INNOVATION AND COLLABORATION:

CATALYST FOR BRAND BUILDING IN INDIA'S DIAGNOSTIC SECTOR

A White Paper accompanying the Webinar on

"The Future of Diagnostics in India:

Technological Advancements and Emerging Trends"

By

AVALON Consulting

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Dr. Ravi Gaur

Partner & Director,
UniDRG Specialty Laboratory
Founder, DRG Path Labs

drgaur61@gmail.com

Mr. Abhimanyu Roy

Executive Director,
Avalon Consulting

abhimanyu.roy@consultavalon.com

Mr. Rajesh Patel

Executive Director,
My Lab

rajesh@mylabglobal.com

Mr. Vineet Gupta

Director – Government Affairs,
Varian Medical Systems (Siemens Healthineers)

vineetm.gupta@varian.com

Mr. Abinash Chaudhury

Lead- Government Affairs & Policy,
Roche Diagnostics India

abinash.chaudhary@roche.com

Mr. Sudhakar Mairpady

South Asia Regulatory & Government Affairs Director,
Becton and Dickinson India

sudhakar.mairpady@bd.com

Introduction

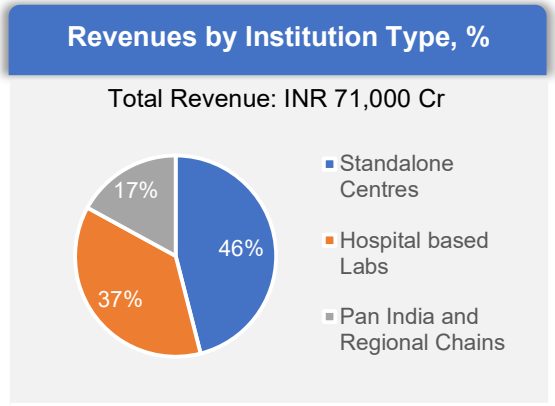
India's diagnostics industry is a critical part of the healthcare sector, playing a pivotal role in disease detection, treatment, and prevention. With a rapidly evolving industry structure, **a large market size of INR 71,000 Cr in FY21 (and projected to grow at 13% CAGR over the next five years)** and a wide range of diagnostic services, the diagnostics industry plays a vital role in improving health outcomes for millions of individuals.

The diagnostics industry involves a variety of inter-connected entities e.g., diagnostic laboratories, hospitals, clinics, research institutions, and medical device manufacturers. These collaborate to deliver a range of diagnostic services while adhering to quality standards, with an expanding network of diagnostic centres and a focus on adoption of new technologies.

The industry's growth is driven by - increasing healthcare expenditure, growing disease burden (especially lifestyle diseases), and rising awareness of preventive healthcare. The sector is also attracting risk capital (of various types (VC / PE and traditional investors) which is supporting investments into expanding infrastructure and deployment of latest equipment.

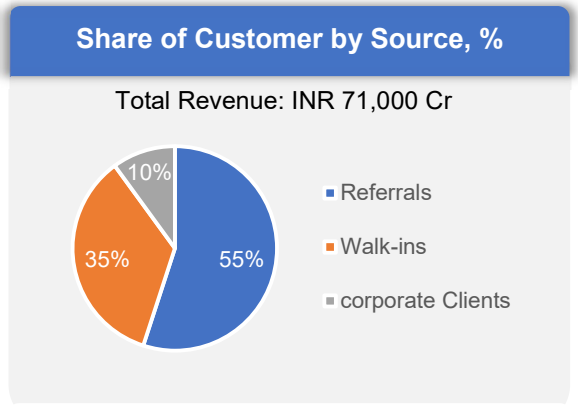
While there is no verified data on the number of diagnostic labs operating in the country, **various estimates peg this number at ~1,50,000 labs (including Pathology and Radiology).**

Revenues by Institution Type, %



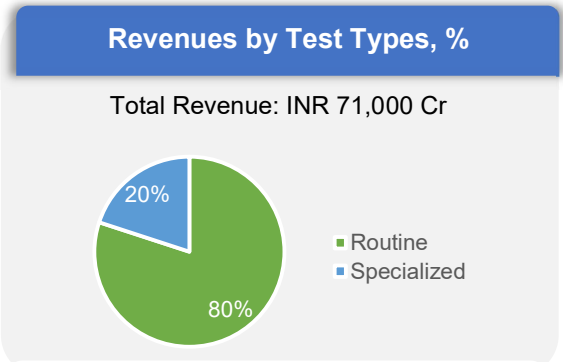
Source: Diagnostics Industry Report by Axis Capital, March'23

Share of Customer by Source, %



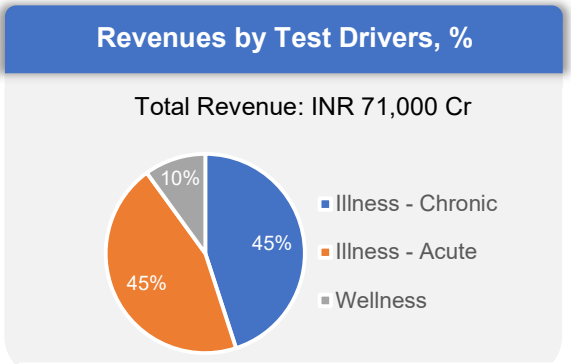
Source: Diagnostics Industry Report by Praxis

Revenues by Test Types, %



Source: Industry Feedback, Avalon Consulting Research

Revenues by Test Drivers, %



Source: Diagnostics Industry Report by Axis Capital, March'23

- **Estimated ~150,000 diagnostic labs with an estimated market size INR. 71,000 Cr and projected to grow at 13% CAGR over the next 5 years**
- **Highly fragmented supply with 46% share of revenue from Standalone Labs. Share of Chain Labs is only 17% of overall revenue and Hospital Labs have 37% share**
- **Doctor referrals is the major source of customers especially for Acute Care**
- **Routine Testing (mainly Pathology) has a lion's share of the overall testing ; share of Specialised Testing is small but growing**
- **Wellness-based tests are yet to achieve substantial penetration, with such tests mainly offered by Organised Players**

The Indian Diagnostics market can be segmented into different categories:

Market Segmentation by Institution Type and Business Realization

Standalone Centres account for the largest share of industry revenue (46%), whereas Chain Labs (National and others) account for only 17% and 37% is with Hospital based labs.

