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Embracing Innovation, Driving Growth Across Healthcare Continuum - "Making in India"

MEDCON 2017

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March 2017

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ACKNOWLEDGEMENT

It gives me immense pleasure to note that ASSOCHAM is organizing 2nd MEDCON-2017 on Pharmaceuticals, Medical Devices, Diagnostics, & Machinery

ASSOCHAM strongly believes that it is important to strike the balance in population's ability to pay with their desire for access to modern care and technology. This requires innovation at all levels i.e. Pharmaceutical through product development business models, systems or services, Medical Devices through material/cost/selection based innovations, Diagnostics through improving the link between clinical needs and development of new tests, Machinery through adherence to global standards and packaging for avoiding counterfeiting and Financing through increasing public health expenditure and awareness on health insurance for minimizing out of pocket expenses.

2nd MEDCON-2017 aims to understand the emerging trends & latest innovations in Pharmaceutical, Medical Devices, Diagnostics & healthcare including new drug discovery, boosting domestic manufacturing of medical devices including diagnostic equipment, surgical equipment and others in line with the "Make in India" campaign as well as to understand the 360 degrees of healthcare delivery i.e. from lab to patients and devise methods to improve healthcare delivery in India. In this context, it is important that I extend my heartiest thanks to Department of Pharmaceuticals, Government of India for supporting this Congress. I also extend my thanks to CSIR and ICMR for their support in this Congress. I also thank our Knowledge Partner Sathguru for its wonderful efforts in putting up this Knowledge Report.

Lastly, I also appreciate the efforts of Mr. Sandeep Kochhar, Mr. Anuj Mathur, Ms. Payal Swami and, Mr. Anshul Gupta for organizing this Congress.

I not only wish the Congress a great success but also assume that ASSOCHAM shall continue to organize such programs for larger public benefits with great degree of excellence.

(D.S.Rawat)
Secretary General
ASSOCHAM

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Executive Summary

Healthcare in India is undergoing transformation across the continuum. Technology is redefining possibilities in healthcare delivery and expanding global industry leadership of biotech and pharma while seeking elusive solutions for sustainably addressing India's needs. Devices and diagnostics are moving into an era of growth driven by unmet clinical needs and greater focus on domestic manufacturing. While there is robust growth across segments, challenges abound and call for attention from both policymakers and industry to sustain the momentum across segments.

Innovation is a common catalyst across the segments for driving growth, increasing value creation, creating sustainable competitive advantage and expanding Making-in-India. In this White Paper, we highlight key innovation trends across healthcare continuum with particular emphasis on the Indian landscape and means to foster greater engagement in manufacturing. With National Health Policy 2017 recently being approved by the Cabinet, healthcare expenditure intended to be increased to 2.5% of GDP and India embarking on a planned approach to bridging the healthcare divide while maintaining industry competitiveness, timing is optimal for this discussion.

Pharmaceuticals – Embracing Innovation to Zoom beyond Current $36Bn

The Indian pharmaceutical industry is a strong incumbent manufacturing success story with significant global leadership in generic formulations and close to $15Bn of exports. Historical industry growth has been largely driven by volumes but future avenues for expanding market footprint and progressing in the value chain entail high focus on innovation adoption. Leading pharmaceutical companies are graduating from substitutable generics and foraying into specialty pharma and complex generics that provide higher pricing and margins in regulated markets and greater competitive advantage in out-of-pocket markets such as India. Additionally, there is selective engagement by the industry in novel drug discovery and development and India-innovated molecules are now a reality. In the drug discovery and development segment, we note increasing use of bioinformatic tools and predictive in-silico modeling. While Indian industry has limited engagement in discovery and development, CROs continue to enjoy notable presence and have embraced this innovation trend. On a relative plane, innovation in manufacturing lags behind and calls for near term attention, especially given the looming quality concerns.

Medical Devices – Innovation Adoption for Expanded Clinical Possibilities

India is at the verge of a tectonic shift and innovation will be a key driver of change in addition to market and regulatory aspects. Prominent innovation trends in the segment include emerging use of 3D printing in medical applications across product development and commercial manufacturing, increasing pursuit of drug device combinations for life cycle management and competitive advantage, innovations in biomaterials expanding possibilities, pervasive use of robotics, artificial intelligence and machine learning for developing smart devices, and leveraging Internet of Things (IoT) to progress towards a more connected continuum of care.

We note a robust and vibrant startup innovation landscape with several ventures focusing on technologically sophisticated yet contextually relevant innovation. Early stage non-dilutive funding has stimulated the startup ecosystem and institutional pipeline has been nurtured as well. At the industry end, there is significant appetite to absorb new technologies, progress in the value chain and build competitive product portfolios. While role models are now emerging, several structural elements across policy, regulatory and markets continue to be deterrents for significant investment in the sector by both Indian companies and multinationals. We believe this segment holds potential for expanding manufacturing but draw attention of all stakeholders to the challenges emphasized in the last section of this White Paper.

Innovations in Diagnostics – Expanding Access and Empowering Clinicians & Consumers

Diagnostics as a segment has witnessed robust growth driven by expansion in overall healthcare delivery, increased use of diagnostics and better healthcare access. We expect 15-20% growth to continue and the segment becoming more receptive to widespread adoption of innovation advancements. In diagnostics delivery, notable trends include greater emphasis on consumer convenience, increase in home collection of samples, digitization of reports and continuing pursuit of PPPs as a means to bridge the infrastructure gap. New frontiers in product innovation include genomics, less invasive testing approaches such as liquid biopsies, and more sensitive and multiplexed Point-of-Care tests across primary care, critical care and home use products. While the innovation landscape in India is very encouraging, widespread adoption challenges need to be addressed to realize the value of the country's innovation pipeline.

Healthcare delivery – Technology Led Transformation and Inclusive Growth

Healthcare delivery comprises about 65% of the Indian healthcare market and reflects growth rates north of 20%. Despite the robust growth, there are significant unmet needs and inefficiencies across the spectrum and glaring inequities in access to healthcare. These challenges have inspired quintessential innovations that can balance cost and quality. We note an active landscape of innovation in delivery models with involvement of public and private sector, and proliferation of startups pursuing technology led solutions in healthcare delivery. Innovations in healthcare delivery are driving patient convenience, increasing efficiency and expanding healthcare access.

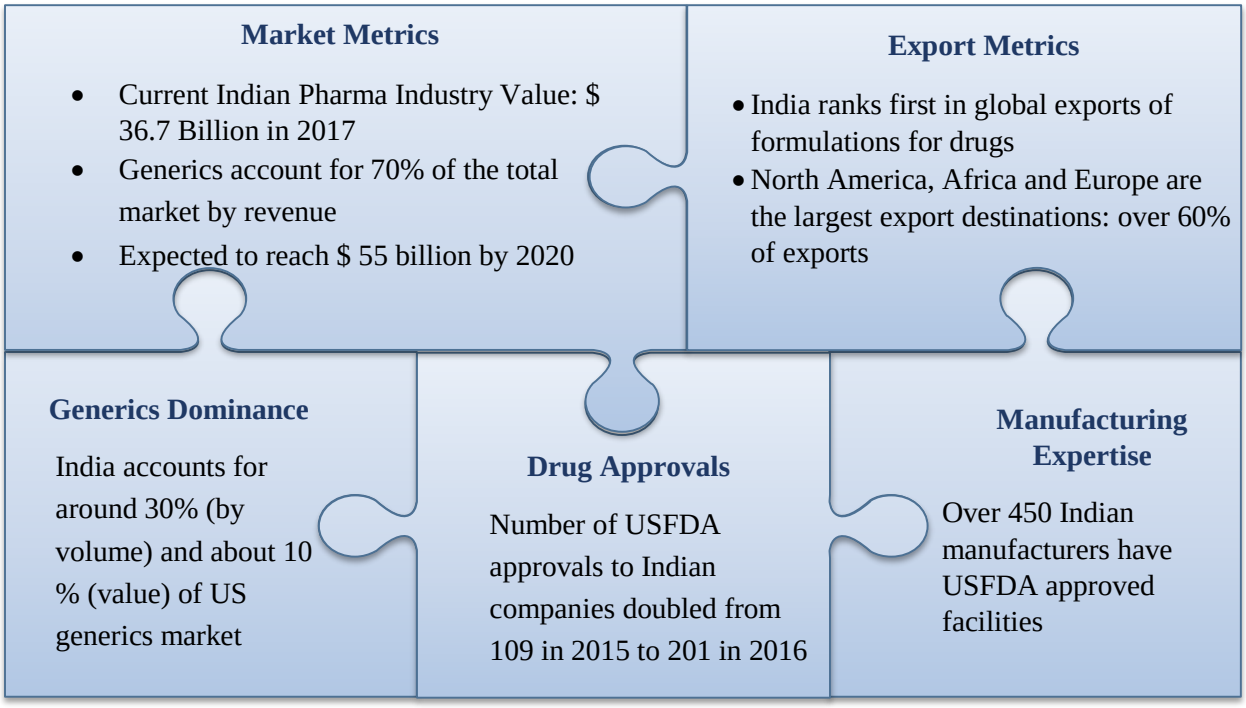
Marching towards Make-in-India – Way Forward and Recommendations

Biotech and pharma are successful incumbent Make-in-India segments and devices and diagnostics segments hold potential to expand local manufacturing by at least five fold if an enabling environment is created. In the pharmaceutical segment, we need to urgently trigger adoption of sustainable solutions to address the current quality considerations plaguing industry's continued competitiveness. Additionally, we need to create a rewarding ecosystem where manufacture of API for domestic markets can be incentivized and the dependency on Chinese imports can end. Devices and diagnostics, on the other end, represent a segment with extreme dependency on imports and call for structural changes to nurture an attractive environment for both Indian companies and multinationals to engage in manufacturing domestically.

Pharmaceuticals

Embracing Innovation to Zoom Beyond Current $36 Billion

The Indian pharmaceutical industry stands tall as one of the few high value industries, where we have cracked the code and actualized a "Make-in-India" success story. India prides itself on a strong incumbent competitor landscape, with more than ten internationally competitive pharmaceutical companies boasting revenues north of $500 million. India today is undeniably a



powerhouse for global pharma, with formulation development, supply reliability and credibility and high volume manufacturing capacity as the key strengths. The above figure depicts some key metrics[1] of the Indian pharma industry.

While we applaud the threshold of success, it is pertinent to note that Indian pharma's focus has traditionally been relatively more centered on volume than value; and investments in higher value product innovation are more recent. Many lessons learnt from within the industry has time and again proven that volume-centric success is unsustainable and the constant quest for higher value realization is necessary to maintain and expand industry's current global footprint. , the best example being India losing out on competitiveness in API manufacturing for domestic supply to China, a low cost competitor that currently supplies 85% of bulk drug requirement. The year 2008 marked the first time when India's formulation exports to regulated markets surpassed that of API exports.

[1] Pharmaceuticals Export Promotion Council (PHARMEXCIL)

Acknowledging innovation as a key ingredient for sustained success, the Indian pharma industry is now gradually enhancing level of innovation being pursued and moving up the value chain to achieve next level of competitiveness in the global arena.

Innovation in Drug Discovery and Development

Because the industry appetite for indigenous novel drug discovery and development is relatively low, Indian Contract Research Organizations (CROs) become an integral link in the pharma value chain. With the global mega trend of outsourcing catching up quickly in the pharma industry, the Indian market teems with pharmaceutical CROs. Two major factors drive innovation adoption in drug discovery and development.

- **Skyrocketing Development Costs:** With the global drug development costs inching upwards of $ 2.6 billion[2] the focus on cost efficiency in drug development has never been higher. Thus, de-risking drug discovery and development is essential and there is elevated market demand for high precision in-silico predictive modeling that could minimize number of molecules that is taken forward to in-vitro testing, thereby minimizing cost of development. Predictive mathematical and statistical modeling is also increasingly being used for Design of Experiments (DOE), in order to minimize clinical trial costs by optimizing number of patients and timeframes to minimize costs.
- **Improved Drug Profiles:** Nearly nine out of ten drugs fail in clinical trials for lack of efficacy and toxicity[3]. Thus the emphasis on advanced in-silico models that can better study protein interactions for better toxicology outcomes is also high.
- **Pursuit of Complex Challenges:** Additionally, with industry maturity, there is active pursuit of finding intelligent solutions to complex healthcare challenges for better outcomes. Companies are increasingly on the look-out for cost effective solutions that maximize the probability of success. Stepping into the era of precision medicine, genomic tools are increasingly gaining importance in drug discovery and development.

Increasing Engagement in In-Silico Platforms across Drug Discovery & Development Continuum: Advancements and possibilities in bioinformatics is gradually expanding to provide the necessary data tools to address the above mentioned lofty challenges in drug development. The

Ligand Explorer™ —a Drug centric structure based platform

- An in-silico platform that uses protein-drug interactions to predict side effect profile of drugs
- Utilizes a unique repository of biologically relevant structural proteomics information across the human and mouse proteomes and identifies a drug-specific set of proteins representing problematic "off-target" protein-drug interactions
- Allows better optimization of pre-clinical candidates eventually resulting in better drug approval rates at lower costs

[2]Tufts Center for the Study of Drug Development, 2014
[3] Clinical Development Success Rates 2006-2015 BIO Industry Analysis. June 2016)

field of in-silico platforms have evolved to great lengths in the past decade to the extent of becoming a part of standard work flow. The level of efficiency it brings into processes and the possibilities it opens are infinite. Ligand Explorer™, by Canadian firm Cyclica is an example of a state of the art in-silico platform for support in drug discovery and development.

As innovation absorption in India grows, domestic ventures with products and service models are quickly evolving to cater to the needs of the Indian CRO industry. Drug repurposing is another area that is gaining interest as an approach to build knowledge on long-established old drugs, existing compounds, and even failed candidates to find solutions for newer indications and in-silico modeling plays a crucial role in enhancing possibilities in this space. For a country like India which has established competency in generics, repurposed drugs present a good near term opportunity to capitalize upon and there are indigenous efforts in this area. For instance, Excelera, a leading Indian informatics company has a specialized platform called GRIP-Global Repurposing Integrated Platform that identifies new indications for existing drugs through the use of data and analytics. The company has landed a considerable number of deals in the drug repurposing space, including the one with Astellas pharma signed in June last year. Another example of domestic innovation in this space are Metaome Science Informatics, and Cerenode, co-founded by ex-Jubilant professionals. Metaome's product "DistilBio" is an analytics platform that collects vast data from different sources such as laboratory data management systems, private and public databases and uses machine learning and statistical models to identify useful patterns for drug discovery.

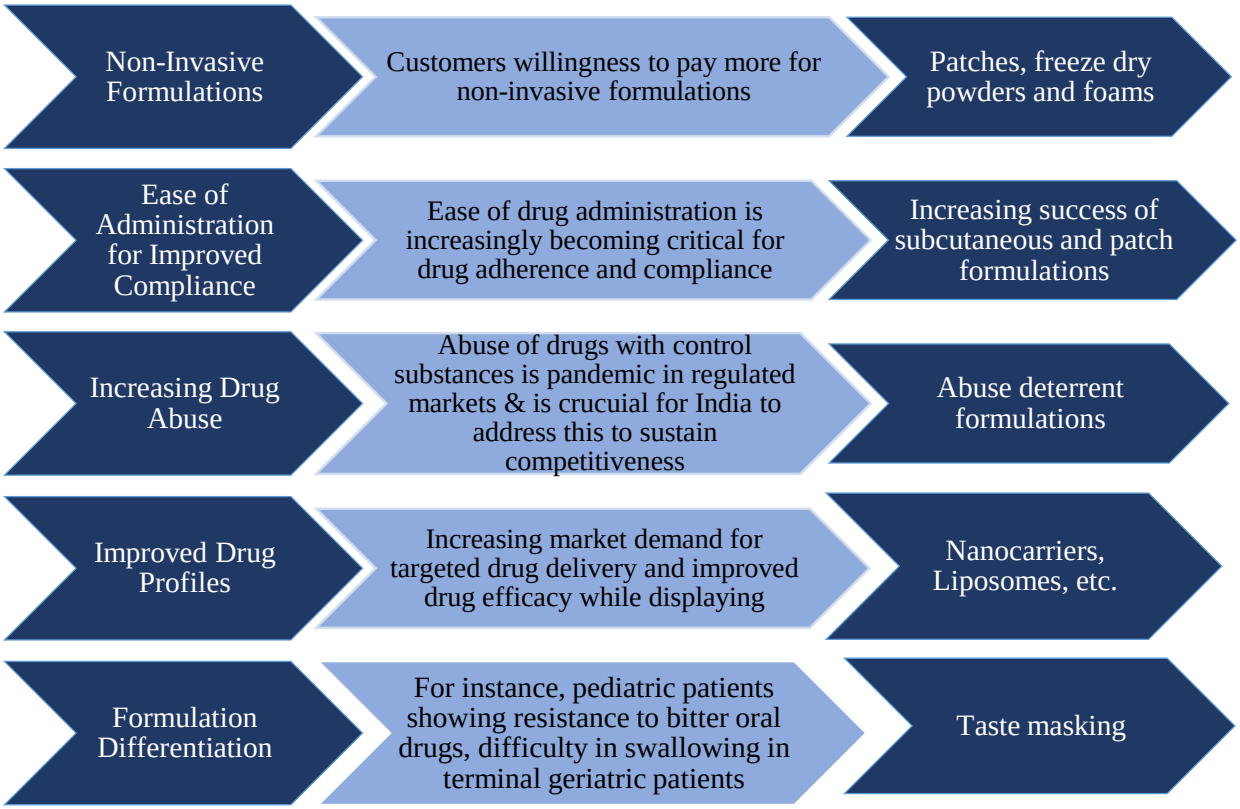
Although high industry appetite for innovation prevails in drug discovery and development, the Indian CRO industry is an amalgamation of few large players and myriad of small and medium sized enterprises. While the tech savvy larger players are better equipped to embrace innovative drug development technologies, standardized SAAS possibilities need to evolve that can enhance the reach of technology throughout the value chain.

