



FINPRO

Diagnostic Center Feasibility Study - India

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Indian Unit of Measure

One Lakh/Lac is equal to One Hundred Thousand

i.e. One Lakh = approx. 1712 Euro

One Crore is equal to Ten Million

i.e. One Crore = approx. 171203 Euro

1 EXECUTIVE SUMMARY

The total Indian healthcare sector is today 34 billion USD and it is projected to grow to nearly 40 billion by 2012. The diagnostic and pathology market is around two percent of the total market. Indian diagnostic market has been growing fast, at 15-20 percent growth rate but there are lots of development needs. The growth rate is estimated to remain the same for the following ten years.

As in all India related issues, again the scale is so amazing - as the Indian interviewees put it: it is all about numbers in India! Also funding is always an issue.

One of the major driving forces is the basic demographic change: the migration to urban cities, with increasing number of people having access to modern healthcare. Consequently, more and more investments are being made in hospitals and clinical laboratories. However, the rural sector is not to be forgotten.- The emerging industry structure is headed towards providing healthcare services as an integrated comprehensive package rather than the traditional concept of providing healthcare infrastructure and reactive medical care. Among the middle and high-income families in India there is a rapidly increasing health consciousness which leads to high demand on preventive health care.

The Indian diagnostic market is clearly divided in two different categories: the non-communicable diseases which are more clearly life-style related, and the communicable diseases which are a big issue in India. Despite the quick economic growth and increasing number of middle class representatives, India is still a developing country with a huge number of rural inhabitants with massive sanitation problems. The basic market requirement is to come up with more indigenous products with affordable prices, bearing in mind that the usability is also in issue: the diagnostic kits should be easy to use, not requiring a doctor.

IVD and Molecular

The Indian IVD market is estimated to be 300 million USD as of 2008-09. The IVD market scenario has seen major development steps in the last 4-5 years and India should very soon catch up with the rest of the world.

Molecular diagnostic has been strongly developing during the past five years, with a growth rate of 15 percent. At many Indian research institutes lots of effort has been invested in it: India has made major progress over the recent years in acquiring competence and credibility in using most sophisticated cutting edge biotechnology tools to understand disease pathogenesis at molecular level. Many institutes and universities have already extensive research exchange and international cooperation initiatives ongoing. Solid basic research is being carried out but there would be more need for applied research.

Research and corporate cooperation status

Based on the interviews carried out at research organizations, it seems that there is still a considerable gap between the academia and the corporate world. Many scientists would like to be involved in projects where companies (and their business interests) were involved. Often, however, business delegation visits and meetings do not lead to any tangible cooperation. This is clearly an opportunity which Finland should seize in further elaboration of the Indo-Finnish cooperation.

Playground

According to the interviews, there are around 20 or so research institutes/universities doing more extensive diagnostic research, several non-governmental organizations (NGO) and around 150 Indian

companies, out of which 50 can be regarded as solid actors and eg. suitable for further screening of cooperation partners for the Finnish party.

Awareness of Finland

Thanks to the cooperation between DBT and Academy of Finland, Finland is rather well-known for its strengths and offering. However, very little tangible cooperation is going on so far. There is interest to find out more and to assess what could really be done together. The Indian party is very open to further discussions, and also they have a realistic understanding of their own weaknesses and challenges.

How to proceed

The Indian counterparts are not only open to further discussions, but they also would like to see more tangible things being done together. It can be in form of increases researcher exchange but the Indians are also willing to work together on business opportunities. Joint R&D project for co-developing products for developing countries would be of first priority. It would be important to identify a pilot project with possibly funding from the both countries and create a joint learning experience. This way of working could then be repeated. The pilot should include both academia and companies. This pilot project would pave the way for the Innovation Centre which is to be established in India.

2 INTRODUCTION

As the Department of Biotechnology in Delhi, India and the Academy of Finland have already had cooperation for several years, Tekes assigned Finpro to carry out a feasibility study on more extensive cooperation opportunities between the two countries. The study focuses on IVD diagnostics covering diagnostic test equipment as well as services. One important perspective was to assess the market needs in India in order to identify the opportunities for the Finnish diagnostic companies in the Indian market place and define ways of tangible cooperation with the two countries.

The study has been carried out by combining desk study methods and interviews with Indian companies and organisations. Finpro run an internal workshop with the team members on the conclusions.

The interviews are listed in an appendix.

In order to make the report more readable, we have collected here a list of the abbreviations used in the text.

ACTREC	Advanced Centre for Treatment, Research and Education in Cancer
AIIMS	All Indian Institute for Medical Sciences
BPO	Business process outsourcing
CCMB	Centre for Cellular and Molecular Biology
CDFC	Center for DNA Fingerprinting and Diagnostics
CDSCO	Central Drugs Standard Control Organization
CVD	Countervailing duty
DBT	Department of Biotechnology
DCGI	Drug Controller General of India
DSIR	Department of Science and Industrial research
ELISA	Enzyme-Linked ImmunoSorbent Assay
ESR	Erythrocyte sedimentation rate
FDA	Indian Food and Drug Administration
GMP	Good Manufacturing Practices
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICMR	Indian Council of Medical Research
ICMR	Indian Council of Medical Research
IIS	Indian Institute of Science
IIT	Indian Institute of Technology
ILS	Institute of Life Sciences
INR	Indian Rupees
LPL	Lal path Labs
MNC	Multinational companies
MOU	Memorandum of understanding
MR	Magnetic resonance
MRP	Maximum retail price
NABL	National Accreditation Board for Testing and Calibration Laboratories
NACO	National AIDS Control Organisation
NCL	National Chemical Laboratory
NGO	Non-governmental organizations
NIB	National Institute of Biologicals
NICD	National Institute of Communicable Diseases
NII	National Institute of Immunology
NIV	National Institute of Virology

