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 $ 10 %

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

By 2020, the Indian market will be the 6th largest globally.

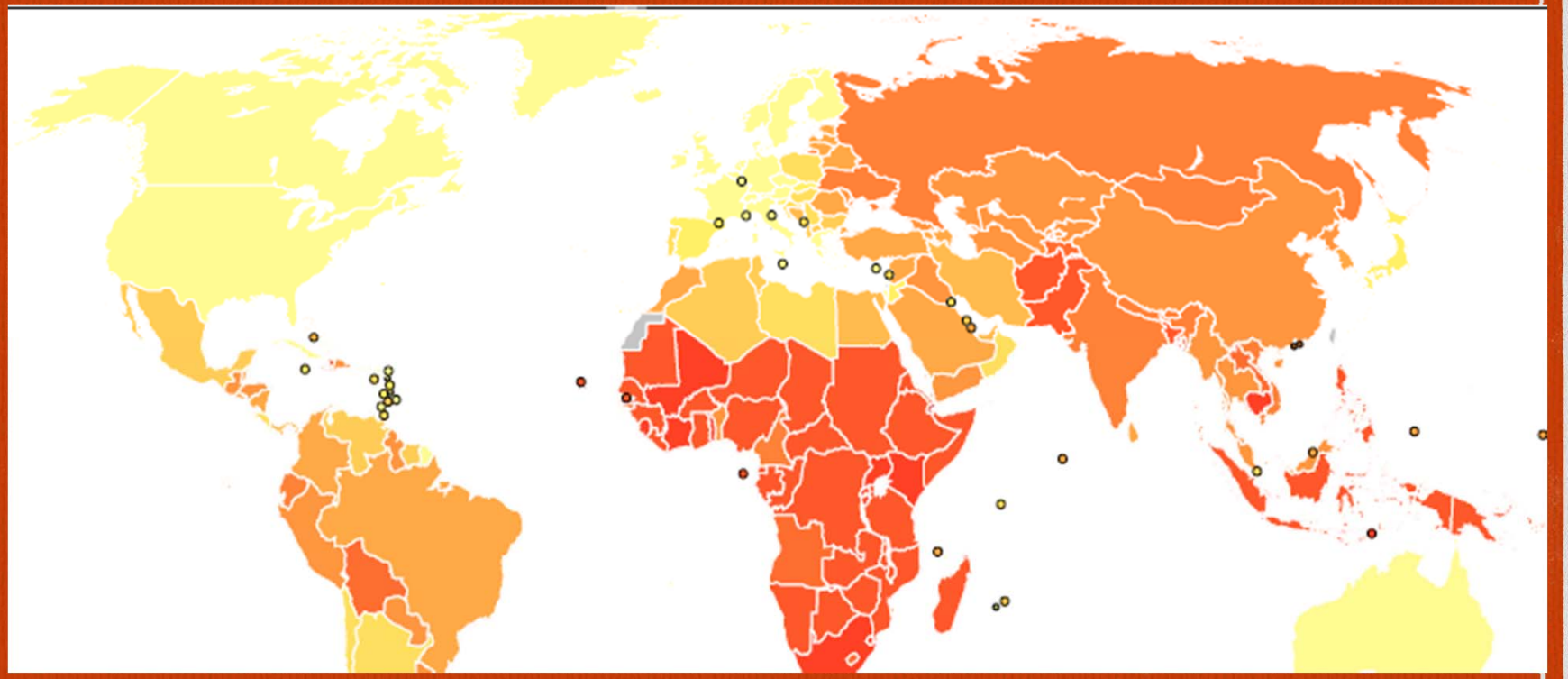
The Perspective from Global Industry

- Opportunites, Uncertainities, 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