A major portion of this business relies on doctor referrals (~55%) whereas walk-ins account for 35% share and corporate clients accounting for the rest. **Doctor influence continues to play a very important role especially in Acute Disease treatment.**

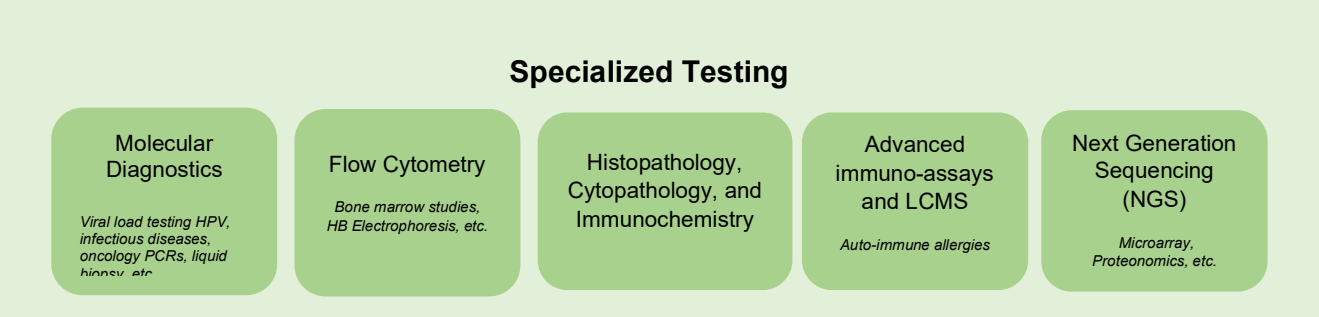
Market Segmentation by Test Types and Test Drivers

The market is dominated by Routine Testing (comprises 80% of market) which includes: Biochemistry, Haematology, Clinical Pathology, Microbiology and Radiology (X Ray, CT, MRI, USG etc.).

Specialised Testing is a relatively new phenomenon with relatively low penetration at present (20% of the market). Within Specialised Testing, **Molecular Diagnostics (using technologies like PCR and NAAT) is finding increased penetration** as there has been a large capacity creation of PCR machines in the last 2 years (driven by Covid requirement). Other Specialised Testing is relatively nascent e.g. Flowcytometry, Cytogenetics / Genomics, Histopathology, Immunohistochemistry, Next Generation Sequencing (NGS) etc.

Routine Testing

Clinical Chemistry	Haematology	Microbiology	Low-end radiology	High-end radiology
• Kidney function test, Liver function test, Vitamins, Hormones, Tumour and Infection Markers, etc.	• CBC,Blood Groups, Coagulation, etc.	• Urine, stool, blood and other body fluids, allergy testing, etc.	• X-Rays, Ultra sonography, etc.	• CT-scan, MRI, Colour Doppler, etc.



Overall, **it is estimated that ~90% of the tests are "Illness" driven** (i.e., post detection of illness) and there is **a huge scope for the share of "wellness" tests to increase** (i.e. preventive / predictive testing).

From a disease perspective the Diagnostics sector has **significant untapped potential to address a large patient burden in India** including lifestyle diseases (which are witnessing increased prevalence) e.g.

- **Oncology Diagnostics:** Cancer is the third leading cause of death in India. Diagnostic tests for cancer include imaging tests, tumour markers, genetic profiling, and molecular testing, enabling early detection and personalized treatment strategies. E.g., HPV DNA testing is a highly accurate and sensitive test available for diagnosing cervical cancer. Insufficient availability and access to screening and vaccines contribute to the high burden of cervical cancer in India, especially in the rural areas.
- **Auto-immune Disease Diagnostics:** A global estimate shows that nearly 700 million Indians - that is, nearly one-tenth of the global population - suffer from some kind of an autoimmune disease, in stages ranging from mild and moderate to severe. The two most prevalent types among Indians are rheumatoid (in women) and ankylosing (in men). Advanced diagnostic techniques, including imaging studies and molecular markers, help healthcare professionals accurately identify autoimmune conditions. This would lead to appropriate and targeted treatment plans, reducing the risk of misdiagnosis and unnecessary treatments.
- **Cardiology Diagnostics**: Cardiovascular disease is the leading cause of death in India, accounting for 26% of all deaths. Widespread penetration of tests such as electrocardiography (ECG), echocardiography, stress tests, and cardiac biomarkers, will significantly enhance the diagnosis and management of cardiovascular diseases.
- **Endocrinology Diagnostics**: Testing for hormone imbalances and disorders, majorly diabetes, which affects an estimated 73 million people, thyroid dysfunction, and adrenal disorders, will facilitate accurate diagnosis and treatment optimization.
- **Infectious Disease Diagnostics:** Detection and identification of infectious agents, including viral, bacterial, and parasitic infections, supporting prompt treatment interventions and public health measures. E.g., Molecular Diagnostics based testing with low TAT is playing a key role in early detection and screening of Tb patients in India.

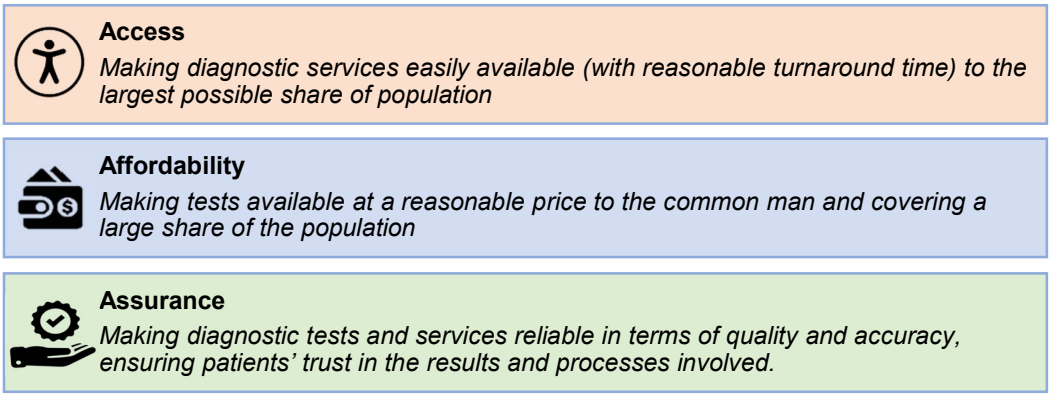
Based on the above, it is evident that:

- The diagnostics sector is highly fragmented and unorganised; however, this will change as penetration of regional / national chains increase along with consolidation.
- Doctor influence continues to play a very important role (comprises 55% of overall customers) especially in Acute Disease treatment.