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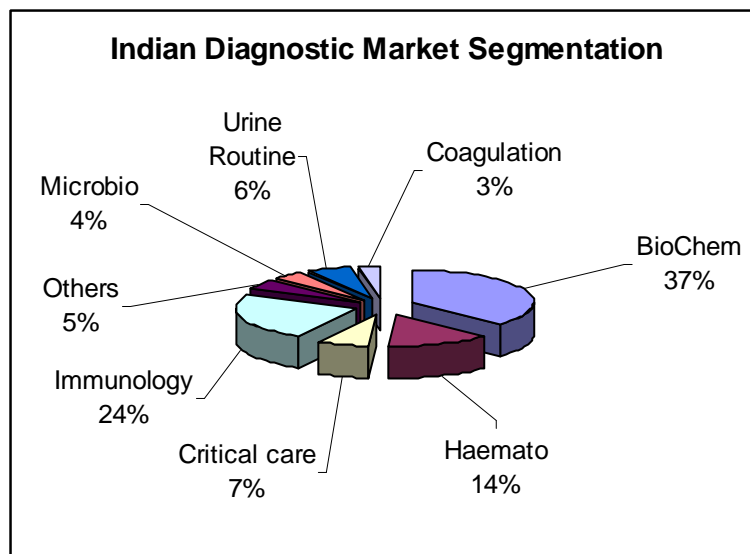
NRI	Non-resident Indians
PATH	Global health welfare NGO
PCR	Polymerase Chain Reaction
POC	Proof of Concept
TBD	Technology Development Board

3 INDIAN DIAGNOSTIC MARKET

3.1 Market Overview

The Indian diagnostic market comprising primarily of reagents and kits is to a large extent import driven. India currently has over 11,500 hospitals and 14,000 diagnostic laboratories. Diagnostics is poised to become a \$700 million industry by 2010 with significant improvements occurring in the area of early detection. Reagents and kits will also be major contributors to growth. There is increasing need for indigenous products with affordable prices.

3.1.1 Diagnostic Market



Today the total Indian healthcare sector, which is currently valued at \$34 billion, is projected to grow to nearly \$40 billion by 2012. The diagnostic and pathology market is around 2 percent of the overall healthcare market. The diagnostic market has been growing at 15-20 percent and by all indications shall continue to grow for another 10 years at this rate.

In Vitro-Diagnostic Market accounts for about 38 percent of the total global medical devices and diagnostic market. The Indian IVD market is estimated to be \$330 million as of 2008-09. The IVD market scenario in India has seen substantial developments in the last 4-5 years and these changes shall continue for decades to come. In a very short time, India is poised to catch up with the global IVD market.

3.1.1.1 Growth Drivers in India

- Increased purchasing power among the middle- to upper-tier economic groups. Along with the increasing wealth of Indians is the emergence of a more Westernized attitude which brings along also increased health awareness. One important sub-sector are the non-resident Indians (NRIs) who have spent much of their lifetime in the West but often return to India in later stage of life. Medical services in particular have flourished with the establishment of "NRI hospitals".

Returning NRIs are accustomed to having regular medical checkups and know well the value of preventive medicine.

- The arrival of multinational corporations in large numbers to the Indian scene has been accompanied by a similar growth in indigenous corporate entities (in particular IT-sector and business process outsourcing (BPO)). New corporate mentality brings along employee health issues, especially those of managers and executives. A parallel development has been the progressive expansion of health insurance programs that cover curative, diagnostic, and health screening programs.
- The rapidly increasing non-communicable disease burden on Indian population, without forgetting the rural masses who still struggle with a vast number of communicable diseases.

3.1.1.2 Growth Restraints in India

- India is a very cost and price sensitive market, i.e. imported products are often too expensive.
- The healthcare spending of the common people is 65% of disposable income, as the healthcare insurance penetration is still in the initial stages, and according to recent studies, lower income groups need to pay bribes to get access to public health structures (in southern states in almost 65 per cent of cases)
- Lack of awareness of newer methods and tests among public healthcare personnel and lack of professionals as such

3.2 Current use of diagnostics in India

3.2.1 Infectious Diseases Diagnosis

Diagnostics	HIV	Hepatitis B	Hepatitis C	Syphilis	Malaria	Typhoid	Tuberculosis	Dengue
Consumption trends	Increasing	steady	steady	steady	Increasing	Steady	Increasing	steady
Type of Testing	ELISA – 65% Rapid – 35%	ELISA – 65% Rapid – 34% Agglutination methods – 1%	ELISA – 80% Rapid – 20%	ELISA – 65% Rapid – 35%	Immunodiagnostic - m	ELISA – 65% Rapid – 35%	ELISA – 90% Rapid – 10%	ELISA – 65% Rapid – 35%
Compound 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	Blood banks are the largest	Blood banks are the largest	Blood banks	Hospitals, Clinical Labs	Hospitals, Clinical Labs	Hospitals, Clinical Labs	Hospitals, Clinical

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	Society (NACO)	consumer of the ELISA, Rapid tests are mostly consumed in clinical labs	consumer of the ELISA, Rapid tests are mostly consumed in clinical labs					Labs
Segment Market Leaders	J. Mitra & Co.	Bayer diagnostics	Bayer diagnostics	Span & Tulip diagnostics	Tulip diagnostics	Tulip diagnostics	Tulip diagnostics	Casil Health Products

3.2.2 Hormones 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 labs and hospitals	Hospitals, Clinics & end users
Segment Market Leaders	Span Diagnostics	Tulip Diagnostics

3.2.3 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 Labs & Hospitals
Segment Market Leaders	Tulip diagnostics

3.2.4 Pregnancy diagnosis

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

3.2.5 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 Labs & hospitals
Segment Market Leaders	Lilac (Tulip Group)

3.2.6 Molecular Diagnostics

In India the market for molecular diagnostics is in 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 in developing country the price issue is very sensitive.

3.3 Needs in Indian market based on interviews

When interviewing Indian organizations and companies, many practical issues related to market needs were mentioned. As the same point of view seemed to come up in several interviews, these seem to be key issues in India and should be considered when developing products for the Indian market.

To summarize the challenge, tests must be affordable, practical, have real clinical value, high specificity and high sensitivity. In short, they must be better as a doctor, and also usable without a medical doctor's presence! There are needs for all kinds of products. In purchasing, decision making factors are real value and utility; meaning if a patient can afford it or if a public hospital can provide it free of charge or on low cost.

3.3.1 What kind of tests are needed

There is need for rapid tests, especially for blood banks but also for rural areas to diagnose if the patient needs to be transferred to hospital. It was mentioned several times, that multiple test kits would be needed instead of separate single tests. Sera-panels are severely required.

In general, high technologies are on request. From technology point of view, there is need and interest in converting technologies into platform, developing diagnostic kits: 3rd generation to 4th generation. Nanotechnologies are needed. Molecular diagnostics is strongly coming in; DNA chips against markers and miniaturization. New era of molecular diagnostics kits has begun also in India.