http://littleecofootprints.typepad.com/.a/6a00e55397a5c288340192abddba84970d-pi

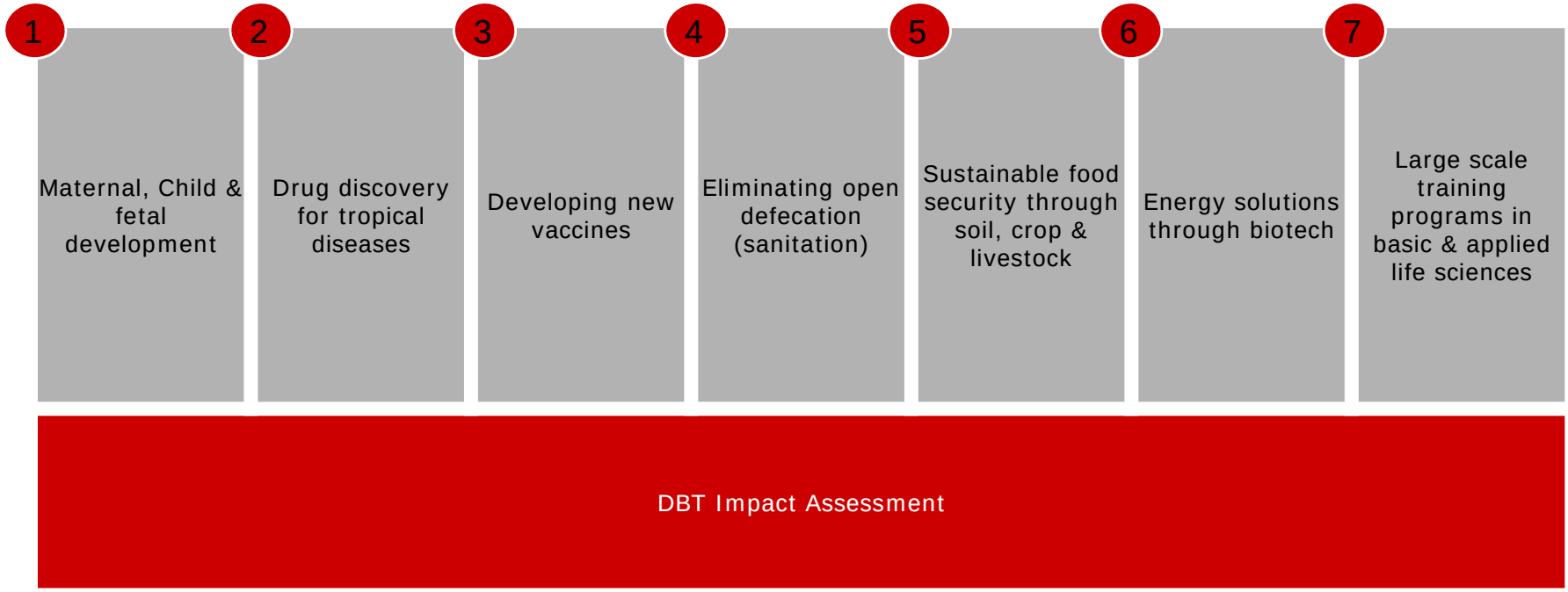
The Department of Biotechnology's (DBT) Perspective in this arena….

DBT intervenes in multiple ways to drive the S&T agenda

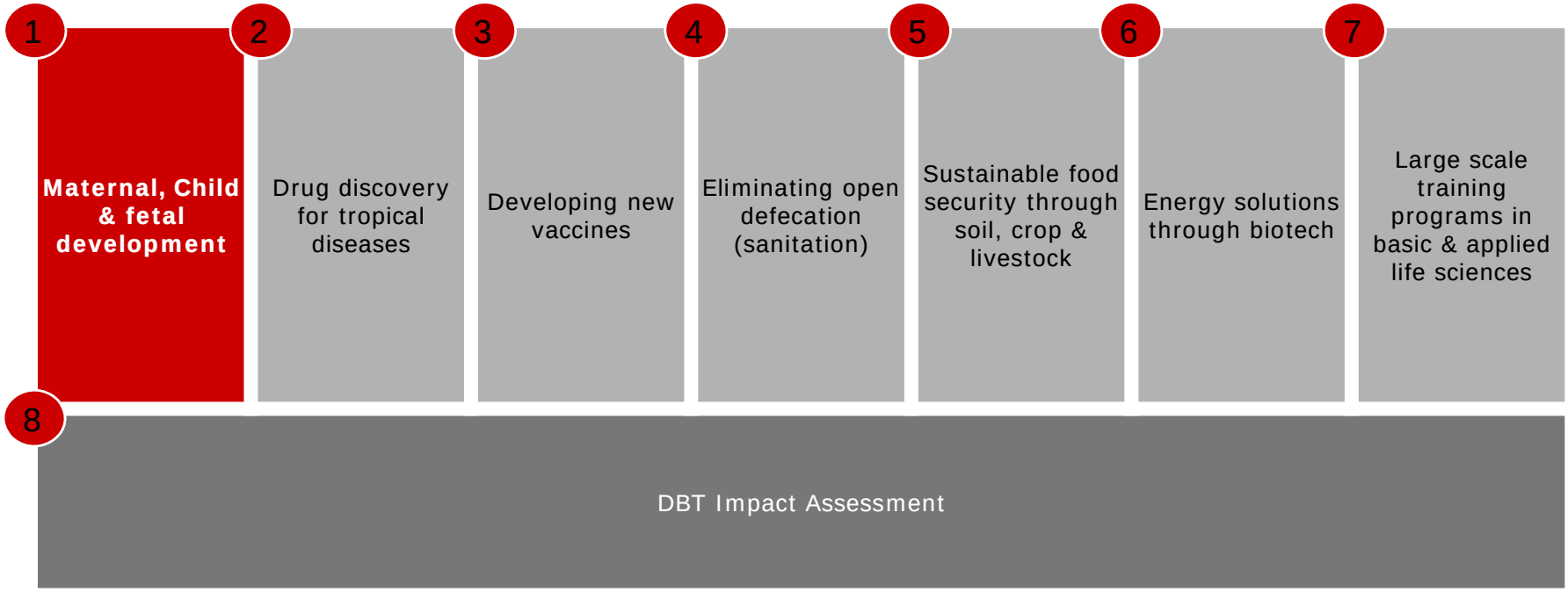
Policy making / Legislative role	Approval / Regulatory role	Market Making / Ecosystem Shaping role	Support for developing technology solutions
• Provide technology inputs to policy & legislative framework	• Provide check-gate for approval, testing for emerging solutions e.g. validated toilet technology, seed certification	• Foster rapid evolution & growth of ecosystem of public institutions, private industry & int'l partners	• 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