- Increased consumer awareness and availability of quality testing will drive a shift from “illness” driven to “wellness / preventive” driven testing. This has significant implications on healthcare costs as screening, early detection and monitoring reduce overall treatment costs. With time this will also impact the customer source and business models i.e., share of referrals may decrease in future.

After rapid growth over the past 15 years (including an unprecedented surge in the Covid phase) the industry is now poised for stable long-term growth which needs to be based on fundamental strengths and underlying growth drivers aided by rapid expansion of a variety of tests and services.

This calls for addressing a few fundamental challenges faced by the industry. These can be summarized as: **3As** – **Access, Affordability, Assurance**.

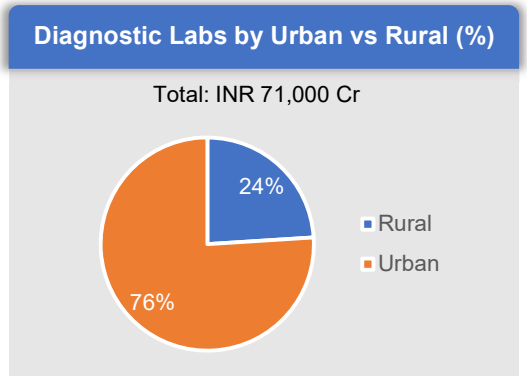


The industry stakeholders i.e., lab service providers, equipment manufacturers and IVD equipment and reagent producers alongwith research institutes and the government need to come together to address these issues, which if resolved, would drive a higher growth of the sector, and enable it to address India’s substantial healthcare challenges.

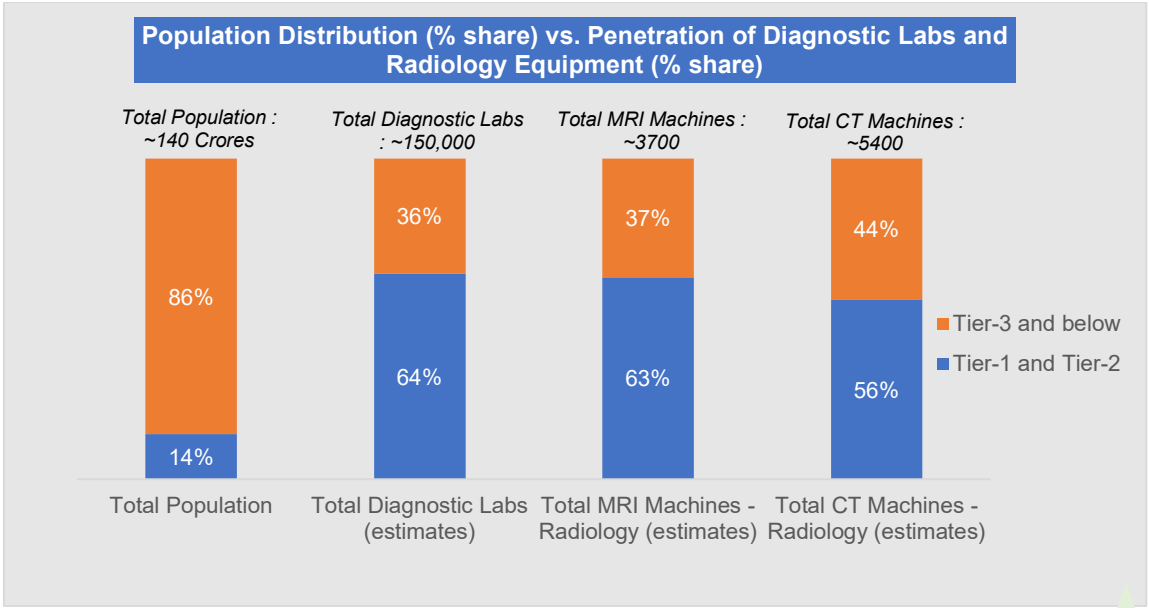
This whitepaper highlights some of these issues and discusses preliminary thoughts on the way forward.

Access

The Diagnostics market is overwhelmingly urban, comprising 76% share of overall revenue of the industry.



Source: Praxis Global Alliance
Report on Indian Diagnostics Industry



Source: www.statisticstimes.com (population data, 2021) and tier-wise share of pathology labs, CT, MRI taken from estimates developed by Praxis Global Alliance

Tier-1 city *– Population greater than or equal 40 Lacs (10 cities)*
Tier-2 city *– Population between 15-40 Lacs (30 cities)*
Tier-3 and below (includes rural India) *– Population less than or equal to 15 Lacs*

Out of the total diagnostics labs of ~150,000, the chain labs (ones with 2 or more labs) account for ~3000 labs and remaining is with the hospital labs and standalones labs

- **Urban areas account for 76% of the industry revenue**
- **Various estimates indicate the skewed nature of geographic distribution of labs - most of the pathology labs and radiology equipment are focused on tier-1 and tier-2 cities (64% of the labs and 55-63% for CT / MRI)**

Routine testing is now widely available across India especially for Clinical Pathology, Biochemistry, Haematology, Basic Radiology (X Ray, USG) etc. However this mainly includes standalone labs in the unorganised sector which have basic equipment and have highly variable quality standards. **The number of well-equipped labs e.g. reference labs and satellite labs of the Chain Lab companies / other Organized Players is estimated at only ~3000 and are mainly present in Tier 1/2 towns.** These players address the wide geographic spread of the market through own **Sample Collection Centres and through B2B route** (servicing samples generated by the unorganised players and other third parties / hospitals).

Moreover, with the presence of Chain Labs being mainly concentrated in the major urban locations **Specialised tests are largely not penetrated beyond Tier 1 / 2 towns** (e.g., Molecular Diagnostics, Flowcytometry, Cytogenetics, Histopathology etc.) **- this presents a major growth opportunity** to provide Specialised Testing.

Penetration in rural India is now reasonably good for Routine Testing (especially where it is adjacent to an urban location). Overall rural India is mainly covered by government hospitals (where infrastructure and quality of diagnostic lab facilities varies widely).

The lack of penetration of quality facilities beyond the Tier 1/2 centers and the low penetration of Specialised Testing has significant implications:

- It hampers the ability to offer a full range of treatment options to patients in the under-penetrated markets resulting in sub-optimal treatment.
- Leads to forced medical travel to centers with advanced diagnostic facilities putting pressure on the healthcare system.
- It is an impediment to early detection and prevention – especially for conditions like cancer or genetic disorders, which rely on advanced screening techniques.
- Lack of Specialised Testing prevents the growth of personalized and precise healthcare interventions resulting in prolonged suffering, ineffective treatments, and worsened health outcomes.