It came out in at least two interviews that India is moving from cheap to more sophisticated tests. This would primarily mean urban areas and private health care, but when patients know they can require latest technology, also public health care must be able to provide it, but at an affordable price!

3.3.2 What needs to be tested

Infectious diseases have the major lead currently in the sense of what is being tested and urgently needs to be tested. From infectious diseases at least TB, malaria, dengue and hepatitis B&C are of high importance in India. Rapid kits for tuberculosis are needed. Proper infrastructure, high safety standards, deep know-how and sufficient time are required for successful TB test. These are rarely available, due to which there are no reliable test results. PCR test for HIV in infants would be needed. At present it is not possible to diagnose HIV of under 18 month infants.

Out of NCD's especially diabetes is emerging. However, many companies already have good selection on this field, so only highly innovative products are interesting. Out of cancer types there seems to be focus at least on breast and cervical cancer, which is a good sign of gender equality and can be a result of national policies stressing the health of women and children.

There is specific need for test kits for blood banks, in which currently five separate tests are required. As it now takes five days to get the results and 300 ml blood is required, nobody really does test the donor blood. This leads to transmission of diseases through blood banks. This challenge would easily be solved with rapid tests with "five tests in one"; HIV, syphilis, malaria as well as hepatitis B and C. Currently the blood is not tested before the blood donation. This means that one donors' blood can contaminate a large number of patients.

Ability to diagnose at earlier stage was given importance. Especially early detection of arthritis, diabetes and breast cancer were mentioned.

Prenatal and neonatal testing is an area that is neglected at least according to one interview. Several diseases could be cured or treated better, if diagnosed in early stage. For instance mental retardation is very costly to the society.

3.3.3 Affordability and usability

Affordability seemed to be the main issue mentioned in most interviews, when discussing the needs. To achieve this, local producing is required in most cases. Tests must be practical and easy to use, as there is not always a doctor available. It was also mentioned, that current tests used in India are not sensitive enough, so tests with better sensitivity and specificity would be needed.

3.3.4 Extreme conditions

Special features of Indian market are the extreme conditions due to temperatures, long distances and missing cold chain in the rural areas. 70% of Indians live in rural areas where there are neither laboratories nor cold chain, so there is a big need for products that are easy to use anywhere. There are special needs because of temperatures both in transportation and storage. How long the product should be stored depends on normal shelf life of the product and whether it is used on regular basis or during campaigns. As vaccines are commonly used soon after being distributed to the area, long storage is not needed, whereas diagnostics are merely used during longer period of time, when patients have symptoms of certain diseases.

3.3.5 Rural areas

For rural areas there are even more special needs. Tests should be usable without doctor. Health workers need be trained to take care of testing and to decide if patient needs to be transferred. Quick tests for diagnostics of infectious diseases are in urgent request. As a special target group, there is big need for neonatal sepsis and pneumonia. There are many undiagnosed diseases in remote areas. There is huge market potential if products are modified to match the needs and sold at cheap prices.

3.3.6 Other similar markets

Genetically Pakistan, Bangladesh, Nepal and other neighboring countries are similar with India and can benefit from the tests developed for Indian market. In India the population is homogenous excluding some minority populations like the Parsis and the Jews, which stay strictly in their own society.

3.3.7 Other aspects

When developing tests for developing country's needs and especially for rural areas, it is responsible 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 to consider also the disposal of diagnostic kit parts..

3.3.8 Future needs

When looking at the future development, it was estimated that health will be becoming more a political issue and public domain. As there will be elections in the spring of 2009, people are asking for better health care and expecting politicians to bring the health issue on their agenda.

Chronic disease burden is increasing, especially cancer, diabetes and cardiovascular diseases. National Rural Health Mission (NRHM) is focusing on common health.

4 FOCUS AREAS AND COOPERATION PARTNERS

4.1 Focus Areas in India

From infectious diseases at least TB, malaria, dengue and hepatitis B&C are of high importance in India. It is a big question, how much offering does Finland have on these fields.

Out of NCD's especially diabetes is emerging. However, many companies already have good selection on this field, so only highly innovative products are interesting. Out of cancer types there seems to be focus at least on breast and cervical cancer, which is a good sign of gender equality and can be a result of national policies stressing the health of women and children. Cardiovascular diseases are another time bomb in India, in addition to diabetes.

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.

For blood banks it would be essential to have rapid tests of malaria, HIV, syphilis, hepatitis B&C. Currently the blood is not tested before the blood donation.

4.2 Research Organizations

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. According to International Centre for Genetic Engineering and Biotechnology (ICGEB) they are the only organization that has put diagnostics kits into the market.

Some of the research institutions and universities that are working with diagnostics are presented in the table below. The activities are rather scattered, and apart from few exceptions, it is extremely difficult to find details about their exact diagnostics activities.

Organization	www	Activities (in Diagnostics)	Other remarks/conclusions
ACTREC Navi Mumbai	www.actrec.gov.in	Cancer diagnostics, especially high-end. Focusing on cancer on children, breast cancer, brain tumors 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 immunosuppressed 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.
All Indian Institute for Medical Sciences (AIIMS) Delhi	www.aiims.edu	AIIMS has research activities in epidemic diseases, and it has done some research work in diagnostics.	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.
Anna University Chennai	www.annauniv.edu	Anna university has active research activities on: 1. Molecular Immunotechnology 2. Immunotechnology 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	Major research activities are conducted on filariasis, typhoid and diarrhea. DBT has funded Anna university for up gradation of its lab. The university also receives funds from Bill Gates foundation. International co-operation includes a MoU with DESY (Deutsches Elektronen-Synchrotron), European union projects and Indo-Swiss project for Intellectual property and technology exchange.