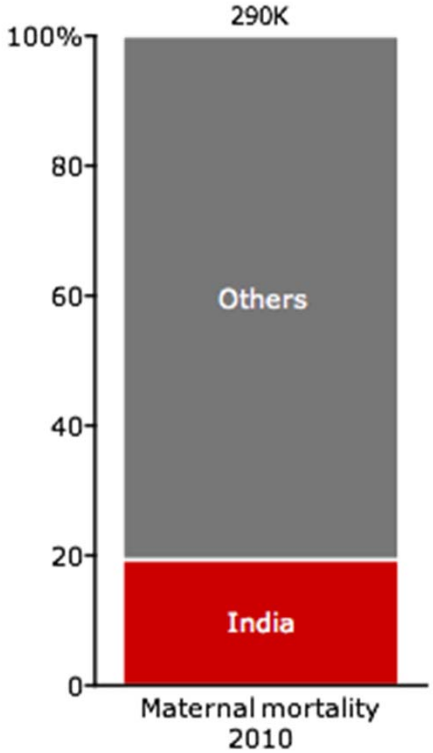


List of initiatives

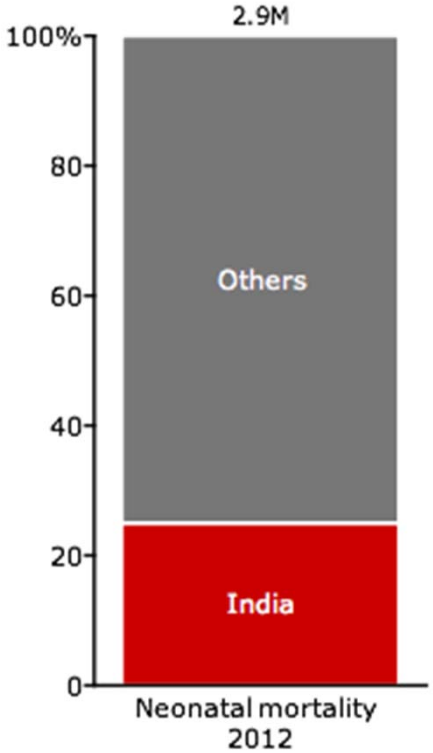


India accounts for highest share of burden for maternal, neonatal and child (<5 years) mortality globally

