are also considered.

In addition, IBAB promotes entrepreneurship in bioinformatics and biotechnology. As a founder member of the National Entrepreneurship Network (NEN), the institute is now expanding its efforts and has extended company-starting assistance to include mentoring. In addition there will be several programs for and by students. Corporate education offered as well as laboratory space for incubatees.

3.3.1.8 Industrial Design Centre, Indian Institute of Technology, Bombay [http://www.idc.iitb.ac.in]

Industrial Design Centre (IDC) at the Indian Institute of Technology (IIT Bombay) offers an environment for academics, research and applications in the field of design. IDC has academic programs in the areas of Industrial Design, Visual Communication, Interaction Design, Animation and Mobility & Vehicle Design.

The aim of the Industrial Design Centre is to prepare students to enter into new creative activities as professional industrial designers who with experience and maturity can reach the highest level of design practice, research and development necessary for the industry.

Several areas have been identified for research. Faculty members along with students and other research and design staff work together on these issues. The centre interacts with industries and institutions for promotion and awareness of design. These are in the form of organizing seminars, conducting short term courses and workshops. In the area of design practice, IDC offers professional design consultancy and advisory services to industries and other organizations. IDC has facilities for bulding working prototypes.

3.3.1.9 IKP Knowledge Park (former ICICI Knowledge Park) [http://www.ikpknowledgepark.com]

Launched by ICICI Bank Ltd. in partnership with the Government of Andhra Pradesh, the Park facilitates business-driven Research & Development and is India's first Wet Lab Research Park in Genome Valley outside Hyderabad. IKP has so far promoted 65 companies in total, about 15 % of which have been of foreign origin.

- Mission: To create a world-class centre for leading-edge business-driven research
- Objective: To encourage and nurture an environment for innovation by developing a life science park
- Focus areas: biotechnology, pharmaceuticals, new materials and telecommunications
- Founders: ICICI Bank & Govt Andhra Pradesh
- Structure: Not for profit
- Ownership: 100% by IKP Trust
- Operational: Since June 2000
- On Offer: Land, lab space, Incubator (lab, equipment, mentorship, legal and IP service, seed fund)

IKP Knowledge Park has set up a Life Science Incubator (LSI) with an incubation space of nearly 3,200 sq.ft. for 8 incubatees to encourage and nurture start-up companies and spin offs in pharmaceutical and biotechnology related areas including medical diagnostics with the support of National Science and Technology Entrepreneurship Development Board (NSTEDB) of Dept. of Science and Technology (DST)

Government of India, Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC).

The LSI includes a 3,200 sq ft Life Sciences Incubator with fully furnished dedicated lab space, shared equipment and an assistance programme that is expected to benefit innovative start-up companies and scientist entrepreneurs.

3.3.1.10 National Institute of Design (NID)
[http://www.nid.edu]

National Institute of Design, located in Ahmedabad, is the only design institute in India also focusing on industrial design. NID provides design education as well as design services to various sectors. Cooperation opportunities exist in product design / re-development as student projects and consultancy services. This can be an opportunity for Finnish companies for re-designing products for Indian market. The institute is also recognised as a scientific and industrial research organisation by the Department of Scientific and Industrial Research, Government of India.

The mandate for NID is to offer world-class design education and to promote design awareness and application towards improving the quality of life by or through the fulfilment of the following:

1. World-class design education to create design professionals of excellence, to help meet India's diverse design needs and create global leaders in Design Education & Research by recognising the changes in economic and business environment in a global context.
2. Encouraging the scaling up of quality design professionals and faculty, through existing and new institutional mechanisms.
3. Becoming a repository of design knowledge, experience and information on products, systems, materials, design and production processes related to traditional as well as modern technologies.
4. Upgrading the design of products and systems of everyday use with an aim to bring in indigenous design solutions by focusing on affordable design for the masses.
5. Undertaking fundamental and applied research to create cutting edge knowledge in diverse areas of design and allied fields.
6. Helping place designers in key sectors of national need for benchmarking of standards of design education and practice, and encouraging them to 'think global and act local'.
7. Offering integrated design consultancy services and providing faculty and students to get familiar with the practical applications of design knowledge; while generating revenues at the same time.

3.3.1.11 International Biotech Park, Pune
[http://www.ibpl.net]

International Biotech Park, a joint venture between Maharashtra Industrial Development Corporation (MIDC) and TCG Real Estate is the first public-private biotechnology park initiative in Maharashtra. The Park offers physical infrastructure only, no business development services -they can provide land to build your own facility or space at multi tenant campus. Other services besides space will be funding (VC, Angel funding). Loose network of service providers e.g. support in approval process, patenting. However, this will not be available at Biotech Park itself, but through their contacts.

Current Status:

- Biotech Park of 81 acres
- Biotechnology regulatory standards modelled on international best practices
- Master Planning & Infrastructure Engineering designed by renowned Pell Frishman, London

- 32 acres of Biotech Special Economic Zone
- Proposed Multi Faceted development which includes Retail / Commercial, Residential, Business Hotel, Food Court & an Entertainment Zone
- More than 40% of the project is developed and occupied by Leading Biotech Companies

3.3.1.12 Venture Studio
[http://www.venturestudio.in]

Venture Studio located at Ahmedabad in Gujarat, India, aims to create an ecosystem of innovation that accelerates regional economic development and create a national and global impact. Venture Studio believes that practicing design-led approaches to business creation will foster an ecosystem of innovation. Venture Studio has a Design Fellow program, in which students, called design fellows, work for 6 months on certain R&D, and business development projects involving design element. Venture Studio partners with Center for Design Research (CDR) at Stanford University, Indian Institute of Management Ahmedabad, IIT Gandhinagar, and NID. Potential collaboration opportunity in design and modification of products and businesses for Indian markets.

3.3.1.13 Rural Technology and Business Incubator, IIT Madras (RTBI)
[http://www.rtbi.in]

RTBI has been funded both by the World Bank's InfoDev Project and the Government of India's Dept of Science and Technology's as the first incubator focusing on rural technologies and businesses in India. In the past two years of its inception, RTBI has established itself as an innovation system offering an influential paradigm for creating ICT based service applications and business models. The Incubator is currently involved in supporting entrepreneurs in building ventures to promote livelihoods, education, healthcare, agriculture, connectivity and financial inclusion in India's rural areas.

3.3.1.14 Sky Quest
[www.skyquestt.com]

SkyQuest Technology Consulting Pvt. Ltd. is a global aggregator & accelerator of intellectual property, focusing in the areas of life sciences, cleantech, agritech, nanotech and ICT. SkyQuest provides customized strategic advisory services like:

- technology transfer, commercialization & deal-making (co-partnering, in-licensing and out-licensing)
- global custom & proprietary search, evaluation and acquisition of early stage technologies
- technology or product specific market & business research
- collaborative & clinical research project management
- soft-landing services

SkyQuest also offers company databases and an online IP marketplace, Innovation Product Research Exchange (IPRX) Portal, with technology offers and requests in the following areas: life sciences including diagnostics, agriculture, nanotech & materials, energy and cleantech, engineering and automation, ICT and electronics, and physical sciences.

SkyQuest operates through its offices in India, USA, Israel, Australia, China, Taiwan & partners in over 40 countries.

3.3.1.15 Indian Angel Network (IAN)
[http://www.indianangelnetwork.com/]

Started in April 2006, the Indian Angel Network is a unique concept which brings together 170+ highly successful entrepreneurs and CEOs from India and around the world who are interested in investing in start-up / early stage ventures. Portfolio of IAN covers the following sectors, technology is the key:

1. Agriculture / Food processing
2. Banking and Financial Services
3. Biotech, Pharma & Life Sciences
4. Clean tech and Water
5. Education
6. Healthcare
7. High end BPO / KPO
8. Internet
9. IT products & services
10. Media, Entertainment and Mobile VAS
11. Retail
12. Telecom & embedded domains
13. Travel, Tourism & Hospitality
14. Other areas that excite Network members

The Network looks at investing upto USD 1 mn, and exiting over a 3 to 5 year period through an IPO, M&A or strategic sale. The Network may consider investments over a million dollars but is likely to do so through syndication.

Indian Angel Network Incubator

Indian Angel Network's virtual Incubator, supported by DST, helps connect chosen entrepreneurs with relevant and experienced Mentors from IAN's members. Working closely with the incubatees, the assigned IAN mentors and incubation managers help fine tune their strategies, identify and plug the gaps and finally putting their ventures on a growth path and enhancing their chances of success. The typical incubation period is 9-12 months maximum extendible to 18 Months period. The key service deliverables of IAN incubator are as following:

1. High Quality Mentoring
    a. To raise the probability of success
    b. To raise the probability of funding
2. Leveraging Network's Network
    a. For enabling & accelerating growth
3. Help in getting access to Funding
    a. Multiple Channels – Help get Grants, Soft Loan and Equity Investment
4. Provide associated services necessary at every step of growth
    a. HR Support
    b. IT Support
    c. IPR Support
    d. Marketing Support
    e. Capacity Building Workshops
    f. Market Research
    g. Any other Services

All the above services come from carefully selected expert groups or individuals that are also passionate about start-ups and work on a competitive fee agreed between them and Incubator on need based service required by the Incubatee.

In return IAN Incubator will hold 5% equity in the private limited company and there is a nominal charge paid at the time of signing up by the entrepreneur to be in the incubator for 12 months. IAN incubator also offers office space that is available to foreign companies.

The main USP that IAN and its incubator offer is the access to a nationwide (and at times overseas) network of investors and domain experts to offer mentoring to companies. They would rather not see themselves as a service provider – one reason why their typical model is 5% equity in the company as against a fee per service provided. Though IAN said they would be willing to work on cost basis for specific services, this is not their usual model- companies opting for this model would not benefit from the network of domain experts/mentors.

Also, the IAN directly may not offer services such as prototype testing, laboratory services etc they are able to facilitate these for companies through their existing network with laboratories, universities and other service providers.

3.3.1.16 European Business and Technology Centre, EBTC [http://www.ebtc.eu/]

EBTC is a programme co-funded by the European Union and implemented by EUROCHAMBRES, the Association of European Chambers of Commerce and Industry.

Activities of EBTC are geared towards generating new business opportunities and technology transfer, with a focus on four priority sectors: energy, environment, transport, and biotechnology. EBTC also addresses market access, IPR, trade and investment issues. EBTC supports EU companies and researchers on their market entry to India and offers hands-on support in the early stages of expansion. Apart from this business focus, the Centre aims to further increase the 'brain-circulation' between the EU and India through promoting joint industry-oriented research and enhancing outward mobility of researchers from EU Member States towards India.

EBTC's Intellectual Property Rights (IPR) Helpdesk provides information about IPR laws in India and recent amendments/judgments in IPR cases as well as their implications for European organizations. Webinars will be conducted by the desk to raise awareness about Indian IPR laws, whilst patent technology landscapes for India will provide preliminary information on the direction of particular technology in India which will help European organizations understand the opportunity and avenues to enter India from a technology perspective. The desk will also voice IPR policy concerns of European SME's to the Indian Government.

Customised IP services will be provided on cost plus basis. EBTC does not provide legal services or opinion to its clients; however, it facilitates these services through empanelled legal service providers. EBTC does overlook that the service provider for the quality of services being provided to the EBTC clients.

EBTC also has a free company profile listing comprised of a large number of businesses and research organizations, both from India and the EU, that have registered in the database. This database serves as a resource for matching potential business and research partners and facilitating collaborations and partnerships in the Indian market. Individual workstations are offered to companies in EBTC’s office premises.

Table 10: Services offered by incubators

	BCIL	CIIE	c-Camp	i2India	IBAB	IIT-B	IIT-K	IKP	MSME Cluster	NID	Pune Biotech park	THSTI[i]	Venture Studio	RTBI	IAN http://www.iitk.ac.in/[ii]	[iii]Sky Quest	EBTC
office space		x	x				x	x			x	x			x	x	x
laboratory space			x		x		x	x			x	x			x	x	
Technology transfer	x		x						x				x		x	x	x
R&D collaboration					x							x		x	x	x	
R&D service			x			x				x			x	x	x	x	
business dev't service	x	x	x	x				x					x	x	x	x	
IPR service	x		x	x			x	x				x		x	x	x	x
patenting service	x		x	x			x	x				x		x	x	x	
legal service	x		x	x			x	x				x		x	x	x	
Networking	x	x		x					x			x		x	x	x	x
equity funding	x	x		x											x	x	
project funding									x						x	x	
product testing						x				x			x	x	x	x	

[1] THSTI may not currently be offering all of these services, but are in the pipeline
[2]IAN provides/operates through partner network, on case by case basis.
[3] Skyquest provides services through partner network, esp. for equity and project funding, on case by case basis.

