Trends in Medical Technologies
Innovation in Middle-Income Countries

• K. VijayRaghavan, Secretary, Government of India, Department of Biotechnology
• WHO-WIPO-WTO, Geneva, Wednesday 5 November 2014
India’s Middle Income Status: Salt and Pepper

• Rich, poor and in-between
Academia

• A rapidly changing scene.
The Perspective From Within
(Indian) Industry
Indian Pharma and Biotech: An under-leveraged global brand

- Neglected Sector:
  - Over-regulated
  - Over taxed
  - Under-incentivized
  - Under-Invested

- Global Value Proposition:
  - Lowest cost producer of Biosimilars
  - Lowest cost producer of Insulins
  - Lowest cost Bio-manufacturing hub
  - Lowest cost Biotech innovator
Indian Pharma (and Biotech)

World’s largest producer of generic drugs
20% in volume of the global generics market
30% volume share of US generics market

Pharmaceutical exports increased at a CAGR of 26% between FY06-13 to reach $10b.

The Indian Pharma Industry is forecast to expand to $45 Bn by 2020.

By 2020, the Indian market will be the 6th largest globally.
The Perspective from Global Industry

• Opportunities, Uncertainties, IP, Clinical Trials, Regulation
India’s Problem:
We are of the wrong colour.
On Every Map

TUBERCULOSIS
Yet, For Every Problem That India Faces..

• The Solutions are Available Through Internal Focus and Global Collaboration
India is Prepared to Grasp the Nettles of Complex Decision-Making

• Yet, People Must be Central
The Department of Biotechnology’s (DBT) Perspective in this arena....
DBT intervenes in multiple ways to drive the S&T agenda

- **Policy making / Legislative role**
  - Provide technology inputs to policy & legislative framework

- **Approval/Regulatory role**
  - Provide check-gate for approval, testing for emerging solutions e.g. validated toilet technology, seed certification

- **Market Making/Ecosystem Shaping role**
  - Foster rapid evolution & growth of ecosystem of public institutions, private industry & int’l partners

- **Support for developing technology solutions**
  - Support core R&D through network of institutions
  - Help overcome capacity hurdles eg. funding, people, project management to potentially breakthrough ideas

Increasing impact of DBT
New Opportunities in New Initiatives

1. Maternal, Child & fetal development
2. Drug discovery for tropical diseases
3. Developing new vaccines
4. Eliminating open defecation (sanitation)
5. Sustainable food security through soil, crop & livestock
6. Energy solutions through biotech
7. Large scale training programs in basic & applied life sciences

DBT Impact Assessment
List of initiatives

1. Maternal, Child & fetal development
   - Drug discovery for tropical diseases
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6. Large scale training programs in basic & applied life sciences
7. DBT Impact Assessment
India accounts for highest share of burden for maternal, neonatal and child (<5 years) mortality globally

~290K women die of pregnancy related causes; ~20% in India

India accounts for more than a quarter of neonatal deaths

>18K children die everyday; india shares 22% of burden

Source: UNICEF child survival report, 2013; WHO
List of initiatives

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Globally, tropical diseases affect ~17% of the population; with India constituting a disproportionately high burden (~30%)…

GLOBALLY ~1.2B PEOPLE AFFECTED BY TDs; 315M AFFECTED IN INDIA

India accounts for up to 40% burden for diseases like rabies and leprosy

Tropical diseases include TB, Malaria, Diarrhea and 17 NTDs

“With more than 290 million Indians suffering from NTDs, India accounts for a major portion of the global NTD burden.”

News Report, 2011

Source: Action on neglected tropical diseases in India, Global health progress, DNDi, WHO, PLOS medicine
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Global and India overview: India has a very high disease burden and mortality rate from VPDs

India has a daly burden ~4x of china and ~24x of Brazil

India has a Mortality rate ~7x of china and ~65x of Brazil

Note: VPDs include DPT, Hib, JE, Measles, Rabies, Rotavirus, Smallpox, Typhoid, TB, etc.

Source: Frost & Sullivan; IMF; Lit Search
India lags global peers in the coverage rates of basic vaccines

DPT

Measles

BCG

Note: All coverage rates are WHO estimates, may differ from NFHS/DLHS figures, DPT3 – Penetration of 3rd dose of Diptheria, Pertusis, Tetanus vaccine
BCG – Penetration of Bacillus Calmette Guerin (anti-tuberculosis) vaccine
Source: WHO coverage estimates 2007; UNICEF statistics
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Currently, India carries a huge burden of open defecation; this is despite significant improvement in last 2 decades.

Multiple flagship programs aim to tackle the sanitation challenge.

**SIGNIFICANT PROGRESS HAS BEEN MADE...**

..yet ~60% of ALL people practicing open defecation reside in India...

Note: Unimproved sanitation includes shared, open defecation & other unimproved facilities
Source: Progress on Drinking Water and Sanitation (2014 Update)
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Globally, improvements in yield are crucial to closing the food security gap as population increases drive demand.

Much of the planet does not have access to optimal nutrition with an increasing population, improved crop production is required to meet demand.