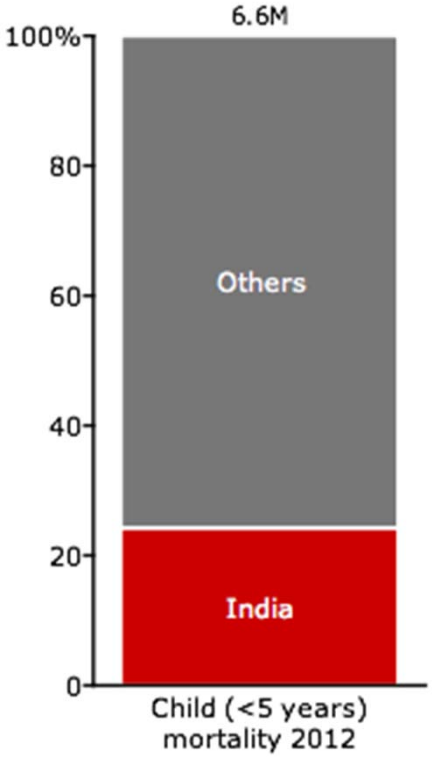
~290K women die of pregnancy related causes; ~20% in india



India accounts for more than a quarter of neonatal deaths

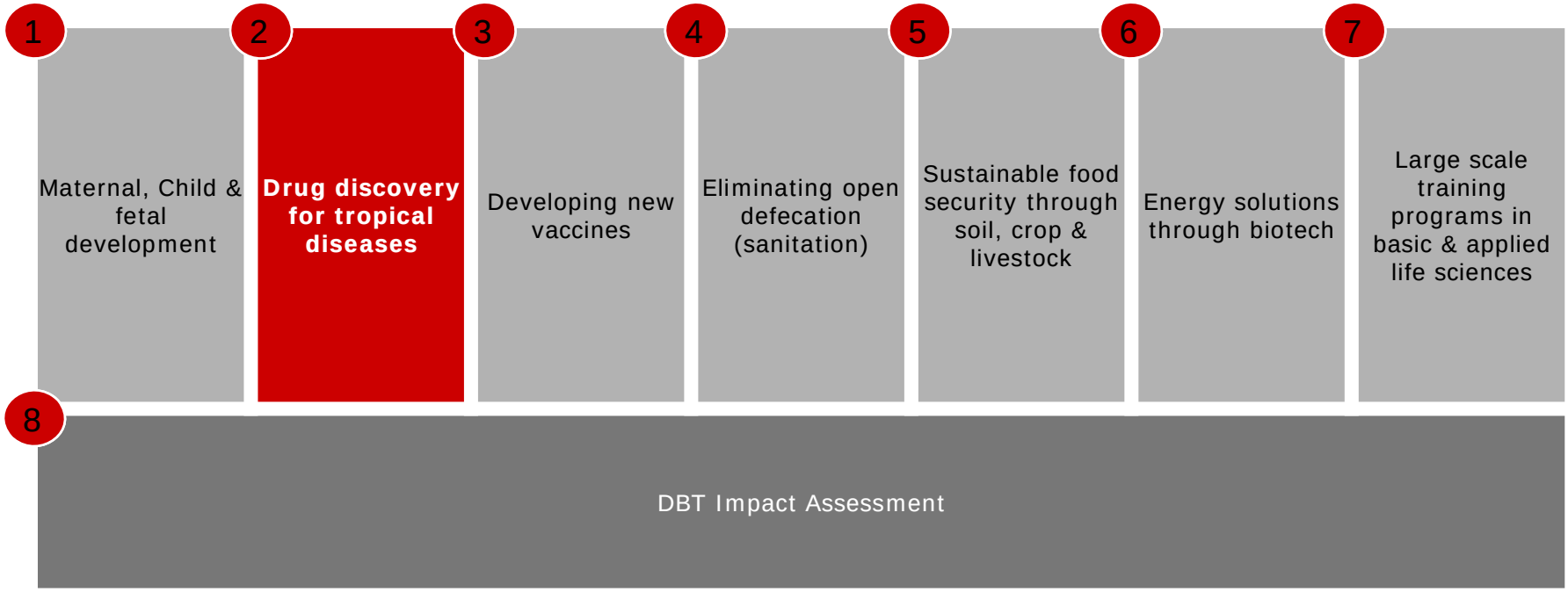


>18K children die everyday; india shares 22% of burden



Source: UNICEF child survival report, 2013; WHO

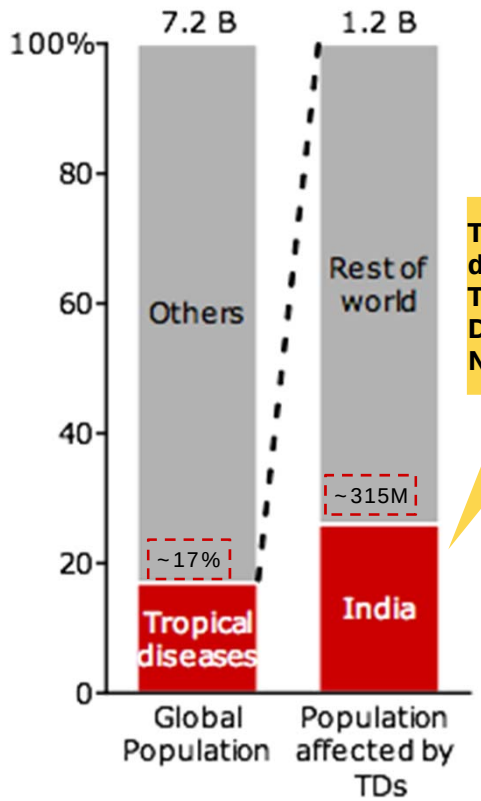
List of initiatives