Department of Biotechnology and Department of Science and Technology play a key role in R &D promotion and funding through their various schemes. Both of these organizations are under the Ministry of Science and Technology.

3.4 Main government organizations and initiatives

3.4.1 Department of Biotechnology
http://dbtindia.nic.in

Department of Biotechnology (DBT) has been set up under the Ministry of Science & Technology to promote and accelerate the pace of development of biotechnology in the country. Through several R&D projects, demonstrations and creation of infrastructural facilities a clear visible impact of this field has been seen. The department has made significant achievements in the growth and application of biotechnology in the broad areas of agriculture, health care, animal sciences, environment, and industry. Besides funding research institutes and research projects, DBT also funds industrial R&D via BIRAC.

3.4.1.1 Biotechnology Industry Research Assistance Council (BIRAC)
http://www.birac.nic.in/

BIRAC has been set up as Department of Biotechnology's interface agency, which serves as a single window for the emerging biotech industries**.** BIRAC has a mission to facilitate and mentor the generation and translation of innovative ideas into biotech products and services by the industry, promote academia – industry collaboration, international linkages and encourage techno entrepreneurship and enable creation and sustainability of viable bio-enterprises. BIRAC runs a number of programs aimed at fostering research and innovation:

1. Biotech Ignition Grant Schemes: centred on or around individuals, or a team of individuals that will help mature nascent ideas into a stage where a start-up company can be envisioned
2. Small Business Innovation Research Initiative
3. Biotechnology Industry Partnership Programme: partnership with industry for high risk discovery led innovation research
4. Contract Research Scheme: facilitating technology validation and development
5. Bio-incubators Support Scheme: create world class quality Incubation space for entrepreneurs and start-ups.

3.4.1.2 Translational Health Science and Technology Institute (THSTI
http://www.thsti.res.in

THSTI is an autonomous institute of Department of Biotechnology, Government of India that seeks to establish collaborations with research institutions and hospitals around India, making this a national undertaking. The goal is by multidisciplinary research to provide affordable technologies and solutions that address global healthcare challenges.

THSTI has following four centres:

1. **Centre for Bio-design and Diagnostics**
   [http://www.thsti.res.in/cbd/about_cbd.php]:

The primary mission of Centre for Bio-design and Diagnostic (CBDD) is to promote an effective translational route of basic findings ultimately into routine applications of major importance, through a multidisciplinary approach, combining new bio markers, novel technological concepts and clinical expertise. CBDD has a tie-up with University of Turku in the area of *in-vitro* diagnostics. The planned educational program with Finland in parallel would provide a multi-discipline training of researchers towards successful scientific careers within the field of diagnostic technologies. Major areas of research would include protein and antibody engineering, detection technologies and concepts, nucleic acid diagnostics, new clinical markers, decentralized diagnostics (Point-of-Care), bio-organic chemistry diagnostic technologies, bio-affinity test concepts and systems, micro-fluidics, miniaturization, different reporter alternatives and multiplexing.

Research areas of Centre for Bio-design include POCT for coeliac disease, blood screening assay for transfusion-transmitted infectious diseases, multi-analyte assay for acute coronary syndrome diagnostics, and development of novel binders for pathogen biomarkers.

One of the aims of CBDD is to encourage industry-academia cooperation and thus support translation of research results to commercial products and healthcare benefit.

2. **Vaccine & Infectious Disease Research Centre**
   http://www.vidrc.thsti.res.in/vidrc/about_us_vidrc.php

Set up by the Department of Biotechnology, Ministry of Science and Technology, Govt. of India , VIDRC is aimed at studying infectious diseases and pathogens with a view to develop effective vaccines and therapeutics.

3. **Paediatric Biology Centre**
   http://www.thsti.res.in/pbc/about_pbc.php

The centre provides translational opportunities of very high quality in novel areas that have not been meaningfully addressed so far with focus on innovative and sustainable intervention strategies for child health.

4. **Clinical Development Service Agency**
   http://www.thsti.res.in/cdsa/about_cdsa.php

Clinical Development Services Agency (CDSA) has been established as a not-for-profit society to provide cost effective, high quality preclinical and clinical product development support services to meet the country's growing healthcare needs. It will tend enterprises; particularly SMEs involved in new technology innovation and facilitate translation of scientific know-how into viable products. The focus of the CDSA is to promote the enhancement of clinical trial capacity in India as per international standards. This would entail developing Centres of Excellence (COE) in clinical research through partnerships with leading institutions conducting clinical trials in India and providing comprehensive and sustained training in clinical research through these COE in order to build a cadre of world class investigators capable of conducting clinical trials for regulatory submissions. Plan is to conduct clinical trials with vaccines and/or diagnostic products for public health diseases.

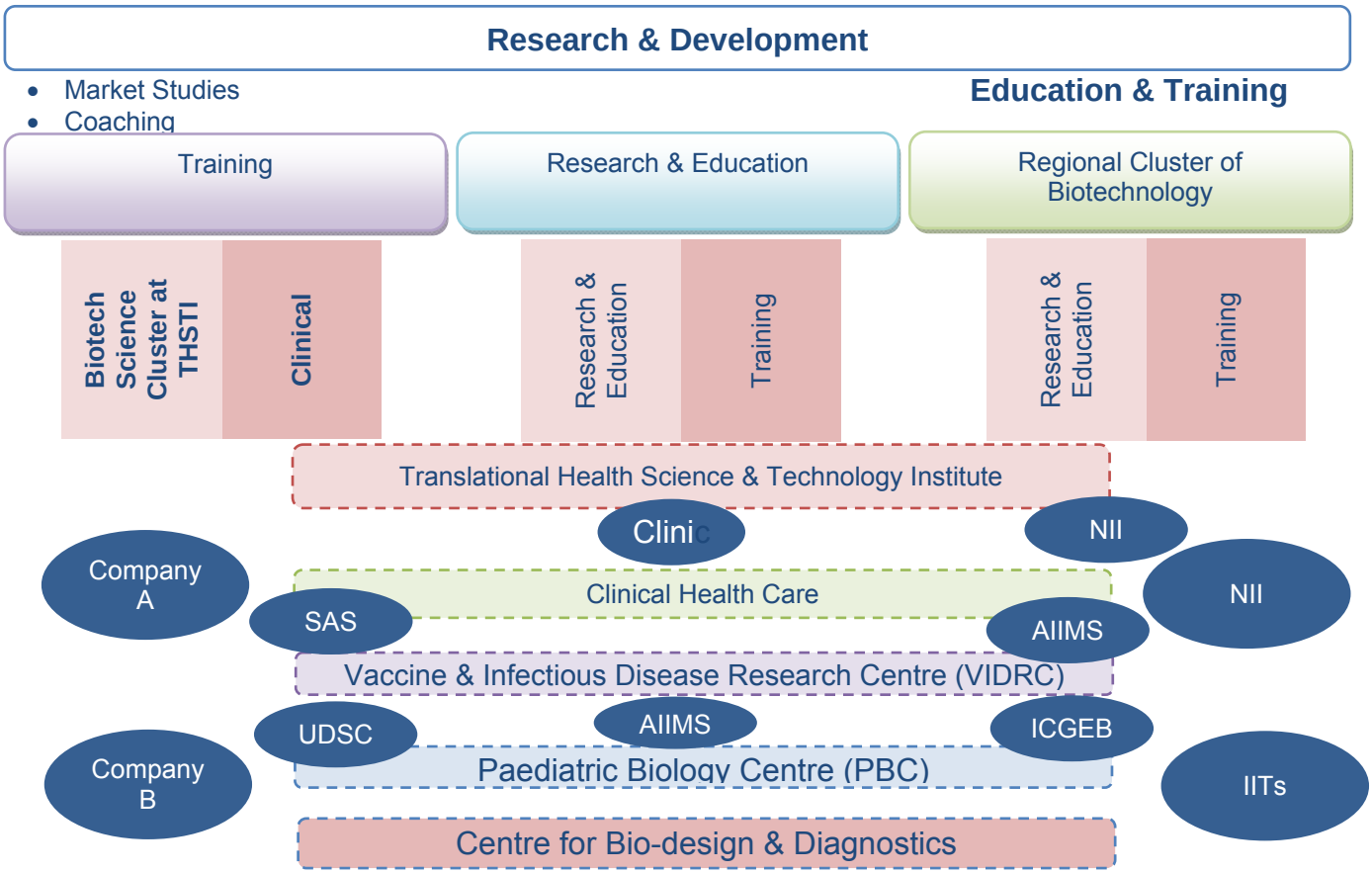


Figure 13 Organisational structure at THSTI

3.4.1.3 National Bio-design Alliance

The Department of Biotechnology (DBT), Govt. of India has initiated a multi-institutional partnership program on Biodesign called the National Biodesign Alliance between Translational Health Science & Technology Institute (THSTI), Regional Centre for Biotechnology (RCB), International Centre for Genetic Engineering and Biotechnology (ICGEB), All India Institute of Medical Sciences (AIIMS), Indian Institute of Technology (IIT) Delhi, IIT Chennai and Christian Medical College (CMC) Vellore. Several new partners are expected to join the Alliance shortly.

This Alliance is coordinated by a secretariat, established at THSTI, an autonomous Institute of the Department of Biotechnology under the Ministry of Science and Technology, Govt. of India. THSTI is a member of the interdisciplinary Health Biotech Science Cluster scheduled to function from Faridabad within 3 years. In the interim THSTI laboratories are functioning from Gurgaon.

The primary mission of the National Biodesign Alliance is to promote research and applications related to affordable implants, devices, *in-vitro* diagnostics and imaging. It will promote an effective translational route of basic findings ultimately into routine applications of major significance. This will be achieved through a multidisciplinary approach, combining new bio-markers, novel technological concepts and clinical expertise. Major areas of research in the field of in-vitro diagnostics will include protein and antibody engineering, detection technologies and concepts.

3.4.2 Department of Science & Technology
http://www.dst.gov.in/

Department of Science & Technology (DST) was established in May 1971, with the objective of promoting new areas of Science & Technology and to play the role of a nodal department for organising, coordinating and promoting S&T activities in the country. The Department has major responsibilities for specific projects and programmes.

3.4.2.1 Global Innovation & Technology Alliance (GITA)
http://www.gita.org.in/

Department of Science & Technology (DST) under the Ministry of Science & Technology and Confederation of Indian Industry (CII) have initiated Global Innovation & Technology Alliance (GITA). The broad objective of GITA project is to promote and facilitate technology partnership between overseas and Indian industry/institutes with the aim of enhancing technology competitiveness of Indian organizations. The technology partnerships can take place through various modes under the framework of national/international laws:

1. Joint Development
2. Technology Transfer/ licensing etc.
3. Joint Venture/Collaboration
4. Any other model

3.4.3 Indian Council of Medical Research (ICMR)
http://www.icmr.nic.in/About_Us/About_ICMR.html

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The Council's research priorities coincide with the National health priorities such as control and management of communicable diseases, fertility control, maternal and child health, control of nutritional disorders, developing alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, blindness, diabetes and other metabolic and haematological disorders; mental health research and drug research (including traditional remedies). All these efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population.

3.5 Indo-Finnish R&D and innovation cooperation

There have been a series of interactions between India and Finland over the past few years in the area of biotechnology and diagnostics:

- 2005: MoU signed between DBT and AF
- 2006: Joint call in Medical Biotechnology (DBT, AF)
- 2007: Joint call in Agriculture Biotechnology (DBT, AF)
- 2008: Joint call in Environmental Biotechnology (DBT, AF)
- 2009: MoU signed between DBT and Tekes
- 2009: MoU signed between DST and Tekes
- 2009: Joint call in Medical Diagnostics (DBT, AF, Tekes)
- 2010: Joint call in Diagnostics (DBT, Tekes)
- 2011: Joint call in Food Biotechnology (DBT, AF)

- 2012: Joint call in Health and Well-Being (DBT, Tekes)
- 2012: MoU signed between Indian Council of Medical Research (ICMR) and Academy of Finland (AF)
- 2013; Joint call in Synthetic Biology (DBT, AF)

Total number of funded projects: 18 (AF) and 13 (Tekes)

More than twenty publications have been produced so far from the jointly funded projects.