Innovation in Drug Formulation and Delivery

Formulation strength is one of the key cornerstones of success for the Indian pharma industry. While drug discovery and development is heavily influenced by disease pathology and patient demographics, technology trends in drug formulations and delivery are largely influenced by larger patient-driven trends and target market driven strategies.

1. Nature of Formulation Innovations

Changing patient lifestyles and growing middle class affordability across the world is changing drug delivery landscape and bringing new unmet needs that provide pharma companies impetus to innovate. Some such formulation technology innovations that are derivatives of end user trends and market needs are depicted in the next image.



2. Indian Pharma Success in Formulation Differentiation

India has long established itself as the manufacturing powerhouse of generics and OTC products, and is globally the largest exporter of these products. However, the industry is at crossroads where maturing markets present some associated challenges to competitors, thereby pushing Indian manufacturers to expand their horizons. Some such roadblocks include:

- Increasing pricing pressures in generics squeezing profit margins
- Declining number of patent expiries
- Intensifying competition in OTC and other pharmacy products

It is thus clear that the industry needs a more sustainable game plan for future success and as market needs differ with geographies, the innovation strategies need to be differentiated for regulated markets and emerging markets.

Formulations for Regulated Market Supply

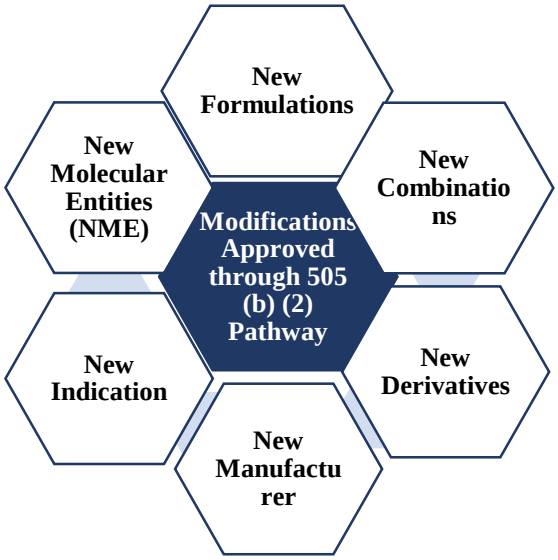
Indian manufacturers have started following a general trajectory of evolving from pure play generic drug or OTC product manufacturers into the next leg of evolution. The industry is gradually transitioning towards portfolio optimization, with many leading Indian companies focusing on strengthening foothold on specific therapeutic areas. In order to support this transition, companies are seen to turn towards building expertise in specialty pharmaceutical products and complex generics.

a. Specialty Pharma—Riding the 505 (b) (2) wave

Indian pharma companies are increasingly focusing on specialty portfolios in specific therapeutic categories and seen to be graduating beyond supplying substitutable generics to the world. This is evident from industry examples such as:

- Glenmark's targeted focus on dermatology, oncology and respiratory
- Dr Reddy's focus on Dermatology - through its US subsidiary Promius Pharma
- Lupin Pharma's focus on pediatrics - proprietary portfolio of branded drugs such as Alinia® and Locoid® Lotion

The focus on building a specialty portfolio is causing many Indian companies to pursue approvals through the abbreviated 505 (b) (2) pathway of US FDA, which allows filing NDAs for drug modifications based on bridging non-clinical/ clinical studies done for an approved reference listed drug[4].



New formulations are the most sought after category of 505 (b) (2) applications, driven by the market need for differentiated formulations such as long acting and abuse deterrent formulations

Cipla's Dymista – A 505 (b) (2) Success Story

- Cipla's Dymista (azelastine and fluticasone nasal spray) is a new anti-histamine and corticosteroid combination for allergic rhinitis that was approved in the US in May 2012 and in Europe in January 2013.
- In June 2013, Cipla partnered with Swedish firm Meda AB and granted global commercialization rights for Dymista. While Cipla became responsible for formulation, Meda was made responsible for clinical development, registration, marketing and sales in global markets.

[4] Pharmaceuticals Export Promotion Council (PHARMEXCIL)

of existing drugs. Many large manufacturers who have the wherewithal to invest and companies that have grown to specialize in specific therapeutic categories are increasingly focusing on participation in specialty pharma sector. Cipla's Dymista is a classic example of an indigenous 505 (b) (2) success story, where an Indian company not just succeeded in securing a specialty pharma approval, but also exhibited competency in successfully taking it to global markets.

b. Foraying into Complex Generics

Complex generic formulations also present itself as the next leg of evolution for Indian pharma, as the industry graduates from being a "me too" commoditized generics play. The industry is slowly making strides in this direction in order to take advantage of higher growth potential in a leaner competitive landscape. Sun Pharma's Doxil market capitalization is a classic example that depicts value realization potential of complex generics and presents a strong case as to Indian pharma needs to accelerate participation in this space.

Sun Pharma's Doxil – A Complex Generic Success Story

- Sun Pharma's US market capitalization for Doxil is a classic case where indigenous expertise in complex formulation brought high value realization for Indian pharma.
- Doxil is Janssen Pharma's proprietary oncology drug, a liposomal formulation of doxyrubicin which came under severe shortage in 2012, due to cGMP issues in manufacturing calling for public outcry and emergency declaration.
- Sun Pharma's Lipodox, a generic version of the drug was quickly allowed to be imported on a rare special case prior to its bioequivalence testing and approval, thereby opening up a large market opportunity for Sun Pharma at the same time alleviating a public health emergency.
- Although it is a one-off success scenario, it stands to prove that pursuit of complex generic formulations that has a first-mover advantage is essential in the next leg of evolution for Indian pharma.

Aside from the fact that complex generics present a high value market opportunity in regulated markets, it can also reinforce Indian contribution in addressing domestic as well as global public health concerns. There are quite a number of indications for which formulation complexity has hindered indigenous generic drug development. For instance, Visceral Leishmaniosis (kala-azar) is endemic to India and India is one of the top 3 affected countries of the world. The disease remains a high public health concern in India owing to its strong links to poverty-related factors. Owing to high toxicity of the target drug Amphotericin B, liposomal formulation of the drug is preferred and till date Ambisome from Astellas Pharma remains the only approved liposomal formulation of the drug available worldwide. This is just one example where a complex generic formulation could help address a global public health concern. Considering India's past success in breaking affordability barriers for global public health needs in vaccines and other pharma categories, complex generics could be the next big area where Indian pharma can shine.

Models for Technology Access for Specialty Pharma and Complex Generic Products

Different companies adopt different models to attain technology access for specialty pharma products, depending upon their scale, R&D strength and financial strength. Some case studies of different tech access models are discussed below:

Indigenous R&D

- **Biocon Oral Insulin**
  Biocon's oral insulin candidate Tregopil is in trials and once approved, it could mark the end of invasive everyday injections for millions of the world's diabetic population
- **Cipla's Respiratory Combination Drug**
  Cipla's Dymista (azelastine and fluticasone nasal spray) is a new anti-histamine and corticosteroid combination for allergic rhinitis was developed indigenously through 505 (b) (2) pathway and outlicensed to Meda AB for worldwide commercialization
- **SPARC's Glaucoma Formulation**
  Sun Pharma licensed Xelpros, a novel once-a-day formulation of the glaucoma medication Latanoprost, that uses Swollen Micelle Microemulsion (SMM) technology for the US market in 2015, in order to build presence in branded opthamology segment.

Partnerships & Licensing

- **Dr Reddy's Collaboration with Foamix**
  With targeted specialty pharma focus on branded dermatology segment, Dr Reddy's signed a worldwide license agreement with Israelian formulation company Foamix Ltd, for the development of novel foam based emollient for Psoriasis in 2007.
- **Lupin's Collaboration with Samyang Corporation**
  Lupin Pharma partnered with South Korean firm for development of Genexol-PM, a a PEG-poly (lactic acid) micelle formulation of paclitaxel with increased therapeutic efficacy for oncology applications.

Mergers& Acquisitions

- **Lupin’s Acquisition of Nanomi B.V**
  Lupin forayed into complex injectables through acquisition of Dutch drug delivery firm Nanomi B.V in 2014 targeting Nanomi’s formulation strength with patented technology platforms for nano and microparticle based drug delivery
- **Kemwell’s Acquisition of Cirrus Pharma**
  Kemwell acquired US based firm Cirrus Pharma in 2013, signifying the importance of formulation strength for CDMOs as well. The acquisition was targeted on strengthening Kemwell’s early stage innovative product development and although Cirrus pharma was resold by Kemwell, the example still signifies the trend in pharma companies seeking formulation strength for competitive advantage.
- **Dr Reddy's Acquisition of Octoplus**
  Dr Reddy's acquired Octoplus in 2012, with specific focus on expanding drug delivery capabilities in injectable formulations.

c. Capitalizing on Abuse Deterrence - an Emerging Formulation Trend

Abuse deterrence is an emerging formulation trend in global pharma industry, mainly for extended release as well as immediate release prescription control substances. The new FDA draft guidance set forth in March 2016, as part of FDA Opioids Action Plan, regulates generic versions of approved opioids with abuse-deterrent formulations. This guidance has spurred renewed market interest in the space. Considering the importance of US as a key export destination of Indian made pharma, Indian companies are seen to be exploring ways to increase their participation in the flourishing market opportunity for abuse deterrent prescription products.

Illustrative Example—Zydus Cadila's US Opioid Play

- Zydus Cadila's recent acquisition of US based Sentynl therapeutics for $171 million has helped it to add muscle in US opioids market.
- Sentynl currently holds the US market rights for Abstral, a unique sublingual abuse deterrent formulation of Fentanyl, relaunched for cancer pain. The product currently has no direct competition in the space.
- This acquisition also reinstates the trend of Indian pharma companies' outbound acquisition interest in developed economies, focused on manufacturing capabilities and market access.

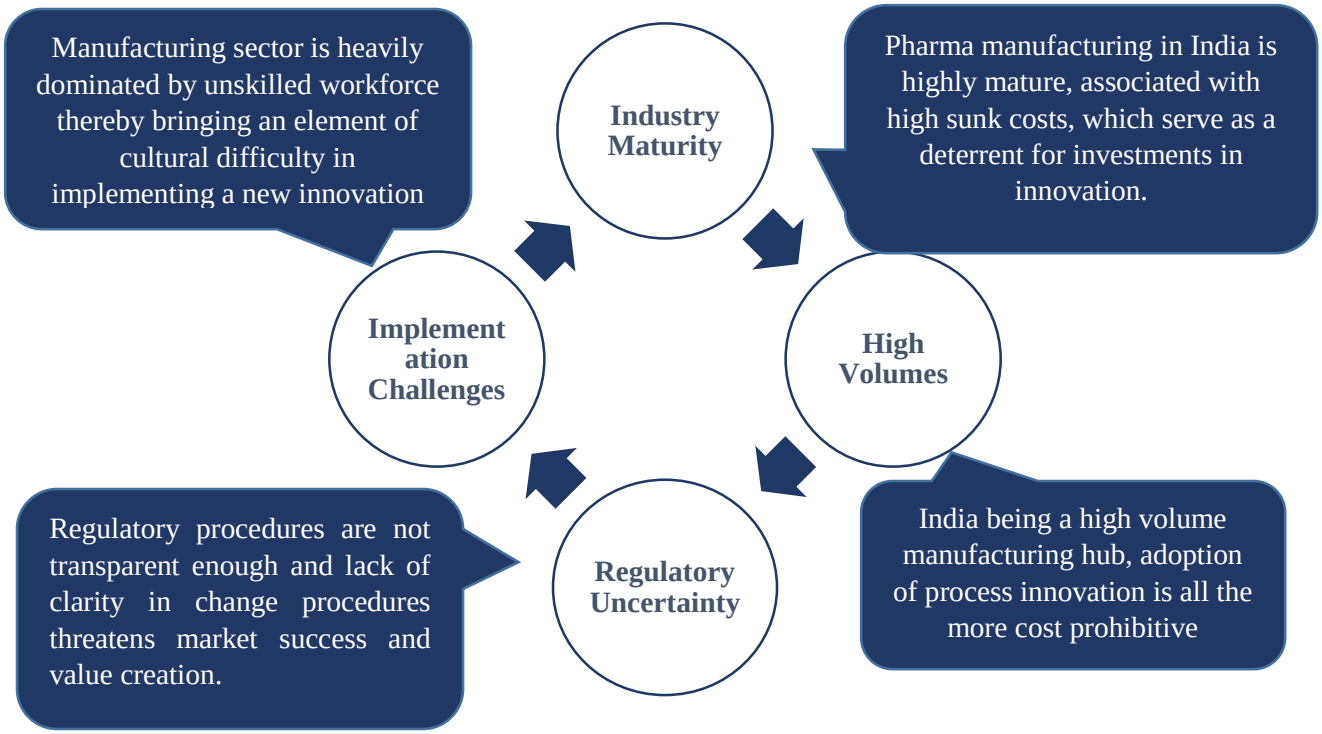
Formulations for Domestic and ROW Supply

With increasingly maturing markets in developed world, westernization of developing economies and prevalence of lifestyle related diseases, the ROW region hold immense growth potential for the pharma industry as a whole. Companies all over the world are turning towards markets such as Russia, Latin America for growth, thus rapidly making these less contested markets competitive. Resting on laurels from regulated market exports, Indian pharma manufacturers are also focusing on slowly expanding footprint in developing economies in ROW markets and replicating the success achieved in regulated markets. While Indian companies had to enter the regulated markets with a low cost substitutable generics proposition, today the industry's focus on building a differentiated specialty pharma portfolio can propel them with a competitive advantage to stage a more powerful entry into ROW markets that can enable market leadership in a near term horizon.

Formulation differentiation also equips them with the arsenal of brand power to stand out of competition in the domestic market, a fair share of which is lost to branded generics from multinationals. Although the recent regulatory scrutiny and negative market attention of fixed dose combinations (FDCs) and price control could be deterrents in success of specialty pharma products in domestic markets, we do not perceive it to be a significant roadblock in clinically utilitarian and beneficial formulations with a public health impact.

Innovation in Pharmaceutical Manufacturing

Being an economical manufacturing destination with lower cost of operations has been a significant contributor for the Indian pharma "Make-in-India" success streak. Thus, even as the other segments of the industry is moving towards differentiation and next leg of progress, the manufacturing sector is heavily lagging behind. Several factors contribute to a poor innovation ecosystem in pharma manufacturing:



Among the challenges highlighted above, industry maturity and regulatory uncertainty rank high in impact. Although willingness to invest in more advanced manufacturing infrastructure in new facilities is adequately high in the industry, pumping investments towards innovation in existing facilities remain cost prohibitive. Regulatory uncertainty is a larger debate where the fear of high amount of sunk cost and delays in market access is weighing heavily on the industry over cost savings and process efficiency that could be brought on by a new innovation. This puts a significant damper on the innovation spirit of the industry and calls for a concerted effort from the industry and regulatory authorities to overcome this challenge.

While such unique challenges plague the manufacturing sector, some driving forces do exist triggering innovative practices. The Indian pharma manufacturing can clearly be delineated into manufacturing of formulations, bulk drugs and pharmaceutical intermediates and the innovation appetite is currently highest in formulations mainly because technologies and necessary machinery

and infrastructure are available. Some of the areas of innovation seen in Indian pharma manufacturing include.

Better Process Efficiency

High volume manufacturing drives a need for continuous process optimization for better efficiency which can in turn result in better profitability. The industry is seen to be taking first steps towards continuous manufacturing, with the aim of reducing process time and also reduce human intervention. The Indian industry is also making significant inroads in improving downstream processing and purification technologies, especially in emerging areas of peptides and biologics where the need to improve yields have a significant role to play in market economics and profitability. The shift from reusable stainless steel bioprocess systems to single use systems is also a fast-emerging global mega trend in pharma manufacturing. Although India is slow to adopt in existing facilities because of high sunk costs, with increasing in-flux of in licensing technology partnerships, we see good potential for emergence of hybrid plants driven by the desire to minimize process changes.

Improved Quality Control

Quality control in manufacturing has recently been extensively criticized with increasing number of FDA warning letters issued to Indian facilities. Process Analytical Technologies (PAT) and automation are becoming a buzz word and companies are opening to embrace innovation. In-line PAT control solutions allows for continuous measurement of critical process parameters (CPPs) that affect critical quality attributes (CQAs), thereby resulting in better end-to-end quality control. The fact that such technologies are available in the western world is expected to make the transition easier within Indian pharma. While electronic lab notebooks are extensively implemented already in drug discovery and development, the adoption is currently nascent in manufacturing, but we perceive higher adoption in the next 5 years driven by intensifying regulatory scrutiny. The desire for improved yields is also propelling the industry towards automation as sometimes processes could be better standardized when manual intervention is low.

Sustainability and Green Excellence

As Indian companies continue to position themselves as partners to the western world, the effects of the quickly progressing global green movement is increasingly being felt in the Indian market as well, mainly with respect to greener methods of effluent management. There is also government and regulatory push in this direction, with more stringent inspections and efforts such as implementation of Common Effluent Treatment Plants (CETPs) by the Ministry of Environment, Forest and Climate Change, Government of India ("MoEF").

Packaging

Packaging is one area where Indian companies are quickly gaining traction, actively embracing innovative technologies in order to stay globally competitive. High innovation appetite in this

sector is also largely driven by increasing attribution of product recalls to issues with packaging and labeling. Serialization, track and trace functions, which were not long ago considered as value added services has today become an industry mandate. Automation is a tangible trend here, with companies moving towards robotized packaging to minimize manual interference.