0.9% Global CAGR over 35 years
India lags behind most other nations in terms of yield (1/2)

Preliminary

Source: FAO
India lags behind most other nations in terms of yield (2/2)

Source: FAO

pulses

vegetables

fruits

Source: FAO
Further, availability and nutrition issues continue to impact India’s ability to fight hunger

Hunger is larger issue in India than in other comparable nations... ...Leading to major impact on population especially children

Source: FAO
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Rapid increase of biotech industry has driven demand for biotech professionals across years

Indian market is growing... ...fueling demand for biotech professionals

Source: IBEF, Biospectrum survey (2007)
With demand, supply has increased over years but industry absorption is significantly low…

Incremental demand and supply of biotech manpower has increased over the years...

... but Only 20-25% under-graduates are absorbed in industry

Note: * 2012 supply figure calculated assuming average duration of Biotech degree of 3-5 years
Source: Biospectrum survey (2007), Biospectrum article (2012)
Shrink the Gorillas by addressing issues squarely. Keep people central.
BIRAC Role in Medical Technologies Sector
About BIRAC

A ‘Not for Profit Public Sector Undertaking’ set up by Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

Established on:
20 March 2012
Stepping-Up the Innovation Ladder
**BIRAC Presence in Medical Electronics**

- An affordable fluorescence reader for point of care diagnostics
- AINA- Software platform being developed for using mobile phone to analyse blood glucose test strips.
- The device for execution procedure for tumor ablation using Maxico (The Integrated planning navigation and Training Platform for Tumor Ablation) launched in the market. *Received USFDA clearance*
- A rapid cost-effective point-of-care diagnostic device with microPCR to diagnose multiple diseases presently Malaria, Dengue & Typhoid developed is ready for market.
- Design and Development of Photo Dynamic Therapy (PDT) Laser System
BIRAC Medical Technologies Investment Portfolio

- **Funding Support**: 3.0 Million USD
- **No. of Companies Supported**: ~ 65
- **30% increase in budget committed from last year in Medical Technologies Sector**
- **Maximum funding in *in vitro* Diagnostics, Interventional Surgery devices followed with Cardiovascular Devices**

BIRAC has provided the much needed impetus to Medical Technologies sector
Capturing Opportunity: Stanford-India Biodesign

- Only 15 programs/centers promoting medical device innovation worldwide
- SIB program implemented at AIIMS & IIT-D is first such program in Asia

*SIB (Stanford India Biodesign)
Stanford-India Biodesign Programme

Department of Biotechnology,
MoS&T, Govt. of India

AIIMS, New Delhi
IIT, Delhi
Stanford University, CA

Indo-US
S&T
Forum

Biotech Consortium India Limited
SIB: Mission

- To develop leaders in biomedical technology innovation in India
- To identify unmet healthcare needs and develop solutions in India
- To help develop low cost, high quality devices for the “common man”
- To help ignite the Indian MedTech Industry

Educate – Collaborate – Innovate

Fellowship – Internship
### SIB Programme: *A model for inclusive innovation*

<table>
<thead>
<tr>
<th>Aim:</th>
<th>To create medical technology innovators and entrepreneurs to foster &amp; promote medical technology innovation in India</th>
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<tbody>
<tr>
<td>Focus:</td>
<td>Implants &amp; devices</td>
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<tr>
<td>Unique features:</td>
<td>Multidisciplinary team; national level selection;</td>
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<td></td>
<td>Training in biodesign process at Stanford; clinical immersion in India;</td>
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<td></td>
<td>Platform to work together for end to end processes (<em>idea generation &amp; selection, IP protection, prototyping, validation, testing, tech-transfer and commercialization</em>);</td>
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<td>PPP:</td>
<td>Collaboration with med-tech industries;</td>
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<td>Challenge:</td>
<td>Ability to walk the last mile</td>
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Devices developed under SIB so far

**Consure** - A new standard of care for the short term management of fecal incontinence.

*Nishith Chasmawala, Amit K Sharma, Sandeep Singh*

**Noxeno** - A simple and effective device to remove posterior impacted foreign bodies for children.

*Jagdish, Jonathan, Siraj, Siddhartha*

**Intraosseous(IQ) Device** - A device to access intramedullary space of long bones to administer fluids and drugs during emergency.

*Jayant Karve, Srinivas Kiran Jaggu, Sandeep Singh*

**Parasafe** - An innovative device to standardize the process of paracentesis for all healthcare facilities.

*Jagdish, Jonathan, Siraj, Siddhartha*

**Relligo** - A novel, low cost device for pre-hospital care in Trauma patients.

*Darshen Nayak, Pulin Raje*

**Bioscoop** - A safer and simple semi-automatic device for liver biopsies.

*Jagdish, Jonathan, Siraj, Siddhartha*

**Sohum** - A low cost device to screen neonates for hearing defects in resource constrained places.

*Nitin Sisodia, Pragun Goyal, Mayank Kumar*

**Variseal** - A breakthrough in the (short-term) emergent management of Upper GI Variceal Bleed.

*Jagdish, Jonathan, Siraj, Siddhartha*

**Neobreathe** - A device for simplifying the process of neonatal resuscitation.

*Avijit Bansal, Ayesha Chaudhary, Mrudusmita Choudhary, Chinmay Deadhar*

**Breathclear** - A device to dislodge mucus from respiratory tract of patients with Chronic Obstructive Pulmonary Disease (COPD).