Through joint project funding with Indian governmental funds Tekes aims to encourage not only research collaboration but especially innovation and business collaboration between Finnish and Indian companies. With DST this will be organised utilising GITA's funding schemes for industrial R&D. With DBT this funding collaboration with be done in trilateral collaboration of Tekes, DBT and BIRAC.

Tekes' proactive functions, including networking events, business development workshops with Indian mentors etc. are meant to support building long-term Finnish-Indian R&D and innovation cooperation and to encourage Finnish companies enter Indian markets. Tekes is constantly considering new, more effective ways to help Finnish and Indian organisations start beneficial partnerships.

3.5.1 Indo-Finnish Diagnostics Research Centre

Themes of Indo-Finnish cooperation include higher education, researcher training and capacity building. In March 2013, THSTI, DBT, and University of Turku signed an agreement on establishing a joint Indo-Finnish Diagnostics Research Centre (IFDRC). IFDRC is meant to strengthen and expand the existing Indo-Finnish collaborations in health and life sciences. The IFDRC will focus on developing timely and affordable diagnostic technologies and applications of mutual benefit and interest to the network of academic, educational and industrial collaborators and the communities in both developed and developing countries. The IFDRC seeks to inspire and catalyse both academic and industrial partnership towards innovative and translational research that can cater to the emerging markets of decentralised and preventive health care related in-vitro diagnostics.

The planned training and educational programs of IFDRC would include multi-disciplinary training of researchers towards successful scientific careers within the field of diagnostic technologies. The already started post-doctoral fellowship programme offers Indian researchers an opportunity to be trained at the Department of Biotechnology of University of Turku, VTT, or at the Institute for Molecular Medicine Finland (FIMM). The fellows may also attend courses organised by the DIA-NET Doctoral Programme in Finland. The first four post-doctoral fellows, funded by DBT, have been selected to start their 2-3 –year period in Finland in 2013.

Business Ecosystem: *in vitro* diagnostics

The overall healthcare industry scenario is upbeat, propelled by a growing economy, shifting demographics, rising disposable incomes, high incidence of lifestyle-induced diseases, new investment avenues and a large pool of talented and cost-effective workforce. Segments reaping the most benefits are hospitals, pharmaceuticals, medical equipment companies, pathological laboratories and other service providers,

The Indian government, on its part, is promoting this sector through positive regulations like the introduction of the Health Bill, which proposes to bring all independent bodies like the Medical Council of India (MCI), the Dental Council of India (DCI), the Pharmacy Council of India (PCI) and the Nursing Council of India (NCI) under a centralized authority. The government is also increasing public expenditure on healthcare to 2.5 percent of GDP from 1 percent, encouraging public-private partnerships (PPP) in hospital infrastructure, and boosting medical tourism. Taking advantage of the prevalent optimistic atmosphere, many foreign players are looking to enter the country, especially in Tier-II and Tier-III cities, which have huge untapped markets.

In India, the diagnostics sector has been witnessing immense progress. Technological advancements and higher efficiency systems are taking the market to new heights. Advanced and cutting-edge technologies are being used in understanding disease prognosis. This has strengthened the sophistication level of participants in the sector.

Diagnostic medical imaging is one of the rapidly growing fields in the Indian diagnostics market. While nuclear imaging is the fastest growing segment, diagnostic lab services is another area that has seen an increase in the number of unorganized players. The increasing demand for automated diagnosis is expected to fuel the segment's growth.

4.1 *In vitro* diagnostics market size

Indian diagnostic market is broadly divided into equipment, reagents and services. The service sector is largely unorganized, with a large presence of players located at the regional or city level. However, a clear and structured format is being established to have better regulations and proper definition for the market.

Size of the Indian in vitro diagnostics market is estimated to be 531 mUSD in 2011 (source: McEvoy & Farmer 2011). Frost & Sullivan is estimating an annual growth of 18% driving the market to $900.2 million by 2016. One important factor for this growth estimate is expansion of corporate hospitals. In addition, the rising prevalence of chronic diseases in rural as well as urban areas creates a vast untapped market for IVD.

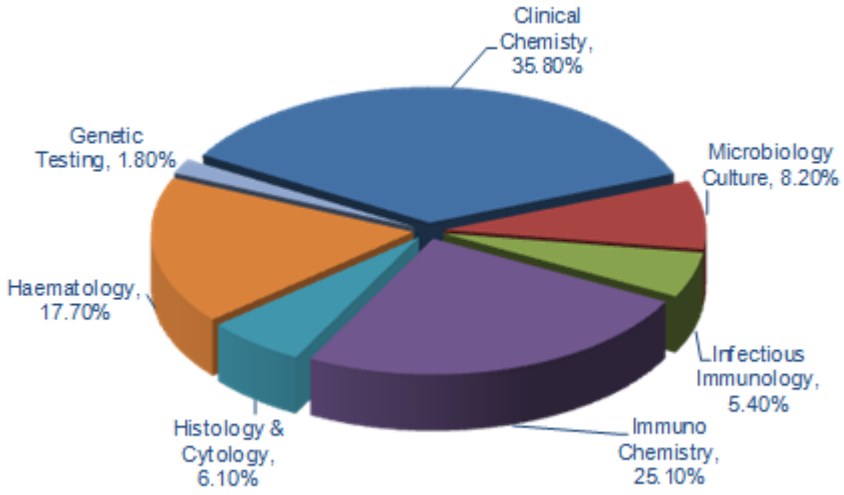


Figure 14 Share of IVD market in India by segment- Clinical chemistry constitutes the largest segment

With a compound annual growth rate (CAGR) of 18.1 per cent from 2009 to 2016, IVD has emerged as one of the most profitable markets in the Indian healthcare industry.

The improving corporate hospital infrastructure and installation of automated and semi-automated biochemistry, immunology, and haematology equipment have enabled the market to achieve this healthy double-digit growth rate.

Lifestyle and communicable diseases are no longer restricted to urban centres, but are spreading to rural areas as well. As a large portion of rural areas do not have even the basic healthcare facilities, several cases remain undiagnosed. Certain statistics state that only one-third of the rural population have access to diagnostic centres. Most patients visit health centres outside the village for diagnosis and treatment. Nearly half of these public sector units don't have treatment facilities for major chronic ailments. These changing disease patterns, rising incidence of diseases, higher healthcare spending, and untapped markets create abundant opportunities for IVD manufacturers. Even hospitals are looking to reach out to patients in tier III cities and rural areas.

Companies will not find it easy going in the unorganized and fragmented IVD market. The major reasons for the market fragmentation are the low entry barriers (leading to the mushrooming of laboratories) and the complete lack of standardization. Only 150-200 laboratories in India have accreditation, and due to the absence of legislation, standardized procedures and equipment are unavailable.

Another significant concern for market participants is the inadequate insurance coverage. Responding to the demand for quality healthcare, most corporate laboratories have introduced cost effective and convenient patient care packages.

4.2 Current use of diagnostics in India

The Indian diagnostics market has been growing rapidly in recent years on account of rising awareness for healthcare, demand for good quality diagnostics, advances in technology and automation of equipment, resulting in reducing the turnaround time for reports and providing quicker diagnosis. With the health insurance cover expected to increase, the health insurance industry will integrate closely with diagnostic centres. As the number of people holding health insurance policies expands and outpatient diagnostics gets covered, health insurance companies will partner with diagnostic centres for standardised services.

The tables below list growth and consumption patterns along with major market players by disease category.

Table 11: Infectious diseases diagnosis

Diagnostics	HIV	Hepatitis B	Hepatitis C	Syphilis	Malaria	Typhoid	TB	Dengue
Consump-tion trends	Increas-ing	Steady	steady	steady	Increas-ing	Steady	Increas-ing	steady
Type of Testing	ELISA – 65% Rapid – 35%	ELISA – 65% Rapid – 34% Agglutinatio n methods – 1%	ELISA – 80% Rapid – 20%	ELISA – 65% Rapid – 35%	Immunodi agnostic – m	ELISA – 65% Rapid – 35%	ELISA – 90% Rapid – 10%	ELISA – 65% Rapid – 35%
Compounde d Annual growth Rate(2004-08)	10.6%	7.7%	7.7%	5.7%	9.4%	5.6%	11%	7.6%
Major Consumers	National AIDS Control Society (NACO)	Blood banks - largest consumer of the ELISA; Rapid tests - mostly consumed in clinical laboratories	Blood banks - largest consumer of the ELISA; Rapid tests - mostly consumed in clinical laboratories	Blood banks	Hospitals Clinical Laboratori es	Hospitals Clinical Laboratori es	Hospitals Clinical Laboratori es	Hospitals Clinical Laborato ries
Segment Market Leaders	J. Mitra & Co.	Bayer diagnostics	Bayer diagnostics	Span & Tulip diagnost ics	Tulip diagnostic	Tulip diagnostic	Tulip diagnostic	Casil Health Products

Table 12: Hormone diagnosis

Diagnostics	Thyroid (T3, T4, TSH kits)	Reproductive Hormones (Fertility Range)
Consumption trends	Increasing	Increasing
Type of Testing	ELISA – 90% , RIA and Chemiluminescence -10%	ofLH- 35%, FSH and prolactin kits – 65%
Compounded Annual growth Rate(2004-08)	7.7%	8.6%
Major Consumers	Clinical laboratories and hospitals	Hospitals, Clinics & end users
Segment Market Leaders	Span Diagnostics	Tulip Diagnostics

Table 13: Blood grouping reagents diagnosis

Diagnostics	Blood Grouping reagents
Consumption trends	Steady
Type of Testing	Haemagglutination
Compounded Annual growth Rate(2004-08)	5.7%
Major Consumers	Clinical Laboratories & Hospitals
Segment Market Leaders	Tulip diagnostics

Table 14: Pregnancy diagnosis

Diagnostics	Pregnancy diagnosis
Consumption trends	Steady
Type of Testing	Immuno-chromatography/ Latex
Compounded Annual growth Rate(2004-08)	5.7%
Major Consumers	Clinical laboratories, nursing homes, practicing gynaecologists hospitals and end users
Segment Market Leaders	Zydus Pathline

Table 15: Cancer markers

Diagnostics	Cancer markers
Consumption trends	Steady
Type of Testing	Fluorescence, ELISA, Chemiluminescence
Compounded Annual growth Rate(2004-08)	5.7%
Major Consumers	Clinical Laboratories & hospitals
Segment Market Leaders	Lilac (Tulip Group)

4.3 Diagnostic needs in the Indian market

4.3.1 What kinds of tests are needed?

Numerous interviews have suggested the tests must be of optimum quality - affordable, user friendly, have real clinical value, high specificity and high sensitivity. Purchasing decision often depends on perceived value and utility; i.e. if a patient can afford it or if a public hospital can provide it free of charge or on low cost. Multiplexed test kits would be favoured instead of separate single tests.

Some of key factors are explained below:

- Affordability and usability: Affordability of tests is a critical factor besides the need to be user friendly. Current tests used in India are not sensitive enough; hence affordable tests with better sensitivity and specificity would be needed.
- Extreme conditions: Local considerations need to be taken into account such as extreme weather conditions and lack of well developed cold chain infrastructure especially in rural areas that account for 70% of Indian population. Special attention hence needs to be paid to storage and transport.

- Rural areas: Rural areas have specific needs especially as a team of doctors is not readily available round the clock. Health workers need to be trained for tests and referrals; rapid tests for diagnosis of communicable diseases are essential as well as tests for neonatal sepsis and pneumonia. There are many undiagnosed diseases in remote areas. More information in Chapter 5 on Rural Healthcare.

- Other aspects: When developing tests for developing country's needs and especially for rural areas, it is advisable to take care of the whole chain. This should not be limited only to the part of the chain covering distribution and storage until the test is used, but also consider the disposal of diagnostic kit parts.

- Molecular diagnostics: In India the market for molecular diagnostics is at a very nascent stage. Out of the available technologies only PCR based technologies have penetrated to a greater extent. Like in the case of immunodiagnostics, companies supplying such diagnostics are initially importing them from established companies abroad. A few indigenous kits have also been developed, but more would be needed, as developing countries tend to be price sensitive.