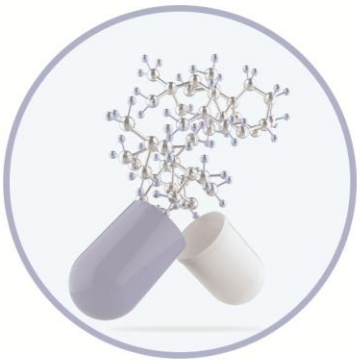
With good amount of innovation absorption of global technologies in the fill-finish sector, we observe two visible trends within the pharma allied industry–

- An increased focus of global strategic investors in the Indian market for allied pharma sectors
- A gradual trend of consolidation in the sector.

Both these trends bode well for the innovation spirit of the sector and as companies continue to grow, we expect them to slowly step into high value growth innovation-driven, IP-led growth areas such as child-resistant packaging and emerge as IP creators for design in the next 5-10 year horizon.

Medical Devices

Innovation Adoption for Expanded Clinical Possibilities & Making-in-India



Medical device sector represents 9% of the overall Indian healthcare industry[5]. Indian medical device market is the 4th largest in Asia and under top 20 in the world. It was valued at $4.2 Billion in 2014 and is growing at a CAGR of 16% over the period of five years[6]. There are several contributing growth factors such as high volume demand, epidemiological transition, growing GDP; and government efforts such as Make-in-India, 100% FDI, medical parks and shared infrastructure facilities buoyed by modest private sector investment.

The industry is at the cusp of a major transitionary phase. The highly import dependent industry (more than 70% by value) has gained significant attention for the potential it holds to contribute to 'Making in India'. Contrastingly, there are about 800 medical device manufacturers in India, but hardly 10% generate a turnover in excess of Rs.600 Million, creating a wide stratification in indigenous manufacturing landscape. Most indigenous manufacturers have historically focused on consumables and disposables.

The current shift reflects Indian companies moving up the value chain steadily. They are building competitiveness through indigenous innovation, absorption of acquiring synergistic and sophisticated technologies from global sources and strategic partnerships. On the other end, MNC's are now seeking to grow beyond the high end of the market and establish presence in the low value segment. They are exploring possibilities such as setting up their own facility (3M in Pune, Becton Dickinson in Haryana), acquiring local manufacturers (Philips Medical System's acquisition of Alpha X-Ray Technologies), developing cost efficient solutions relevant to the Indian context (GE's low cost warmer) and even introducing products from Chinese acquisitions in India (Orthopedic devices – Stryker and Medtronic).

However, the segment still struggles with fundamental problems such as an inverted duty structure that often favors importers over manufacturers and slow regulatory reform. Public health procurement channels for innovative devices have also been underdeveloped and call for attention.

Despite the above challenges, devices represent the segment where greater change is expected in the next five to ten years. We discuss below pervasive innovation trends observed across segments of devices and glimpses from the evolving the Indian landscape.

Pervasive Innovation Trends across Device Categories

1. Drug Device Combinations – The Convergent Opportunity

Drug device combinations offer attractive growth opportunity for both drug and device companies. Device innovation is emerging as preferred lifecycle management strategy and source of competitive advantage for several drugs. There has been an unmet need for novel drug delivery mechanisms to improve medication adherence, drug absorption including less frequent dosing,

[5] IBEF Healthcare Report 2017
[6] FICCI and Quintiles IMS reports

extended-release formulations, easy administration and targeted delivery and device innovation has helped address some of these priorities. Self-injecting insulin pens are a pertinent example of drug companies leveraging device innovation. The recent Epipen pricing controversy in the US also highlights how proprietary devices have been used tactically for competitive advantage by drug companies even in the case of highly established drugs. At the other end, integration of drugs for various objectives has allowed device companies also to provide more clinically attractive solutions and seek growth opportunities. One of the older examples would be the case of drug eluting stents that now dominate markets globally. We have outlined below some of the popular areas of innovation for drug device combinations:

a. Vascular: drug-eluting stents, coated vascular prostheses

High incidence of cardiac ailments, coronary artery disease in particular, has paved way for minimally invasive solutions offered by drug-eluting stents. They combine the polymer and drug to achieve coronary revascularization and at the same time deliver anti-proliferative drug at the target.

b. Drug delivery: transdermal patches, inhalers, drug pumps

In India, drug pumps, insulin in particular, has seen an unprecedented demand, owing to 65 million diabetic patients. Insulin pumps have been in use for a considerable time, but the new pumps are being designed to be smarter, smaller and programmable, to detect insulin level and systemically release it. While insulin pumps are wearable, implantable pumps for direct CNS delivery are also being developed.

Simultaneously, innovations in nanotechnology has enabled targeted drug delivery reducing off-target toxicity and dosage quantity. Antibody-based delivery and similar technologies in particular will make delivery of large molecule drugs easy and convenient.

c. Orthopedic: Bone implants/cements

The new generation of bone implants are not only bio absorbable but also contain pellets of antibiotic drugs to be delivered at the site of the morbidity. Recent FDA approvals and clearer regulations have escalated the development of combination products and consecutively research has transpired beyond USA. Combination products has seen convergence of pharma and devices industries to co-develop products. This also presents an opportunity for CDMO's in India to grow and offer novel solutions to address this unmet need.

Large pharma players have been actively involved in technology development like Sun Pharma's Levulan Kerastick for treating actinic keratosis or Dr. Reddy's Zembrace SymTouch pen to treat acute migraines.

India's strong pharma industry offers ripe collaboration opportunities for device companies to co-create value and seek growth opportunities.

2. 3D Printing – Rapid Prototyping, Lean Manufacturing and Customized Products

3D printing has seen unfettered growth and acceptance across several industries like automobiles, aircraft and gaming. It has begun to make its mark on the medical device industry as the next

generation additive manufacturing process, navigating through evolving regulatory policies. 3D printing technology has evolved substantially and can work with materials ranging from wood to plastics to polymers to metals. It has found application and is expanding possibilities across product development and commercial manufacturing:

a. **Product development** – As a Rapid prototyping method, it is being employed by researchers and manufacturers to speed up the development cycle, engage in cost effective design iterations and ultimately shorten the time to market. It has lowered barriers to entry as it is relatively easier to begin prototyping efforts with a desktop 3D printer as compared to traditional CNC machining approach with heavy equipment. This is very pertinent in the Indian context where shared infrastructure and technical expertise for design, prototyping and validation is still hard to find for ventures and academic institutions.

b. **Medical models for surgical and educational use** – 3D printing is being increasingly used globally and in India for creating medical models and educational replicas in a rapid and cost effective manner. This paves the way for more experiential educational experience and very importantly, improving surgical outcomes by providing surgeons a critical tool for to plan and prepare more effectively. Companies in India today are able to supply such medical models at an affordable price range of Rs.5,000 to Rs.20,000 thereby creating the possibility of widespread adoption. Mumbai-based company, Anatomiz 3D, helps surgeons customize solutions and plan treatments. In a recent example, Anatomiz, helped print the 3D model of tongue and tumor using thigh muscle for an oral cancer patient to remove the tumor and recreate the tongue. Similarly, Bangalore based DF3D focuses on supporting cranial maxillofacial orthopedic surgeons and can ship a model to any surgeon in India from their Bangalore location in two days.

c. **Customized implants and other devices** - 3D printing is the ideal solution for personalized prosthetics, bionics and orthotics for low volume custom production. 3D printing expands possibilities for clinical intervention in areas such as orthopedics and trauma. While this area of application is relatively nascent on the adoption curve, we anticipate progressively increasing acceptance and high innovation quotient from the clinical community over the next five to eight years. Examples of innovators in India include Ratna Nidhi Charitable Trust, a Google grant winner of $350,000, designs and manufactures 3D printed Jaipur Foot. They are currently conducting a pilot study and aim at serving 200 amputees in the near future. Orthopedic implants are the next dimension of innovation. Medanta: The Medicity successfully performed a surgery on the failing spine of a woman and inserted for the first time a 3D printed titanium implant.

d. **Tissue engineering and other applications** - An additional nonlinear innovation has been in the field of tissue engineering. Pandorum Technologies, makes 3D-engineered human tissues that can be used for testing. The manufactured tissue mimics actual human tissue,

allowing researchers to avoid testing on animals and humans. This will propel avenues for transplantable 3D organs addressing the acute shortage of human organs available for surgical transplantation.

3D printing has the potential for being cost effective- low lifecycle cost, low tooling cost; efficient- reduced material wastage, accelerated lead time and customizable- design flexibility. To truly realize the potential in device development and prototyping, India needs to urgently bridge the void with shared resource facilities that can be equipped with common infrastructure for design, rapid prototyping and validation. Given the advent of 3D printing, such common facilities are becoming more capital efficient and easier to operate. To open commercial application avenues especially in more regulated device categories such as hip and knee implants, the global regulatory landscape needs to evolve. Overall, the potential clinical impact of medical applications of 3D printing are exciting and it is crucial that India maintains the innovation momentum to pursue locally relevant solutions.

3. Biomaterials

Biomaterials have been constantly evolving from metals to polymers to ceramic to newer bio-absorbable variants and combinations involving collagen and stem cells to become more bioinert, bioactive and biodegradable. They are finding application in wound healing, orthobiologics, cardiac implants, dental implants and targeted drug delivery.

In cardiovascular space, the third generation of stents gaining popularity and adoption is bio-absorbable stents which prevents stent thrombosis, avoids alteration in vessel geometry and fracture, and additional cost of replacing/removing stents through a second surgery. The most popular product available on the market today is Abbott Vascular's Absorb™. Recently Meril launched its indigenously made bioresorbable cardiac scaffold (BVS), a naturally dissolving cardiac stent made out of biodegradable material and used for clearing blockages in arteries of the heart.

Meril Life Science

Meril, a Gujarat based company has developed bioresorbable cardiac scaffold 'MeRes100' which is biodegradable naturally dissolving stent. It has found application in coronary as well as peripheral arteries for clearing blockages. It has received approval for its coronary variant from the Health Ministry of India.

This global innovation absorption in Indian context where millions of people are suffering from heart ailments will make indigenously made cutting edge technology available to people at affordable price. This is a source of pride for India since bioresorbable stents are still considered frontier technology even in the global cardiovascular devices market.

Biomaterials have found myriad of applications in orthopedics through orthobiologics. Orthobiologics are made from substances found naturally within the body and uses biomaterials

and cell-based therapies to speed up the recovery process. They can include Bone Graft Substitutes (Autografts, Allografts, Bone Morphogenic Proteins (BMPs), Demineralized Bone Matrix (DBM)), Viscosupplements (hyaluronic acid – HA), Bone Growth Stimulators, Platelet Rich Plasma (PRP), and Bone Marrow Concentrate, Stem Cells and others.

Chronic and rapid wound healing and dermatological treatment/enhancement applications have been at the forefront pushing innovation and advancement in biomaterials. Bioactive nanoglass fibers, dermal fillers, collagen scaffolds, polylactic acid variants are some of the areas of research.

Similarly, biomaterials are finding application in dissolvable sutures, adhesives, lubricants, concentrated antibiotic delivery at the site of morbidity, dental implants, arterial prostheses, ophthalmic lenses, semipermeable membranes for dialysis, heart valves, among several others.

Material innovation is also creating and redefining new possibilities in device innovation. The most appropriate example would be MiraCradle highlighted at the end of this section. It is an innovation in Phase Change Materials (PCM) at the heart of the development of a novel CE marked neonatal cooler by Pluss, a VC funded Indian venture to address the glaring unmet need for neonatal cooling devices across India and other low and middle income countries.

Leading Indian academic institutions have been engaged in this area of research and have made notable contributions:

- National Chemistry Lab in Pune has developed several successful technologies like-polyethylene implants for reconstructive surgery of maxillofacial bones, which is commercialized by BioPore Surgicals,
- Development of novel resorbable silk-based bone graft implants, bone fixation screws and membrane based oxygen-enriched air generation system, which are licensed to start-up companies,
- Novel expandable biliary stent being developed in collaboration with a biotech start-up company.

There is potential for India to further increase the momentum of innovation engagement to encourage more India specific as well as globally relevant solutions that are backed by sophistication in material science innovation.

MiraCradle™

India accounts for great burden of neonatal deaths. Challenges in treating birth asphyxia are twofold – high price (USD 25,000 to 30,000) of current imported devices that make them inaccessible to majority of Indian health system and significant dearth of clinical capacity to perform therapeutic hypothermia treatment (THT). Currently rudimentary treatment is offered through use ice packs, which is not clinically recommended.

To address this problem Pluss Advanced Technologies (Pluss) has developed an innovative CE marked neonatal cooling device MiraCradle™, priced at 1/10th the current imported device for treating neonatal birth asphyxia. This device fills the void in neonatal cooling in low and middle income countries.

Pluss is a VC funded Indian company with expertise in materials research and manufacturing. The device expands the market of medtech device through use of innovative materials in healthcare industry to create a technical sophisticated yet affordable solution. MiraCradle™ now has more than 100+ installations in India with impeccable KOL feedback and is expanding its presence globally.

4. IoT – Breaking Down Silos and Promising Connected Care

Technology providers, technology users, information aggregators, information analysts and patients have in the past worked in silos. However, IoT is creating possibilities for a more integrated and responsive platform for the industry to work together and sharpen their efficiencies. IoT is defined as- "The Internet of Things (IoT) is a network of physical devices and other items, embedded with electronics, software, sensors, and network connectivity, which enables these objects to collect and exchange data"[7]. In addition to cost containment, IoT also allows to keep up with constant innovation and shorter product lifecycles, gather real time data for augmented intelligence, and create end-to-end communication from wearable/implantable/ingestible diagnostic tools to treatment decisions to ICU monitoring to post-discharge care. While, IoT has given a blueprint to create value, we are still in nascent stages of effort to capture such value. Big Data companies are championing the phenomenon by nurturing intrapreneurs and incubating several startups. One such example is Oxyent.

Oxyent offers latest Cloud Computing, Big Data & mobility enterprise solutions. They have recently designed iNICU device that captures data from various monitors of NICU. It allows doctors to tweak parameters of measurable outcomes or change alarm thresholds. This additionally permits remote monitoring and dataset collection for analysis. It is being backed and mentored by IBM under the 'Smartcamp' effort.

[7] Internet of things for smart cities, IEEE Internet Things J. 2014

Several innovative companies in India and other countries have integrated connectivity building blocks in their devices and are positioned competitively to succeed in the emerging ecosystem with greater IoT penetration. Other notable examples that have emerged are Spectral Insights, Forus Health, Cardiac Design Labs, Closeconnexions among others. Globally, medical device industry leaders have spelt out the objective to transition into more service oriented businesses; and connecting devices with greater central control paves the way for that. Indian IT companies are already deeply engaged in this transition as one of the largest segments of service providers to global medical device companies.

While there is immense global potential for Indian device companies also to leverage the emerging opportunity, it would be optimal to first begin with implementing solutions in the Indian healthcare setting. India will have to work on creating a stronger backend to realize the full potential. Better data security measures, infrastructure to support IoT, reach of 'internet' to rural areas, education and training in designing and use of technology will have to be undertaken before unleashing the strengths of IoT. Furthermore, the new generation of devices being innovated and manufactured will have to incorporate sensors and microprocessors for future integration with IoT networks.

5. Miniaturization and Portability of Devices

Driven by need for portability, extension of applications, less invasiveness, enhanced performance & safety, cost optimization, lighter yet more power; medical devices are trending toward miniaturization. This has benefited public health, private health and patients likewise. It has facilitated rendering of better medical services in remote, previously inaccessible areas. Within hospitals, it has improved the device utilization, floor utilization and patient throughput. For patients, it offers possibility of home healthcare. Miniaturization is being witnessed in implantable, imaging and diagnostic devices as well as treatment equipment.

a. **Implantables**: With the increasing use of drug pumps such as insulin pumps and increasing wireless connectivity with smartphones, efforts to reduce the size of pumps are being made. For e.g. Jewel Pump designed by Debiotech, Switzerland, is a miniaturized Patch-pump with 500U insulin for up to 7 days use. Additionally, it is detachable at will, watertight for bathing and swimming, includes direct access bolus buttons and a discreet vibration & audio alarm. Pacemakers have been constantly evolving since their genesis and have reached a stage where the pacemaker has reduced to size of a vitamin capsule. Medtronic and Abbott acquired St. Jude Medical are pioneering the research. St. Jude Medical recently got FDA approval for their smallest "wireless" MRI-compatible pacemaker.

Figure: Evolution of Pacemaker through Innovations [Source: Auro Blog]

b. **Diagnostics**: Miniaturization of X-Ray, Ultrasound devices etc. are pushing them towards handheld technology without compromising the quality and accuracy of diagnosis. This expands the reach of devices to rural areas, disaster sites, and even in ambulances, permitting a broader portfolio of offering for PoC.
c. **Treatment equipment**: Miniaturization has also permeated to treatment equipment enabling therapies such as dialysis at home. Globally more advanced solutions such as ingestible pill with camera to assist during endoscopic procedures, such as that developed by Olympus, are mushrooming. India will need the impetus to explore these more advanced territories and exploit the commercial potential.

Despite the indisputable potential of miniaturized devices, there are several technological barriers like heating, integration with existing modalities, data accuracy, precision and high R&D cost, that need to be overcome. Several Indian institutions are engaged in this area of innovation. Healthcare Technology Innovation Center (HTIC) in IIT Chennai has developed a cardiac arrhythmia screening device in a miniaturized form (handheld) and Hyderabad based startup Monitra Health is now pushing the boundaries further by developing a wearable option. Portable and miniaturized solutions offer value across highest value and lowest resource settings.

Forus Health

Forus Health is a Bangalore based technology firm backed by Accel Partners, IDG Ventures and Asian Health Fund which focuses on preventable blindness. They currently have noble innovative system in space of retinal imaging.

3nethra is a highly integrated ophthalmology device for pre-screening and identification of potential eye diseases.