*Vishal Agale, Sonakshi Pandey*

**Transferlife** - A simpler way to transfer non ambulatory patients from one bed to another.

*Mansi Agarwal, Shhji Malhotra, Pooja Singh*

**Sharps** - A safe & better way to manage sharps during surgical procedures.

*Vishal Agale, Sonakshi Pandey*
Devices developed under SIB so far cont..

**Brün** - A cost effective solution to assess fetal wellbeing to reduce intrapartum stillbirths.
*Anirudh Chaturvedi, Prashant Jha, Abhinav Ramani, Balaji Teegala*

**d.Rx** - A mobile application to quickly reference brand names, dosages and prices of drugs sold in India.
*Anirudh Chaturvedi, Prashant Jha, Abhinav Ramani, Balaji Teegala*

**Handy** - Simplifying hand hygiene in hospitals with improved accessibility and functionality.
*Aanan Khurma, Neeraj Jasmathiya, Saurabh Bag, Ripunjay Chachan*

**NeoCap** - A novel cost effective way to prevent neonates from environment induced damage.
*Aanan Khurma, Saurabh Bag, Akhilesh Gupta, Monika Singh*

**Uthishtami** - An uplift device to help elderly rise independently from a sitting position.
*Deepali Chandrathe, Sneha Venkat, Rahul Das, Chetan*

**Neonatal Care Kit** - A complete kit that simplifies the process of giving KMC to neonates without causing fatigue to the provider.
*Aanan Khurma, Sahaj Ghose, Saurabh Bag*

**AccuFeed** - An accurate way to insert Nasogastric tube in patient with neurological dysphagia.
*Neha Shetty, Medha Tyagi, Himanshu Gupta, Ageyaya Dwivedi*

**Thorashield** - A safer way to perform pleural tapping in patients with pleural effusion in order to reduce the complications during the procedure.
*Vaisakh N.J, Nitesh Jangir, Saaransh Jain, Ankita Kashyap*

**Hanitizer** - An intuitive way to increase compliance to WHO prescribed hand hygiene guidelines in health care settings.
*Aanan Khurma, Saurabh Bag, Jagdish Chaturvedi, Neeraj Jasmathiya*

**Saakar Kit** - An efficient way to distribute medications to patients in the resource constrained settings in order to minimize mismanagement of medication.
*Aditya Pasupuleti, Jovis Johny, Basava Kumar*

**Needs Manager** - A mobile application to assist innovators to manage their observations and translate them to meaningful need statements.
*Aanan Khurma, Jagdish Chaturvedi*

**iWe** - A Transillumination device for peripheral vein detection in pediatric patients.
*Vishal Agale, Megha Agrawal, Ramakant Beesetty, Chondni Kabra*
Technologies licensed

’Sanford India Biodesign’
Licensed Technologies

Fecal Incontinence Device
Soft Tissue Biopsy Device
Limb Immobilization Device
Auditory Impairment Screening Device
Neonatal Resuscitation Device
Assistive Device for Enteral Tubes

Aspiration Device

Nasal Foreign Body Removal

Patient Transfer Device

Abdominal Paracentesis Device
Technology to enable accessibility of high quality cataract surgery to rural India

- First-in-India: Exclusive Ministry of Health approval for pilot
- Engineering design innovations to meet safety and sterility
- Successful pilot led to Ministry of Health approval for multi-year operation
- 1000+ surgeries and continuing....
Technology to address cost and skill barriers in ophthalmology

• **Ophthalmic image computing**
  – Computational extraction of quantitative information from eye images
  – Visual information present in images: anatomical, neuro-vascular, pathological

• **Capabilities**
  – **Disease screening:**
    • High scalability
    • Timely identification
    • High throughput
  – **Diagnosis:**
    • Quantitative visualization for enhanced clinical workflow
  – **Disease progression:**
    •
Industry partnership with Forus Health, led to technology successfully reaching the field

“3nethra”, ophthalmic imaging device from Forus Health, an Indian startup

• Affordable
• Non-expert operable
• Portable

Powered by Eye PAC technology’s computing intelligence,
Developing affordable diagnostic instrumentation in India

Proven expertise in med-tech R&D and engg.

Develop diagnostic equipment

Market leader in rapid test kits for diagnostics (HIV, Dengue, Malaria)

Accelerated product development & Market deployment Feb - Dec 2014

- Current scenario: Imports of over Rs. 100 crore of kits and equipment
- Early mover in indigenous development of quantitative tests for lifestyle disorders
  - HTIC develops instrumentation, J Mitra develops diagnostic kits
- To develop and manufacture quantitative rapid diagnostics in India