4.3.2 What needs to be tested?

There is urgent need for developing tests for diagnosis of communicable diseases especially tuberculosis, malaria, dengue and hepatitis B&C. Rapid diagnostics for tuberculosis is needed as are tests for early detection of arthritis. Well-developed infrastructure, high safety standards, sufficient know-how and time are required for current tuberculosis tests to perform well. These are rarely available due to which test results may not always be reliable. Prenatal and neonatal testing would be important as infant mortality is still high and the illiteracy rate of women in India is still high, meaning that also extensive education of mothers is needed. Nucleic acid based test for HIV in infants would be needed. At present it is not possible to diagnose HIV in infants younger than 18 months.

Within non-communicable diseases, diabetes and cardiovascular diseases are perhaps the biggest focus area of companies, hence new products introduced in the market need to be highly innovative. There is strong emphasis on breast and cervical cancer as a result of implications on women and child health.

There is specific need for test kits for blood banks, in which currently five separate tests are required – for malaria, HIV, syphilis, hepatitis B&C. As it now takes few days to get the results, blood is usually not tested before blood donation. This leads to transmission of diseases through blood banks. This challenge would easily be solved with rapid tests, i.e., "five tests in one".

Sera-panels are also urgently required.

4.4 Companies in this sector

There are approximately 60 diagnostics companies in India, of which 15-20 companies are actively engaged in R & D. According to various sources there are more than 150 companies marketing clinical diagnostics products in India. The majority is small importers and distributors of foreign manufacturers' products. About 50 companies constitute the most crucial segment of the industry comprising:

- Large local companies manufacturing, for example, other pharma products but importing diagnostics
- Local companies manufacturing animal diagnostics products
- Small local companies manufacturing only one product

- Leading multinational companies some of which manufacture products in India whereas others simply import and market them.

Large companies in general tend to work with various diseases and various technologies. There are only few Indian companies that have been able to develop quality products that are also of interest in foreign markets.

Table 16: Indian diagnostics companies

Company	Products / services	Other remarks
Accurex Biomedical http://accurex.org	Accurex product offering 1. Clinical (Biochemistry reagents) 2. Urinalysis (Urinal strips) 3. Diabetic care (Glucometer) 4. Instruments (Clinical Chemistry Analyzer, portable urine analyzer)	
Agappe Diagnostics www.agappe.com	Products: 1. Reagents • Clinical chemistry • SyRe (Biochemistry) • SyRe (Immunoturbidimetry) • Controls/ Calibrators • SEROLOGY • Hemoscreen • Coagulation Reagents • Urinal analyzer • Analyzer reagents • Infectious Rapid card Test • Infectious ELISA • Hepatitis Markers • Torch panel • Glucometer (reagent strips) 2. Instruments • Clinical Chemistry Analyzer • Hematology Analyzer • Coagulation Analyzer • Sodium & Potassium Analyzer	
Bhat Biotech www.bhatbiotech.com	Bhat Bio-tech is specialized in the design development, manufacture and marketing of diagnostic products and Biotechnology based products. Diagnostic test devices are for various types of tests like, Pregnancy, HIV, Hepatitis, Malaria, Dengue, Chikungunya, Swine Flu (H1N1), Syphilis, TB, Cardiac Markers, Dry Chemistry, Bio-Chemistry, Haematology & Immunology and ELISA`S used in the analysis of body fluids in human. In Life Science related products, the company is engaged in manufacture and marketing of Genomics (DNA, RNA),	

	Proteomics, Teaching kits, Lab Instruments, Dehydrated culture media, Animal studies, Contract research and Drug discovery services and kits.	
J. Mitra www.jmitra.co.in	J. Mitra group has product offering of 1. Rapid test kits • HIV range • HCV range • HBV range • Malaria range 2. ELISA test kits • HIV range • HCV range • HBV range • DENGUE range • LEPTO range • TB range 3. Confirmatory Tests • HIV range 4. Blood Grouping Range	J.Mitra has a good reputation in the industry. The company focuses on POCs for infectious diseases like HIV and malaria. One of the aims is to manufacture mass products at very affordable prices. These products are then sold through WHO.
Medsource Ozone Biomedicals Pvt. Ltd. www.ozonebio.com	Medsource Ozone product range includes 1. Instruments • RT1904-C (Chemistry Analyzer) • RT2100-C (Fully Automated Microplate Reader) • RT-2600CMicroplate Washer） 2. Bio-Chemistry • Liquizone a - Amylase MR • Liquizone Alkaline Phosphatase • Liquizone Bilirubin • Liquizone Calcium • Calcium MR • Liquizone Calcium • Liquizone Chloride MR • Liquizone Cholesterol MR • Liquizone Creatinine MR • Liquizone SGOT • Liquizone Microprotein • Lyphozone Glucose • Liquizone Haemoglobin • Liquizone Glycosylated Haemoglobin 3. Rapid Diagnostic Products	
RFCL www.rfcl.in	RFCL focuses on IVD, animal healthcare, laboratory solutions and custom synthesis through its four strategic business units.	
Span Diagnostics Ltd. www.span.co.in	Span Diagnostics Ltd. has products for pathology & clinical laboratories. Products: 1. Diagnostic Reagents & Kits	

	• Blood banking products • Clinical Chemical reagents • Hematology • Infectious Diseases Serology • Histopathology Products • Antibiotic Discs for Bacterial Sensitivity Test • Pregnancy Test • Laboratory accessories 2. Instruments • Biochemistry • ELISA • Hematology • Chemiluminescence 3. Industrial & Research Products • Microbial identification system 4. Veterinary Products	
Transasia Bio-Medicals www.transasia.co.in	Transasia Bio-Medicals is focused on Bio-Chemistry, Hematology, Urine Analysis, Coagulation, ESR, Critical Care, Immunology, Liquid Handling System in making instruments and Reagents	Offers a complete suit of IVD products in collaboration with leading companies like Sysmex, Medica, Grifols, Diesse,
Trivitron http://trivitron.com/	Key focus segments include CID(Cardiology & Implantable Devices, Imaging Sciences, Diagnostics (IVD)) and COD(Critical Life Support Solutions (CLSS), Ophthalmology and Dental Technologies).	Trivitron Healthcare has acquired Finnish Ani Laboratoriesystems, a player in in- vitro diagnostics, for €15.8 million in 2012.
Tulip Group www.tulipgroup.com	Tulip Group is an Indian group of diagnostic companies, which manufactures and markets IVD reagents and kits. Products offered: 1. Immunohaematology Reagents 2. Immunology Reagents 3. Cardiac Markers 4. Cancer Markers 5. Parasitology Range 6. Infectious Disease Range 7. Instrumentation (Coagulometers, ELISA reader & washer)	The group consists of 7 companies: Tulip Diagnostics (P) Ltd, Microxpress, Orchid Biomedical Systems, Qualpro Diagnostics, Zephyr Biomedicals, Coral Clinical Systems, BioShields, Tulip Marketing (P) Ltd, Crest Biosystems, Lilac Medicare (P) Ltd. Orchid, is known well for its quality products developed for mass markets and also sells through WHO.
Xcyton http://xcyton.com	Development of first indigenous ELISA kit for the detection of HIV infection called HIV CheX, following with the development of indigenous ELISA products for the detection of Hepatitis C (HEP CheX C), Neurocysticercosis (CYSTI CheX) and Japanese encephalitis (JEV CheX). Conception and invention of Molecular	The Company also has a strategic tie-up with Qualigens fine chemicals, a division of pharma major Glaxo SmithKline Pharmaceuticals Ltd for marketing its HIV and hepatitis diagnostic kits across the country.

	Diagnostic products for improved diagnosis of Critical Care Infections, Syndrome Evaluation System- the world's first Critical Care Therapeutic Decision Support System. XCyton's Syndrome Evaluation System (SES) allows for the simultaneous identification of multiple organisms inclusive of Bacteria, Viruses, Fungi and Parasites, in a specific test from a single sample.	
Yashraj Biotech www.yashraj.com	Yashraj biotech manufactures antigens of native human origin which can be used either as standards a/o calibrators in various assay formats, or immunogens for raising antibodies or for laboratory based r&d. Monoclonal antibody products will soon be available for use as reagents in diagnostic kits.	

4.5 Indian diagnostic laboratories

Indian market has evolved into an outsourcing market for diagnostics testing. It is for example estimated that specialized tests like molecular diagnostics or hormone related tests cost 70-80% less in India than in US.

A new legislation, 'Clinical Establishment Act' has been passed by the Indian Parliament to allow existence of ONLY accredited laboratories in India. Around 40 laboratories in India have received international recognition in the form of College of American Pathologists (CAP) accreditation. National certification of diagnostic laboratories is the responsibility of National Accreditation Board for Testing and Calibration Laboratories (NABL), an autonomous body under the aegis of Department of Science & Technology, Government of India. Around 250 diagnostic centres in India are NABL accredited. There is a clear increase in the number of accreditations for the government hospitals from the National Accreditation Board for Hospitals and Healthcare Providers (NABH).

While the entire health care industry in India is growing 13-15% annually, the Indian laboratory industry is growing at the rate of 20-25%; with the molecular diagnostics segment growing at 25%.

Table 17: Leading diagnostic laboratories in India

Company	Profile & products	Other remarks
Metropolis Health Services www.metropolisindia.com	Corporate chain of diagnostics centers with 50 state-of-the-art laboratories. Capability to carry out over 3,600 routine investigations with over 100 technologies (e.g. biochip, DNA sequencing, pathology, radiology)	Growing inorganically; also on overseas expansion and planning to handle outsourcing jobs.
SRL Diagnostics www.srldiagnostics.com	SRL (formerly Piramal Diagnostics) has 79 diagnostic centres and 120 collection centres. Additionally, through their joint venture DDRC SRL Diagnostic Services, operate 62 laboratories and 7 collection centres in the state of Kerala.	Tie-ups with UK-based organizations for outsourcing
Wellspring www.npilphadke.com	Wellspring has 70 pathological laboratories in 35 cities.	Planning to invest INR 2.50 billion to expand its diagnostic chain in 75 urban centers across the country in the next two years.
Dr Lal PathLaboratories www.lalpathlaboratories.com	LPL is India's largest chain of pathology laboratories serving 10 million customers every year. It plans to have 175 laboratories by 2014.	Established an international alliance with Corning Nichols Institute, California (Now known as Quest Diagnostics Nicholas Institute) for testing its rare and complex investigations.
Thyrocare www.thyrocare.com	Thyrocare's services are available across all states via over 600 dedicated collection centers, which enable blood samples to reach the centralized processing laboratory at Mumbai.	
Anand Laboratories www.anandlab.com	Anand Diagnostic Laboratory is a full range lab in south India.	

Business ecosystem: food diagnostics

In India there are multiple bodies controlling different parts of the food chain from field to fork. Different ministries have their separate fields of responsibility requiring extensive coordination among the different responsible organisations. These are listed below:

a. Ministry of Agriculture controls primary production
b. Ministry of Food Processing Industries controls food production
c. Ministry of Health and Family Welfare controls retail sector
d. Ministry of Commerce looks after food trade and export
e. Ministry of Finance controls export and import taxes
f. Food safety and standard Authority officially established in the beginning of 2008 is supposed to cover the whole food chain from field to fork and is responsible for the implementation of Food Safety and Standard Regulations (2011)
g. In state level the control and inspection is taken care of by Food and Drug Authority (FDA)

In comparison, Finland's Ministry of Agriculture and Forestry controls both agricultural & food production, mainly food trade including food exports and imports. EVIRA is the controlling body for domestic production as well as food imports –except for plant origin products, which are controlled by Customs laboratory.

5.1 Food safety and standard act

Food Safety and Standard Act was given in 2006. Regulations for implementation of the Food Safety and Standard act came to force in August 2011. The main clauses under the Regulations are:

1. Registration and Licensing of Food Business: All Food Business Operators in the country will be registered or licensed in accordance with laid down procedures. No person shall commence any food business unless he possesses a valid license.

2. The Registering Authority shall issue a registration certificate and photo identity card; the Authority shall also carry out food safety inspection of the registered establishments at least once a year

3. The Food Business Operator shall ensure that all conditions of license as laid down under the Regulations as well as comply with all safety, sanitary and hygienic requirements at all times. Failure to comply with provisions of the regulation will attract legal action under the provisions of the Act.

4. Food Business Operators shall ensure that the Registering or Licensing Authority always has updated information on their food business establishments and shall inform the relevant Authority of any modifications/additions/changes in product category, layout, expansion, closure or any other material information based on which the license was granted and such information shall be conveyed before the changes occur.