Its attributes such as being simple, portable and rugged device with requirement of minimal trained personnel makes it an ideal fit for Indian healthcare scenario and rural settings.

Currently, 3nethra has reached 1200+ installations in 25 countries

Monitra Healthcare

Monitra Healthcare is a spin out of 'T-Hub' in Telangana. They are focused on developing a wearable cardiovascular monitoring strip which transmit vital parameters to the physician

This wearable device overcomes limitations posed by bulkier devices such as Holter Monitors. Monitra is also exploring a lease model for this device.

Monitra is also building a robust product pipeline and have partnered with DuPont, USA for developing a breathable yet waterproof stick-to-skin biomaterial through a grant from the United States India Science & Technology Endowment Fund (USISTEF).

While this is a focus of several Indian innovators, given the potential for clinical benefit as well as value creation, there is merit is fostering even greater momentum.

6. Robotics

Robotics is moving beyond the realm of traditional repetitive jobs like assembling to more versatile approach areas like healthcare. Robotics offers a minimally invasive solution which reduces complications, human error, ergonomic drawbacks, enabling a more controlled, controllable environment for surgical manipulation, better vision due to magnification and machine learning for greater precision, reducing chances of blood loss and tissue damage. Robotics by definition is not limited to full scale automated machines and taking over surgeries with little human assistance, but also extends to individualistic elements like robotic arms. In healthcare, most common robots in existence are human controlled, human delegated and human supervised. Robotics has branched into motion controlled and voice controlled devices and are largely used for:

a. Surgery

Surgical application is the hallmark of robotic development. Compared to any other application area, surgical segment has witnessed the highest advancement and acceptance. Robotics is being employed in treatment in therapeutic areas like urology, gynecology, thoracic, pediatric, general surgery, head and neck and bariatric surgeries. This also enables surgeries being performed from a remote location with similar and in some cases better health outcomes. Some commonly identifiable systems are:

- Da Vinci system with arms and human like wrist motion being used for prostate surgery and eye surgery
- The Sedasys system used to give anesthesia in routine endoscopy and colonoscopy procedures
- Nanorobots to cross the blood-brain barrier for treatment of infection, cancer and type 1 diabetes

Perfint Healthcare

Perfint Healthcare is a Chennai based medical technology firm backed by IDG Ventures and Accel Partners.

Specialty: They are focused on developing Interventional Oncology and tumor ablation for patients with critical tumors.

Innovation: In Oct 2013 they have launched "Maxio Robotic system" which is first indigenously made robotic platform that diagnose, plan and deliver drug to destroy tumors. This has been approved by USFDA in 2014, China and Japan in 2015.

Clientele: Tata Memorial Hospital, Jaslok hospital, Narayana Health, Medanta, Global Healthcare

Pipeline: Sonio which will deliver comprehensive solution by integrating Imaging and Energy delivery.

b. Rehabilitation

Robotics in rehabilitation is being used for dealing with disability, faster recovery from disability, providing support in the form of exoskeletons like Ekso Suit and prosthetics. Robotics can compensate for the patient's inadequate strength or motor control and can be individually calibrated to suit the patient need. Globally, rehab centers have installed robotic systems for increasing motor functions in stroke patients, for instance, as well as assisting in collecting and storing samples for diagnostics. In India, adoption is still at a very nascent stage and has been limited to bigger corporate players such as Apollo Hospitals, which offer robotic Neurorehabilitation and houses following robotic systems:

- LOKOMAT for intensive locomotion therapy
- ARMEO for functional therapy of the upper extremities
- ERIGO for early rehabilitation and patient mobilization

c. Hospital and Pharmacy

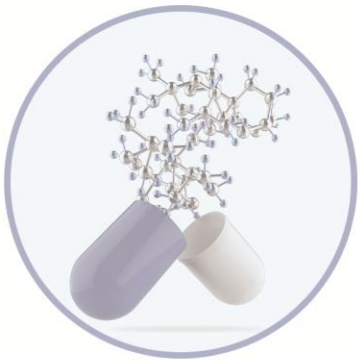
Robotics in pharmacy has taken automatic dispensing to next level of efficiency, streamlining processes, controlling costs and improving precision. In India, Rowa Smart System, developed in Germany is being used at Aster Medicity (Kochi) to arrange inventory, check date, make records and dispense them accurately to the patient.

In the hospitals, robots are being used for disinfecting the patient rooms and operating suites. For e.g. high-intensity ultraviolet light delivered by Xenex Germ-Zapping Robot. Biggest challenges in adopting robotic alternatives in India is the steep learning curve, cost and time required for setup. Major efforts are required in terms of capacity building for widespread adoption of robotic surgery so that the application and presence is not limited to metro cities. Some of the more aggressive companies in robotics today are:

Vattikuti Technologies	Bengaluru based Distributor of high end robotic systems planning to install 100 Da Vinci robots by 2020. Completed 32 installations till June 2016. Da Vinci Costs between $1.2 million and $2 million in India
Stryker	Stryker was first to invest into robotics with the acquisition of MAKO Surgical
Smith & Nephew	Smith & Nephew acquired Blue Belt Technologies' Navio robotic system in Jan 2016
Medtronic PLC	Mazor Robotics, a leading developer of innovative bone mounted surgical robotic guidance systems, entered into two strategic agreements with Medtronic in May 2016. Medtronic plans to launch the robot before 2019, and will have the first systems rolled out in India
Zimmer Biomet	Zimmer Biomet has acquired majority stake in a France-based company focused with ROSA Robotic System for brain and spine surgery which already has regulatory approval in Europe and achieved FDA clearance in January 2016. There are 82 ROSA robots installed worldwide
Verb Surgical	Verb Surgical, a startup supported by Johnson & Johnson debuts robot-assisted surgery prototype in January 2017

Diagnostics

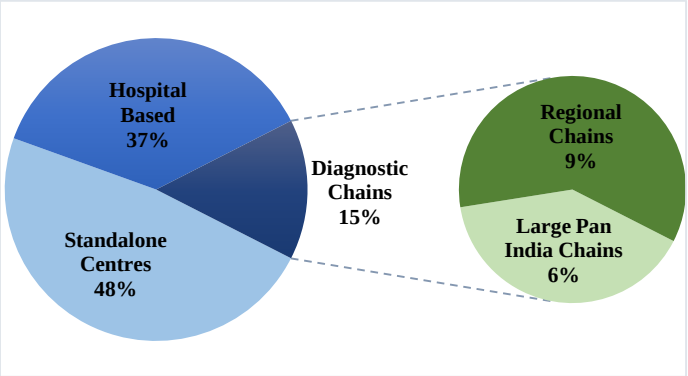
Expanding Access and Empowering Clinicians & Consumers



Given the criticality of diagnostics as a basis for clinical decisions, the segment has witnessed robust growth over the last decade. The use of diagnostics is rapidly expanding and today, more than 70% [8]of treatment decisions are based on professional diagnostic tests. We estimate that the size of the Indian diagnostic market was around $8.9 Billion in 2016 and contributed to 3% of the overall healthcare industry. With strong industry tailwinds, we anticipate that the 15-20% growth rate will be sustained for most of the next decade[9]. This growth is largely attributable to evolving disease landscape and need for targeted therapies, attention towards early intervention and prevention, increasing insurance penetration, expanding public and private healthcare spending, growing medical tourism, increasing sophistication and overall expansion of healthcare delivery.

Diagnostic market can be classified on the basis of:

- In-vitro diagnostics (IVD): Precursors like Biochemistry, Microbiology, Histopathology, Hematology and Coagulation and the more recently evolving areas like Genetics, Molecular diagnostics and Immunology
- In-vivo diagnostics: Imaging
- Application: Infectious disease, diabetes, oncology, cardiology, STD etc.
- Users: Hospitals, labs, self-testing, academic institutes and others
- More popularly into services, devices and data management



Irrespective of classification, the entire segment is highly fragmented, unregulated and unorganized. Of the almost 100,000 diagnostic centers in the country, only 711 have NABL accreditation. The dis-proportionate distribution of different centers is indicated in Figure beside.

Figure: Distribution of Diagnostic Centers

Source: CRISIL Report, Dr Lal PathLabs Annual Report 2016

Several of the organized reference labs and diagnostic chains have been PE funded and have expanded through acquisitions of brownfield projects. Spurred by successful exits, the private equity funding appetite continues and provides impetus for further expansion of the organized

[8] Source: Quest Diagnostic, JP Morgan Healthcare Conference, The Lewin Group, Inc. The value of diagnostics innovation, adoption and diffusion into health care
[9] Primary Research and Sathguru Analysis

segment. As the overall diagnostics segment expands, the unorganized labs are also growing at a robust growth rate.

While pan India chains offer the promise of quality, they simultaneously create a price differential for the same services and have therefore historically catered to tier 1 pockets of higher affordability. However, an increase in capital flow across the continuum and dissemination of innovation, are enabling larger corporate players to expand their reach to untapped potential of tier 2 and 3 cities and unlock the more complex and abstruse growth areas. Similarly, these innovations are also enabling smaller centers to scale-up, achieve equitable quality goals and manage volumes.

Innovation advancement and adoption pervades diagnostic equipment and delivery models. While scale-up challenges abound and pace of adoption varies across the spectrum, several of these innovations hold significant potential to revolutionize healthcare access and clinical possibilities.

Innovations in Diagnostics – Expanding Access, Empowering Clinicians & Consumers

1. Delivery Innovation: Expanding Convenience with Home Collection of Samples and Digital Report Delivery

Hub and spoke model of sample collection through satellite collection centers has been used for a long time. There is now an upward trend of extending sample collection from lab franchises to consumers' 'homes'. This is enabled by advancement in IT as well as sample preservation technology. This trend expands catchment area for diagnostic centers and also allows users and patients to deliver samples from the bedside. This increased convenience for consumers is resulting in expanded use of diagnostics and improved compliance.

A parallel innovation trend in diagnostic delivery is digitization of diagnostic results. This offers the twin benefit of removing the barrier of distance & time and also getting rid of archaic paper based recording system for easy future access. Today, these services are being offered by not just bigger centers like SRL, Dr. Lal Path and Metropolis, but are also being employed by several smaller regional & mom-and-pop shops to attract volumes and increase visibility in this highly competitive market.

While this innovation addresses needs of tier 2 and tier 3 cities; to reach even more inaccessible strata of the society at the bottom of pyramid, the solution lies in more rapidly expanding innovation in PPP models that have emerged over the last few years.

2. Public Private Partnerships (PPP): Working Together to Bridge Unmet Need for Reliable Diagnostic Services

PPP has been touted as the most efficient mechanism for infrastructure development, extending innovation to BoP, capacity building, creating financial momentum and bringing equity in healthcare services across different sections despite disparity in economic and social development.

PPPs hold great promise to bridge the healthcare divide in diagnostics. However, until three years ago this model of diagnostics delivery was hardly explored. The recent willingness from all stakeholders to explore such partnerships in diagnostics paves the way for bridging infrastructure gaps and engaging private sector to develop required operating capacity to ensure wider availability of reliable diagnostics. Until such focus on reliable diagnostics is extended to every corner of India, quality healthcare will remain a wistful dream.

PPPs have been pursued in the states of Punjab, Jharkhand, Uttar Pradesh, Himachal Pradesh and Maharashtra. Andhra Pradesh and Bihar are also creating more nurturing and fertile environment for encouraging public and private partnerships.

Table: Most of the recent PPPs in diagnostics

Year	State	# labs	Private partner	Monetary Value	Public entity
2016	UP	22	SRL limited	NA	District Hospitals
2016	Jharkhand	12	Medall Healthcare & SRL Limited	NA	District Hospitals
2015	Jharkhand	27	Medall Healthcare & SRL Limited	$2 Million	District Hospitals
2015	Jharkhand	25	HealthMaP Diagnostics	NA	District Hospitals
2015	Haryana	8	HealthMaP Diagnostics	NA	District Hospitals
2014	Maharashtra	22	GE Healthcare & Ensocare group	Rs.150 crore	District Hospitals
2014	Punjab	21	GE Healthcare & Ensocare group	Rs.90 crore	District Hospitals
2013	HP, Potentially Assam, MP, Rajasthan	24	SRL limited	NA	District Hospital
2011	Andhra Pradesh	4	Medall Healthcare & Wipro GE Healthcare	Rs.25 crore	Teaching Hospitals
2004	Jaipur	1	Vardhaman Medicare	Rental & maintenance fees	SMS Hospital

Traditionally the PPPs have been largely in IVD, but the trend also reflects participation of device and equipment companies with interest in imaging. While the continuing appetite for such PPPs is encouraging, it is pertinent to note that the level of current activity addresses a very small part of the real unmet need in India. There have been concerns from several private players that the reward mechanism currently built into such PPPs do not justify participation of large chains with emphasis

on quality. The relatively slower pace of such partnerships considering the expanse of unmet need calls for an engaged and open dialogue between leading diagnostic delivery companies, imaging companies, healthcare delivery institutions and the Government on incentivizing price delivery models that can render PPPs appeal to all stakeholders.

3. Genomics: Embarking on New Frontiers of Healthcare

Genetics is the newest frontier in diagnostics and is triggering a required paradigm shift in providing targeted, predictive and preventive solutions. Role of genomics has expanded from rare genetic disorders to common diseases such as cancer, diabetes, stroke etc. and is emerging as a critical part of standard clinical workflow. Genomics is broadly finding application in following interwoven and yet distinct areas:

- **Personalized medicine:** Personalized medicine implies using precision diagnostics to design tailored treatment solutions based on a person's unique molecular and genetic profile. It leapfrogs over the current 'trial and error approach' and is empowered by scientific breakthroughs that have allowed such genetic information to be used in development of diagnostics and drugs and have brought down costs for widespread clinical adoption. One of the earliest and most prominent examples of personalized medicine is the use of trastuzumab (approved in 1998) for HER2 positive breast cancer patients. About 30% of breast cancer patients overexpress HER2 protein and were not responsive to standard therapy. It has now been demonstrated that adding an antibody drug like trastuzumab to their chemotherapy regimen has reduced risk of recurrence by about 52%.[10]

  Molecular tests for HER2 that form the basis of such clinical decision-making are now widely available and are offered by most labs in India as well. Other examples of molecular and genetic testing that guide choice of treatment options are the companion BRAF V600E Mutation Test for treating late stage melanoma with vemurafenib and blood sample based genetic testing for predicting risk of rejection and immunosuppressant drug choices in case the of heart transplantations.

Strand Life Sciences Pvt. Ltd.

Strand Life Sciences is a global genomic profiling & Bioinformatics Company focusing on the use of precision medicine diagnostics aimed at cancer care and inherited diseases. Strand offers:

Tissue-Specific Tests for identifying approved therapeutic options for colon, lung, and breast cancers using NGS, FISH and IHC platform

48-gene Test for identifying cancers of unknown origin metastatic and refractory cancers, and rare and aggressive cancers that have failed standard lines of treatment using NGS

152-gene Test is a hot-spot based gene test employed for identifying potential therapeutic options approved for other indications as well as in clinical trials and uses NGS test method

[10] Personalized Medicine Coalition, "The Personalized Medicine Report," 2017

An integrated element of personalized medicine are is companion diagnostics, the epitome of convergence of pharma, diagnostics and bioinformatics/genetics. As we usher in this era of tailored and more effective therapies, we hope a collaborative environment that is mutually rewarding and further pushes boundaries for clinical benefit.

- **Predictive medicine:** Predictive tests are pre-symptomatic and can identify mutations that increase a person's chances of developing disorders with a genetic basis. Currently application is most common in prenatal and neonatal screening and predicting high susceptibility to certain types of cancers and other rare diseases. For example, studies have demonstrated that women with BRCA1 mutation have a 55% to 65% risk of developing breast cancer by age 70 (vs 12% in the general population)[11].

  Several diagnostic possibilities available to identify such a mutation is empowering women with a family history of breast cancer to be screened more vigilantly and where appropriate, take preventive steps to preempt disease occurrence. Predictive testing is also empowering parents to make informed decisions on quality of life of their children by creating possibilities for early detection of high risk exposure to inherited disorders and dilapidating birth defects. Prenatal screening for Down syndrome is now offered in several countries and neonatal screening panels (based on day 5 blood spot screens) often cover sickle cell disease, cystic fibrosis, congenial hypothyroidism and six inherited metabolic diseases. NHS (UK) offers this entire panel as an option to parents and all US states currently test infants for phenylkenonuria. Such early screening allows early treatment and better disease management. Complementary developments are also being made in Preimplantation genetic diagnosis. This equips couples with high genetic risks to use clinical advances in IVF, screen embryos prior to implantation and thus offers a less morally heavy solution to prospective parents.

- **Prognostic medicine:** Prognostic markers measure disease progression and assess probability of response to treatment options, equipping clinicians with timely information to make more informed decisions on disease management. For example, Oncotype DX and MammaPrint aide clinicians in treating breast cancer, the former by determining if women with certain types of breast cancer are likely to benefit from chemotherapy and the latter by identifying early stage breast

Mitra Biotech

Mitra's flagship phenotypic platform CANscript, has a portfolio of 15 product types to detect various forms of cancer. It enables physicians to select the most optimal drug combination by testing a tumor sample against various drug combinations simultaneously in a laboratory setting that mimics the actual human tumor microenvironment and therefore helps design the right combination and sequence of drugs to be administered.

[11] Antoniou A, Pharoah PD, Narod S, et al. Average risks of breast and ovarian cancer associated with BRCA1 or BRCA2 mutations detected in case series unselected for family history: A combined analysis of 22 studies. American Journal of Human Genetics 2003; 72(5):1117–1130

cancer patients who are at risk of distant recurrence following surgery. These tests include single-gene testing for cardiac diseases and pediatric disorders, pharmacogenomics testing as well as multiple-gene panels for hereditary cancer, neuromuscular disorders, hematological disorders and retinal degeneration. Additionally, microarray analysis is also commonly used for tracking progression of breast, prostate and lung cancer.