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

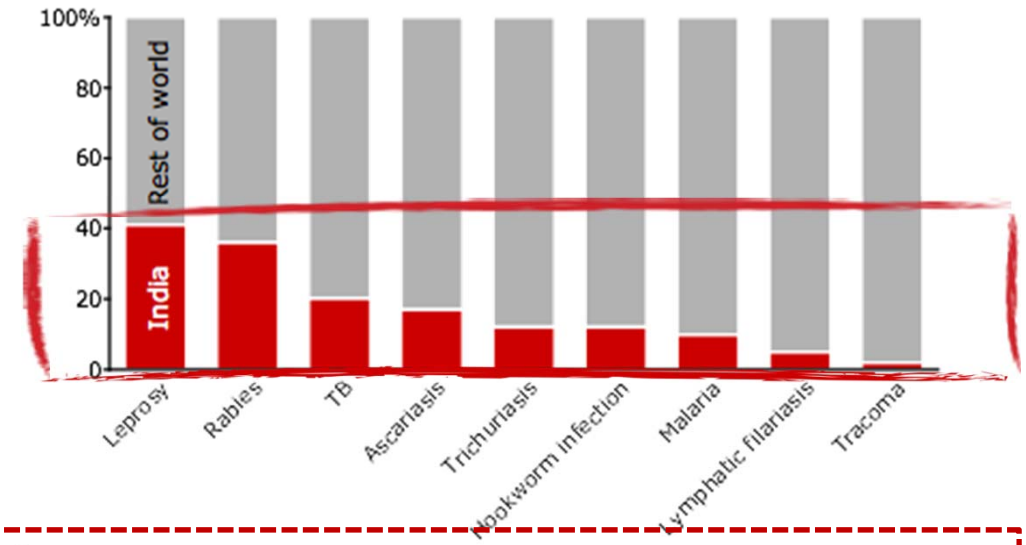
People affected globally (2011)



Tropical diseases include TB, Malaria, Diarrhea and 17 NTDs

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

Cases of leading tropical diseases



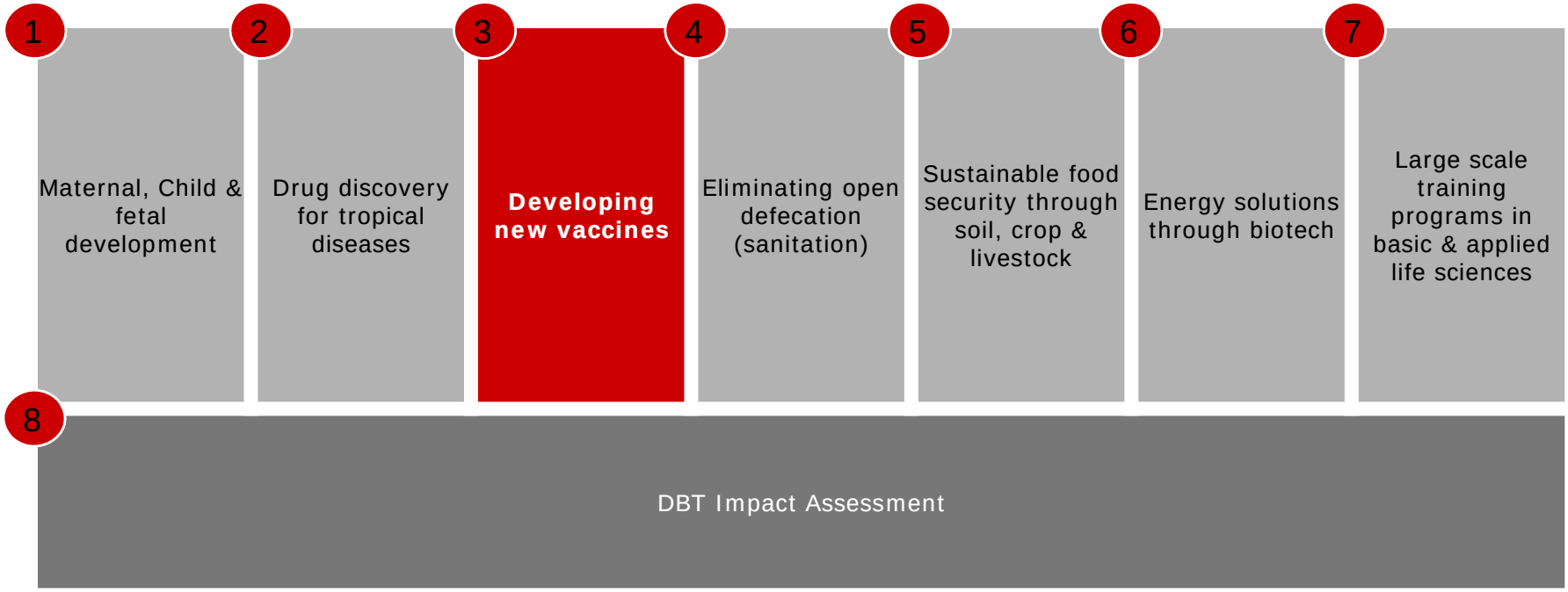
No. of cases in India	0.09 M	0.02 M	2 M	140M	73 M	71 M	24 M	6 M	1 M