5. The States/Union Territories may, if required, designate an existing advisory committee at Panchayat (local village level)/district/state level or where such a committee does not exist, constitute an advisory committee to assist, aid or advise on any matter concerning food safety.

5.2 Key growth drivers

Requests and standards for export manufacturing are set by the importing country and requests are known by the exporting food manufacturers. Number of food processing companies having ISO certificates increasing. In retail sector chains want to guarantee product quality. Retail sector is growing, but has still only a small percentage of consumer trade with majority of the trading happening in the markets and small kirana stores. Companies have their own quality control. This is especially common with exporting manufacturers as well as MNC's. Also local brands e.g. Amul, Mother Dairy, Reliance have built their own quality systems in order to protect their brand reputation. Foreign food processing companies are setting foot in India. They want to keep same quality as globally also when producing for the Indian market. Further on, many of them are producing also for SEA and Middle East market. There are awareness programs funded by the government on supply chain management and in quality control.

5.3 Relevant organisations in food diagnostics

5.3.1 Food safety & standards authority of India (FSSAI [www.fssai.gov.in]

The Food Safety and Standards Authority of India (FSSAI) is a Statutory Regulatory Body under Ministry of Health & Family Welfare, Government of India, established under Food Safety and Standards Act, 2006, as a single reference point for all matters relating to Food Safety and Standards, Regulations and Enforcement. FSSAI, constituted in September 2008, has a mandate of laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. Other activities of FSSAI are:

1. Framing of Regulations to lay down the Standards and guidelines in relation to articles of food and specifying appropriate system of enforcing various standards thus notified.
2. Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses.
3. Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories.
4. To provide scientific advice and technical support to Central Government and State Governments in the matters of framing the policy and rules in areas, which have a direct or indirect bearing of food safety and nutrition.
5. Collect and collate data regarding food consumption, incidence and prevalence of biological risk, contaminants in food and residues of various contaminants in foods products, identification of emerging risks and introduction of rapid alert system.
6. Creating an information network across the country so that the public, consumers, Panchayats etc receive rapid, reliable and objective information about food safety and issues of concern.
7. Provide training programmes for persons who are involved or intend to get involved in food businesses.
8. Contribute to the development of international technical standards for food, sanitary and phyto-sanitary standards.
9. Promote general awareness about food safety and food standards.

Food Safety and Standardization Act is available at http://www.fssai.gov.in/AboutFSSAI/FSSAct.aspx

5.3.2 Directorate of Marketing and Inspection (DMI) [http://www.agmarknet.nic.in/dmiwelcome.html]

The Directorate of Marketing and Inspection implements the agricultural marketing programmes of the Union Government under the supervision and control of Union Ministry of Agriculture. It aims at bringing integrated development of marketing of agricultural and allied produce in the country. DMI enforces the Agricultural product Grading and Marketing Act (1937). Grades and standards (AGMARK standards) are prescribed for agricultural and allied commodities.

5.3.3 Bureau of Indian standards (BIS) [http://bis.org.in]

Bureau of Indian standards (BIS) formulates Indian standards required in food processing sector and looks after its implementation through promotion and through voluntary and third party certification system.

5.3.4 National Accreditation Board for Testing and Calibration Laboratories (NABL) [http://www.nabl-india.org]

National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science & Technology, Government of India, and is registered under the Societies Act. NABL has been established with the objective to provide Government, Industry Associations and Industry in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration laboratories. Government of India has authorised NABL as the sole accreditation body for Testing and Calibration laboratories.

5.3.5 Central Food Technological Research Institute (DFTRI) [http://www.cftri.com]

Central Food Technological Research Institute (CFTRI) is a constituent laboratory of Council of Scientific & Industrial Research (CSIR), Ministry of Science & Technology with the objective of adding value and utility to agro-resources through R&D and contribute to sustained development, food security and food safety; aiding and promoting the development of food industry through inter-disciplinary, innovative and state-of-the-art solutions; setting national standards for food quality, and spread food quality consciousness all around as well as work towards integration of the food supply chain from the cultivator to the consumer so that cultivators get optimal returns from processing, and consumers get the food that they want, when they want, where they want, in whatever form they want and at affordable cost

5.3.6 Central Institute of Post Harvest Engineering and Technology (CIPHET) [http://ciphet.in]

The Central Institute of Post-Harvest Engineering and Technology (CIPHET) was established in 1989 as a nodal institute to undertake leading research in the area of the post-harvest engineering and technology appropriate to agricultural production catchment and agro-industries. The objectives of CIPHET - to undertake basic, applied, strategic and adaptive engineering and technology research in post production sector of produce of plant origin, livestock and aquaculture produce including agriculture structures and environmental control, quality and safety; to act as national repository of information on processes, equipment, products and technologies on post harvest engineering and technology; to transfer technology and provide advisory and consultancy services and promote entrepreneurship among other areas.

5.3.7 Institute for Analysis of Dairy, Food and Cultures Laboratories Pvt. Ltd (IADFAC) http://www.iadfac.com/

IADFAC Laboratories was established in 2006 with the key objective to provide authentic food and water testing facilities serving food industry entrepreneurs, manufacturers, restaurateurs, retailers, and customers to initiate a safe food culture.

IADFAC assesses product quality, safety, compliances for non-contamination & spoilage, verifies processes and also assists in cost control. The lab empowers personnel to build technical competence. Promoted by first generation technocrats, the company is led by an eminent group of food technologists, microbiologists, nutritionists and market analytics. IADFAC follows international quality systems. The laboratory incorporates a detailed Quality Policy. The Laboratory is also certified in conformance with ISO:IEC17025 - 2005 by National Accreditation Board for Testing and Calibration Laboratories (NABL), and ISO 9000:2000 system.

5.4 Private laboratories providing services to food processing industry

There are several private laboratories providing services to Indian food industry. Some of the most important ones are the following:

- TÜV [http://www.tuv-sud.in]
  - Auditing, inspection, testing, training, HACCP
- Equinox Laboratories (http://equinoxlab.com)
  - Food testing (microbiological, nutritional)
- Reliable Analytical Laboratories (http://www.reliablelaboratories.org)
  - Food testing, training
- APEDA recognized laboratories
  - 23 laboratories all over India
- Companies' own laboratories

At present the analytical testing providers are focusing on the following areas:

- Nutritional Labelling
- Toxic Elements Analysis
- Microbiological Analysis
- Chemical Analysis
- Food Contaminants
- Preservative Identification
- Stability Testing
- Antibiotic Residue Analysis
- Pesticide Residue Analysis

5.5 Implications to food industry

The key growth driver for food analytics is essentially the export market. Companies use their own quality control program to guarantee high quality of products in domestic market and third party certification to fulfil export requirements. However, quality control is voluntary and not mandated by authorities.

5.5.1 Monitoring of primary production - agriculture

Raw material quality is a major bottleneck for FPI exports. Regulations of importing country must be followed. The following is being analyzed:

- Mykotoxines
- Pesticides
- Residues
- Heavy metals
- Drugs & antibiotics

National monitoring systems are required to study emerging nutrient deficiencies and excesses in various agro-ecological cropping and management systems.

5.5.2 Challenges in monitoring of food processing in India

Ministries have funds allocated to development of agriculture and food processing industry in India - funding is at Central Government level, whereas development of agriculture and food processing are State matters.

Food processing and retail companies have built their own control systems in order to guarantee good quality of their products. There is lack of adequate quality control and testing methods in line with international standards.

Exporters face the biggest challenges in control and quality requests- poor quality of laboratories, low level of value addition, high post harvest loss, weak and ineffective supply chain, lack of training, etc are major challenges.

5.5.3 Analytics for exports

- Regulations of importing country must be followed
- Raw material quality is bottleneck for FPI exports
- Control testing kits are used for in-house quality to see if product quality is within acceptable limits
- For exports, products need to be tested in laboratory
- 20 laboratories certified
- Importing country might accept testing in the country of origin or require their own tests
- When community provides joint facilities, often also laboratory is included
- Packaging mainly for export products only
- 6 laboratories authorized to test packaging

Business Ecosystem: environmental analytics

6.1 Environmental monitoring

India has a relatively extensive set of regulations designed to improve both air and water quality. Its environmental policies have their roots in the Water Act of 1974 and Air Act of 1981. These acts created the Central Pollution Control Board (CPCB) and the State Pollution Control Boards (SPCBs). The Ministry of Environment and Forests (MoEF), created in its initial form in 1980, was established largely to set the overall policies that the CPCB and SPCBs were to enforce.

The environmental monitoring services sector in India is closely related to and driven by current legislation in monitoring air and water quality in India. The CPCB along with SPCB is responsible for monitoring air and water quality.

India was listed fifth amongst the poisonous gas emitting nations in the world. With pollution levels rising across the country, revised National Ambient Air Quality standards for twelve pollutants were notified in 2009 by the Ministry of Environment and Forests (MOEF). Pollutant includes gases like sulphur dioxide, nitrogen dioxide, ozone, carbon monoxide, ammonia and particulate matters below 10 micron, below 2.5 micron size.

CPCB coordinates the air quality monitoring regime through its nation wide programme known as National Air Quality Monitoring Programme (NAMP). Under NAMP, using a network that consists of 342 pollution monitoring stations, the CPCB regularly monitors four air pollutants viz ., sulphur dioxide (SO_2), oxides of nitrogen such as NO_2, suspended particulate matter (SPM) and respirable suspended particulate matter or particulate matter of less than 10µ size (commonly called PM10 or RSPM). The monitoring of meteorological parameters such as wind speed and wind direction, relative humidity (RH) and temperature are integrated with the monitoring of air quality.

In addition, the monitoring has been extended to parameters such as carbon monoxide (CO), ammonia (NH_3), respirable lead, hydrogen sulphide (H_2S) and polycyclic aromatic compounds (PAHs) in select cities.

The Central Pollution Control Board (CPCB) is the chief regulatory agency on water quality issues in India. It collaborates with State Pollution Control Boards (SPCBs) and Pollution Control Committees (PCCs) to implement the various policies and regulations that govern water quality management and to monitor the nationwide network of water quality monitoring stations in India.

There is a need to increase the monitoring of water quality at source and of the impacts of discharged effluents. CPCB has put in stringent requirements for controlling water pollution, including water from municipal wastewater treatment plants. Research suggests that these requirements, along with some on-going problems with ground water quality and issues with effluents from plants will increase demand for monitoring equipment and services.

6.1.1 Ambient air quality monitoring

At present apart from the cities many other major polluting industries in India like power, cement, steel, oil and gas, fertilizer, chemical, pharmaceutical are being asked to continuously monitor their pollutants by using Continuous Ambient Air Quality Monitoring System (CAAQMS) and submit daily, monthly and annual reports on specified pollutant criteria to the authority.

Apart from demand driven by industrial growth, the air pollution control equipment market has received adequate growth impetus from the Ministry of Environment and Forest through the revision of National Ambient Air Quality Standards (NAAQS). The recent revision has lifted the cap between industrial and residential areas. Five new pollutants such as ozone, benzene, benzo-a-pyrene, arsenic, and nickel have been included in the revised standards. Fine particulate matter (size less than 2.5 micrometer), which affects the respiratory system has also been included. The ministry has also set up agencies to enforce these standards. The revision of NAAQS is a major initiative to implement clean technologies in the air pollution control segment. CPCB is also working on developing standards for nitrogen oxides for thermal power plants.

In the long run, as awareness about air pollution rises, in conjunction with the stronger regulatory enforcements and stringent regulations kick in, the need for continuous monitoring of the concentrations of key pollutants like particulate matter, nitrogen oxides, mercury, oxides of sulphur, carbon monoxide, and other hazardous air pollutants (HAPs) becomes vital. These continuous emission monitoring systems (CEMS) aid in determination of compliance or non-compliance on a continuous, real-time, and on-site basis using qualitative and quantitative parameters at key points in the facility like stack, boiler, process heaters, incinerators etc.

Value Drivers for the Market:

- Increased awareness about deleterious effects of air pollution
- Revision of NAAQS
- Growth of Indian Industries and in particular the power industry
- Strong regulatory enforcements and penalties
- Voluntary environment sustainability initiatives by industries
- Relatively lower total cost of ownership compared to the hefty penalties imposed due to noncompliance

The prime driver for this market is enactment and enforcement of environmental regulations, which is perceived to be weak in India. The awareness about the detrimental effects of pollutants in the ambient air is becoming profound and therefore is the need for on-line real time systems to check the excesses. The competition as it stands today, in India is quite moderate and there are only few companies offering CEMS and other analyzers.