India is experiencing vibrant activity in B2P (Business to Physician) genetic testing across startups and larger reference labs. Companies such as Strand Lifesciences, Medgenome, Datar Lifesciences and Mitra Biotech are leading the way in engaging with the clinical community to create awareness and foster wider adoption of Next Generation Sequencing (NGS) based tests and panels that can aide clinical decision making. However, our research indicates that level and pace of clinical adoption varies across the range of testing possibilities. Prenatal and neonatal testing is finding wider adoption within the clinical community, driven by expanding healthcare delivery at the middle to high end in this specialty. On the other hand, we note relatively lower pace of adoption within oncology. While global tests such as Oncotype DX have been available in India for several years, majority of the clinicians still prefer empirical decision making in a therapeutic area where affordability limits treatment options for majority of Indian patients and clinical delivery capacity is still sparse and overburdened. We are enthused by emergence of Indian companies with global standards (Strand's labs are CAP and NABL accredited), competitive test portfolios and awareness building efforts that can expand markets. Datar Genomics for instance is collaborating with Apollo Hospitals to aggressively expand clinical adoption and commercial market penetration. Indian firms are also willing to collaborate with global counterparts to expand options for Indian patients - such as the collaboration between MedGenome and Natera Inc. to perform the Panorama test locally in India. Given the clinical promise of emerging genetic diagnostic possibilities, we hope extensive clinical education and a multi-stakeholder approach can widen the net of adoption in the near future.

Lastly, we also note an active landscape of engagement in consumer focused genomic tests and products with ventures such as Mapmygenome and XCode offering consumers elective choices for genetically tailored solutions in fitness, nutrition, skincare etc. While this is complementary to the B2P testing growth, hard to surmount challenges lie ahead such as the capital intensiveness of a consumer focused effort and need for consumer education.

Overall, India is placed competitively to ride the genomics wave to catapult healthcare delivery approaches. However, to realize the true potential of these possibilities, it is essential we engage in a multi-stakeholder approach to widen adoption at a national level. Countries across the world, from US to China are betting on the future of personalized medicine and all stakeholders in India need to act now to stake our claim on that map.

4. Minimally Invasive / Less Invasive Testing

Another area with significant innovation advancements in diagnostics is in discovery and development of less invasive and non-invasive diagnostic tests. This includes innovation in novel biomarkers in body fluids such as blood or saliva, sensitive testing platforms that expand the utility of known biomarkers and sensitive imaging technologies that pave the way for avoiding confirmatory invasive tests post-imaging. Within this overall trend of less invasive testing, we elaborate further on the most notable global development – liquid biopsies based on Circulating-free DNA (cfDNA) and Circulating Tumor Cells (CTCs) that flag off a new era of cancer diagnostics.

Liquid Biopsies - Circulating-free DNA (cfDNA) and Circulating Tumor Cells (CTCs)

Cancer mortality is the biggest cause of concern in recent times and is attracting research in diagnosis and treatment. Circulating tumor cells are the cells released from primary tumor and circulate in peripheral blood causing metastasis. While tissue biopsies have been the standard for molecular evaluation, characterization of CTCs as circulating biomarkers offer a minimally invasive diagnostic tool which can be drawn easily and repetitively. Despite their numerous advantages, there are technological challenges in isolating and identifying these markers. Emerging technologies address these gaps by offering solutions that require minimal sample volume and preparation, better isolation tools like microfluidic enrichment systems, and improved sensing mechanisms through magnetic nanotechnology. There is only one FDA approved device- Johnson and Johnson's Veridex (CellSearch system) but there are over 30 companies seeking to develop the next generation of technology to use biofluids for liquid biopsy.

China is emerging as the front runner is developing technologies to work with biofluid biopsies. India too has the potential to meet the volume demands and also deal with high cancer onslaught (India registered over 500,000 cancer related deaths in 2015)[12] and hence manifest Make-in-India effort. Today very few labs in India have CTCs testing facilities like Oncquest, Neeli Genetic Services, MedGenome, Datar, and Core Diagnostics to name a few and most tests are offered as follow-up tests to measure effectiveness of chemo/radiation therapy or assess recurrence of cancer.

> *"The clinical use of liquid biopsy is one of the most transformational thing that's going to happen in oncology in terms of impact on cancer management in next 5 years. Liquid biopsies are going to completely change the rules of engagement for patient management and clinical practice.*
> *Whenever new technology comes out, it looks like it's going to be an add-on, but I think, it's going to become a commodity. As we get more precise in our care, this will be part of the landscape of a doctor making an accurate and very precise diagnosis."*
> ***Dr. Ravi Gaur- COO, Oncquest Labs Ltd.***

[12] National Institute of Cancer Prevention and Research

It has a wide application in identifying tumors of unknown origin or deep seated tumors which are harder to access such as lung cancer or colon cancer. Given the non-invasive nature, potential of being low cost if research and development investments are made and widespread adoption is triggered, liquid biopsies hold significant potential to redefine cancer care in India. However, this calls for an intensified research and engagement validated for Indian demographics, augmented education in administering the test and reading the results and conclusively engagement from all participants to accelerate pace of clinical adoption. Industry leaders also believe in the promise of the technology.

5. Point of Care (PoC)

Point of Care diagnostics, especially in infectious diseases, are very crucial in a country like India because they reduce the turnaround time, increase availability in areas with infrastructure gaps and address the glaring dearth of skilled labor. In addition to such disruptive PoC tests for infectious diseases, there are significant innovation advancements globally in PoC tests for critical care as well as for home use. We outline below innovation landscape across all these three segments:

a. Infectious Diseases

Infectious diseases PoC are very pertinent in the Indian context and provide screening information and diagnostic information for clinical decision making even in low resource setting with negligible access to diagnostic capacity. Today, they are most commonly used for testing of streptococcal pharyngitis, STDs, influenza, respiratory infections and vector borne diseases such as malaria and dengue. The current standard for infectious disease testing has been antigen or antibody capture method using a lateral-flow immunochromatographic system. India has significant product development and manufacturing capacity for standard lateral flow tests owing to high disease prevalence, organic volume growth, export potential and easily adoptable innovations. Current industry landscape includes more established companies such as Meril Life Sciences, Premier Medical Systems, Bhat Biotech etc. and emerging product development companies such as Bigtec labs, Reametrix, Wrig Nanosystems, MicroX Labs etc. India today has an active product development landscape in infectious disease PoC and significant strides have been made in the areas of integration of sample preparation for PCR techniques, real time PCR, shift from single to multiplexed lateral flow, reader devices and imaging technologies for visual digitization, modular LAMP based diagnostics, hand-held molecular tests and non-invasive breath tests. We are

marching towards next generation of PoC tests including Lab-on-chip integration, highly sensitive and specific reagents for testing, which is augmenting capacity to deal with volumes. The only element that needs attention is the urgent need to create a clear and accelerated adoption pathway for infectious disease PoC tests that have significant public health potential. For instance, we note laudable innovation in RT PCR with TB panels and other molecular TB diagnostic tests for mutli-drug resistant TB. While several of these ventures are embarking on exploring private markets, gaining adoption in public markets has been an elusive quest so far. To realize the public health of such PoC diagnostics, it is critical we create accelerated and easy to explore public health adoption pathway and government procurement systems. This is also very important to maintain and further enhance the current level of innovation engagement in the segment.

b. Critical Care

In a critical care setting such as emergency rooms, ICU, ambulatory services and at the site of incidence/accident, timely diagnostics are very vital and often lifesaving. In critical care, challenges are confounding and unpredictable and therefore strengthening every line of treatment is significant. Most commonly used critical care diagnostic tools are electrolyte & metabolite analyzer, Blood gas analyzer and predominantly coagulation management tools. The gold standard in India is use of individual and modular systems for testing. Integrated and automated systems can improve the quality of care by reducing the potential for errors, consolidating analytes in one cartridge and employing multi-use analyzers.

There is active innovation engagement globally in developing more sensitive and rapid PoC tests for use in critical care. For instance, there has been notable global advancement in developing more sensitive and accurate cardiac biomarkers (troponin) with extended evaluation beyond inflammatory, acute muscle injury, and cardiac stress. Similarly, there have been several advances globally in development of sensitive markers for traumatic brain injury (TBI) to be used at emergency room bedside as well as rapid screening at accident site Such innovation in PoC includes both development of more sensitive biomarkers as well as innovation in technology platforms such as microfluidics that provide for increased sensitivity, efficiency and multiplexing.

India has vibrant engagement in innovation in PoC diagnostics for infectious diseases, but here is currently limited engagement in critical care PoC. For instance, while it is encouraging to note that troponin is now being offered by several large labs in India, there is limited thrust on development or adoption of a rapid and PoC test for troponin. Given the robust technology development landscape in several other countries, this could be an attractive area for Indian companies currently engaged in PoC tests to partner globally, absorb and adapt innovation; and thereby bridge this void and provide contemporary and clinically impactful possibilities in Indian critical care.

c. Home Healthcare/ Self-diagnostic Devices

The increasing emphasis on preventive medicine, early detection, affordable options and convenience of testing has made the home self-diagnostic and monitoring equipment market very lucrative. In India as well as most other countries, blood glucose monitoring devices, blood pressure monitoring and pregnancy test kits are popular categories in home use PoC diagnostics. Additionally, in more developed economies, there is increasing interest in various other PoC products such as strep throat rapid testing kit, allergy testing, UTI testing, Cholesterol testing kit, thyroid testing, apnea & sleep monitoring and very recently even DNA testing.

Innovation in home use PoC tests include efforts to broaden the utility of tests, lower costs per test, improve reliability and sensitivity and create better connectivity. For instance, in the case of blood glucose monitors, there is now expansion of testing possibilities to include HbA1c and cholesterol, lower cost of test strips and improved connectivity with USB and Bluetooth integration. Home healthcare devices reflect participation from companies at two ends – global majors such as Philips healthcare, Omron HealthCare Inc., Roche Diagnostics, Abbott Diagnostics and Bayer Diagnostics- and Asian manufacturers largely concentrated in China, Taiwan and Korea. The Indian market reflects a similar structure for glucose and BP monitoring devices where there is negligible domestic production. In the case of lower value products such as lateral flow based pregnancy test kits, there is greater domestic capacity and import dependency is minimal. Given the growing domestic demand for such home care PoC devices and significant export potential, there is immense potential to foster domestic production on the backbone of structured technology access partnerships.

6. Wearable Health Tracking- Mobile Diagnostics

There has been a surge in number of wearable health tracking devices being launched every year. These inventions include smart watches, tracking bands, glasses & contact lenses, derma patches, clothing like bras, consumable pills for continuous monitoring to name a few. The more popular devices in the market are presently used for fitness monitoring, but the new wave of innovation aims at monitoring more clinically utilizable parameters like breast health, skin health, cardiovascular health, asthma monitoring, nicotine levels, blood glucose levels, bed sore and ulcer prevention due to inactivity during hospitalization. Another domain being explored is in treatment and management of neurological disorders to modify behavior and treat anxiety, depression; monitor and prevent seizure, stroke etc. Devices used for continuous monitoring of chronic diseases have a unique value proposition because their sensors are capable of monitoring multiple biomarkers, including those associated with diabetes (e.g. trace ketones to signal low insulin), hypertension, and certain lung conditions.

These devices are also being developed analogously with companion as well as independent mobile applications with blue tooth capabilities to collect real time data received through biosensors. Proliferation of these technologies has been relatively higher in developed nations and has only very recently taken off in India. The more commercially available devices in India are

limited to smart watches, fitness bands and applications integrated with mobile applications. However, India is poised to become one of the largest markets for wearable medical device technologies in the near future. Some of the most recognizable brands are Fitbit, Garmin, Omron, Apple, Zephyr, Xiomi, but a modest number of Indian startups have also emerged like Cardea Labs.

For wearables to truly transgress the boundaries of high clinical utility, regulatory frameworks across the world need to evolve to create clearly laid down pathways. This will hasten the potential clinical impact from empowering patients and clinicians with more real time and continuous data for clinical interventions in both chronic and critical care settings. We anticipate that the next decade will be remembered as the era of the wearables with globally significant level of activity in development and adoption of wearables across wellness, fitness and healthcare applications.

Healthcare Delivery

Rethinking Business Models, Technology Disruptions & Beyond

Indian healthcare industry worth $100 billion continues to reflect growth rates north of 20%; and it is notable that close to 65% of this market comprises of healthcare delivery[13]. The growth continues to be driven by increasing willingness to pay, insurance penetration, enhanced care possibilities in the urban mid to high income segments and a gradual overall expansion of healthcare access. Medical tourism has been on the rise owing to the fact that healthcare costs are a small fraction of costs incurred in USA or UK. This has created a need for new dimension of luxury care beyond traditional systems of healthcare access.

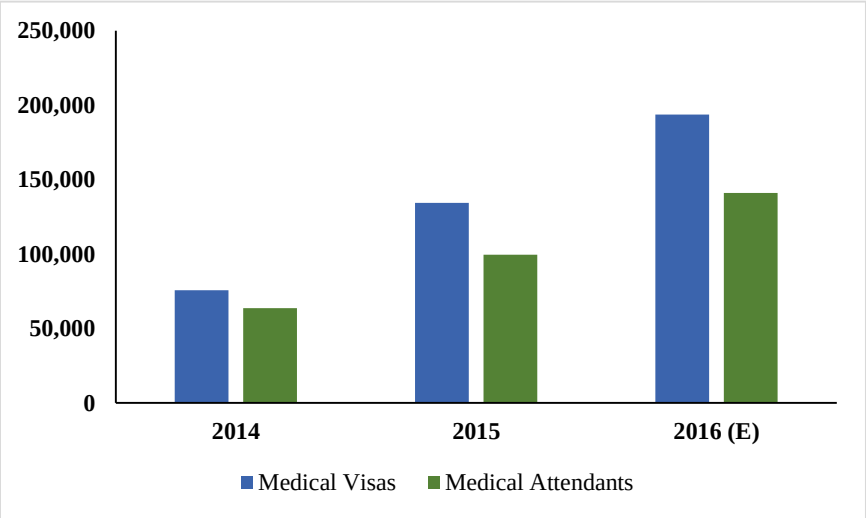


Figure: No. of Foreign Tourists Arrivals in India on Medical Visas
Source: Ministry of Tourism, Factly

The Government has responded with capacity enhancement initiatives like two new AIIMS in Gujarat and Jharkhand, addition of 25000 post graduate seats in medicine, upgrading 1.5 lakh primary health centers to health & wellness centers etc. However, the expanse of unmet needs calls for innovative solutions that can be executed at scale. These challenges have inspired quintessential innovations that can balance cost and quality. We note an active landscape of innovation in business and delivery models with involvement of both the public and private sector and proliferation of ventures leveraging technology advances for solutions in healthcare delivery. Breakthroughs in information gathering, research, treatments, and communications have given healthcare providers new tools to work with and fresh ways to practice medicine.

We discuss below most prominent healthcare delivery trends in Public and Private Indian healthcare delivery.

1. Public Health: Public Private Partnerships

Though, there are deficiencies across private and public health resources, the paucity is more pronounced in rural and public care. The most efficient way to bridge this gap and grow in symbiotic convergence is to work together through PPP models. PPP in India gained momentum under Millennium Development Goals.

[13] IBEF Sector Report, February 2017

However, the success of PPP has been stymied by loss of momentum and disengagement from private sector due to unattractive rate of return. Subsequently, the initiated PPP engagements have not seen the scale up and spread in other states as anticipated. Therefore government needs to orchestrate improved governance models and can additionally engage with other multilateral agencies like World Bank and Asian Development Bank for advisory and assistance.

Notable examples of successful initiation of PPP in Healthcare Delivery

- Arogya Raksha Scheme in Andhra Pradesh
- Telemedicine initiative by Narayana Hrudalaya in Karnataka
- Rajiv Gandhi super specialty hospital in Karnataka
- Chiranjeevi project in Gujarat,
- Mobile health services in West Bengal

2. Private Health: Single Specialty Hospitals

Indian healthcare industry has been witnessing a gradual shift in focus from multi-specialty to single-specialty centers. Single specialty hospitals and centers started with ophthalmology and dental clinics, but have now expanded to gynecology, diabetics, cardiovascular and gastrointestinal facilities. Prominent chains have also set foot in this landscape by launching brands like Fortis La Femme and Apollo Cradle, offering comprehensive treatments in the focused therapeutic segment. This has enabled cost efficiencies due to economies of scale, lower cost of setting up as opposed to multispecialty centers, higher quality offerings due to specialization and broader spectrum of choices to users with customized experience. Growing PE and VC investment in this sub-sector is a testament of success of this business model innovation and the fillip from multi-specialty to single specialty hospitals.