While the organized players can enable penetration of the various tests through the Hub-and-Spoke model involving Pick-up Points, Collection Centres and Labs (Satellite Labs and Reference Labs), **the main challenge here is the logistics**. **Poor connectivity and poor quality of transportation infrastructure lead to increased operational costs** - one of the key reasons hampering further penetration of the organized players into these regions, thereby denying the local demographics of the advanced tests alongside the basic ones. Also, with underutilization of their current capacity (~70% as per industry feedback) any new region-level expansion strategy will hinge upon the capacity utilization of the current diagnostics network of these players.

There are various innovative solutions being tried out to address “Access” issues. E.g. **mobile and suitcase labs**, while at their very nascent stages in India, can drive quick access to the diagnostic tests with the concept of **“lab moving to the patients”.** Drones are also being tried out for transporting samples from mainly remote areas and in cases needing a quick

turnaround time during emergencies. However a major challenge for all these innovative solutions is the cost of technology, thereby limiting its adoption to a handful of players currently.

A recent development in driving "Access" is the **adoption of the PPP model for making available quality testing in government hospitals**. This involves a tripartite agreement between the government institution / private service provider / equipment marketer and can involve undertaking capex as well as operating the lab (inside the govt. hospital) under a win-win arrangement which enables testing at low cost to government. This model has faced some challenges in terms of compensation to service providers however it continues to be a prominent model with > 100 such projects implemented. This model can be a key driver of increased "Access" especially by state governments which may take up the implementation of NEDL (National Essential Diagnostics List) in their respective states.

Another transformative development in driving "Access" could be through widespread adoption of Point of Care Testing (PoCT). This could take various forms including testing in non-lab environments (in small clinics / GP offices) and various types of self-testing by patients. Various PoCT technologies are already wide available in India e.g. the popular self-testing glucometers as well as hand-held Blood Analysers which provide quick results for blood gas, electrolytes, metabolites, oximetry etc. These technologies could potentially enable a complementary business model which directly reaches the patient / doctor bypassing the lab / hospital.

Thus, addressing the "Access" issue would require a debate on various points e.g.

Can there be a collaboration between existing players (especially for Specialized Testing) to "share" infrastructure, plan new capacity around "clusters" and have better utilization of logistics providers for lower cost of sample transport? E.g. how to drive better utilization of PCR machines which are lying unused as Covid

How can Point of Care Testing (PoCT) technologies, and drone-based sample collection and delivery be used to drive increased availability of tests in remote areas? Can PoCT tests be made available in a basic clinical set-up outside of hospitals and labs? What would be the implications on ensuring quality standards, test reliability and costs?

How can PPP models be used more efficiently to drive increased availability of quality testing in government hospitals especially in rural areas?

Affordability

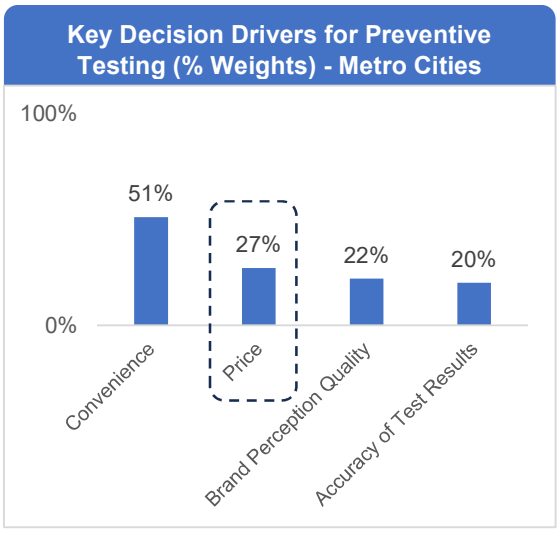
"Affordability" is crucially linked to "Access" and solving for both together creates a virtuous cycle of – low pricing, high volumes and profitable operations. While **India offers one of the lowest cost of diagnostics for the patients**, adoption is constrained even at these prices given the limited financial resources and inadequate health insurance coverage.

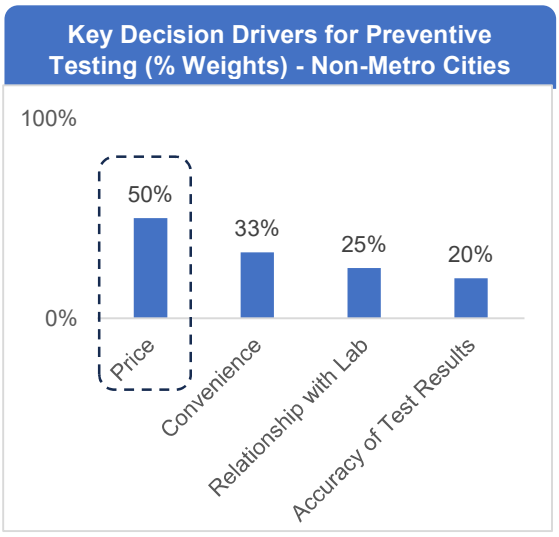
The high industry fragmentation and **low economies of scale of the standalone players inhibits capacity creation and competitive pricing**. Larger players are able to secure favourable contracts with equipment suppliers (e.g. equipment on lease with mark-up on reagent revenue), which enables access to the latest equipment as well as reasonable pricing, whereas the smaller players are not able to compete on that basis.

Industry feedback indicates that the **major types of Routine Testing / Pathology tests are by and large "affordable"** for a significant portion of the population especially in urban centers. Comparison of price data for various Chain Labs shows negligible increase in the overall average price over the past 5 years (though some of the leading National players have increased prices). This is due to increased competition driving down prices (especially fuelled by the entry of online players and other new entrants with aggressive pricing strategy).

However, **areas like Radiology and Specialized Testing** e.g. Molecular Diagnostics have not witnessed a significant price drop and **continue to be "expensive" for the common man**.

Recent consumer research on purchase behaviour of patients indicates that **Price is a critical factor for decision making especially in Wellness segment**.





Source: Findings of a consumer survey on purchase behavior of preventive test by Metropolis / Bain and Company

Price is one of the critical decision-making criteria for Preventive Testing – especially in non-metro locations.

There are 3 key challenges in driving "Affordability":

High share of imports of both diagnostic equipment and IVD reagents which leads to higher cost

Low focus on locally developed R&D and technology in diagnostics which leads to continued dependence on imported technologies

The inherent "competitiveness" disadvantage suffered by the smaller players due to their sub-scale and fragmented nature, hence the need for larger players to emerge in the industry (consolidation)

This has resulted in low penetration of key diagnostic equipment in India e.g. equipment like CT / MRI / X Ray machines are significantly under-penetrated in India compared to other developing countries.