6.1.2 Water monitoring

With the assistance of the SPCBs and PCCs, the CPCB has set up a network of monitoring stations under the National Water quality Monitoring Programme (NWMP).

The inland water quality monitoring programme in India is presently operated under a three-tier system that includes Global Environment Monitoring System (GEMS), Monitoring of Indian National Aquatic Resources System (MINARS) and Yamuna Action Plan (YAP).

The objectives of National Water Quality Monitoring Programme are:

- For rational planning of pollution control strategies and their prioritisation
- To assess nature and extent of pollution control needed in different water bodies or their part
- To evaluate effectiveness of pollution control measures already is existence
- To evaluate water quality trend over a period of time
- To assess assimilative capacity of a water body thereby reducing cost on pollution control
- To understand the environmental fate of different pollutants

- To assess the fitness of water for different uses

Water quality is monitored monthly or quarterly at surface water stations and groundwater stations are monitored half yearly.

The Department of Ocean Development has been managing the Costal Ocean Monitoring and Prediction Systems (COMAPS) in collaboration with the Ministry of Environment and Forests since 1991. The aim is to collate baseline data and carry out efficient monitoring of marine pollution.

Laboratories that analyse samples under the N.W.M.P participate in the Analytical Quality Control (AQC) programme under GEMS. The primary objective of the AQC programme is to evaluate the reliability and accuracy of analytical data generated by a laboratory. The collection of water samples for monitoring is not a high-technology process. Long travel times of samples from the monitoring station to the laboratory without adequate preservation affects the results of the samples. Additional reasons for concern are disparities in analysis methods, quality control of chemicals used for analysis, lack of software to carry out trend analyses of data and insufficient training for data management and interpretation of the data generated.

Water quality monitoring is critical in order to assess the exact nature and extent of pollution abatement required, and it is an important tool to measure the effectiveness of pollution control measures already in place. At present, there is limited interpretation of data for planning ahead and consequently improvements made to the system are inadequate. It is also essential to proactively disseminate information generated - which is currently difficult to access - to citizens.

Despite shortcomings in the water monitoring regime, progress and improvements are slowly being made. The proposed increase in the number of monitoring stations and the revamped river conservation programme are changes in the right direction

6.1.3 Water analysis instrumentation

India, China and several countries from developing markets are expected to drive up the demand for global water analysis instrumentation in coming years.

Laboratory-based water analysis instruments represent the largest product segment in the water analysis instrumentation market, while online systems for water analysis instrumentation are likely to emerge as the fastest growing market segment

Despite the low degree of penetration of online water analysis instruments, as compared to the laboratory-based systems, the segment continues to witness technical advances, given their use in industrial applications for the analysis of industrial effluents as well as industrial process water.

Industrial applications represent the key end-use market, as automation is a necessary component of a majority of industries and on-line systems feature advantages, such as real-time evaluation and feedback.

However, the growth and penetration of these systems in other end-use markets is limited by the high investments involved. Nevertheless, growth in Online Systems for water analysis instrumentation market is most likely to be driven by their application in the end-use industries as the laboratory-based systems market is highly saturated with very few innovations in the past several years in terms of technology as well as innovations.

Rise in competition is gradually aiding in product differentiation, price reduction, and technology enhancements, which in turn is fuelling market growth in the water analysis instrumentation market.

Municipal bodies and civil societies are generally cautious of embracing new technologies. However, the market is now at the cusp of transforming itself from being a niche technology, and is expected to gain substantially as civil utilities and municipal bodies in these emerging markets begin to increase their use of water analysis instrumentation for better wastewater treatment and potable water.

Rural health market

7.1 Market overview

The living environment in rural India is prone to communicable diseases hence the need for regular, updated information on diseases which this segment of population is susceptible to and the corresponding treatments. Rural population lacks information on the various emergency and other medical services in their vicinity as well as awareness about free health services provided by the Government and NGOs. Most widely used sources of health information are family, friends and neighbours besides rural health workers, practitioners and local pharmacists. However, there is still immense need for reliable and quality information on health services and service providers. There are a growing number of telemedicine and mobile health services provided by government, private players and NGOs catering to their needs.

Private sector financing plays a significant role in India's healthcare system. This may provide an opportunity to leverage private sector resources through PPP models and, thus, improve the health care system. All the same, PPP as a formal policy instrument continues to be at a nascent stage with many state governments still organizing themselves to engage the private sector effectively and many continuing to experiment with the partnership concept.

Merely 34 per cent of the total rural population in India have access to diagnostic centres for chronic ailments like diabetes, heart and kidney diseases, says a study carried out by the Chronic Care Foundation (CCF). The study revealed that 86 per cent districts with high rural population did not have enough basic diagnostic tests required for treating these chronic diseases. Only 34 per cent people living in rural areas found access to diagnostic centres. Nearly half of the Public Sector Units (PSU) surveyed did not have treatment facilities for any of the three ailments.

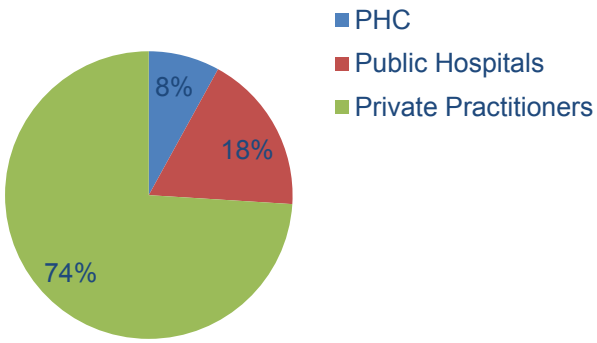


Figure 15 Medical Care sought by Rural Households

Most people visited healthcare centres outside their village due to non-availability of services, stated the study. 80.9% of PSUs in rural areas did not have treatment facility for any of the chronic ailments. Further, the findings revealed that only 45% of the total respondents found easy access to medicines. It was most difficult for those suffering from stroke and chronic kidney diseases. The study showed there was high dependence on private facilities due to inadequate services at government-managed units. Sterilization is the most common treatment method used in rural areas. Primary health care units lack infrastructure. Moreover, lack of basic education made it extremely difficult for the populace to understand measures to prevent chronic diseases.

7.2 Specific features in rural health care

1. 750 million people constituting 74% of India's population live in 636000 villages.
2. Indian healthcare services are highly skewed in favour of urban population which accounts for only 26% of the Indian population.
3. A doctor available per 1000 of rural population is 0.5. Rural doctor to population ratio lower by 6 times when compared with urban areas.
4. 66% of rural population in India does not have access to critical medicine.
5. 31% of the population travels more than 30 kms seeking healthcare in rural India.
6. Rural beds to population ratio lower by 15 times when compared with urban areas.
7. Villagers spend 1.5 times more compared to urban counterparts for the same illness.
8. out of 10 medicines in rural areas are substandard.
9. 22 million population is pushed below poverty line annually due to healthcare expenditure alone, 40% of hospitalization expenditure funded by borrowed money of sale of assets.

7.3 Health care challenges and needs in rural India

Healthcare in rural areas is a major problem, also on account of high allopathic cost. Doctors are unwilling to be posted in rural areas. Alternative medicines are frequently administered. Often a nurse or anyone having worked at a hospital in any role, howsoever insignificant, becomes the "*doctor*" of the village. Medical Council of India has invested heavily in allopathic medicine, but have not been proactive in providing training. In addition, the self-proclaimed doctors don't want to come out in the open as they fear legal action against their practice.

Initiatives currently functioning in urban areas are not effectively promoted and hence not penetrated into these communities. There is widespread negligence in these communities regarding healthcare services, hence dire need to create awareness around and setup facilities for them. Effective communication strategies need to be deployed to ensure effective uptake of the same in the community.

Despite these challenges, the rural health sector has witnessed success stories highlighting the need to adopt suitable business and service models and learn as well as adapt to challenges facing the population. Some examples are Nokia Life Tools – a mobile service that enables rural population make better informed decisions not only regarding healthcare but also agriculture, education and entertainment; ZMQ – a software company that develops health based educational games; Rural Technology and Business Incubator (RTBI), a spinoff of Indian Institute of Technology (IIT) Madras that supports start-ups with inclusive agendas supported by wireless technologies; Health Technology Innovation Centre, IITM – an institute that has developed several health technology product prototypes in industry cooperation, e.g. a modern cataract surgery clinic taken in a bus to rural patients.

Some learning's from rural health projects are:

1. Illiteracy has not proven to be such a big problem, as shared phones are quite common
2. Written information is more reliable than voice only.
3. Information needs to be available in multiple (=local) languages
4. It is crucial to develop a sustainable financial and operational model which can be scalable
5. Must have global approach; design with bigger vision, even if started with a pilot
6. Utilize existing human network systems, e.g. ASHA, mobile recharge centers, MFI (Micro Finance Institute) structures, or community-based organisations like village health clubs.

Specific needs in rural health care

1. More trained personnel serving the rural population.
2. Qualified doctors (rural scenario currently dominated by unqualified private practitioners).
3. Infrastructure like hospital beds, medical equipment etc.
4. Technology for telemedicine to work.
5. Increased contribution by private sector.
6. Information on right to receive healthcare facility, nearest centres providing these facilities and benefits, importance of health insurance and schemes.
7. Health information, medical advice, health maintenance, hygiene, good eating habits.
8. Information on treatment cost, consultation fees, benefits for rural population, any reimbursement options, Self Help Groups (SHG) for financial assistance etc.
9. Platform to raise concerns and solve problems faced by rural population in availing healthcare services.
10. Reliable service in case of health emergencies.
11. Awareness about services and initiatives setup for the benefit of the community.

7.4 Potential of ICT to improve health care in rural India

- 65% of 1100 million are literate.
- 60% of rural India has access to TV coverage.
- 400,000 villages already have telephone connections.
- Mobile users in India: 865 million (as of 31st December, 2012) of which 533 million are urban and 332 million rural (Source: Telecom Regulatory Authority of India, TRAI)
- Broadband subscribers in India: 15 million (as of 31st December, 2012) (Source: Telecom Regulatory Authority of India, TRAI)
- Well-established competence and talent in hardware, software

In addition, available information channels should be reliable and user friendly in their key role of highlighting benefits accruing through available healthcare services and schemes.

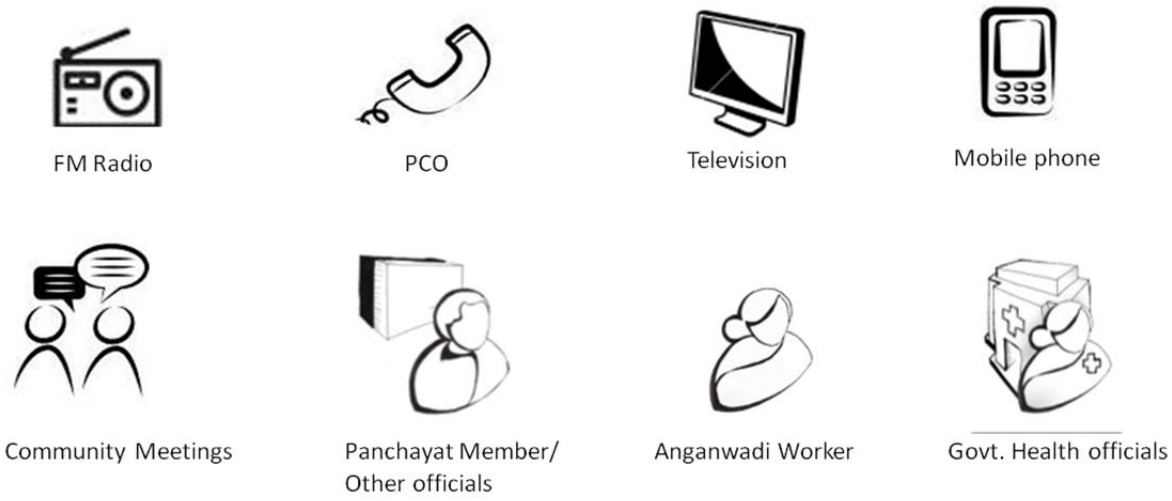


Figure 16: Modes of dissemination of information in rural areas

7.5 Public initiatives

7.5.1 National rural health mission

The National Rural Health Mission aims to provide effective healthcare to rural population throughout the country with special focus on 18 states, which have weak public health indicators and/or weak infrastructure.