Table: Key PE Deals in Singe Specialty Hospitals

Date	Target	Investor	Specialty	Deal Value ($ Mn)
2016, Oct	Oasis Centre for Reproductive Medicine	Invascent Capital	IVF	6.2
2016, Jul	Motherhood	TPG Growth	Pediatric	33
2016, Jun	Eternal Heart Care Centre and Research Institute	LIC Housing Finance Ltd,	Cardiovascular	15.03

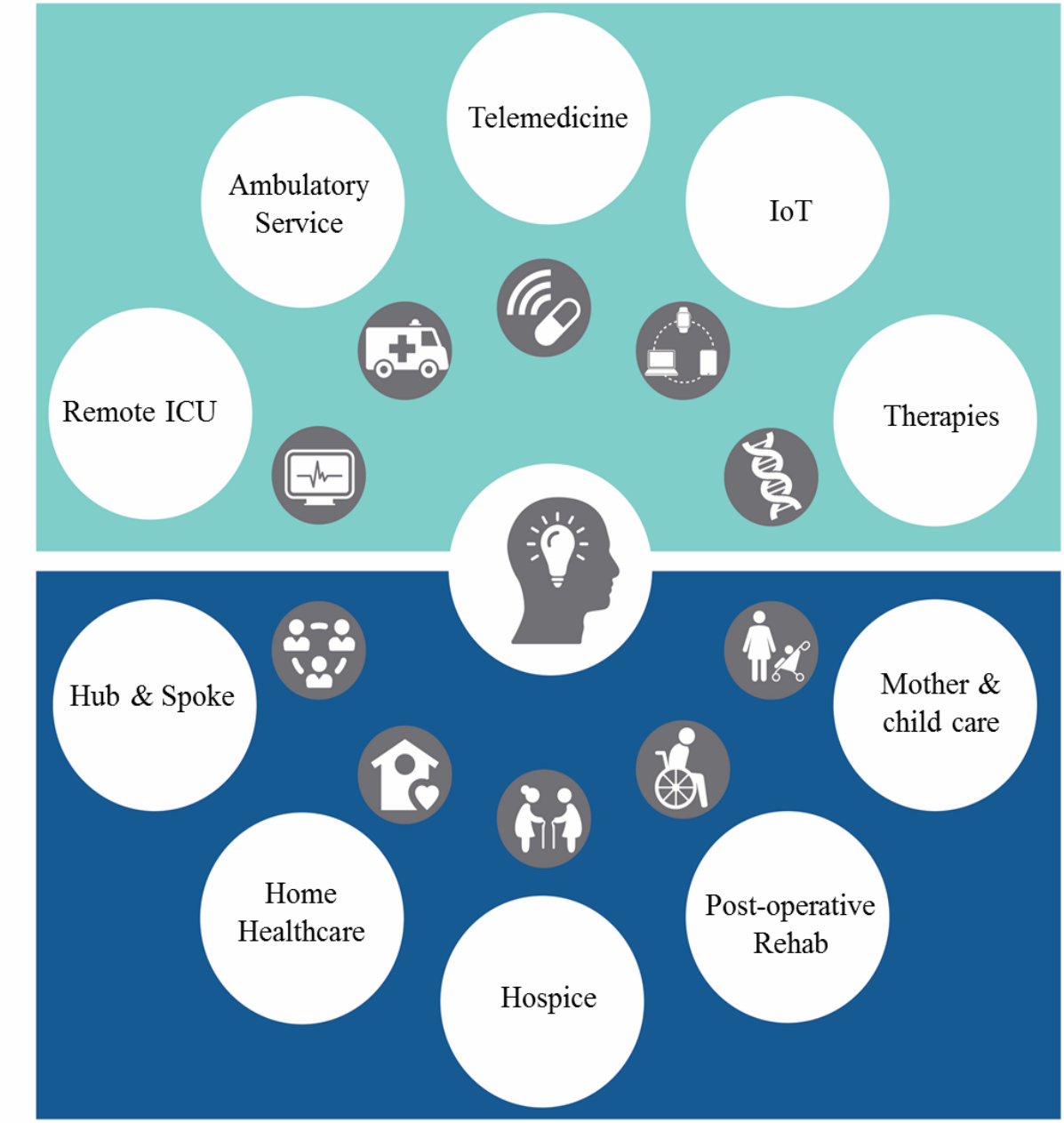
Date	Target	Investor	Specialty	Deal Value ($ Mn)
2016, May	Address Health	Gray Matters, Unitus seed Fund	Pediatric	1.5
2016, May	Cytecare Hospitals Pvt. Ltd.	Kamini Arvind Rao, Naz Haji	Oncology	24.72
2016, Apr	Cancer Treatment Services International (CTSI)	TPG Capital	Oncology	
2016, Aug	Nephroplus	Sealink Capital , IFC	Renal	15
2015, Oct	Asian Institute of Gastroenterology Pvt. Ltd.	Quadria Capital Investment Management Pte. Ltd. Samara Capital	Gastroenterology	40 9.78
2014, Aug	DCDC Health	Pragati India Fund	Renal	10
2014, May	Vasan Eye Care	Sequoia, WestBridge, GIC	Ophthalmic	50

Source: VC Edge

Innovation Ecosystem in Healthcare Delivery

Innovation in Healthcare Delivery Models

Healthcare delivery is contextual and solutions are specific to the delivery ecosystem in any country. Despite growth in healthcare delivery as a whole, as highlighted above, there are glaring gaps in the continuum of care, significant inequalities in delivery capacity and inefficiencies that need to be addressed. We discuss below, areas of emerging innovation in India in healthcare delivery models.



1. Hub and Spoke Model

As a model for expansion and growth, there is increasing adoption of hub and spoke model to provide high-end healthcare affordably and to scale. The model works sustainably because of the increase in volumes which in turn fuels revenue growth. Most urban hospitals have initiated hub and spoke model in urban areas sharing assets and resources and then expanded to semi-urban and gradually to rural areas. Currently, the spokes cater to diagnosis, routine treatment and follow-up care. Health Care Group, for instance, has 17 spoke hospitals centralized around four urban hubs in Bangalore, Gujarat, Mumbai and Chennai. While specialists at the 4 hubs have access to high-end sophisticated equipment and capability to perform complex procedures, the spoke facilities

provide basic care and referrals for the hubs. The hub and spoke configuration has not only made its footprint in multi-specialty, but has also expanded to single specialty care. For instance at IVF clinics, where particular physicians are the assets and growth drivers, clinical diagnosis, treatment planning and all outpatient consultations are done at the spoke while procedures such as implantation are done at the hub. Within Indian context, this model is helping build capacity across different strata, educating physicians by giving them larger volumes to work with and better and shared resource utilization. This model has also solved the problem of scarcity of high skilled practitioners in rural areas. For example, LVPEI has hired and trained local graduates to function as optometrists who are guided by ophthalmologists in the urban centers.

2. Home Healthcare

A complementary development in pain management and treatment is nursing at home. Major hospital chains like Max Healthcare, Hinduja, Apollo, Fernandez and Columbia Asia have ventured into offering their own home care services. Despite that, the segment is dominated by startups that are either VC funded or backed by foreign players or through domestic joint ventures. Examples include

- Portea - a VC funded startup that is now operating in 13 cities,
- Bayada - one of the largest private home health firms in the US, took a 26% stake in India Home Health Care (IHHC) to expand outside it home city of Chennai.
- HealthCare at Home – a joint venture between Dabur, India and HAH, UK, which provides services ranging from routine procedures such as injection administration to home chemotherapy, to post surgery care and pre and post-natal service to name a few.

Recently launched e-pharmacies (1mg, Netmeds, mChemist etc.l) complete the loop on convenience of health at home and represent the latest business model innovation in comprehensive home healthcare delivery.

3. Hospice Care

With ageing population (estimated 200 million people above the age of 65 by 2018) and onslaught of AIDS, CNS disorders and cancer afflicted patients, palliative care and day cares have become very relevant. India features at the bottom of end-of-life care in the global league- ranked 67 out of 80 countries in 2015[14] and therefore this presents a profound opportunity to explore and capitalize the underpenetrated domain. Kerala has been exemplary in palliative and end-of-life care in India, and has inspired several centers in the states of Gujarat and Maharashtra. Given the significant unmet demand and potential for disruption, we anticipate greater interest from larger corporates as well as startups in this area.

[14] WHO Quality of Death Index 2015

4. Post-Operative Rehab Center

There is a growing scope for post-surgery rehab centers to reduce the operational cost and burden on existing system and also to provide psychosocial support to the patient and their family. For several procedures with longer recovery times like hip or knee replacement, CABG, complex fractures, spinal surgeries, organ transplants, cancer treatment, post-surgery rehabilitation provides the professional care, faster recovery and support to families. While this model has propagated successfully in several countries, it remains underexplored in India. Anurag Rehabilitation and ActivOrtho are some of the established rehab centers in metros. Hyderabad based startup SuVitas Holistic Healthcare Pvt. Ltd., raised first round of capital and is planning to expand to 18-20 centers in tier 1 and 2 cities with an average bed capacity of 100 per center. This is another nascent segment with potential for significant increase in momentum over the next five years.

5. Prenatal and Postnatal Care

Apart from rehab centers for traumatic surgeries, various support services for pre-and post-natal care have also emerged. In India, like several other Asian countries, there is an immense cultural influence in mother and child care. Sangopan, for instance, provides holistic pre and post-natal care ranging from massages to Lamaze classes and workshops to deal with postpartum depression. With single specialty corporate hospitals have now emerged as holistic maternal and child healthcare providers and Practo, Sangopan and other startups provide support at home, this trend could evolve into more comprehensive and specialized services. A global benchmark demonstrating the potential in a similar cultural context are the Korean joriwons, postpartum care centers which provide 24X7 care to the mother and child.

6. Remote ICU Monitoring

Remote ICU monitoring is a growing trend within India and is also a high value export opportunity. Within India, it provides a smart solution for bridging the glaring critical care capacity gap and avoidable shifting of patients to distant tertiary care centers. Notable initiatives include CritiNext, a Fortis GE collaboration, Apollo's eICU and INTeleICU. The trend is now extending beyond large corporate groups and individual intensivists, and smaller practice groups are now embarking into this service offering, especially in the value export segment where they remotely monitor critical care units in US and other high income countries.

7. Ambulatory Services

Critical and emergency care in India is plagued with issues of resource allocation and distribution. Ambulatory services are the first point of healthcare delivery for critical care and unplanned hospitalization. The biggest challenges facing the existing system are unavailability due to distance, ill-equipped infrastructure to deal with emergencies, lack of accountability and untimely

response rate. Ambulances are an opportunity for cost reduction and increasing healthcare efficiency by serving as the starting point of medical response and treatment.

There are a few avenues for innovation to address the above shortcomings.

- **Improving the response time and availability:** Startups like Tata backed MUrgency, StanPlus and Ambee serve as a helpline and locate the nearest available ambulance and best route to navigate through traffic congestion.
- **Ambulances as Mobile Diagnostic and Intensive Care Units**: This is a two pronged approach. On one end ambulances can serve as a mobile diagnostic unit which can allow administration of treatment as rapidly as possible and on the other it can serve as mobile ICU to prevent any adverse event and possibly stabilize the patient. This can be enabled by advancements in continuous monitoring and telemedicine. Next generation ambulances such as the ones used by Kokilaben Ambani Hosptial represent the future of first response care and call for national initiatives for large scale adoption.
- **Air Ambulances**: A periphery trend that has seen limited activity is the areas of air ambulances to air lift patients from accident sites and for medical emergencies. Given the lack of a payor ecosystem for mass rollout, this service is now being provided by few startups only for the high end paying customers in India and for medical tourists.

Technology Enabled Innovations

Pervasive application of technology is changing the paradigm of healthcare. While technology disruption of several other industries is quite advanced, it is only at the beginning of the curve in healthcare. However, we are now witnessing a rapid penetration of technology enabled innovations across the spectrum. In out of pocket markets such as India with significant unmet needs and inefficiencies in healthcare delivery, we note a more rapid pace in both development and adoption of such innovations in healthcare as compared to developed markets with more stringent regulations and payor controlled environment. We discuss below some of the areas of technology enabled innovation that are most prominent in the Indian healthcare context.

1. Patient Convenience, Improved Accessibility and Efficiency in Delivery – The Era of Mobile Applications

The friendly family doctor who anchored care belongs to a bygone era. Despite the proliferation of corporate hospitals and the growing healthcare delivery landscape, physician patient connectivity has remained poor. Early and currently most popular apps to be rolled out in the Indian healthcare system (Practo, Lybrate etc.) addressed this and created ease of access to providers through a mobile platform. As in the case of Uber as well as other mobile based disruptors, aggregation, accelerated scalability and efficiency has been the value proposition of healthcare apps as well. Case in point is the home healthcare and telemedicine focused apps. While agencies providing nursing care at home always existed, the apps have enabled an explosion and rapid scale-up through a mobile based approach (Portea, Callhealth etc.)

Limited consumer awareness and transparency results in healthcare being one of the most imperfect markets. Several apps are now addressing information gap by aggregating providers across hospitals and diagnostics centers on web and mobile platforms where consumers can compare prices for diagnostic tests and surgical procedures and make more informed choices (DoctorC, Caremotto etc). Health and wellness has also emerged as an area with significant innovation in technology enabled connectivity, advice and standardized scale-up models (Curefit, Healthfyme etc.).

Table: Key PE Deals in Technology Companies

Date	Target	Investor	Specialty	Deal Value ($Mn)
30-Nov-16	Sidqam Technologies Pvt. Ltd.	SQue Capital, Grace Capital Ventures LLC, Soham Vencaps	SAAS based EHR	1.2
28-Oct-16	Cyclops Medtech Pvt. Ltd.	Kalaari Capital Advisors Pvt. Ltd.	Wearable diagnostic solutions for neurological diseases	0.1
20-Sep-16	Purplebits Infosystems Pvt. Ltd.	Lead Angels, Kellygamma Advisors LLP	EHR services	
11-Aug-16	Advenio Tecnosys Pvt. Ltd.	Kstart Capital	AI/ML solutions for Biomedical Image Processing	0.1
22-Jun-16	Tricog Health Services Pvt. Ltd.	Blume Ventures India Fund II, Inventus Capital Partners Fund II	Cloud connected EG Devices	1.87
27-May-16	Cyclops Medtech Pvt. Ltd.	Chandanmal Pukhraj Bothra	Wearable diagnostic solutions for neurological diseases	0.15
25-May-16	Tricog Health Services Pvt. Ltd.	Amnyk Group Inc., Equipments and Spares Engineering India Pvt. Ltd.	Cloud connected ECG Devices	0.22

Date	Target	Investor	Specialty	Deal Value ($Mn)
31-Mar-16	GreenOcean Research Labs Pvt. Ltd.	CIIE Initiatives	PoC solutions and EHR solutions	0.02
1-Oct-15	iKure Techsoft Pvt. Ltd.	Intellecap Impact Investment Network	IOT monitoring platform for vitals diagnosis	0.03
20-Jul-15	Oxstren Wearable Technologies Pvt. Ltd.	Next Orbit Ventures Fund	Wearable technologies	0.16
30-Jun-15	Attune Technologies Pte. Ltd.	Norwest Venture Partners, Qualcomm Ventures	Software solutions for Hospitals, Clinical and Pathology labs	10
19-May-15	Cooey Technologies Pvt. Ltd.	Subhash Chander Goyal	IOT monitoring platform for chronic diseases	0.47
10-Feb-15	Careway Health Pvt. Ltd.	Healthstart India Pvt. Ltd. , Pradeep Kumar Jaisingh, Suhail Chander, Sunil Baijal	Inpatient food order management system	0.03
24-Jan-15	Tricog Health Services Pvt. Ltd.	Amnyk Group Inc., Equipments and Spares Engineering India Pvt. Ltd., Bangalore Software Services Pvt. Ltd.	Cloud connected ECG Devices	0.45
1-Jan-15	SigTuple Technologies Pvt. Ltd.	Accel India IV L.P., Binny Bansal, Sachin Bansal, Debanjan Mukherjee, Nirupa Bareja	AI for diagnosis	0.76

Source: VC Edge

At the provider end too, there are several ventures today leveraging opportunities with potential to introduce efficiency, enhance patient experience and maximize revenues. This segment includes

mobile and web platforms for enabling primary care to specialist referrals as well as tier 2 to tier 1 referrals.

The active angel and venture capital funding landscape is supporting this robust level of activity and we anticipate that the momentum will only go up further. However, the next five years will also be a test window for business models and tangible value creation. We expect that fewer ventures will pursue small problems within the overall healthcare maze and there will be more connected and integrated solutions converging providers, consumers and other stakeholders. Aggressive competition will continue and the best value creators will thrive. At the end, the patient and the ecosystem will gain the most.

2. Telemedicine, Internet of Things (IoT) and Connected Care

Historically, most of the healthcare modules and systems have been disaggregated and have functioned in silos. There has been negligible focus on information capture, analysis and use in treatment decision making and all devices within the system have operated in silos. With India's strong backbone of globally recognized strength in information technology, we perceive significant activity during the next five years in the realm of connected care – telemedicine being more digitally empowered and IoT entering operating theaters, intensive care units and even primary care.

Telemedicine: Immediate impact of more digitally connected care is reverberating in evolved telemedicine initiatives. Telemedicine initiatives as a means to bridge the healthcare divide have been pursued in India for more than 15 years now. The current digital transformation empowers established efforts as well as emerging ones to connect providers and patients in models with significantly greater clinical impact and outcomes. Several point of care diagnostic devices including Bigtec and Bhat Biotech's RT PCR include digital connectivity to transmit test results in a real time.

LVPEI's Telemedicine Initiative

A public health focused ophthalmic institution such as LVPEI has innovated to go beyond optometry and baseline outpatient services in its 144 rural(or tier 3) vision centers to digitally connect their best ophthalmologists from the tertiary care centers to examine rural patients through a digitally connected slit lamp.

Internet of Things (IoT): Without being crowned for doing so, IoT is quietly pervading remote healthcare in India and creating possibilities for enhancing the overall national capacity. What is required is a coordinated national effort to realize the potential and maximize public health impact. IoT is rapidly impacting critical care, primary care and care for specific groups such as geriatric populations, patients with neurodegenerative diseases and patients needing palliative care. IoT is also proving a boon for the aging population and continuous monitoring via apps, sensors, SoS and other devices, by providing early detection and faster response to emergencies. This trend has

globally gained significant momentum with market leaders such as Medtronic investing in future ready smart technologies.

Connected pacemakers, blood pressure monitors and insulin pumps with diabetes sensors have been pursued for several years. Collaborations with technology majors contributing expertise in Artificial Intelligence (AI) are pushing the boundaries for such possibilities. For instance, Medtronic and IBM Watson have co-developed Sugar IQ, a cognitive app that can predict hypoglycemic (low sugar) episodes up to three hours before it happens. For such apps to be truly impactful, the connectivity needs to go beyond the device and the patient to seamlessly include the provider ecosystem.

