Health care innovations and medical technology: reaching the unreached
India ill equipped to meet the growing needs of the population.
Brilliance and talent in medicine, engineering & basic sciences has forced the world to look eastwards to seek low cost high quality medical care
India the Information Technology hub of the world.

Our focus:

► To understand the practical challenges, the interlinkages, and barriers that have resulted in stunted growth of innovation in med-tech in India

► To understand the unmet needs in the health landscape and potential bridge that health innovations and medical technologies can provide.

► To deliberate on appropriate solutions to build a vibrant ecosystem and an enabling environment

► Larger buy-in of stakeholders
Health care provisioning levers & stakeholder relationships

<table>
<thead>
<tr>
<th>Demand Side</th>
<th>Supply Side</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory bodies</td>
<td>Healthcare Service Providers</td>
</tr>
<tr>
<td>People at large and Patients</td>
<td>Pharmaceutical sector</td>
</tr>
<tr>
<td></td>
<td>Med Tech Devices Sector</td>
</tr>
<tr>
<td>Health Insurance &amp; Financing</td>
<td>Academia—Research &amp; Development and Production of skilled manpower</td>
</tr>
</tbody>
</table>

Enabling Regulatory Environment With Adequate Incentive & Disincentive Mechanism

Accessible, Affordable & Quality Care
Med-tech industry in India

Segmentation of Indian med-tech market – 2013

- Diagnostic imaging: 33%
- Orthopaedic and prosthetic products: 8%
- Patient aids: 4%
- Dental products: 10%
- Consumables: 27%
- Others: 18%

Indian medical device industry (in US$ billion)

- 2008: 2.0
- 2009: 2.0
- 2010: 2.4
- 2011: 2.8
- 2012: 3.0
- 2013: 3.7
- 2014E: 4.4
- 2015E: 5.5
- 2016E: 6.7
- 2017E: 7.9
- 2018E: 9.4

Medical technology is the utilisation of technology from any walk of life into the field of medicine.

- Indian medical devices market is among the top-20 in the world,
- Fourth-largest medical device industry in Asia after Japan, China and South Korea.
- The Indian industry was valued at US$3.65 billion in 2013, growing at a CAGR of 12.1% for 2008–2013. The industry is forecasted to reach US$9.4 billion by 2018.
- Catering to 20% of the world’s population, impacting global disease burden significantly, and having been one of the leading producer of low cost reengineered drug markets of the world our role in the medical devices market should have been much more significant.
Geo political situation and the local manufacturing market

Leading suppliers by product area and geography, 2012 (US$ million)

<table>
<thead>
<tr>
<th>Product areas</th>
<th>US</th>
<th>Germany</th>
<th>China</th>
<th>Japan</th>
<th>Ireland</th>
<th>EU-27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumables</td>
<td>64.8</td>
<td>28.5</td>
<td>35.6</td>
<td>19.2</td>
<td>20.8</td>
<td>90.6</td>
</tr>
<tr>
<td>Diagnostic imaging</td>
<td>232.6</td>
<td>97.7</td>
<td>146.9</td>
<td>78.3</td>
<td>2.2</td>
<td>241.5</td>
</tr>
<tr>
<td>Dental products</td>
<td>13.9</td>
<td>14.8</td>
<td>13.7</td>
<td>4.3</td>
<td>1.08</td>
<td>29.8</td>
</tr>
<tr>
<td>Orthopedic products</td>
<td>89.47</td>
<td>16.5</td>
<td>17.56</td>
<td>2.5</td>
<td>30.4</td>
<td>63.6</td>
</tr>
<tr>
<td>Patient Aids</td>
<td>73.6</td>
<td>19.3</td>
<td>28.4</td>
<td>3.47</td>
<td>64.1</td>
<td>126.6</td>
</tr>
<tr>
<td>Others</td>
<td>186.4</td>
<td>176.9</td>
<td>81.6</td>
<td>49.0</td>
<td>4.0</td>
<td>271.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>661.0</td>
<td>353.9</td>
<td>323.9</td>
<td>157.0</td>
<td>122.7</td>
<td>823.8</td>
</tr>
<tr>
<td><strong>% age share</strong></td>
<td>27.1</td>
<td>14.5</td>
<td>13.3</td>
<td>6.4</td>
<td>5.0</td>
<td>33.7</td>
</tr>
</tbody>
</table>