Medical Device/Component	Import Dependence (% share of India Market)
IVDs*	65%
Implants	77%
Consumables	65%
Equipment*	85%

Source: As per research done by Avalon Consulting in 2019, with findings extrapolated to 2023

*Equipment includes Radiology Equipment (diagnostics) and Others; IVDs includes equipment, reagents / test cartridges etc.

The path to "localisation" of key equipment has been gradual but steady. The major MNC players have begun to increase the level of value addition in India – from pure assembly of equipment to some level of local sourcing of components. Indian players have also entered some of these products and are contributing to local value addition.

Some of the key equipment which could be the focus of further localisation include: X-Ray; CT: MRI; Endoscope ; Linear True Beam ; BTA / GMA Radiation etc. Focus on localization of key components for imaging equipment could include X-Ray Tubes / High Voltage Generators / Detectors / MR Amplifiers / Power Supplies / Coils etc.

The recently announced PLI Scheme on medical devices has allotted several projects for manufacturing of the above products in India. This is an important first step towards increased localisation.

However, an overall strategy for promoting localisation requires a **systematic approach to implement a Phased Manufacturing Program (PMP) for select products** – with initial zero import duty on components (to encourage assembly) followed by progressive increase in import duty on components (to encourage component localisation). This would require a

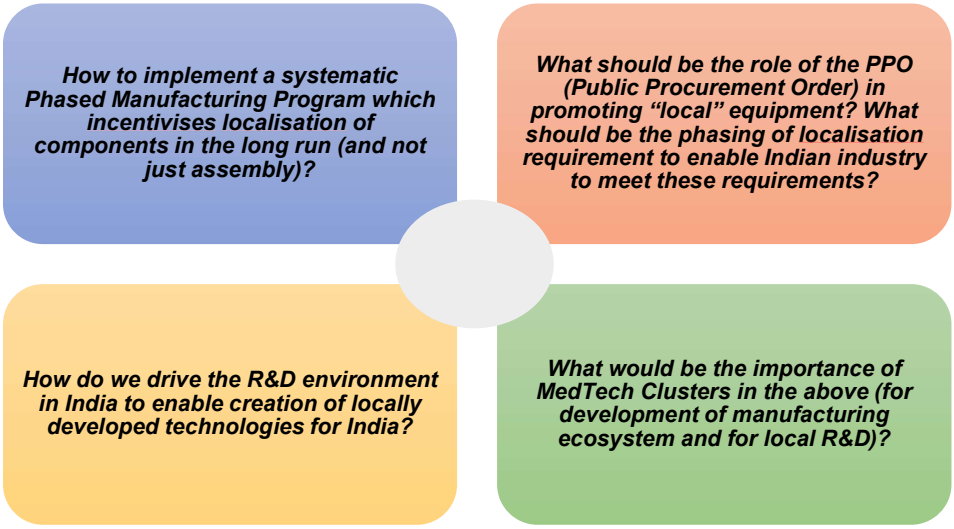
careful analysis of the prevalent inverted duty structure and design the scheme accordingly. This is similar to the strategy followed in the case of Mobile phone manufacturing and ecosystem development.

Localisation levels are slightly better in case of IVD instruments and IVD reagents. **These are the 'low hanging fruits' for immediate indigenization**. Dedicated clusters for manufacturing of RM required for IVD reagents (e.g., antibodies, antigens, special proteins, enzymes) will further help reduce imports. Govt. institutes can be encouraged to produce these (with suitable regulatory oversight from CDSCO and cGMP status).

Similarly, there needs to be a focus on localisation of consumables e.g., Specialty Steel (Needles), high grade plastics (Catheters, Syringes tec.), nitrile (Gloves)

While cost reduction is essential, maintaining the quality and reliability of diagnostic equipment should be a primary consideration. Balancing affordability with quality is crucial to ensure that diagnostic equipment meets the necessary standards and provides reliable outcomes.

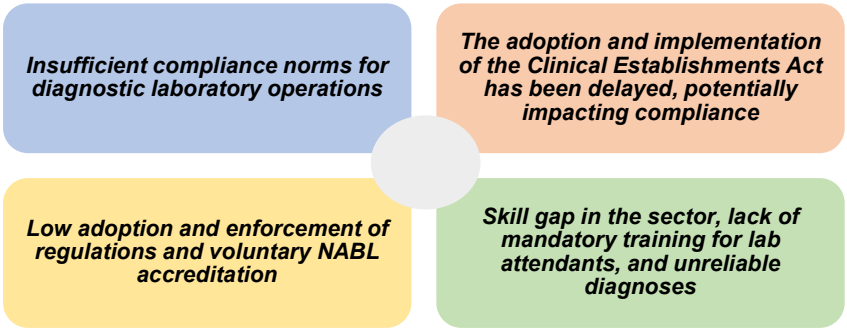
Thus, addressing the "Affordability" issue would require a debate on various points e.g.



Assurance

From a patient perspective, **service assurance** in terms of equipment quality, test process efficiency, accurate diagnosis and reporting lead time are critical. The regulatory system needs to ensure the diagnostic devices are clinically validated and are operated under the required processes and conditions.

However, several challenges exist in the current system:



Insufficient Compliance Norms for Diagnostic Laboratory Operations

As per the current regulations there are very basic compliance norms for establishing a diagnostic laboratory in India. E.g., most Indian states require complying with the **Shops and Establishments Act**, and a few other local requirements (NOCs from the local municipal authorities, registration with the Biomedical Waste Disposal Body, etc.). However, these requirements are not adequate nor standardised – hence they do not ensure the diagnostic labs are *"ready for seamless patient service delivery".*

The Central Government has attempted to resolve this challenge through **Clinical Establishments Act**, covering the minimum standards required to run a diagnostic laboratory. However only ***12 States*** and ***7 UTs have*** so far adopted it and the subsequent on-ground implementation is a major concern. The delay in adoption and implementation seems to be around the following:

- Majority of the existing labs, who are small players, would not be able to meet the standards prescribed by the regulation.
- Attempts made towards compliance would increase the cost of operations, especially for the small players, possibly making them unviable.

Another factor leading to poor patient service delivery is **voluntary accreditation norms for diagnostic labs.** Such voluntary practices lead to variations across 3 Ps across labs – Process, People and Performance. **Only ~1,000 "clinical pathology" labs are currently NABL accredited** countrywide i.e., about ~1% of the total labs in the country. Similarly, penetration of voluntary accreditation with QAI (Quality and Accreditation Institute) is also low.