The Mission has the following objectives:

1. To raise public spending on health from 0.9% GDP to 2-3% of GDP, with improved arrangement for community financing and risk pooling.
2. To undertake architectural correction of the health system to enable it to effectively handle increased allocations and promote policies that strengthen public health management and service delivery in the country.
3. To revitalize local health traditions and mainstream AYUSH (local health streams- Ayurveda, Unani, Sidha, Homeopathy) into the public health system.
4. Effective integration of health concerns through decentralized management at district, with determinants of health like sanitation and hygiene, nutrition, safe drinking water, gender and social concerns.
5. Address inter-state and inter district disparities.
6. Time bound goals and report publicly on progress.
7. To improve access for rural people, especially poor women and children to equitable, affordable, accountable and effective primary health care.

7.5.2 Other government initiatives

Health is a state subject in India meaning, that the implementation of health care services is entirely on the responsibility of the state governments. However, there are several national programs that are central government initiatives. Most important national level initiatives are listed in table 18.

Table 18: Government healthcare initiatives in rural areas

Initiative	Focus Areas
National Vector Borne Disease Control Programme	Malaria, Dengue, Filaria, Encephalitis and Chikungunya
TB Control Programme	Launched in 1997. More than 11 million patients treated. 70% case detection achieved
Blindness Control Programme	Cataract surgeries, school eye screening programme, Encouraging donation of eyes, Training of Ophthalmic surgeons, support to voluntary organizations.
Leprosy Education Programme	Leprosy elimination programme was funded by World Bank. Brought down the prevalence by 85%
Iodine Deficiency Disorders	Surveys to assess magnitude of Iodine deficiency disorders, supply of iodized salt, resurvey every 5 years
ASHA	Provide every village with a trained female community health activist- ASHA (Accredited Social Health Activist). Selected from village itself and accountable for it. Interface between community and public health system.
Disease Surveillance Projects	Decentralized state based surveillance programme. Detection of early warning signals of impending outbreaks and help initiate an effective response in a timely manner
AYUSH	Created in 2003, AYUSH Stands for Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy. **Objectives**: • To upgrade the educational standards in the Indian Systems of Medicines and Homoeopathy colleges in the country. • To strengthen existing research institutions and ensure a time-bound research programme on identified diseases for which these systems have an effective treatment. • To draw up schemes for promotion, cultivation and regeneration of medicinal plants used in these systems. • To evolve Pharmacopoeial standards for Indian Systems of Medicine and Homoeopathy drugs.

7.6 Business ecosystem: rural health

7.6.1 Stakeholder analysis

Community awareness is generally raised through teams of local persons that interact with villagers and inform the target group of benefits of the service/product being offered. These persons can be from organizations' local area offices or through NGOs working in the area. It is crucial to take into account cultural, religious, societal and other local factors while undertaking promotional activities. Local teams engaged in promotional activities need to earn villagers' trust before launching the service/product.

Involvement of influential villagers also provides an impetus to the uptake of the service/product. These influencers can, for instance, be the village sarpanch (Head of Panchayat), headmaster of village school, teacher at school, doctor at health centre. Promotional campaigns can take the form of community gatherings, seminars, camps (e.g. health camps) and other means suitable to the offering and village.

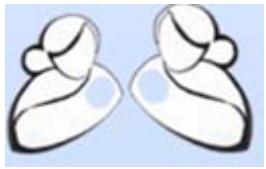
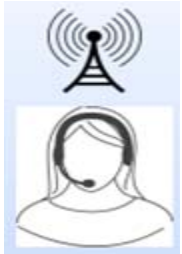
7.6.2 Possible roles and revenue models

Figure17: Stakeholders in rural healthcare

Table 19: Examples of possible business models in rural healthcare highlighting role of each stakeholder

Function	Central Govt.	State Govt.	Private Players	Finnish SMEs
Infrastructure	Guidelines for areas to setup centres, basic facilities and requirements	Partial – when there is a current setup which requires restructuring Nil – completely new centre	Complete setup of infrastructure	Potential to provide hardware and setup support
Front end Operations	Health schemes, quality check guidelines	Monitors compliance with norms and guidelines	Complete responsibility	Involvement in activities in delivery chain management, subsidized treatment, Electronic Health records and its maintenance
Human Resource Management	Nil	Partial or Nil	Training and recruitment of people from the community or outside	
Technology Support & Data Management	Nil	Control back end operations for schemes, health records etc.	Front end technology setup, data management servers, research and support	Potential for involvement in setting up ICT structure, setup, data management servers, research and support
Funding	Certain percentage provided	Rest of the funding - State govt. Has the freedom to decide the involvement of private players in the funding	Potential for investment	Funding with private players

Table 20: Examples of service and delivery models in rural healthcare

Delivery Mechanism	Revenue Model
1. Health Care Centre at Village level • Link doctor or practitioner in the community into the medical helpline loop and setup an ICT enabled health centre • They would handle the front-end operations of collecting medical information from community and serve as entrepreneurs for the initiatives at the village level operations • ICT system with Electronic Health Records of patients • These practitioners connected to other doctors in the city hospitals who would provide expert opinion • Referral would be made depending on the severity of the medical condition to better hospitals • Additional helpline number for any health care assistance • Dedicated personnel to collect information on difficulties, concerns, complaints on government services 	• Normal charges for consultation • Discounted rates for medicines disbursed by centre
2. Health Scheme Integration with SHGs • Extend services of SHGs to provide assistance on health care schemes • SHGs equipped with money transfer facilities in case of healthcare emergencies • Promotional activities to rebuild trust in health services in the community 	• Fixed slab for different services
3. Alerts on Specific Healthcare Concerns • Database of mobile users from service provider used to identify and target customers for specific information • Subscription to the portal would enable to receive messages on the mobile phone related to the topic chosen 	• Free registration • Nominal charge for messages

Finnish opportunities & challenges

8.1 Experiences of Finnish companies doing business in India

Finnish companies need to look at India as a long term strategic market that can be tapped not only for the abundant skilled workforce and huge domestic market besides cost effectiveness but also as a base to tap clients located elsewhere. As with other countries, there can be challenges at the beginning but these get resolved soon, overcome by the immense opportunities that the Indian market has to offer. Foreign companies stand to gain immensely by tapping the huge local talent base for R & D and innovation, come up with their 'local innovations' that can be utilized for other emerging markets as well.

8.1.1 Strenghts of Finnish companies

- Solid research base and pioneering technology especially diagnostic technologies, biotechnology, telecom and green technology
- Finnish credibility and technological expertise is well established
- Proven technology and solutions, potential for implementing and testing these in Finland for Indian companies
- Finnish innovation system
- Innovative ideas and technology from Finland that have been doing well in Europe can be brought to India and some customization undertaken to meet market and customer requirements

8.1.2 Strengths of Indian business ecosystem creating opportunities for Finnish companies

- Long term strategic market
- Many segments in India are still undeveloped and not already divided among multinational companies or local giants.
- High IT maturity levels
- Fast pace of development
- Skilled workforce: sourcing right people for right job
- Service-oriented
- Strong English-speaking workforce
- Huge base of engineers/graduates, strong university base
- Huge domestic market
- Cost-effective R & D
- Working in a challenging environment greatly helps in product development, move up value chain
- Co-creation with local researchers and end-users, including affordable innovation with global market potential
- Good place to do business
- As a late adopter, India has the advantage of leapfrogging to latest technology

8.1.3 Challenges in doing business in India

- Convince top management to have operations in India.
- Bureaucracy leading to delays.
- Visa issues: frequent employee travel is required at short notice.
- India perceived as a complex market with complicated tax laws, rules & regulations
- Infrastructure bottlenecks, high infrastructure costs, connectivity.
- Differences in work culture.
- There may be some cultural issues.
- Challenging work environment – need to engage closely with client, on 24x7 basis.
- Aggressive marketing is required to showcase Finnish companies' offering.

8.1.4 Considerations for Finnish companies

- Business environment and practices are different across different Indian states, private; work/business practices are different in private sector when compared with Government.
- Select the right mode of market entry: own establishment or representation/distributor.
- Selection of the right local partner is very crucial. Monitor the partner on a regular basis.
- Develop India-specific strategy: Finnish business and HR practices may not necessarily work.
- Bridge the cultural gap.
- Gain extensive field experience: at times, simultaneous presence in multiple strategic geographical locations is beneficial.
- Be visible: aggressive marketing and media presence are essential.
- Closely engage with client at all times and constantly evolve offering to meet requirements
- Overcome fear of entering India: India is diverse but good local knowledge, team and contacts are useful.
- Complement each other's strengths; establish R&D linkages with industry/ research institutes/ academia. Adopt suitable R & D co-operation model – in-house/ partly-outsourced/ fully outsourced.

Decision-making for Indian markets needs to be quick and execution very prompt.

8.2 Summary of Finnish opportunities in India

8.2.1 Summary of potential areas for Indo-Finnish *in-vitro* diagnostics collaboration

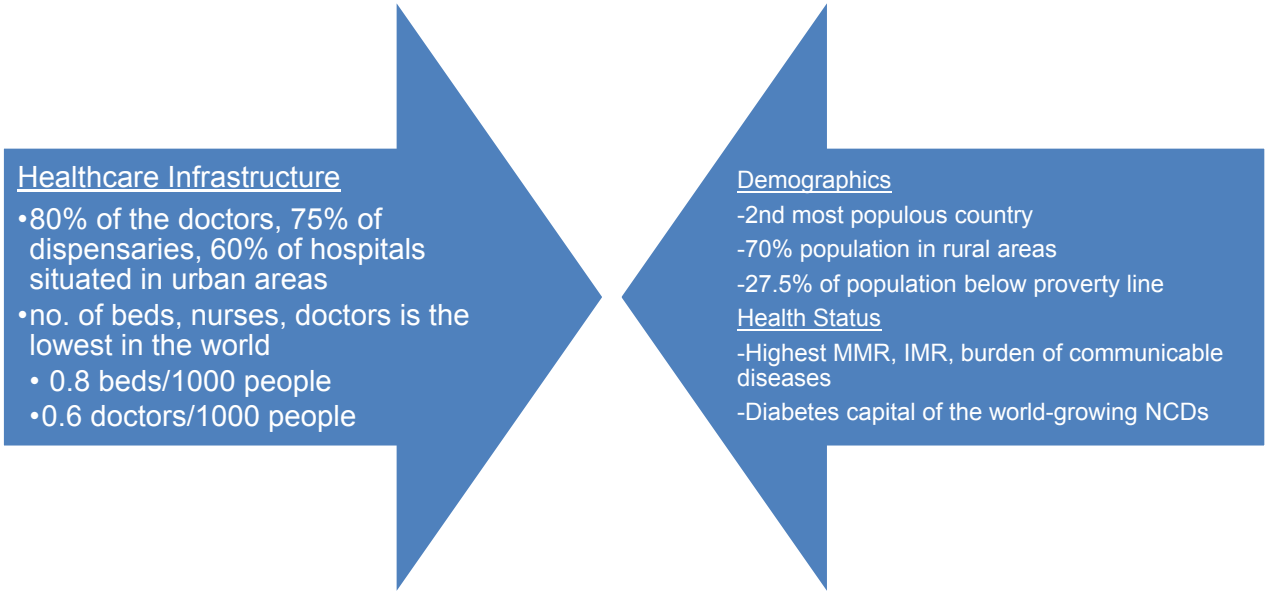


Figure 18: Demographics and the existing healthcare infrastructure in India offer opportunities to Finnish companies

Technological needs

- Quality Diagnostic Kits at affordable prices
- Rapid tests for blood banks and rural areas
- Multiplexed test kits instead of separate single tests
- Easy to use diagnostic kits: Minimal requirement of a qualified technician
- Automation and increasing efficacy of indigenously developed Kits
- High-tech solutions including nanotechnology
- Molecular diagnostics is strongly emerging. New era of molecular diagnostics kits has begun also in India.
- Need for products and solutions that can withstand extreme weather conditions and lack of well developed cold chain infrastructure especially in rural areas.