In the emerging era of connected care, we envision equal innovation contribution from large majors such as Medtronic and IBM, young ventures as well as healthcare providers. Also, as anchors of care, hospitals and clinicians are powerhouses of knowledge and information required to power such connected care with Artificial Intelligence (AI) and cognitive modelling. Leading Indian hospitals have noted the power of such AI, big data and connected care and are embarking on efforts such as:

- Apollo's nascent big data platform,
- Kokilaben Dhirubhai Ambani hospital's digitally connected ambulance and
- LVPEI's collaboration with Microsoft on MINE for AI modelling to predict refractive error progression.

While large part of the provider ecosystem is yet to engage in the digital wave, embracing the transformation will be inevitable in the future and we see more engagement from Indian hospitals in this direction. However, to see this it is pertinent that the IT enabling in hospitals is strengthened and the country itself has robust HER guidelines and certification processes. This will be a critical precursor for this nascent wave to include several Indian hospitals as it globally expands.

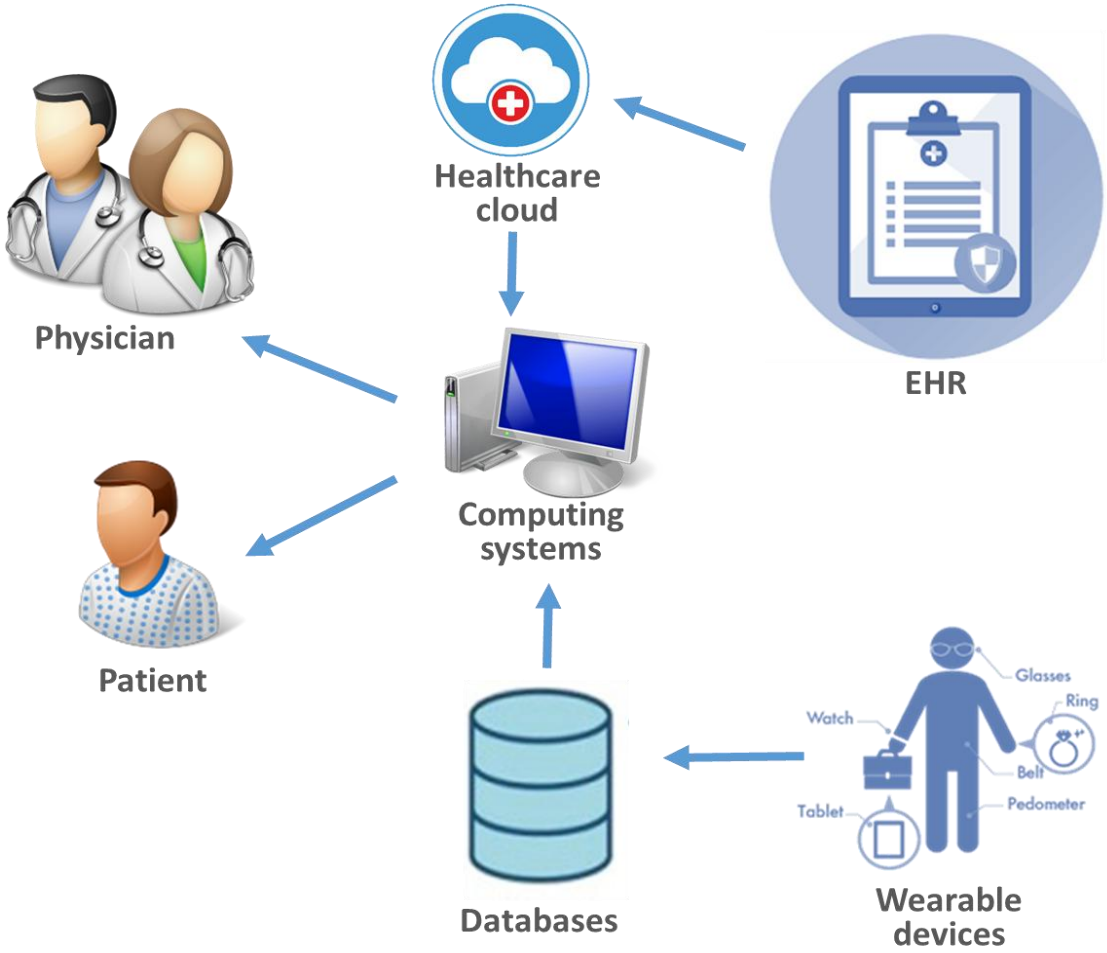


Figure: Information Technology in Healthcare delivery

Innovations in Therapies

Innovation in therapies have been historically driven by pharma and device companies. Globally, clinical centers of excellence have also been epicenters of therapy innovation. As primary observers of clinical problems, clinicians are placed in an optimal position to conceptualize and develop solutions. Even in India, we are excited to highlight the nascent trend of hospitals emerging as drivers of therapy innovation. We outline below areas with more intense engagement:

1. Regenerative Therapies

Globally, regenerative therapies are witnessing wider acceptance and escalating growth rates, with cell based products constituting the largest market share. Hospitals have been one of the drivers of research in autologous therapies. These are therapies where the cells harvested from an individual

are processed outside the body and re-introduced for particular clinical applications in the same person. They are now emerging as significant contributors even for allogenic therapies as well

Illustrative Examples of Regenerative Therapy Innovations

- LVPEI's Simple Limbal Epithelial Transplant (SLET), a novel surgical technique for treatment of unilateral limbal stem cell deficiency, is pushing boundaries and replacing the conventional radical tissue transplant and complex culture techniques.
- RMS has also been involved in R&D for delivery of advanced cell therapy treatments and has developed Chondron, to restore patient's own cartilage for Autologous Chondrocyte Transplantation (ACT).
- AIIMS led a major multi-center trial to analyze role of stem cells in repairing tissue damaged during acute heart attacks, where other treatment process, including a cardiac bypass surgery fails to adequately improve the heart function.
- Fortis has also forged a collaboration with US venture TotipotentRX Cell Therapy to provide stem cell based therapies and engage in collaborative research.

where donor stem cells are used. With allogenic therapies, there is greater potential to productize the therapy and thus commercialize on a larger scale. Several leading hospitals in India are providing stem cell based therapy as well as developing novel therapy protocols. These include AIIMS Delhi, PGI Chandigarh, CMC Vellore, AFMC Pune, Manipal Hospital Bangalore for neurological, hematological, hepatic and cardiac disorders and LVPEI and Shankar Netralaya for ophthalmic applications.

With the National Guidelines for Stem Cell Research in place and zeal in leading healthcare institutions to innovate in this frontier area, we stand at the threshold of transformative clinical possibilities in regenerative therapies for Indian patients. As we dive deeper into this phase, we need to ensure that the country enjoys strong enforcement of regulations and there is focus on providing well validated treatments to patients.

2. Organ Transplants

In India, skin transplant has been done for several generations. However transplantation of other organs has been a challenge owing to paucity of donors and the technology to preserve them for longer times and deliver them in timely manner. This has propelled development in two streams:

- Cadaveric harvesting
- Artificial organs through tissue reengineering

Chains like Global Hospital specialize in organ transplantation bringing together the donor and receiver at the same place, thereby increasing the probability of successful transplantation. They have successfully conducted 200 kidney transplants in the last 3 years. Additionally, hospitals have developed novel or more cost efficient preservation media for donated cornea and are deeply

engaged in development of regenerative therapies in areas such as liver transplantation. Again, given the intimate understanding of the clinical considerations, hospitals have been forerunners in this area of innovation and are active collaborators with research institutions to co-develop solutions.

3. Biobanking – Expanding Clinical Possibilities, Discovering Indigenous Biomarkers

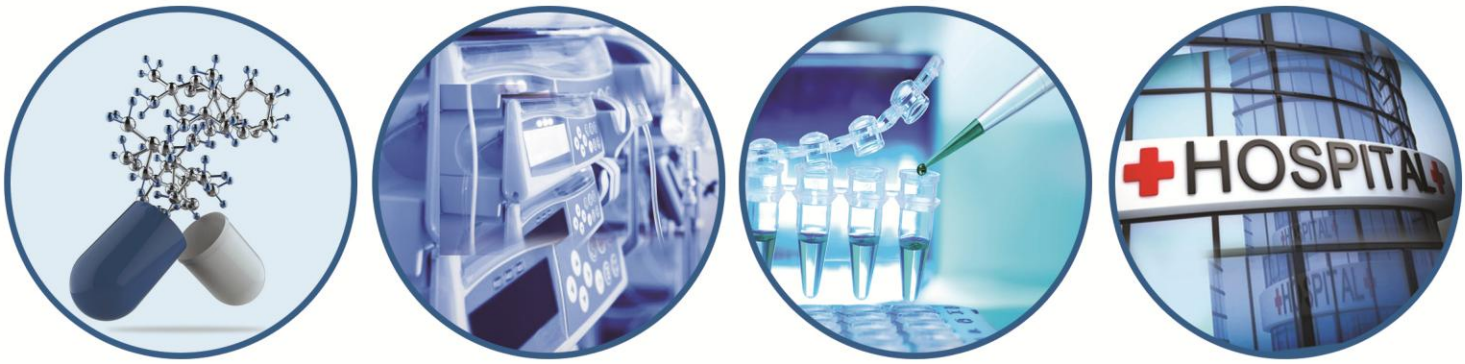
BioBanking of tissues, sperms & eggs, blood, umbilical cord etc. is enabling advanced treatment options as well as research (e.g. biomarkers) for advancing science. Given the evolving possibilities on genomics, it is critical that India strengthens research for identification of novel biomarkers and development of therapeutic solutions for domestic population. Some indicative efforts are highlighted below:

- Leading hospitals such as Apollo Hospitals and Tata Medical Center have already embarked on this effort. Apollo Hospitals and Saarum Innovations - have formed a joint venture to create a world-class human bio-bank and personalized medicine company Sapien Biosciences in Hyderabad. Sapien has exclusive access to the entire Apollo network for its bio-banking needs and house collection of high-quality samples under strict anonymity, along with associated medical data of the patients.
- Equally, the Tata Medical center and Tata Translational Cancer Research Centre also run a biobank for annotated tissue, blood and other samples.
- Likewise, due to increased awareness of Sperm and Egg banking, many of the oncology hospitals have been tying up with IVF Centers to preserve gametes of cancer patients before initiating chemo and radiation therapies.
- Increasing disease complexities and future treatment promises makes preservation of umbilical cord and stem cells incumbent.
- Lastly, even in the case of infectious diseases, our clinical institutions have been active in isolating strains causing the disease and have thus laid the foundation for development of vaccines and therapeutics. The most notable example is that of S116E strain for rotavirus isolated by Dr. Bhan in the 1980s while in AIIMS, This strain is the basis of the first India indigenously developed rotavirus vaccine, Bharat Biotech's Rotavac.

As the delivery ecosystem evolves, Indian hospitals are rising to the challenge and deepening their engagement in innovation advancement. With healthy appetite for collaboration, we foresee leading clinical institutions emerging as epicenters of not just clinical delivery, but also innovation advancement.

Making-in-India

Conclusion and Recommendations



Conclusion and Recommendations

Make in India effort by government is providing the strong backbone that the healthcare Industry needs to leapfrog from its nascent, unorganized and less evolved phase to a global force and yet provide affordable quality healthcare locally. Below we enumerate the impact of Make-in-India across healthcare.

Pharmaceuticals

Make in India Success

India being called the "Pharmacy of the World" is no easy feat and the pharmaceutical industry is undeniably one of the most mature sectors within Indian healthcare ecosystem. Today, we export medicines to over 220 countries of the world. As the industry lies in the comfort of its glorious past, it is crucial to take stock of the favorable factors that have contributed to this success and strengthen those further, and also understand the challenges that needs to keen attention to chart a sustainable path for future success.

Several key attributes have helped in the "make in India" success of the pharma industry. The favorable government thrust on the industry and a supportive export ecosystem driven by the Pharmaceuticals Export Promotion Council (PHARMEXCIL) have been instrumental in providing the Indian pharma industry excellent access to global markets and successful value realization. The nature of competition has also had a crucial role to play and today we have a good number of pharma stalwarts equipped with the financial strength to be movers and shakers in global markets.

Progressing Towards a Robust Tomorrow

India is likely to remain the epicenter of pharma manufacturing, for both supply and demand side reasons. While it is poised well to continue its dominant position, the following key enablers are essential to propel the industry forward.

a. Incentives to promote API Manufacturing:

India is a leading exporter of bulk drugs to many regulated and ROW markets. With the export appetite stealing all the limelight, the domestic market is underserved by incumbents and it is ironic that much of the API for the domestic market is contributed by low cost Chinese imports. As India continues to flourish in the formulations space, the potential that exists for local players in APIs is largely unaddressed. Thus, it is an urgent necessity to foster "Make in India for India" in API manufacturing to capitalize on the lost market share, reduce our dependency on China and establish self-sustainability. The government has to quickly take cognizance of this looming market erosion that calls for careful consideration of market economics and facilitate effective means of affordable healthcare access that is also balanced with the objective of retaining attractiveness of local markets for domestic players.

b. Green Chemistry:

Although the thinking on environmental sustainability has served as the starting point for green manufacturing, other practices such as substitution with enzymes as biocatalysts in

API manufacturing are slowly beginning to take shape in the industry, albeit slower as there is no regulatory thrust or incentive. Incentivizing green manufacturing could enable a greener economy and at the same time inculcate innovation spirit in the much ignored manufacturing sector.

c. Urgent Needs for IoT Platforms Implementation in Quality Control:

The increasing frequency of FDA inspections in India and the upward trend in warning letters has put the industry in a panic drive. In an export driven market, where credibility weighs high to maintain market share, at this point in time India cannot afford this kind of reputation compromise that has the potential to break the market positioning we enjoy in global markets. This trend in turn is pushing companies to think on ways to improve quality control and testing. Technologies based on IoT platforms, are the way forward, to decrease manual interventions and for the industry to redeem itself from quality related allegations and the urgency for embracing innovation in this space is extremely time sensitive.

Devices, Diagnostics and Delivery

Marching towards a stronger and more evolved industry landscape in India for devices, diagnostics and delivery is critical for several reasons – encouraging indigenous solutions to contextually relevant unmet needs, addressing quality and product gaps, expanding pricing and product options and steering away from import dependency (from high cost regions for high end products and China/Taiwan for commoditized products).

There is no easy solution to accomplish the Make-in-India objective. Given the complex ecosystem, it is critical we appreciate challenges, identify initiatives that are impactful and make fundamental structural changes required to foster sustainable industry engagement. We discuss below developments that are steering the industry forward and challenges that continue to hinder realization of the real potential.

Notable developments – Industry, Academia and Government

While certain industry centric developments are more mature, others are relatively nascent. However, we note critical contributions in the evolving ecosystem from three distinct segments of the industry:

a. **Multinational companies (MNCs) focused on developing contextually relevant solutions and manufacturing in India:**

With the backbone of technology and innovation strength nurtured over decades, the multinational companies form an important part of the ecosystem offering contemporary technologies and critical clinical solutions. In this segment, multinationals such as GE and Philips Healthcare standout for their efforts to develop solutions that are relevant in the context of low and middle income countries such as India. While the overall impact of such innovation is yet to be realized due to immature commercialization channels, there are several notable innovations including Philips Healthcare's low cost catheterization lab, GE Healthcare's handheld ultrasound device Vscan Access and Lullaby infant warmer. This has also had a

significant ecosystem spillover effect with innovators from these companies turning entrepreneurs (Forus Health, Perfint, DF3D etc.). The trend of multinationals innovating in India is now expanding with Stryker announcing an innovation center in Gurgaon and Medtronic exploring greater potential from its engineering center in Hyderabad. This powerful trend needs to be further encouraged and nurtured.

b. Emergence of mid-sized medical device companies pursuing complex and globally competitive product portfolios:

Meril is the best example to illustrate potential for technology focused Indian companies to redefine industry structures in India and pursue highest value markets globally. Established in 2006 by the Bilakhia group, Meril now boasts of an impressive portfolio of CE marked and FDA cleared products in orthopedic devices, cardiac devices, diagnostics, endo-surgery and ENT. The company sought global technology collaborations and built in-house innovation capacity, both with the objective of developing a contemporary and competitive product portfolio. Recently, Meril launched India's first bioresorbable stent, a frontier technology that is yet to establish itself even in global markets. Meril has also established its footprint in more regulated markets such as US and serves as a role model in the industry. We note a broader industry trend today of companies assuming greater risk appetite, seeking technology differentiation and embarking into more complex products. For instance, within the orthopedic devices segment companies such as Sharma Orthopedics and Biorad Medisys are now going beyond the trauma and spine segment to compete in the knee and hip segments. Both have leveraged technology collaborations to arm themselves with competitive portfolios including products that are now CE marked.

While this is one of the most encouraging trends in the Indian medical devices and diagnostics segment, the pace of change is disappointing. The funding landscape is ripe with several private equity funds focused on the segment. However immature market structure and policy issues stand in the way of this trend becoming an industry wide transformational phenomenon.

c. Innovation led ventures with focus on sophisticated technology development:

The last decade has been foundational for innovation activity in device and diagnostics startups. Spurred by non-dilutive funding avenues, there has been a surge in startups and several of them have pursued sophisticated technology development for complex products. Leading examples of such ventures include Forus Health, Perfint Healthcare, Bigtec Labs, Pluss Advanced Technologies and other startups highlighted in this publication. Encouraging and maintaining this momentum is critical to ensure that we have a holistic medtech ecosystem in India. While emergence of startups continues unabated and is only further expanding, we need to ensure that there is a continued focus on technologically sophisticated solutions that are scalable and the glaring gap in scale-up risk capital is addressed.