Therefore, **low adoption and enforcement of regulations (Clinical Establishments Act, mainly) and voluntary NABL / QAI accreditation are key challenges** as they enable low quality entry barriers for diagnostic laboratories, impacting patient service delivery.

Skill-gap Leading to Process Inefficiencies

There is a **severe shortage of skilled manpower at various levels including Pathologists, Radiologists, Lab Technicians, Attendants etc.** For instance, there is ~1 radiologist per 100,000 people in India, compared to 1 radiologist per 10,000 people in the United States; similarly there are 14 pathologists per million people in India, compared to 65 per million people in the United States. Therefore, even if new diagnostic labs come up, lack of manpower will be a barrier to providing quality services.

Skill levels of the existing manpower base continues to be a challenge (especially for technicians / attendants in the small, standalone labs). E.g., there are **no mandatory training / qualification requirements for hiring Lab Attendants based on industry requirements**, leading to improper sample extraction / imaging processes and unreliable quality of diagnosis.

This is evident in the concerns expressed by leading industry players on **rising industry attrition and the growing trend of hiring high-end resources (trained pathologists / radiologists) on a part-time basis** to maximise utilisation.

The growth of the diagnostics sector would be stunted if a complementary growth in the low-end and high-end skilled manpower is not available. This requires a planned effort and collaboration between Industry and government. The **Sector specific Skill Councils are a significant first step in this regard.**

Implications of Technology on Regulation

With the growing adoption of new diagnostic technologies e.g. AI in diagnostics and Software as a Medical Device there is a need to assess the applicability of current requirements for testing and registering such equipment and diagnostics.

Similarly, use of patient data from wearables to provide diagnostics and healthcare services opens up several regulatory issues related to norms and quality standards as well as data confidentiality required for such a healthcare ecosystem.

Thus, addressing the "Assurance" issue would require a debate on various points e.g.

Should the regulatory norms for setting up labs be made more stringent than the current regulations across states? Should NABL accreditation be mandatorily implemented across states? How should this be phased and what will be the impact on the industry?

How to solve the skills issue – separately for the major qualifications (Radiologist / pathologist) as well as for junior level resources (Lab Technicians etc.) What initiatives can be jointly undertaken by industry and government in this regard?

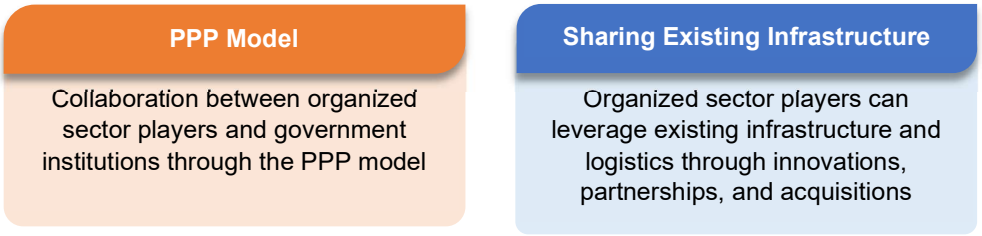
What are the regulatory implications of new technologies (mHealth/AI/Software-As-A-Medical Device) for India?

Potential Areas for Innovation and Collaboration – Preliminary Thoughts

While the Indian diagnostics industry has challenges across the **3As** as described above, the industry, government, academic institutions etc. have been working together to address these challenges to unlock the sector's long-term growth. It is the close-knit "collaboration" and innovation" by various industry stakeholders that would drive solutions for the industry.

The following is a preliminary list of a few high-impact measures which can help propel the growth of the sector to the next level and thereby address the challenges through the **3As:**

- **Innovative Strategies for expansion**



1. **PPP Model:** Leading organised sector players could focus on collaborating with government institutions (hospitals, medical colleges, etc.) on the PPP model –. to increase their coverage of Tier 2 and below centres. The prime benefits of such PPP models include quicker penetration of the structured, organized players and therefore access to quality diagnostics services in remote locations. This would further leverage the increased healthcare coverage already available to semi-rural / rural areas through Ayushman Bharat.

2. **Innovations to "Share" Existing Infrastructure and Logistics to lower overall costs and increase the penetration of Specialised Testing:** The Organised sector players could focus on driving better utilisation of existing infrastructure as well as logistics cost to make available Specialized Testing outside of Tier 1 and 2 centers. This could include partnerships with the smaller players, or acquisitions. This would not only increase their penetration into tier-3 areas and below, but also for the end consumer, the price per test, the efficiency, the basket of test offerings and the quality would increase – thereby touching upon all the **3As** of challenges.

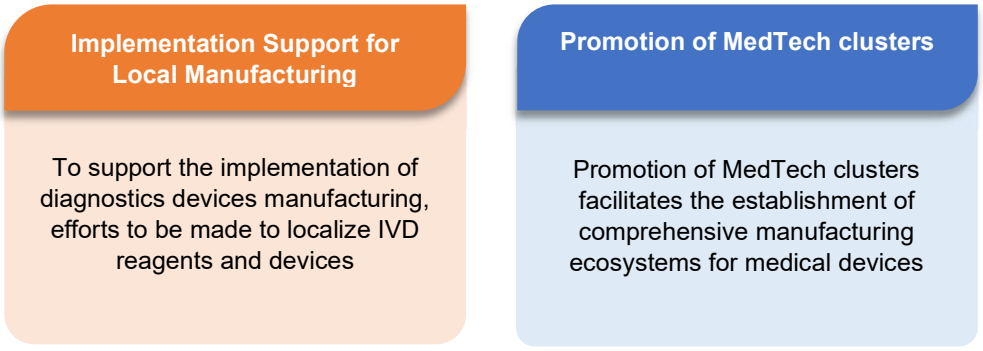
- **Industry-wide standardization**

1. **Clinical Establishments Act:** Adoption of this central government act by all states with a grace period agreed in consultation with the industry stakeholders would help in establishing improved standards. End objective should be harmonization of Indian standards with the global standards.

2. **Focused implementation of quality accreditation standards:** Accreditation through NABL / QAI / others could be made mandatory or implemented in a more focused manner for all diagnostic laboratories at a state-level, with a grace period worked out with the industry stakeholders. This will ensure that the best-practices in Laboratory operations (testing stage, pre-analytical stage, analytical stage and reporting stage) are practiced. Accreditation would also ensure that such labs get an enhanced brand perception and trust-factor among the patients, leading to more walk-ins and partnership opportunities viz. with the local hospital and the corporates.