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

News Report, 2011

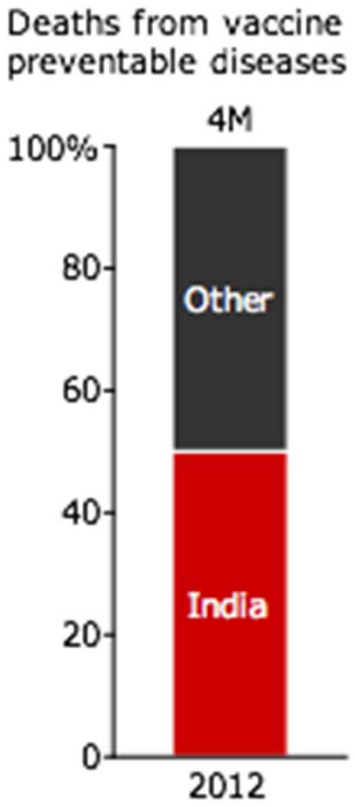
Source: Action on neglected tropical diseases in India, Global health progress, DNDi, WHO, PLOS medicine

List of initiatives

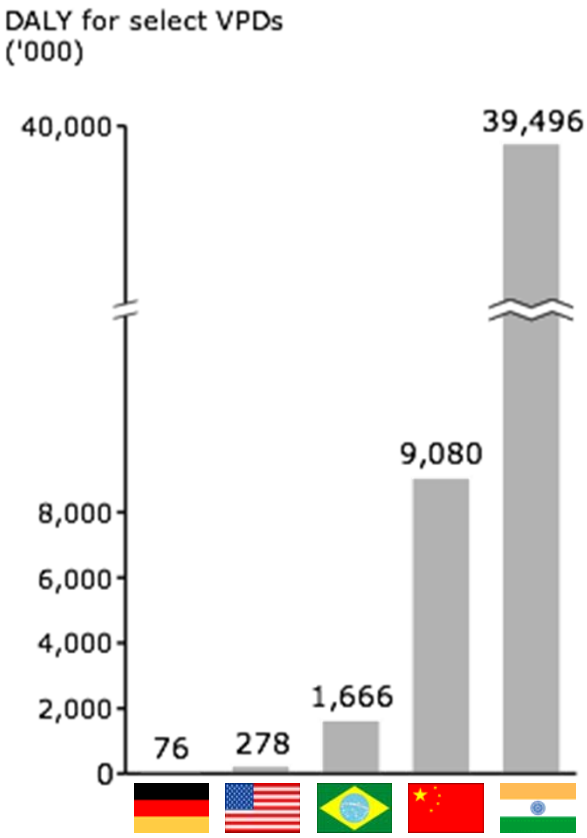


Global and India overview: India has a very high disease burden and mortality rate from VPDs