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Center for DNA Fingerprinting and Diagnostics (CDFC) Hyderabad	www.cdfd.org.in	CDFC has diagnosis activities for genetic diseases <ol style="list-style-type: none"> 1. Clinical Genetics (Prenatal stage) 2. Cytogenetics 3. Biochemical Genetics 4. Molecular Genetics 	CDFC diagnostic test activities are related to genetic diseases which relates to human like mental retardation and any genetic disorder (like chromosomes) with the patients. CDFC provides direct consultation for patients, but they are not involved any research activity on diagnostic kits.
Centre for Cellular and Molecular Biology (CCMB) Hyderabad	www.ccmb.res.in	Centre for Cellular and Molecular Biology has research activities in <ol style="list-style-type: none"> 1. Genomics 2. Bioinformatics 3. Molecular biology 4. Genetics and evolution 5. Biochemistry & Biophysics 6. Cell Biology & Development 7. Biotechnology and Biomedicine 	CCMB has research activities of the drug discovery on the available disease model like <ol style="list-style-type: none"> 1. Alzheimer 2. Hepatitis-B 3. Colon Cancer 4. Leukemia 5. Atherosclerosis 6. Diabetics (type I & II) Their projects are funded by DSIR (department of Science and Industrial research) and Indo-French seminars on Bioinformatics and Proteomics.
Delhi University South Campus	www.south.du.ac.in		
Indian Institute of Science (IIS) Bangalore	www.iisc.ernet.in	IIS has active research activities in <ol style="list-style-type: none"> 1. Cryogenic technology 2. Ecological science 3. Microbiology & Cell biology 4. Molecular biophysics 5. Molecular Reproduction 6. Development & Genetics 	IIS has research activities in virology and microbiology. Diagnostic activities are mainly for cardiovascular and diabetics. IIS would be interested in co-operation in this field.
Indian Institute of Technology (IIT) Chennai	www.iitm.ac.in	IIT Chennai has active research e.g. for HIV and cancer cells	They are involved in discovery of antibodies for the virus and pathogenesis; development of a test for the food particles (rapid test development for identification of living pathogens via biosensors) and drug development.
Indian Institute of Technology (IIT) Delhi ¹	www.iitd.ac.in	IIT Delhi has active research activities in <ol style="list-style-type: none"> 1. Biotechnology <ul style="list-style-type: none"> • Production of Podophyllotoxin, an anti-cancer drug, by plant cell fermentation • Method for Specific integration of T7 RNA Polymerase gene into the Chromosome of Corynebacteria - T7 promoter 	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 DBT. IIT would be interested in the intellectual property with a Finnish counterpart in the field of

¹ Also other IITs (like Mumbai and Kanpur) have done some research work for diagnostics.

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		based shuttle vector and shuttle vector system	knowledge of biomedical and electronics engineering for product development of compatible sizes for commercialization .
Institute of Life Sciences Bhubaneswar	www.ils.res.in	Institute of Life Sciences has active research activities in <ol style="list-style-type: none"> 1. Infectious disease biology 2. Gene function & regulation 3. Transitional research & technology development 	ILS has developed nano-particulate drug delivery systems for cancer therapy (breast & prostate) cells. They are also working on the other areas for therapy development for leukemia, 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
International Centre for Genetic Engineering and Biotechnology (ICGEB)	www.icgeb.res.in	ICGEB is focused on developing technologies for developing country needs. The organization is capable for working with any diagnostics. The Centre employs currently 36 PhDs. According to ICGEB, they are the only research organization that has put diagnostics kits (e.g. for hepatitis and dengue) into market. Next step is to work with tuberculosis and develop bio-markers for it.	ICGEB has lot of experience in international collaboration. However, Finland is the only country for diagnostics cooperation. Since two years ICGEB has collaboration with university of Turku and especially with Kim Petterson. They have worked for Academy of Finland /DBT-funded projects and signed an MoU. The next joint project idea is to develop multiplex POC test (blood test from fingertip) for remote areas, with difficult conditions.
National Chemical Laboratory (NCL)	www.ncl-india.org	NCL focuses research activities in <ol style="list-style-type: none"> 1. Catalysis 2. Biochemical Science 3. Organic Chemistry 4. Polymer Science 5. Physical and Materials Chemistry 6. Chemical Engineering Science 	NCL has research activities like testing the enzymes inhibitors with HIV-1, plasmeprin and fungal protease for drug development for human healthcare.
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 involved in body's defense, host-pathogen interactions and related areas. NII has 42 faculties each of them having their own labs. NII has core research activities in <ol style="list-style-type: none"> 1. Immunity and Infection 2. Reproduction and development 3. Molecular design 	NII research activities are more focused on pathogenesis of the viruses of HIV & Typhoid.

		4. Gene regulation	
National Institute of Virology Pune	icmr.nic.in/pinstitute/niv.htm	NIV research activities are focused in <ol style="list-style-type: none"> 1. Animal house 2. Hepatitis 3. Measles 4. Virus 	NIV is recognized as the WHO (world health organization) regional collaborating center for reference and research on Arboviruses, and national reference center for Hepatitis and influenza

From the secondary sources and interviews with the scientists, we understand that the most of the research projects are funded by the Department of Biotechnology.

Apart from the organizations presented above, a US based NGO PATH, developing the healthcare sector in developing countries, has done remarkable work in diagnostics sector in India. Diagnostics is an important area of PATH's work also globally: The organization is at the forefront of this field, inventing and supporting the development of POC diagnostic tests that will help families in poor countries to get fast results and the right treatment. PATH has an R&D setup in US.

PATH has been present in India since 1978. It has offices in five Indian states employing over 80 people. PATH works in the largest and poorest states of India in a close collaboration with both central and state governments; aiming at undertaking complementary action. It knows the problems of the poorer section of the population; has done lots of work to find out their diagnostics needs and has access to wide network for distributing diagnostics products. The organization is involved not only in developmental projects aiming at improving the access to diagnostics and deepening the local know-how, but it has also undertaken technology transfer from Seattle R&D unit to Indian companies (e.g. rapid tests for several diseases). The objective of the technology transfer is to manufacture, and ultimately sell, the products locally at low costs. PATH also assists the companies in the regulatory process and market access.

PATH is currently conducting one-year-long study focusing on what PATH could do in future in diagnostics in India. For example all government projects and schemes have been assessed. The next task is to choose the most potential areas for future work; look even in more detail into the users' needs and then select the future focus areas.

4.3 Companies in India

It is difficult to give an exact number of diagnostic companies in India. 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 solid part of the industry. This figure includes:

- large local companies manufacturing for example other pharma products but importing the diagnostics ones
- local companies manufacturing animal diagnostics products
- small local companies manufacturing only one product

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- the leading multinational companies out of whom some manufacture the products in India whereas some only import and market them.

Large companies in general do not have specific focus areas; they tend to work with various diseases and various technologies.