3. **Skill development:** Establishing more institutions offering courses (both long term and short-term courses) in Radiology and Pathology would negate the gross shortage of skilled doctors and match the magnitude of labs across the country. Also, at the lower skills level for technicians and attendants, basic country-wide standards in terms of qualifications can be established prior this set of workforce joining the sector. Both these measures would lead to an improvement in supply of talent of diagnostics labs professionals across the country.

- **Local manufacturing of Diagnostic Equipment and Reagents**



1. **Implementation support for the diagnostics devices manufacturing:** While government has rolled out the PLI scheme for Medical Devices (CT scan, MRI, Ultrasonography, etc.) with an outlay of **~INR. 3,400 Crores**. A focused effort on

localising IVD reagents and IVD devices also needs to be made, with a focus on specific raw materials for reagents etc.

2. **Promotion of MedTech Clusters:** Dedicated clusters for manufacturing of medical devices would help set up the entire ecosystem of manufacturing for the medical devices in specific clusters across different parts of the country. The National Medical Devices Policy, 2023 announcing the promotion of such MedTech Clusters is a step in the right direction.

Leveraging Technology: A Critical Enabler for a Modernised Diagnostics Industry

Technology adoption across the diagnostics value chain can drive quality, process efficiencies, and offer convenience to both the lab professionals and the patients.

The key National / Regional chain labs in India are well-equipped in terms of their "digital operations" – their infrastructure (comprising the reference labs / satellite labs / collection centres etc.) are networked and seamlessly share data. Their workflows across sample collection, pre-analytical and post analytical / reporting etc. are highly digitised and automated to a large extent.

In the second rung of labs the penetration of digital technologies is lower; however, many of these labs operate with some type of a LIMS software (actual usage in daily operations will vary across these labs). However, many of the standalone labs in the unorganised sector need to undertake major initiatives in technology to raise their overall quality and efficiency.

Faster adoption of technologies can drive improvements in the following areas:

- Faster and more efficient diagnoses
- Remote diagnostics
- Data-driven insights and predictive analytics

The following table provides an overview of various technologies, their areas of impact and the potential scale of adoption from an Indian Diagnostics context:

Solution Type	Digital Solution	Impact	Penetration Among Organized Players
Diagnosis Technologies	**AI in Medical Imaging**	Medical image analysis through AI would help in reducing errors while detecting the accurate spot of treatment, lowering TAT	**Low,** *the technology is new and hence low adoption rate*
	Smart wearables for real-time diagnostics	AI-driven Smart wearables capture real time data and transmit it to an interface where the doctors/ patients can get access, thereby enabling quicker identification of risky-health parameters and initiate action	**High,** *these products have penetrated well in the major cities, tier-2 and below regions are the next growth drivers*
	Predictive Genomics	Predictive genomics technologies based on Indian genetic databases will help identify potential diseases at and disease-pattern identification at the local demographics level through aggregation of genetic data	**Low,** *these tests are only adopted by large, organized players, thereby have a very low penetration currently*

Service Delivery Enhancement	**Pathology Workflow Automation**	Sample labelling, sample's workflow decision automation by integrating the sample identity with the LIMS, thereby positively impacting the pre-analytical and the analytical throughput, and also aiding in end-to-end sample traceability	**High,** *well adopted by major players*
	Omni-channel diagnostics services platform	App-based tests scheduling, location independent testing and digital reports delivery, aiding in accessing any lab of a given chain driving convenience to the patients	**Medium,** *while in-app services are available omni-channel service delivery is yet to be adopted by majority of the chains*
	Teleradiology	With low penetration of high-end radiology equipment, Teleradiology can aid in location-independent analysis of radiology test images, thereby driving access to smaller regions	**Low,** *few of the national chains have adopted, tried and tested this technology to full-scale*
	Digital Pathology	Using computer-based technology, digital pathology utilizes virtual microscopy to analyze digitized specimen slides, enabling remote diagnostics	**Low,** *few of the national chains have adopted, tried and tested this technology to full-scale*
	Point of Care Technology (PoCT) Devices	PoCT devices can be used for in-clinic diagnosis and faster detection of unusual health parameters, thereby aiding in quick patient care	**Low,** *PoCT devices are yet to penetrate into major hospitals and well-known clinics*
Optimizing Healthcare delivery	**Big Data and Analytics of patient data at a Hospital/Chain labs/Aggregated level**	With a large set of patient data, patterns of disease incidences at a local demographics level can be predicted, and accordingly diagnostics offerings can be tuned to suit the local needs	**Low,** *the adoption rate by the national chains is yet to take off*

Further penetration of the digital solutions customised for the diagnostics sector can be developed through partnerships with the local, strong Indian IT ecosystem and software companies, thereby potentially enabling faster adoption and further innovation.

Government Initiatives for the Diagnostics Sector

While there are several initiatives that have been outlined earlier to address the **3As** earlier, the government has actively proposed a key set of initiatives that would be implemented in the near-term thereby further benefiting the diagnostics sector. Some of these are as below:

- Towards the end of 2025, more than 134 types of diagnostic tests will be offered for free at the district level under the flagship PM Ayushman Bharat Health Infrastructure Mission by 2025
- The healthcare mission was announced in Budget 2021-22 – with an outlay of Rs 64,180 crore. According to the plan rolled out by the Ministry of Health, 14 tests will be made available at sub-health centers; 63 tests at the primary health centers; 97 tests at the community health center and 134 tests will be available at the district hospital level; Integrated public health labs will be set up in all 730 districts
- At the state level, five regional branches and 20 Metropolitan units of National Centre for Disease Control. At the national level, Integrated Health Information Platform (IHIP) will be established,
- At the district level, 17,788 New Rural Health and Wellness Centers will be set up; 11,024 New Urban Health and Wellness Centers will be set up; critical care Hospital Blocks will be established in 602 districts, with population of more than 5 lakh.
- At the district level, strengthening of the existing 80 Viral Diagnostics and Research Labs will be undertaken. At the state level, 15 New Bio -Safety Level III laboratories will be operationalized. At the national level, four new Regional National Institutes for Virology will be operationalized; and the Regional Research Platform (Digital) for WHO Southeast Asia region will also be set up.
- The Indian Council of Medical Research (ICMR) has joined hands with IITs to set up centers of excellence for strategic Make in India product development and their commercialization in the medical device and diagnostics sector

The objective of these initiatives is to develop “more for less for more” to ensure wider product outreach with a mandate to promote ‘Global Affordable Need-Driven Healthcare Innovation’ (GANDHI). This is expected to have significant impact on improving access to affordable quality healthcare, particularly for middle and lower-income segments of India, thereby also having a positive implication for the diagnostics sector.