Academia and Government

There are several far-reaching initiatives triggered by various public stakeholders. The most notable developments include the following:

a. **Creating translational research platforms, bridging structural barriers to innovation and seeking a domestic pipeline:**

Research converging clinical, engineering and biochemical expertise has been structurally difficult in India given the institutional silos in the Indian education system. Forerunners such as the Sree Chitra Tirunal Institute in Trivandrum have contributed impactful innovation in devices. However, the larger ecosystem needs to be transformed to create a ripe landscape where academia provides the research and innovation advantage to industry. Several initiatives triggered in this direction during the last decade include:

- The Healthcare Technology Innovation Centre (HTIC) located at IIT Madras (IITM), a joint initiative of IITM and Department of Biotechnology (DBT).
- The National Biodesign Alliance (NBA), a multi-institutional partnership program in Biodesign initiated by the Department of Biotechnology (DBT) and includes partners such as IIT Delhi, IIT Madras, All India Institute of Medical Sciences (AIIMS), and CMC Vellore among others.
- Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum - Biomedical Technology Wing (BMT Wing), committed to medical device development, research and teaching.
- The Stanford-India Biodesign (SIB) programme initiated by the Department of Biotechnology (DBT) with partners in All India Institute of Medical Sciences (AIIMS) and IIT Delhi.
- The Centre for Biodesign and in-vitro Diagnostics at Translational Health Science & Technology (THSTI), Faridabad.

While the recent efforts imply a more engaged and applied research system, India needs multi-fold increase in focus on contemporary research in academia that can support industry with competitive products and technologies. Nurturing this potential during the current decade will be important to propel Indian industry towards its potential.

b. **Creating non-dilutive funding avenues and riding the startup wave:**

Unlike more mature innovation ecosystems such as US, EU and Israel, there was historically negligible amount of extra-mural funding from the Government for ventures to pursue technology innovation. During the last decade, initiatives taken have addressed this gap and provided the required stimulus to trigger innovation engagement in startups and SMEs. Non-dilutive grants that ventures can access today extend across idea exploration, proof of concept and clinical validation and enable technology de-risking. This has prompted both globally experienced people of Indian origin and experienced scientists from industry to take the entrepreneurial plunge in India. BIRAC, setup by the Department of Biotechnology has funded over 400 start-ups through grants, with contributions from

the Department of Science and Technology (DST), Government of India and other public bodies.

c. **Medical Technology Parks and Incubators – Addressing void in common infrastructure:**

While obtaining space for operations has not been a challenge in-principle, device companies continue to struggle with no access to common infrastructure required for product design, development or validation and for smaller scale commercial operations (such as HA coating facilities in the case of orthopedic implants). A major initiative in this direction has been funding for incubators from NITI Ayog (under the Atal Innovation Mission), BIRAC (under BioNest), DST (under National Initiative for Developing and Harnessing Innovation) and announcement of medtech parks by several state governments. If developed in a manner that provides required common infrastructure, creates a vibrant innovation ecosystem and ease of operations, the medtech parks hold potential to expand engagement from both domestic companies and multinationals, especially given the 100% FDI scenario. Three parks are being established by the states of AP (electrical devices), Maharashtra (consumables, orthopedic implants and surgical instruments) and Gujarat (disposables). At the proposed parks, companies will have access to readymade infrastructure as well as quality control units, logistics, regulatory and engineering services. Low cost rentals and revenue-support services for companies are also being considered. The parks will help small entrepreneurs tap into the expertise of larger companies and could help reduce manufacturing costs and logistics costs significantly.

d. **Initiating change in regulatory framework:**

Competitiveness of India produced products has always been lower due to a poor regulatory framework and a relatively low enforcement environment. With the exception of 15 categories of medical devices regulated as drugs, other devices marketed in India did not need any regulatory approvals. Additionally, there have been several unauthorized manufacturers even for the ones that needed a regulatory approval. This affected the industry two-fold – poor credibility associated with Indian manufactured products and preference for multinational products that had global regulatory approvals such as CE marking or FDA clearance, and increasing influx of poor quality devices from China.

The Medical Device Rules 2017 notified on 31st January 2017 by the Ministry of Health and Family Welfare is a significant development in this direction. The Rules confirm to Global Harmonization Task Force (GHTF) framework and classify medical devices based on associated risk. Building on this momentum, it is critical that the Government also creates an enforcement focus, addresses implementation capacity gaps and realizes progress on the Medical Devices Act that has been long overdue.

Continuing Challenges and Recommendations

While there have been significant developments, we are far from realizing the objective of an ecosystem that is attractive for medical device manufacturers – domestic and multinational. Until we create an attractive market where there is sustained competitiveness for domestic companies, the desire to have an expanded local manufacturing will remain a dream. Similarly, until barriers such as duty structure issues are addressed and markets are attractive, multinationals will remain on the periphery of Make-in-India for medical devices. We have highlighted below key continuing concerns and recommendations:

1. **Inverted Duty Structure:** Despite certain revisions, the current duty structure is still skewed, for several medical device categories and favors imports over indigenous manufacturing. In these cases, import duty on final products are significantly lower than the duties on imports of raw materials. Although there is cognizance of this challenge, efforts taken towards addressing it lacks in scale. For instance, even with the recent hike in duties for orthopedic implants, importers pay a mere 7.5% duty, while the import of materials like titanium can be as high as 28%.

   This renders local manufacturers uncompetitive and drives continuing dependence on imports. It essentially undermines all other developments under Make-in-India and calls for urgent attention.

   Policy makers need to address this problem and rationalize duty structures across medical device and diagnostic products to create a conducive environment where Indian manufacturers can be competitive.

2. **Funding Gap for technology scale-up and commercialization:** While there are avenues for non-dilutive funding and advancing until proof of concept, there is still significant gap in risk capital for funding innovative product development. Pioneering Indian ventures have struggled to raise initial and progressive rounds of venture capital funding required for capital intensive product development pathway for healthcare products.

   While funds created under Startup India holds potential to dclog this problem, the trickle down to venture capital funds and investible capital has been extremely slow and there hasn't been any significant change in the funding landscape in high-risk venture capital funding for product development in the last three years.

   To maintain the momentum in startup activity and to create pathway for Indian startups to advance to markets, domestic and global, it is pertinent that this funding gap is bridged on priority. While we now boast of a rich domestic pipeline in medtech innovation, the transition to marketed products and clinical benefits heavily rests on this challenge being addressed**.**

3. **Augmenting healthcare delivery capacity:** The Indian public health care system is constrained for capacity. Government's new National Health Policy is a step forward in

achieving Universal Health Coverage goal. The policy aims at increasing public healthcare expenditure to 2.5% of GDP from the current 1.4% with more than two-thirds of those resources going towards primary healthcare. It also safeguards delivery of comprehensive primary healthcare through the 'Health and Wellness Centers'. Additionally, it will ensure availability of 2 beds per 1000 population, provide for free drugs, free diagnostics and free emergency and essential healthcare services in all public hospitals. It also focuses on preventive measures to bring down neo-natal mortality and increase life expectancy. The initiative and goals are commendable.

It is critical that there is focused and accelerated execution that fosters private sector participation and aggressively bridges capacity gaps in public healthcare while creating a structured pathway for adoption of innovative technologies for public health applications.

4. **Nascent markets and unevolved structures:** Given the historically skewed industry structure and immature market channels, the Indian medical devices market calls for attention on key structural considerations that severely impair the attractiveness of the market and serve as deterrents to corporate investments:

   a. **Procurement mechanism and market channels:** Medical device market channels in India are underdeveloped for most product categories, especially innovative ones. Public health procurement is still price driven with poor mechanisms for uptake of an innovative device or diagnostics. To compound the problem further, there has been a historical challenge of public tenders calling for CE marked and FDA cleared devices.

   While the lack of clear public health procurement pathway affects most companies, it has a more severe dampening effect on innovations that have public health potential and have greater dependency on public healthcare system for reaching the intended beneficiaries. For instance, more than three highly innovative and sophisticated TB diagnostic products developed by Indian ventures have been waiting for widespread commercialization for want of procurement mechanisms. Though there have been mechanisms created more recently where innovative products could be submitted for consideration for Government procurements, ventures have expressed concerned about the pace of the process and there has been limited success until now.

   Even private markets suffer with immaturity. It suffers with fragmentation across all stages of supply chain. Several private hospitals have a preference for a higher priced device as it allows them to increase their billing. Finally, the complete lack of transparency results in a pricing challenge that is way more complex than it appears on the surface. All these factors are detrimental to industry growth and investments.

   It is critical that the policy environment is revamped to usher in a more structured market with easer to access channels across public and private healthcare systems. Public healthcare procurement processes need to be revisited to create pathways for adoption of innovative products and to steer away from a purely price based approach. Transparency

should be required of all stakeholders in the private healthcare system and unethical practices should be curbed.

b. Market Reward Mechanism: Given the immature market structures highlighted above, market penetration remains a challenge for most companies. Over that, recent threats on price capping add further restraints to an already challenged market. While price capping ensures affordability across the healthcare system, a universal approach such as this has dire consequences for Make-in-India and overall attractiveness of the industry.

A blanket approach of capping prices across the market serves well for commoditized or genericized products. However, in medical device categories where innovation is pertinent to meet unmet medical needs and foster competitiveness for indigenous manufactures, price control is detrimental as it serves as a deterrent to such innovation engagement. Shrinking the overall market size renders it unattractive for new entrants as well as existing players.

While equitable healthcare access is very important to accomplish, the means to do so need reconsideration. A possible solution is a balanced price control through value-based pricing, which is determined by the success of the product and procedures through measurable health outcomes. An alternative solution is cross-subsidization as exemplified by the Vaccine industry. Indian vaccine industry is a recognized manufacturing success story led by stellar innovation absorption. In this case, segments with higher affordability pay higher prices for the vaccines which gets translated into subsidized vaccination supply for Indian and global public immunization. Curbing of both private and public markets renders such cross-subsidization impossible and holds the threat of companies curbing investments or companies exploring ex-Indian markets like Indian API manufactures have done.

c. **Regulatory Overhaul:** Historically, only a minority of domestic manufacturers have attempted to obtain the Indian regulator's certification, let alone CE or USFDA, thereby causing an uncurtailed growth of the unorganized sector and subpar quality of manufactured products. The industry holds potential to increase manufacturing footprint several fold and fuel an innovation engine to build sustained competitiveness. A key driver will be accelerated regulatory reform and implementation focus. As highlighted above, an environment of enforcement needs to be created, implementation capacity needs to be strengthened and long overdue Medical Device Act needs to be steered into existence.

Complementary to creating a nurturing environment for innovation and building momentum for progression, government needs to orchestrate a strategy to sustain the innovations for a longer run by ensuring better proliferation across primary, secondary and tertiary care. The government needs to anchor the efforts to embrace innovation and drive growth underpinning the Make-in-India theme. The segments holds significant growth potential and the next decade will be critical to realize it.

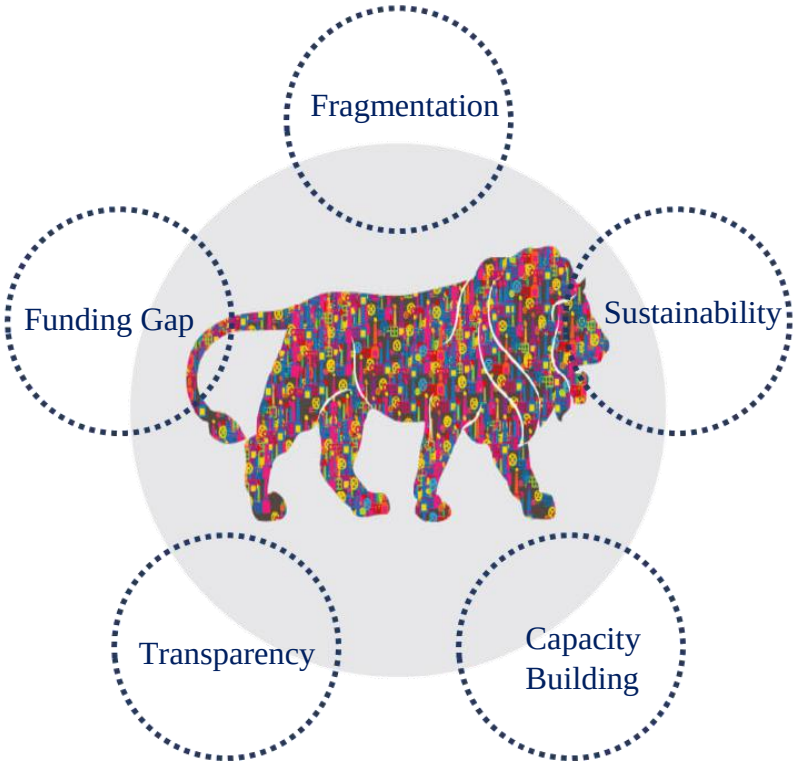


Figure: Making-in-India, the road to success

Abbreviations

Abbreviation	Full-Form
AIDS	Acquired immune deficiency syndrome
AIIMS	All India Institute of Medical Sciences
API	Active Pharmaceutical Ingredient
B2C	Business to Consumer
B2P	Business to Physician
BoP	Bottom of Pyramid
CABG	Coronary artery bypass grafting
CAGR	Compound annual growth rate
CDMO	Contract Development and Manufacturing Organization
CII	Confederation of Indian Industry
CNS	Central nervous system
CRO	Contract research organization
EHR	Electronic Health Record
EMR	Electronic Medical Record
FDA	Food and Drug Administration
FDI	Foreign direct investment
GDP	Gross domestic product
ICU	Intensive care unit
IVD	In vitro diagnostic
IVF	In vitro fertilization
MNC	Multi National Company
MRI	Magnetic resonance imaging
NABL	National Accreditation Board for Testing and Calibration Laboratories
NGS	Next-generation sequencing
NHS	National Health Service
NICU	Neonatal intensive care unit
PCR	Polymerase chain reaction
R&D	Research and Development
ROW	Rest of World
RT PCR	Reverse transcription polymerase chain reaction
STD	Sexually transmitted diseases
WHO	World Health Organization

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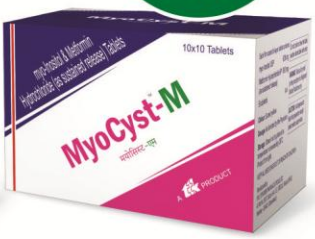

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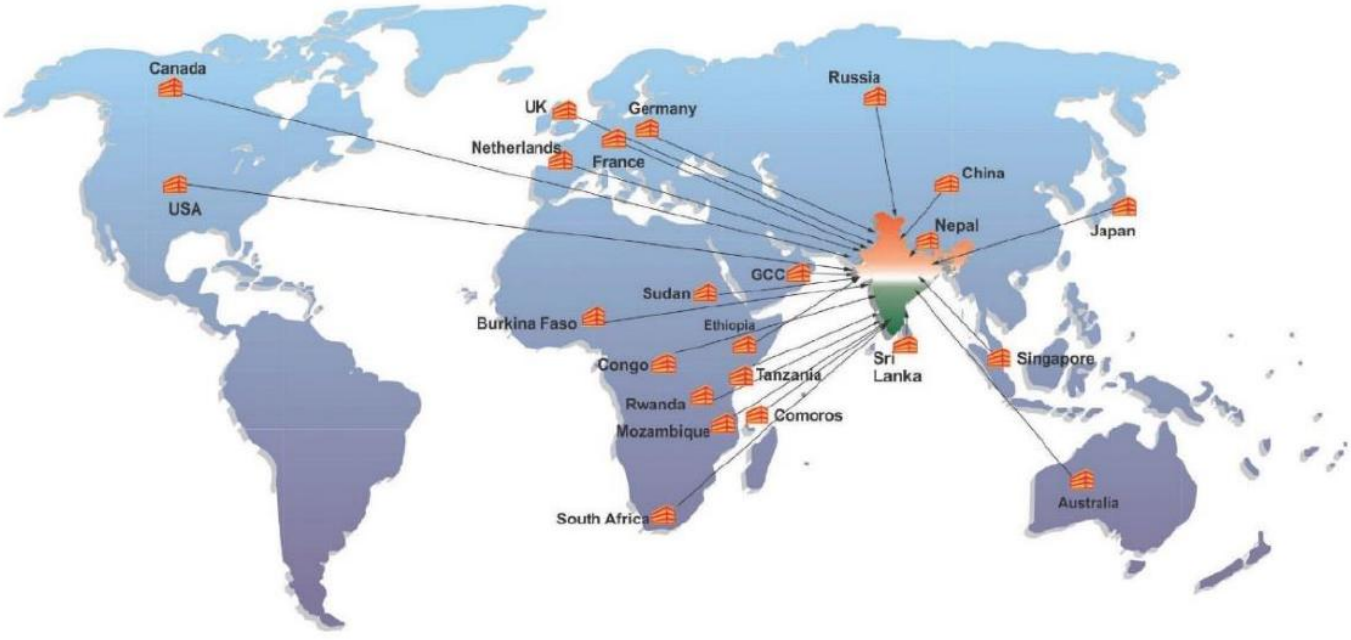
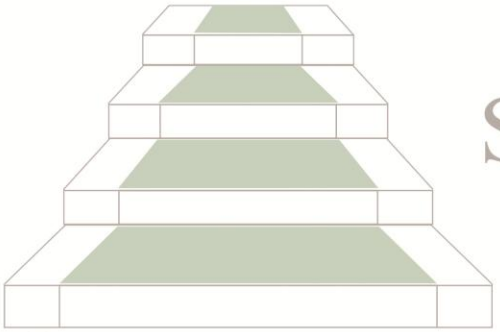
ASSOCHAM OVERSEAS OFFICES



The pictorial presentation of the world map does not purport to be the political and geographical maps of the world and India and is not drawn to scale. This is only indicative.

ASSOCHAM International Department



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