The major local human diagnostics companies manufacturing the products are presented in the table below. There are only few Indian companies that have been able to develop quality products that are also of interest in foreign markets.

Company	www	Products / services	Other remarks
Accurex Biomedical	http://accurex.org	Accurex product offer ranges from 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	Agappe Diagnostics has experience in vitro diagnostics. Products: 1. Reagents <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Clinical Chemistry Analyzer • Hematology Analyzer • Coagulation Analyzer • Sodium & Potassium Analyzer 	
Bhat Biotech	www.bhatbiotech.com	Bhat Bio-tech India (P)Ltd is specialized in the design, development, manufacture and marketing of diagnostic test devices for various types of tests like, Pregnancy, HIV, Hepatitis, Malaria, Dengue, Chikungunya, Syphilis, TB, Cardiac Markers, Dry Chemistry, Bio-Chemistry, Hematology & Immunology and ELISA'S used in the analysis of body fluids in human. Products: 1. Diagnostic kits & instruments 2. Teaching kits & instruments 3. Recombinant proteins and reagents	
J. Mitra	www.jmitra.co.in	J. Mitra group has product offering of 1. Rapid test kits <ul style="list-style-type: none"> • HIV range • HCV range 	J.Mitra has a good reputation in the industry. The company focuses on POCs for

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		<ul style="list-style-type: none"> • HBV range • Malaria range <ol style="list-style-type: none"> 2. ELISA test kits <ul style="list-style-type: none"> • HIV range • HCV range • HBV range • DENGUE range • LEPTO range • TB range 3. Confirmatory Tests <ul style="list-style-type: none"> • HIV range 4. Blood Grouping Range 	infectious diseases like HIV and malaria. One of the aims of the company is to manufacture mass products at very affordable prices. These products are then sold through WHO.
Orchid Biomedical Systems (Tulip Group)	www.tulipgroup.com	<p>Orchid Biomedical Systems offers a product range of</p> <ol style="list-style-type: none"> 1. Fertility range (Urine Strips) 2. Infectious Diseases range (Dipsticks) 3. Parasitology Range (Dipsticks) 	Orchid, as J.Mitra, is known well for its quality products developed for mass markets and also sold through WHO.
Medsource Ozone Biomedicals Pvt. Ltd.	www.ozonebio.com	<p>Medsource Ozone product range includes</p> <ol style="list-style-type: none"> 1. Instruments <ul style="list-style-type: none"> • RT1904-C (Chemistry Analyzer) • RT2100-C (Fully Automated Microplate Reader) • RT-2600CMicroplate Washer) 2. Bio-Chemistry <ul style="list-style-type: none"> • 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	<p>Span Diagnostics Ltd. has products for pathology & clinical laboratories.</p> <p>Products:</p> <ol style="list-style-type: none"> 1. Diagnostic Reagents & Kits <ul style="list-style-type: none"> • Blood banking products • Clinical Chemical reagents • Hematology • Infectious Diseases Serology • Histopathology Products • Antibiotic Discs for Bacterial Sensitivity Test • Pregnancy Test • Laboratory accessories 2. Instruments <ul style="list-style-type: none"> • Biochemistry • ELISA • Hematology 	

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		<ul style="list-style-type: none"> • Chemiluminescence <ol style="list-style-type: none"> 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 in collaboration with leading cos like Sysmex, Medica, Grifols, Diesse, Fujirebio a complete suit of products in IVD
Trivitron	http://trivitron.com/	Trivitron has 156 product offerings and 7 divisions <ol style="list-style-type: none"> 1. Critical Care 2. Diagnostics 3. Imaging 4. Neurology 5. Renal care 6. Surgical Technologies 7. Trivitech 	
Tulip Group	www.tulipgroup.com/index_final.htm	Tulip Group is the Indian group of diagnostic companies, which manufactures and markets IVD reagents and kits. Products offered: <ol style="list-style-type: none"> 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 consist 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
Xcyton	http://xcyton.com	XCyton's product range consists of all ELISA products <ol style="list-style-type: none"> 1. HIV CheX and HEP CheX C 2. JEV CheX (This kit uses tissue culture antigen) 3. CYSTI- CheX (detection kit) 4. DENGUE - CheX 	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.
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. The monoclonal antibody products will soon be available for use as reagent in diagnostic kits.	

According to Dr. Navin Khanna from ICGEB the leading Indian companies are Orchid Biomedicals (Tulip Group) and J. Mitra. Dr Chander P. Puri, CEO of Yashraj Biotech, has been active in proposing the cooperation between India and Finland. At least these should be considered as potential partners in diagnostics centre. Both these companies focus mainly on POC's for infectious diseases like HIV and malaria: Both the companies' aim is to manufacture mass products at very affordable prices. These products are then sold through WHO.

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The list of other companies (both distributors and manufacturers) can be found in appendix.

Diagnostic Test Service Market –Companies

Indian market has evolved into an outsourcing market for diagnostics testing. It is for example evidenced that that specialized tests like molecular diagnostics or hormone related test cost 70–80 % less in India than in US. The major players in the field of diagnostics test services are presented in the table below:

Company	www	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 Ranbaxy	www.srlranbaxy.com	India's first central clinical reference lab, which caters to 25,000 doctors, 650 hospitals and close to 1,000 smaller pathology labs.	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 PathLabs	www.lalpathlabs.com	LPL has 13 labs in the country and 250 sample collection centers.	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 Labs	www.anandlab.com	Anand Diagnostic Laboratory is a full range lab in south India.	

5 REGULATIONS

5.1 Regulatory Process for Diagnostics

The Indian IVD market is highly regulated. Diagnostic kits and reagents belong to the category of drugs, and are regulated by the Indian Food and Drug Administration (FDA), Central Drugs Standard Control Organization (CDSCO) (<http://cdsco.nic.in>), functioning under the Directorate General of Health Services. 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

- Dr. SURINDER SINGH,
- Phone: +91-11-23236975
- Email: dcg@nb.nic.in

The state drug offices / State FDA's are then responsible for example monitoring of quality of drugs and diagnostics products manufactured by respective state units and those marketed in the state.

All the diagnostics products to be manufactured or sold in India require license. For licensing purposes the IVD devices have been divided into two groups: *critical* and *non-critical devices*. Critical devices include the ones used for:

- HIV
- HBsAg
- HCV
- Blood grouping reagents
- Malaria tests

All others are considered non-critical.