Learnings from Role Models in Global Diagnostics Industry

Ireland and Singapore are two examples of global leaders in the MedTech space which can provide a vision and roadmap for development of the Indian Diagnostics industry. These countries have developed their industry with distinct approaches and specific levers as outlined below:

Factors	Ireland	Singapore
Key Growth Theme	***Cluster-based growth***	***R&D and Technology-driven growth***
Talent Availability	• With about ~300 companies in the MedTech space, Ireland has a strong supply of talent with ~40,000 people part of the sector. • Also, industry-academia alignment with institutions offering specialized courses on Medical Technology (University of Galway, for example)	• Already a MedTech hub for the ASEAN region, wide talent available and consistent by the government to upskill talent with initiatives such as SkillsFuture. • Government support to (budget - $100 Million) to support companies' upscaling and skills training.
Government Policy	• Policies toward establishing and encouraging MedTech clusters across the country, with the value-chain companies, institutions, government bodies, etc. all in proximity to each other. • Low Tax rate – 12.5% for companies earning revenues less than USD 750 Mn	• Strong focus on regulations and implementation with all medical devices regulated – Class A to Class D, and standardized globally and aligned with Global Harmonization Task Force (GHTF)
Research and Development	• Encouragement towards R&D driven by close Industry-Academia • interaction with Feasibility and research grants, plus a tax credit of 25% for R&D activity	• With Top Universities, known for R&D with global R&D labs for ~25 MedTech MNCs • Ranked 2nd among Asian economies in Global Innovation Index (2022)

Thus, the pathways adopted by these countries provide various pointers for India:

- Cluster-based approach for Medical Devices Manufacturing with easy access to academia and government agencies
- Focus on R&D and Skill Development
- Stable regulatory norms followed by nationwide implementation
- Quality Standards in alignment with global norms

Conclusion

While the diagnostics industry is poised for strong future growth driven by underlying demand drivers, but this growth is sustainable only if the key stakeholders i.e., industry players, government bodies and academic institutions collaborate to implement the right set of levers around – regulations, focus on innovation, localization of value chain and adherence to global quality standards.

While there are challenges in this regard, this whitepaper highlights a set of initiatives which can be debated as part of the panel discussions during the seminar. Implementing these will require “Innovation” and “Collaboration” across key stakeholders. These initiatives together can propel the growth of the Indian diagnostics industry, along with creating awareness on various digital solutions that can take the industry to the next level.

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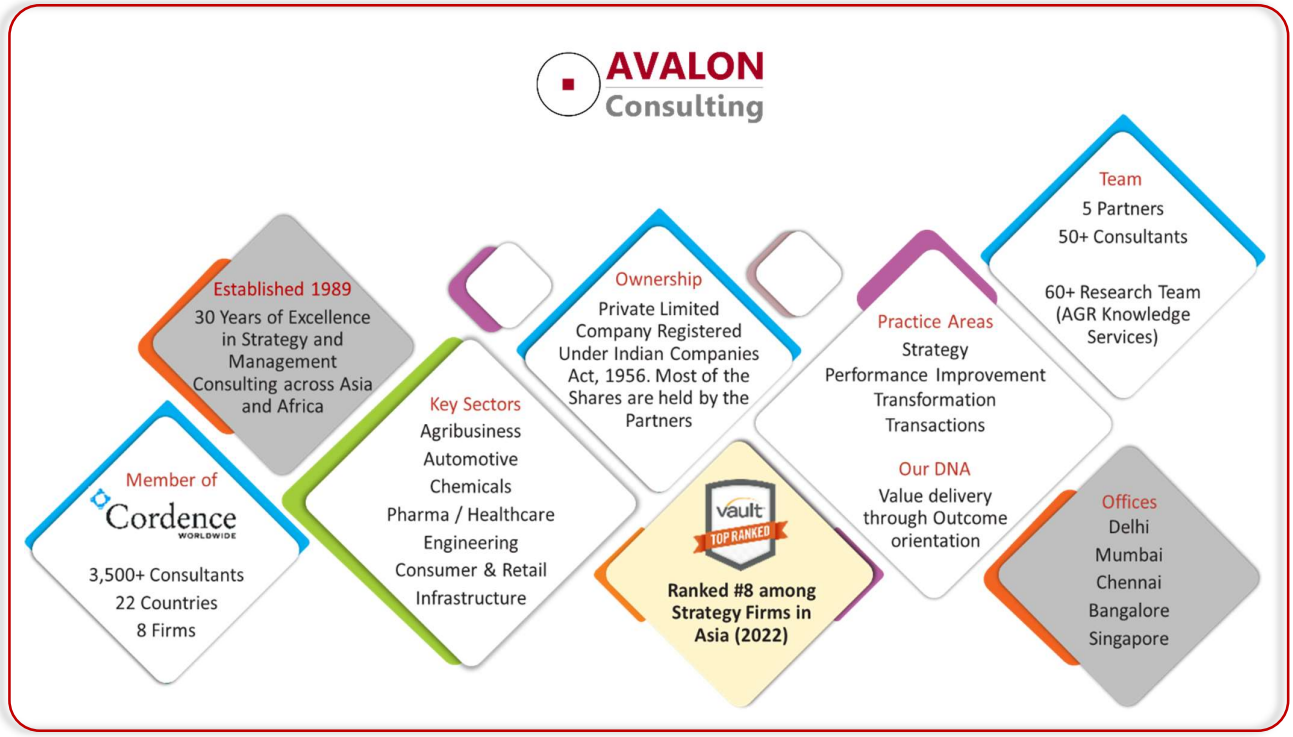

CONTACT

Dr. Ravi Gaur, Webinar Chair (Assocham),
Partner & Director,
UniDRG Specialty Laboratory, Founder DRG Path Labs,
drgaur61@gmail.com
+91 98109 98405

Abhimanyu Roy
Executive Director
Avalon Consulting
abhimanyu.roy@consultavalon.com
+91 98104 55670

Deepak Sharma
Deputy Director
National Council of Medical Devices & Diagnostic
ASSOCHAM
deepak.sharma@assocham.com
+91 95993 60096

Seema Naqvy
Assistant Director
National Council of Medical Devices & Diagnostic
ASSOCHAM
seema.naqvy@assocham.com
+91 72909 21110