Analyses needed

- Communicable diseases: tuberculosis, HIV, malaria, dengue, leprosy and hepatitis B&C, diarhhoea, Chikungunya, Leishmaniasis, Japanese encephalitis are of high importance in India.
- Non Communicable Diseases: Diabetes is a strong area (many existing players, hence need for innovative products).
- Early diagnosis of breast and cervical cancer, bone marrow transplants.
- Testing of blood at the time of donation to blood banks to avoid contamination.
- Prenatal and neonatal testing

- Rural health care has specific needs, partly due to extreme conditions and partly because the health problems affecting the rural areas are different from those in urban areas. Products can be developed in Finnish-Indian cooperation, tested in the Indian market and then sold to other similar markets in neighbouring countries or in developing countries with similar needs.

Indian diagnostic companies are open for collaboration in:

- Joint development of diagnostic kits
- Supply/Purchase of Antigens/Antibodies/Primers
- Validation of Primers/Probes
- Evaluation and Certification of Developed Kits
- Custom Manufacturing
- Custom Development
- Automation of POC diagnostics
- Increasing performance of developed kits
- Access to EU Markets

Collaboration Models in India:

- Low cost & high quality manufacturing hub
- Contract research
- Contract manufacturing
- Co-marketing alliances
- In-licensing of technologies/validated primers/probes etc. (Low Up fronts)
- Out-licensing of indigenously developed technologies
- Cross Licensing of technologies
- Joint ventures

8.2.2 Summary of potential areas for Indo-Finnish food diagnostics collaboration

Indian food exporters need to follow the regulations of the import country. After the implementation of Food Safety and Standard Regulations in 2011, also domestic manufacturers need to pay more attention to the hygienic standards as well as guidelines for self-control systems. Largest brands and retail chains have been following the best practice standards already earlier to protect their high quality brand image, but the new requirements are a big burden for many small producers, which need to find cost effective solutions to fulfill the standards. There are business opportunities in offering technologies to Indian food processing companies

- Technologies and rapid testing methods for in-house quality control
- Cooperating with APEDA
    - Many Indian food exporters are certified by APEDA and use APEDA recognized laboratories
- Partnering with Indian diagnostic companies who see market potential in food diagnostics
    - Innovative technologies applied for food industry
- Offering laboratory / quality control services
    - Testing must be in line with Indian / importing country legislation

8.2.3 Summary of potential areas for Indo-Finnish collaboration in environmental analysis

Environmental Monitoring

- There is a need to increase the monitoring of water quality at source and of the impacts of discharged effluents.
    - Stringent requirements for controlling water pollution, including water from municipal wastewater treatment plants.
    - On-going problems with ground water quality and issues with effluents from plants will increase demand for monitoring equipment and services.

Air Quality Monitoring

The prime driver for this market is enactment and enforcement of environmental regulations, which is perceived to be weak in India.

- Increased awareness about deleterious effects of air pollution
- Revision of NAAQS
- Growth of Indian Industries and in particular the power industry
- Strong regulatory enforcements and penalties
- Voluntary environment sustainability initiatives by industries
- Relatively lower total cost of ownership compared to the hefty penalties imposed due to noncompliance
- The awareness about the detrimental effects of pollutants in the ambient air is becoming profound and therefore is the need for on-line real time systems to check the excesses.

Water Monitoring

- Tools for proactive dissemination of information generated to citizens.
- Water analysis instrumentation
- Laboratory-based water analysis instruments represent the largest product segment in the water analysis instrumentation market
- Online systems for water analysis instrumentation are likely to emerge as the fastest growing market segment

Where to get information

Finpro's Global Life Sciences industry team consists of more than 30 experts globally. The team supports Finnish healthcare & wellbeing, eHealth, pharmaceutics, biotech & diagnostics, agriculture and food industry companies in various ways. Finpro's services include e.g. market evaluation in target market, sales and marketing channels and business operation models development, as well as new client and strategic partner search. All this is possible through team members'industry expertise and excellent networks with local health care institutions as well as diagnostics and agricultural experts.

India's economic strength and market dominance is here to stay. Finpro's team, with its Finnish and Indian experts are ready to help the Finnish companies to benefit from the various opportunities that India offers to them.

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Tekes is the main governmental expert organisation for financing research, development and innovation in Finland. Tekes' funding and services are designed for promoting challenging and innovative research and development projects in companies, universities, other university-level institutions and research institutes. Every year, Tekes finances some 1,500 business R&D projects, and almost 600 public research projects. The main target group consists of SMEs seeking growth in internationalisation. Tekes encourages companies to renew their businesses and increase their international competitiveness.

More information about Tekes' offering: http://www.tekes.fi/en/

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Abbreviations

ACTREC	Advanced Centre for Treatment, Research and Education in Cancer
AF	Academy of Finland
AIIMS	All Indian Institute for Medical Sciences
ALP	Arm's Length Price
APEDA	Agricultural and Processed Food Products Export Development Authority
API	Association of Physicians of India
AQC	Analytical Quality Control
ASHA	Accredited Social Health Activist
ASSOCHAM	Associated Chambers of Commerce and Industry of India
AV	Assessable Value
AYUSH	Ayurveda, Unani, Sidha, Homeopathy
BCD	Basic Customs Duty
BCIL	Biotech Consortium India Ltd
BIPP	Biotechnology Industry Partnership Program
BIRAC	Biotechnology Industry Research Assistance Council
BIS	Bureau of Indian Standards
BPL	Below Poverty Line
BPO	Business Process Outsourcing
CAAQMS	Continuous Ambient Air Quality Monitoring System
CAGR	Compound Annual Growth Rate
CAP	College of American Pathologists
CBDD	Centre for Bio-Design and Diagnostic
CBDT	Central Board of Direct Taxes
C-CAMP	Centre for Cellular and Molecular Platforms
CCF	Chronic Care Foundation
CCMB	Centre for Cellular and Molecular Biology
CDA	Central Drug Authority
CDFC	Centre for DNA Fingerprinting and Diagnostics
CDSA	Clinical Development Service Agency
CDSCO	Central Drugs Standard Control Organization
CE	Combinatorial Extension
CEMS	Continuous Emission Monitoring Systems
CEO	Chief Executive Officer
CHI	Community Health Insurance
CIF	Cost, Insurance and Freight
CIIE	Centre for Innovation Incubation and Entrepreneurship
CIPHET	Central Institute of Post Harvest Engineering and Technology
CNS	Central Nervous System
CO	Carbon Monoxide
CoE	Centre of Excellence
COMAPS	Costal Ocean Monitoring and Prediction Systems
COPD	Chronic obstructive pulmonary disease
CPCB	Central Pollution Board
CRO	Contract Research Organization

CSIR	Council of Scientific & Industrial Research
CST	Central Sales Tax
CVD	Counter Veiling Duty
DBT	Department of Biotechnology
DCGI	Central Drugs Standard Control Organization
DCI	Dental Council of India
DDT	Dividend Distribution Tax
DESY	Deutches Elektronen-Synchroton
DFTRI	Central Food Technological Research Institute
DISCOM	Distribution Company
DIT	Department of Information technology
DMI	Directorate of Marketing and Inspection
DNA	Deoxyribonucleic acid
DPT	Diphtheria Pertussis Tetanus
DSIR	Department of Science and Industrial Research
DST	Department of Science and Technology
DTAA	Double Tax Avoidance Agreement
EC	Education Cess
ELISA	Enzyme-Linked Immuno Sorbent Assay
EOU	Export Oriented Units
ESI	Employees' State Insurance scheme
ESIS	Employer Social Insurance System
ESR	Erythrocyte and sedimentation rate
EU	European Union
FD	Fixed Deposit
FDA	Indian Food and Drug Administration
FDI	Foreign Direct Investment
FICCI	Federation of Indian Chamber of Commerce
FiDiPro	Finland Distinguished Professor Programme
FPI	Food Processing Industries
FSH	Follicle-stimulating hormone
FSSAI	Food Safety & Standards Authority of India
GDP	Gross Domestic Product
GEMS	Global Environment Monitoring System
GENCO	Generation Company
GMP	Good Manufacturing Practises
GST	Goods and Services Tax
HACCP	Hazard analysis and critical control points
HAP	Hazardous Air Pollutants
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HQ	Head Quarters
HR	Human Resources
IADFAC	Institute for Analysis of Dairy, Food and Cultures Laboratories Pvt Ltd
IAN	Indian Angel Network
IBAB	Institute of Bioinformatics and Applied Biotechnology
ICGEB	Centre for Genetic Engineering and Biotechnology

ICMR	Indian Centre for Medical Research
ICT	Information and Communication Technologies
IDC	Industrial Design Centre
IFDRC	Indo-Finnish Diagnostic Research Centre
IIM	Indian Institute of Management
IIS	Indian Institute of Science
ILS	Institute of Life Sciences
IMR	Illness Management and Recovery
INR	Indian Rupee
IPO	Initial Public Offering
IPR	Intellectual Property Rights
ISO	International Organization for Standardization
IT	Income Tax
IT	Information Technology
IVD	In vitro diagnostic
KPO	Knowledge Process Outsourcing
LH	Luteinizing Hormone
LPL	Lal Path Laboratories
LSI	Life Science Incubator
M&A	Mergers & Acquisitions
MAT	Minimum Alternate Tax
MCI	Medical Council of India
MFI	Micro Finance Institute
MIDC	Maharashtra Industrial Development Corporation
MINARS	Monitoring of Indian National Aquatic Resources System
MMR	Maternal Mortality Rate
MNC	Multinational Company
MoEF	Ministry of Environment and Forests
MoU	Memorandum of understanding
MRP	Maximum Retail Price
MSME	Micro Small Medium Sized Enterprise
NAAQS	National Ambient Air Quality Standards
NABH	National Accreditation Board for Hospitals and Healthcare Providers
NABL	National Accreditation Board for Testing and Calibration Laboratories
NACO	National AIDS Control Society
NAMP	National Air Quality Monitoring Programme
NCD	Non Communicable Diseases
NCI	Nursing Council of India
NCL	National Chemical Laboratory
NCR	National Capital Region
NEN	National Entrepreneurship Network
NGO	Non-Governmental Organization
NIB	National Laboratory
NICD	The National Institute of Communicable Disease
NID	National Institute of Design
NII	National Institute of Immunology
NIV	National Institute of Virology
NOR	Not-Ordinarily Resident

NSTEDB	National Science and Technology Entrepreneurship Development Board
NWMP	National Water Quality Monitoring Programme
OECD	Organisation for Economic Co-operation and Development
PAH	Polycyclic Aromatic Compounds
PAN	Permanent Account Number
PBC	Paediatric Biology Centre
PCC	Pollution Control Committees
PCI	Pharmacy Council of India
PCO	Public Call Office
PCR	Polymerase Chain Reaction
PET-CT	Positron emission tomography - computed tomography
PHC	Primary Health Care
PhD	Doctor of Philosophy
PIC	Promoting Innovative Clusters
POCT	Point of Care Testing
PPP	Public-Private Partnership
PSU	Public Sector Undertaking
PSU	Public Sector Units
QC	Quality Control
R & D	Research and Development
RDT	Rapid Diagnostic Test
RH	Relative Humidity
RIA	Radioimmunoassay
RNA	Ribonucleic acid
ROI	Return On Investment
RTBI	Rural Technology and Business Incubator
SAS	Substance Abuse Services
SBIRI	Small Business Innovation Research Initiative
SEA	South East Asia
SEZ	Special Economic Zone
SHG	Self Help Group
SME	Small and Medium Sized Enterprise
SPCB	State Pollution Control Board
SPM	Suspended Particulate Matter
SS-GATE	South South Global Assets and Technology Exchange
STP	Software Technology Parks
STT	Securities Transaction Tax
TAN	Tax Deduction and Collection Account Number
TB	Tuberculosis
TDS	Tax Deducted at Source
THSTI	Translational Health Science and Technology Institute
TNEB	Tamil Nadu Electricity Board
TPO	Third Party Organization
TPR	Transfer Pricing Regulations
TRANSCOM	Transportation Company
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TSH	Thyroid - stimulating hormone
UDSC	University of Delhi South Campus

UK	United Kingdom
UNPD	United Nations Development Program
USP	Unique Selling Proposition
VAS	Value Added Services
VAT	Value Added Tax
VC	Venture Capital
VIDRC	Vaccine and Infectious Disease Research Centre
WHO	World Health Organization
WTO	World Trade Organization
YAP	Yamuna Action Plan

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[i] THSTI may not currently be offering all of these services, but are in the pipeline
[iiii] IAN provides/operates through partner network, on case by case basis.
[iii] Skyquest provides services through partner network, esp. for equity and project funding, on case by case basis.