- Med-tech market is **largely based on imports**, primarily refurbished market contributing close to 75% of the market.
- Imports in India are grown from US$1.3 bn in 2007 to US$2.4 bn in 2012 and the exports have stagnated
- Calls for a focused approach to address the medical device market
The innovation life cycle

**Ideation**
- Concept identification
- Need assessment
- Understanding the market

**Innovation & design**
- Product design
- Lab testing
- Clinical trial

**Adoption**
- Fulfilling regulatory requirements
- Fulfilling IP requirements

**Go to Market**
- Engaging with manufacturers
- Successful use of product by end user –
Challenges & barriers
What have we done until date

► Recognized med-tech as a separate segment
► Laid foundation for institutionalization of innovation
  ► SIB—collaboration with academia internationally--seeding ideas, understanding innovation
  ► BIRAC –Section 25 co—single window for emerging bio-tech industries to enhance strategic research and innovation
► Millennium Alliance under the leadership of FICCI in partnership with USAID—network to bring the actors together to scale innovation
► CAMTech India-Jugaadthon—ideate and co-create, recognize innovation
### Challenges: Regulatory & institutional framework

#### Ideation and concept
- Lack of med-tech focused regulation that feeds into national health policy
- State-level variations in import regulation
- Lack of a single window for all legal compliances
- Absence of structured FDI policy

#### Innovations and design
- Lack of med tech SEZs and innovation parks
- Lack of preferential imports for raw material over finished products
- Overdone licensing—complete renewal for every small incremental improvement

#### Adoption
- Lack of a separate central regulatory body to certify medical devices
- Mandatory clinical trials even for FDA approved products
- Transparent and structured procedure for adoption

#### Go to market
- Lack of Risk-based categorisation
- Lack of tax breaks to encourage indigenous manufacturing
- No preferential imports for raw material over finished products

- Lack of role clarity, considerable overlap between ministries (Health, commerce, drug) w.r.t current regulation regime
- Bureaucratic hassles—perceived and real
- Absence of indigenous centralised certification programs to validate marketable products
### Challenges: Social & Physical Infrastructure to Promote Innovation and R&D

**Social and Physical Infrastructure to Promote Innovation and R&D**

<table>
<thead>
<tr>
<th>Ideation and Concept</th>
<th>Innovations and Design</th>
<th>Adoption</th>
<th>Go to Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>▶ Lack of institutional mechanism under cross sectoral mentorship to ensure cohesiveness of teams</td>
<td>▶ Lack of proper hospital infrastructure</td>
<td>▶ Constrained technology development and translation--valley of Death</td>
<td>▶ Absence of validation by user experts</td>
</tr>
<tr>
<td>▶ Few need identification and assessments undertaken</td>
<td>▶ Absence of a prototype super-marts</td>
<td>▶ Poor service quality in health facilities deters adoption</td>
<td>▶ Rising cost of validation-clinical trials of FDA approved products</td>
</tr>
<tr>
<td></td>
<td>▶ Few med tech incubation centres, R&amp;D labs</td>
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<td>▶ Lack of involvement of manufacturers during ideation</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>▶ Absence of an ancillary ecosystem - multi – layered, multi skilled capacity conducive for creation of med-tech design environment.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▶ Lack of stimulus to trigger scientific acumen</td>
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</tbody>
</table>
Challenges: Lack of Funding

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<tbody>
<tr>
<td><strong>Ideation and concept</strong></td>
</tr>
<tr>
<td>Rarely available early stage funding or angel funding to encourage young innovators.</td>
</tr>
<tr>
<td>Constrained funding for incremental innovations</td>
</tr>
<tr>
<td>Lack of coordination between funding agencies</td>
</tr>
<tr>
<td><strong>Innovations and design</strong></td>
</tr>
<tr>
<td>Ill-structured financing and reimbursements mechanisms — piecemeal approach</td>
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<tr>
<td>Lack of adequate documentation of adverse reaction to offer requisite comfort to certifying and funding agency</td>
</tr>
<tr>
<td><strong>Adoption</strong></td>
</tr>
<tr>
<td>Reduced governmental participation</td>
</tr>
<tr>
<td>Complex procedures on government funding</td>
</tr>
<tr>
<td>Reduced adoption</td>
</tr>
<tr>
<td><strong>Go to market</strong></td>
</tr>
<tr>
<td>High capital costs.</td>
</tr>
<tr>
<td>Absence of incentives to encourage local manufacturers.</td>
</tr>
<tr>
<td>Lack of institutional arrangement to create a base for export.</td>
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**Challenges: Lack of collaboration, knowledge sharing and mentorship programmes**