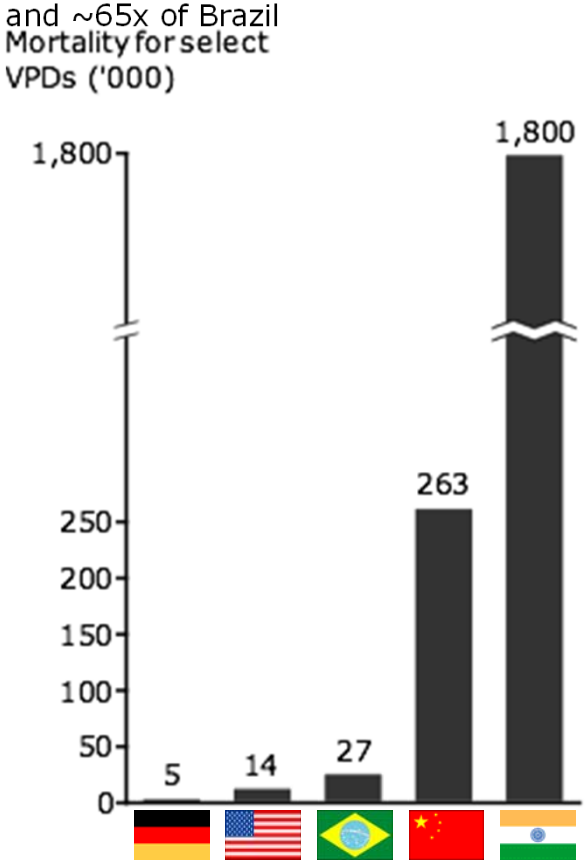
India accounts ~50% of mortality



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

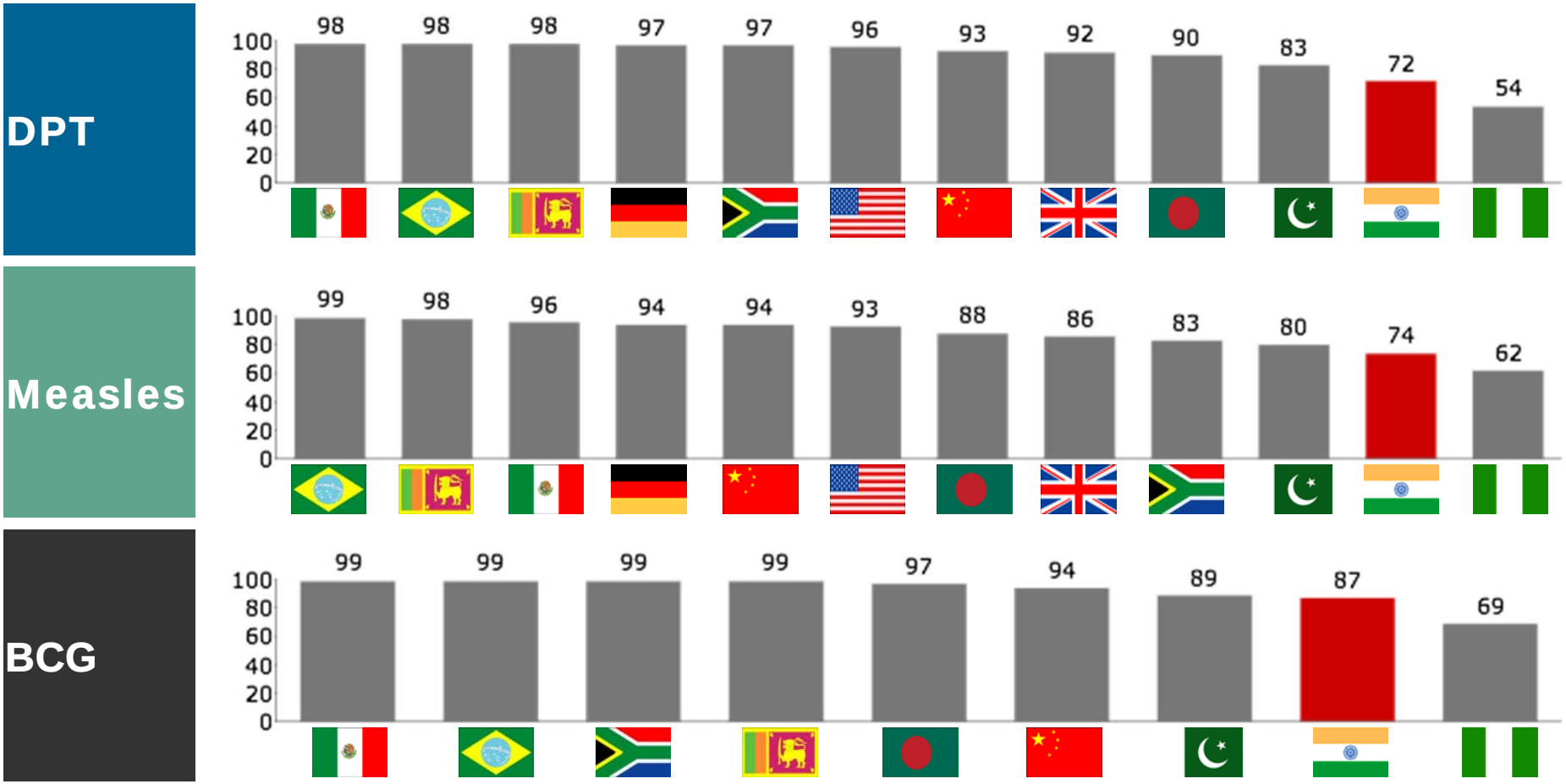


India has a Mortality rate ~7x of china and ~65x of Brazil