The licensing procedure for *critical devices* is as follows:

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-critical 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.

As can be seen, the regulatory system exists. The enforcement is the problem, since especially the state authorities have limited control capabilities. Thus in practice quality control of diagnostics products is still highly insufficient, and there are lots of products of questionable quality in the market.

5.2 Regulations Related to Imports

Licenses & Certifications

Critical diagnostics products are regulated under the Drug and Cosmetics Act 1940 and the Drugs and Cosmetic Rules 1945, and must be registered before they can be sold in India. They also require an import license. As in case of manufacturing, CDSCO is the leading organization responsible for quality control of imported diagnostics products. It is also the licensing authority for the approval of new products proposed to be imported.

Registration Certificate:

- Application for registration certificate in respect of the premises and the devices meant for import into India is required to be made by the manufacturer or importer or his agent in India.
- The application is to be submitted with the Drugs Controller General.
- The registration fee is USD 1000 per product to be registered.
- The application should accompany bank challans showing requisite fee paid, Form 40 (format provided by the DCGI) Power of Attorney to the Indian Agent/Office and dossiers.
- As per Drugs & Cosmetics Rules the registration process will take 9 months.

Import License:

Licenses are issued individually for each product. The license can be obtained by Indian agent/distributor/manufacturer. The following documents are required for each application:

1. Form-9 (format provided by the DCGI) prepared by the manufacturer and attested by the Indian Embassy in the manufacturers country
2. GMP (Good Manufacturing Practices) certificate
3. Company Registration certificate
4. Free Sales Certificate in the country of manufacture
5. Manufacturing License
6. Country of Origin Certificate
7. List of countries where the product is already being exported.
8. ISO / TUV / CE certificate.
9. Batch Release Certificate (for any one batch)
10. QC certificates (for any one batch)
11. Package Inserts
12. Empty cartons and packaging

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%).

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- 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 the 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:

				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:

1. Batch release certificate for the specific lot sent
2. Shelf-life certificate stating that the products shipped have more than 60% shelf-life at the time of landing in India
3. 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

- Maximum Retail Price (MRP).

5.3 Intellectual Property Rights (IPR) Rules

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

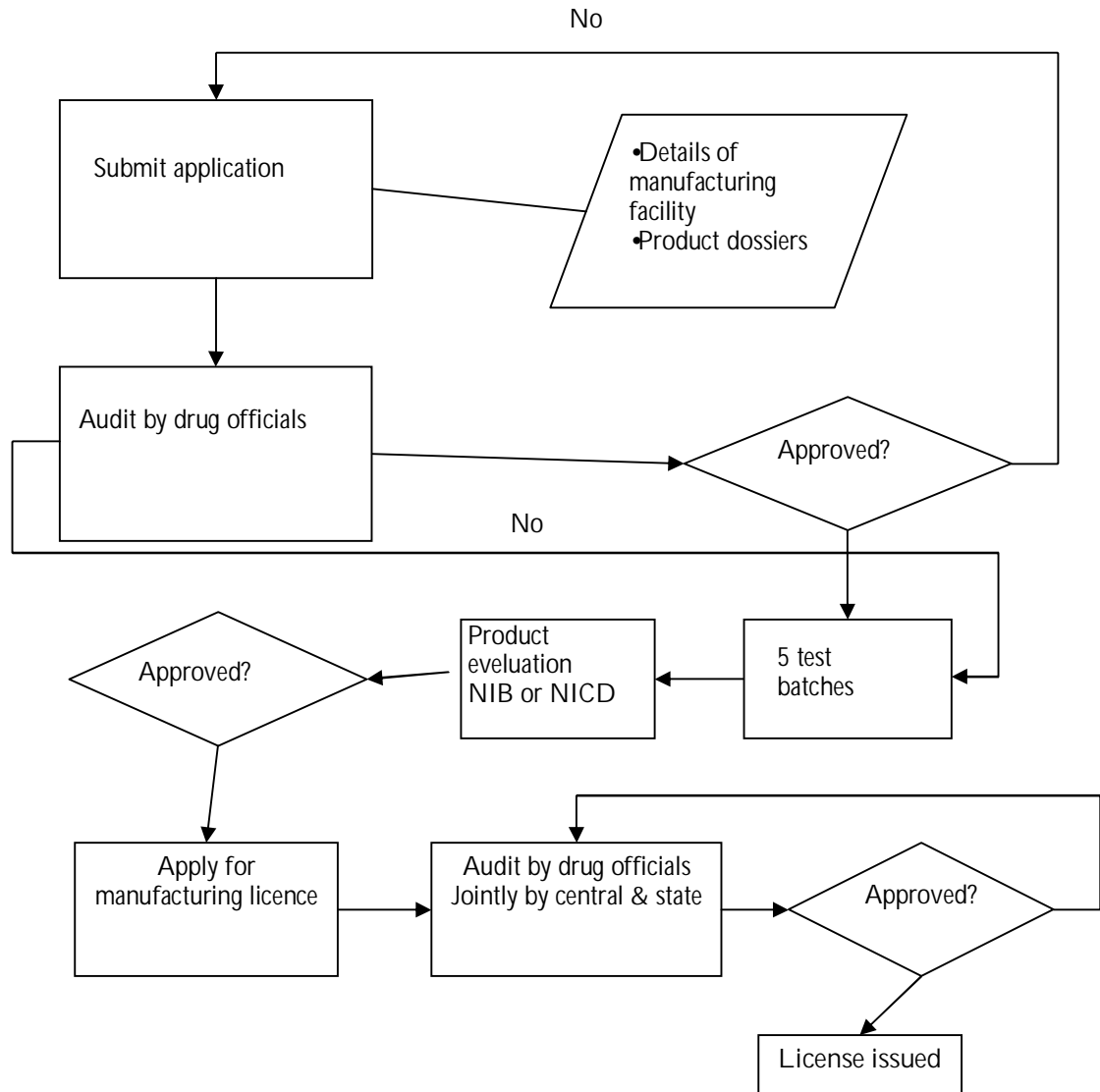
- processes
- products
- apparatus, tools and machinery
- inventions, capable of industrial application.

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.