Collaboration — knowledge sharing and mentorship programme

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<tr>
<td>▶ Far and few institutionalized national and international collaboration embrace innovation to facilitate innovation and entrepreneurship</td>
<td>▶ Absence a knowledge mine and platform to discuss success, failures and lessons learnt</td>
<td>▶ Lack of awareness, dialogue, collaboration between key stakeholders to understand challenges around adoption</td>
<td>▶ Lack of industry dialogue to share technology that can be used in health care.</td>
</tr>
<tr>
<td>▶ Need for greater dialogue between innovators and manufacturers at proof of concept stage.</td>
<td>▶ Absence of an autonomous body for mentorship across all stages of innovation.</td>
<td>▶ Far and few institutional mechanisms for MNCs to adopt innovators and design teams</td>
<td>▶ Lack of collaboration between stakeholders to co-create an environment of combination science</td>
</tr>
<tr>
<td>▶ Lack of sharing platform and forum to discuss case studies on innovations that worked and why, which failed</td>
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Creation of a sustainable ecosystem

The need for a sustainable ecosystem clearly emerges as the solution to nurture innovation, uphold patient safety, in our efforts to offer comprehensive continuum of care provided; thus ensuring accessible, affordable high quality care through med-tech innovation.
Strong regulatory environment

Create an autonomous regulatory body with collaborative controllers

- Risk-based regulation thus eliminating the need to enlist devices.
- Appropriately qualified regulatory personnel.
- Providing a robust framework for IP laws to protect innovators' interest.

Indian Regulatory framework

- Rationalising med-tech approval processes to make innovations a commercial success.
- Independent regulation for medical devices outside the Drugs & Cosmetic Act, 1940.
- Supporting R&D and innovative initiatives by providing tax breaks and funds.
Strong institutional framework

**Innovator**

- **Early stage of innovation:**
  - Is directed by regulatory body to appropriate incubation center based on the kind of innovation

- **Regulatory requirement for registration/certification**
  - Based on risk categorization

**Innovations**

- **Quality Assurance team**
  - (Independent)
  - Empanelled Technology incubation centers - Mentorship programmes

- **Quality Control team**
  - (Independent)
  - Empanelled Experts
    - Experts: Multi disciplinary

**Adoption stage of innovation:**
- Based on Risk categorization, different risk certification shall be awarded.
Co-creation through combination science

- Creation of a skilled talent pool that is multidisciplinary and multi-layered.
- An ancillary ecosystem should be simultaneously developed.
- Creation of a knowledge platform to share knowledge around innovation, its processes, licensing, manufacturing, marketing, advocacy and adoption.
- Create platform for presenting innovative products to public through trade fares.
- Incentivize innovation and glamorize innovators to promote innovation.

**Diagram: Co-creation through combination science**

- **Collaborations with various stakeholders resulting in nurturing of skill sets conducive of medical device industry**
- **Domestic innovation focusing on socio economic conditions**
- **Customization/reverse engineering after need assessment**
- **Encouragement of multidisciplinary/multi-layered skill sets**
- **Creation of jobs - e.g., Prototypers, service engineers**

**Education & training - combination science**

- **Accessibility**
  - Affordability
  - Maintenance
  - Appropriate use of device
Breaking market barriers and market expansion of med tech manufacturing

- Position the domestic healthcare infrastructure to drive demand for affordable quality technology products.
- Revolutionising technology: Need to position India as the hub of frugal innovation and focus on exporting these devices to the developing world.
- Integrate innovation and growth of med-tech industry with the forthcoming Health policy to catalyse the systematic uptake of med-tech innovations.
- Setting up SEZs to boost local manufacturers and prototype firms to reduce cost of manufacturing.
- Evidence based research and funding.

**Diagram:**
- Distribution Networks
- Value Addition to user
- Commercial viability of device
- Interfacing & networking
- Product design

**Linking the Innovators to the market**
Collaboration with stakeholders globally

Vibrant ecosystem to promote growth of medical technology industry in India and ensure affordable accessible and high quality health care.

India - Market needs

Innovation Ecosystem
- Industry bodies
- Government Regulators
- Manufacturers
- Innovator:
  - Ideation
  - Innovation
  - Entrepreneurship
- Technologist
- Clinicians
- Funders, Donors, Venture Capitalist, Angel networks

Global - Market needs

Capacity Co-creation
Thank you