Patenting process has 12 stages:

1. Identification of patent opportunity during project progress. Is the invention a) 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)

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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. Courts

6 POTENTIAL AREAS OF COLLABORATION

6.1 What Indians see as strength of Finland

Finland was mentioned to be leading globally in diagnostics field. As this was mentioned in several interviews, it is not only the opinion of one person. It was especially stressed by the ones who had already experience fro cooperation with Finns in the diagnostics sector, but also others seemed to be aware of the Finnish strengths.

In general, it is seen that Finland has good scientist. The reason for this is the sufficient focus put on diagnostics both in universities and in the industry. The dedication for long term development of diagnostics sector was praised and the name of Professor Kim Pettersson was mentioned by few interviewees. As diagnostic field is appreciated in Finland, good students want to specialize in it and they are further encouraged to continue to their PhD and post doc studies as well as to move to the private sector as well.

One big difference between Finland and India is, that in India results are expected so soon that there is no possibility for long R&D period. The Finnish strength in new innovations lies in allowing longer ROI times. Without the possibility to dedicate time and money for studies which are not yet guaranteed to be successful there will not be any remarkable new findings and innovations.

Some focus areas that were mentioned to be strong in Finland are molecular biology related new technologies, nanotechnology and genetic screening.

6.2 What Indians see as strengths of India

India is a tempting market, because of the size and growth, which is expected to continue. Market will continue to develop as middle class is growing. At the same time also health awareness and quality consciousness are increasing in urban India. This all will lead to growing demand for high quality tests and test equipment.

Another strength of India is the quantity and quality academic research. It was stressed in several interviews, that there is large number of important science, engineering and biomedical research institutes and universities in India. This large pool of scientists is highly qualified, but currently merely focusing on academic research. Some institutes have links to the private sector and in principle collaboration is possible, but not widely practiced.

Public-private-partnership - concept (PPP) is successfully used in India in many sectors including health care. (PPP is a mode of implementing government programs in partnership with the private sector. Private in this context can mean all non-governmental agencies like corporate sector, partnership firms, voluntary organizations, self-help groups, individuals and community-based organizations. The roles and responsibilities of the partners may vary from sector to sector. Most common PPP models are: service contracts, management contract, collocation, joint venture and BOL (build, own and lease). For service contracting, most common is to outsource the non clinical support functions such as cleaning, catering, laundry, security, building maintenance as well as clinical care services like laboratory services and specialized clinical services. PPP benefits both the public and private sector. It is cost effective allowing higher productivity and better utilization of facilities. Service provider is able to reduce the risks. Increased volume of the services will spread the fixed costs and increase the profitability. Larger masses can be treated and the focus is in the customer, who will get the best possible care. The government can participate in four roles: regulator, facilitator, provider and payer.)

India is also good outsourcing destination due to low cost manufacturing and existing quality certificates. Looking at the specific fields, India has good capacity to develop antibodies, to produce reagents and antigens as well as designing the proteins. CRO offering is seen as Indian strength with good clinical research capacity, large patient pool and possibility of rapid recruitment. There is a large chain of service laboratories, hospitals and medical units in India. Further on, if there would be need to extend these services, in India the costs for creating and maintaining such units is low compared to other locations.

6.3 Expectations for the Indo-Finnish cooperation

Many interviewees saw that partnerships with industry are needed, because in India innovations are stuck in laboratories. Cooperation should be enhanced both between Finnish and Indian sides, but also between academia and industry. Indian diagnostic cluster has to be built and as Finland has strong diagnostic cluster, Indians could learn this cluster thinking and ways of cooperation from Finns. Finland could assist in implementing similar model in India as well.

There would be a huge need in Indian market for inexpensive tests. Government role is very important in pushing and enabling new tests to be used in Indian market. Sufficient marketing budget must be there for new tests to allow successful commercialization and product launching. It was seen by several interviewees, that India would serve as good platform for R&D and test market. Technologies developed by the centre would be interesting not only to India, but for whole of the developing world.

Soft funding is needed for R&D.

The following issues came out from the interviews:

- Focus should be initially on infectious diseases and blood banks
- Prenatal and neonatal testing
- Breast cancer testing
- Early diagnosing with regard to almost any disease, with the objective to shift towards preventive healthcare

When talking about the possible Diagnostic center, it was seen that it should be multifunctional, not focusing on one sub-sector only. The Indo-Finnish Center must be self standing and industry should be investing, too. At the same time it was seen, that the center should not be only commercial but also serve as national research institute, having programs leading to new products. One view to the center was that it should have contract manufacturing facility. Physical set-up in India would make more sense. Then the center could do in-house technology development, in which the industry, companies

especially from Finland, should be involved from the very beginning. The work could go on until prototype stage and then the focus should be on transfer of know-how to India.

Even if there has already been good cooperation, it was seen that the degree of joint work could still increase a lot. Opening Indo-Finnish diagnostic center would be very important for the development of the diagnostic sector in India and for development of the cooperation. It was also mentioned, that Ph.D program on diagnostics should be part of the center's agenda. Regarding the structure of the center, an advisory board was seen important in managing the center.

6.4 What could the Indian diagnostic industry offer for Finnish organizations and companies

Here listed examples which came up in the interviews:

Yeshraj can offer production and R&D facility. Yeshraj aims to reduce cost of molecular diagnostics. Yashraj is looking for cooperation in which new diagnostic kits would be developed for the Indian market utilizing new innovative technologies and low cost production methods.

Actrec is open to cooperate with anyone focusing on cancer diagnostics. Actrec wants to become partner with any company or organization to reduce cost of product development. Actrec: can provide facility for pet CT spec. Actrec is interested in developing applications for that.

LabIndia would like to develop tests or testing equipment for prenatal and neonatal screening in cooperation with the Finnish companies or organizations. At the present, LabIndia has similar cooperation with a Norwegian company in order to develop breast cancer testing.

PATH is interested in hearing more and possibly being part of the network. Path has good network and channel to public hospitals and especially to rural health care. They have studied Indian diagnostic market extensively for 8 months now, so the knowledge could be utilized for mutual benefit.

Reliance Life Sciences is happy to offer CRO services in the assignment bases to Finnish companies.

Avesthagen in Bangalore could provide solid expertise on international cooperation models with a clear business focus.

6.5 Focus areas for cooperation

From infectious diseases at least TB, HIV, malaria, dengue, leprocy and hepatitis B&C are of high importance in India. Of NCD's especially diabetes is expanding rapidly in India. However, many companies already have good offering on this field, so only highly innovative products are interesting. Out of cancer types there seems to be focus at least on breast and cervical cancer, which is a good sign of gender equality and can be a result of national policies stressing the health of women and children. Also bone marrow transfers were brought up.

For blood banks it would be essential to have rapid tests for five diseases in one. Currently blood is not tested before the blood donation. This means that one donors' blood can contaminate the whole lot and a large number of patients. Could there be also some other practices of the Finnish "Veripankki", which could be adapted for the Indian environment?

Prenatal and neonatal testing should be developed. However, the challenges for creating the market for tests and testing equipment are first in the regulation for routine testing of the fetus, newborn and infants. A big issue affecting the voluntary tests is that currently less than 15% of Indians are covered for the health care costs. This affects the rate of diagnostics especially in the cases in which the health problem is not suspected. Thus this problemacy is not up to the Finnish actors to develop and decide, but could be taken up in the conversations to support the development of prenatal and neonatal testing.

Rural health care has specific needs, partly due to the extreme conditions and partly because of the specific health problems different than in the urban areas. There would be a huge market for products and services developed for the developing country conditions. Products could be developed in Finnish-Indian cooperation, tested in the Indian market and then sold to other similar markets in near by countries or in all developing countries.

Ranking of importance:

1. Infectious diseases
2. cancer
3. metabolic disorders

7 CONCLUSIONS AND RECOMMENDATIONS

7.1 Joint interests

Finnish companies' needs for cooperation vs Indian counterparts (examples only)

Interest area	Indian organizations/companies	remarks
Biomarker discovery	Yashraj	
Antibody technologies / engineering	Yashraj, J Mitra, Tulip	
Recombinant proteins	Bhat Biotech	
Detection technologies	Lab India?	
Sensors	IIT	
Micro&nano technologies	IIT	
Low cost manufacturing methods	J Mitra, Tulip, IIS	
Bioinformatics	CCMB, IIT	
Computational methods		maybe IIT B'Bay
CRO	Reliance Life Sciences	Also other companies in the field, but RLI is the largest

7.2 Cooperation modes

Subcontracting opportunities exist at least in manufacturing and CRO services fields.

7.2.1 CRO

Clinical research/studies can be outsourced to India, where there is good offering of CRO services both by commercial companies, hospitals and clinics. India's assets in this field are availability of qualified research personnel and documented clinical samples, which are crucial.

7.2.2 R&D collaboration

As many tests need to be developed or at least tested to be suitable for the population concerned, India would be good destination for product adjustment. As Indian market is similar to other developing countries, which make the half of worlds' population, India would be good test market for product evaluation. Actrec e.g. would be happy to cooperate with any company focusing on inexpensive products for developing markets.

7.2.3 Manufacturing

When talking about India, many Finnish companies might be interested in low cost manufacturing. As inexpensive products are in big request especially in price sensitive lower income mass market in India, cutting the costs both in product development and manufacturing would be key issues. Indian companies and organizations with similar interests could be suitable partners.

IIS Bangalore has been focusing on low cost production methods. Large manufacturing companies like J Mitra and such could be potential collaboration partners. Cost structure must be build to be feasible and beneficial for both companies of course, but as the volumes would be large, the total revenue can be even better than selling smaller number of products with bigger overhead per product.

7.2.4 Product launching and marketing

Consumer product marketing is costly, especially launching of the products. As the patients trust the doctors sometimes blindly, convincing the doctors is a key. However, educating the consumers to request new and affordable diagnostic tests would push the doctors and clinics to use them, despite better royalties from the more expensive ones.

Large number of Indian diagnostic companies is merely marketing and distributing other companies products. Thus there would be several potential distribution partners, which already have existing sales network and experience from the market.

7.3 Cooperation platform

We strongly recommend the model proposed by Kim Pettersson, in which the Diagnostic Center is a platform for 1-4 projects. Cooperation should be started in the form of one concrete pilot project, which can in the first stage be coordinated and facilitated by Finpro. Activities can grow by adding more projects when FinNode Innovation center will be opened in India and there is a dedicated person.

7.4 Recommendations for next steps

In the November 2008 meeting in India between the Academy of Finland, Tekes and Department of Biotechnology the parties should discuss and analyze also the outcomes of this study, in order to identify the sectors a/o topics which would best suit for the deepening of the cooperation and extending it to the companies. This process requires strong input from Tekes and the Academy and Finpro would like to take the role of a facilitator.

We suggest that the Finnish companies and organizations should to join Tekes for a fact finding trip to India in April 2009. Finpro would organize a match-making event with a seminar/workshop and individual meetings with Indian actors in conjunction of Bio Bangalore –event.

Ideas of concrete Indo-Finnish cooperation projects should be borne latest during the meetings in Bio Bangalore and feasibility of the ideas to be studied and projects formulated during summer 2009. DuO funding could be utilized for the coordination and facilitation work including negotiations with the Indian parties as well as raising the interest among Finnish companies and coordinating their participation in order to get a pilot project started. In this way a larger project would be up and running by the end of 2009, serving as a concrete spearhead for the FinNode India, which is estimated to be opened in India during 2010.

Interviews

Person name	Designation	Co/organisation
Dr. Sarika Gupta	Scientist	National Institute of Immunology
Dr. V.S. Chauhan	Director	The International Centre for Generic Engineering & Biotechnology (ICGEB)
Prof. Sunil Nath	Head Biochemical Engineering & Biotechnology	Indian Institute of Technology, Delhi
Mr. P.S. Subramaniam	General Manager	J. Mitra & Co. Ltd.
Mr. D.G. Tripathi	Director	Tulip Diagnostics Pvt. Ltd.
Dr. Hemant V. Borgaonkar	Technical Consultant	Labindia
Dr. S. Sarin	Director	The Advanced Centre for Treatment, Research & Education in Cancer (ACTREC)
Dr. Chander P. Puri	CEO	Yashraj Biotechnology Ltd.
Prof. D.Narasimha Rao	Chairman, Division of Biological Sciences	Indian Institute of Science
Mr. Manan Bhatt	Sr. VP (ext relations)	Avesthagen Ltd.

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Dr Sami N Guzder	CSO Science and Innovation	Avesthagen Ltd.
Dr. K.Kaliraj	HOD Biotechnology	Anna University Chennai
Dr. Anju Chadha	Center of Biotechnology	Indian Institute of Technology (IIT) Chennai