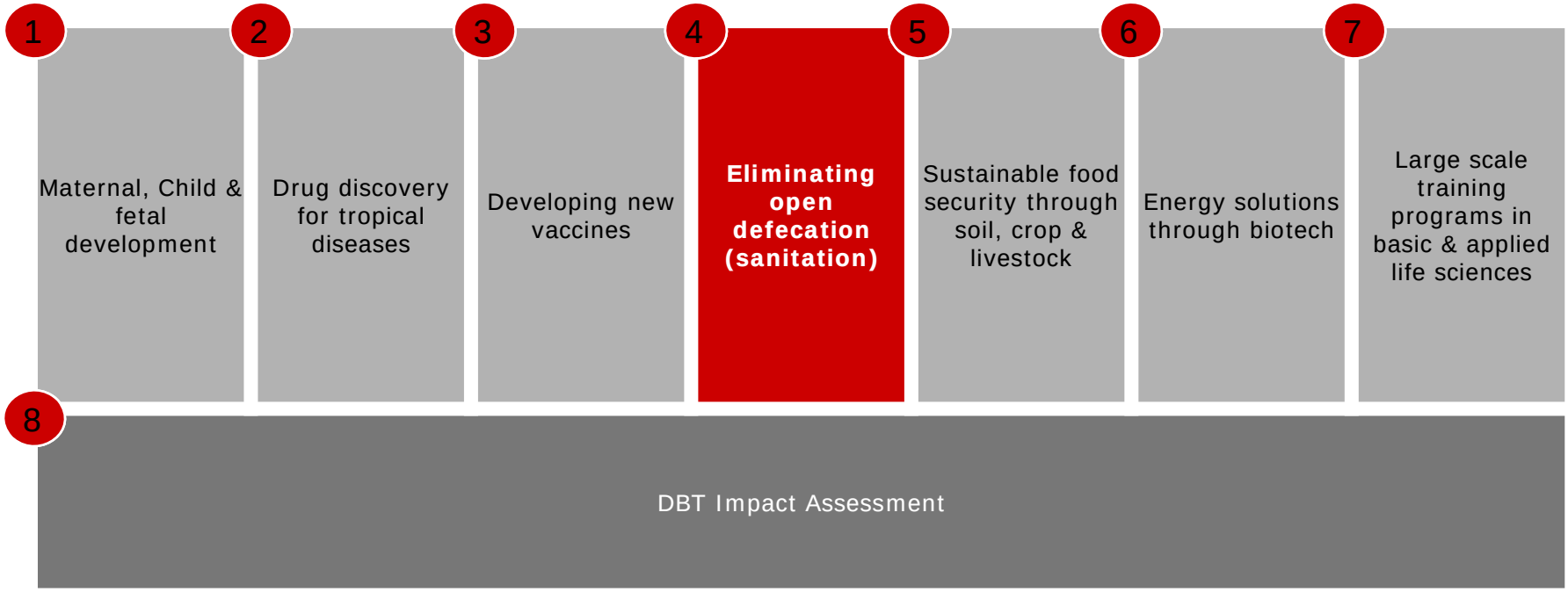
Note: VPDs include DPT, Hib, JE, Measles, Rabies, Rotavirus, Smallpox, Typhoid, TB, etc.
Source: Frost & Sullivan; IMF; Lit Search

India lags global peers in the coverage rates of basic vaccines



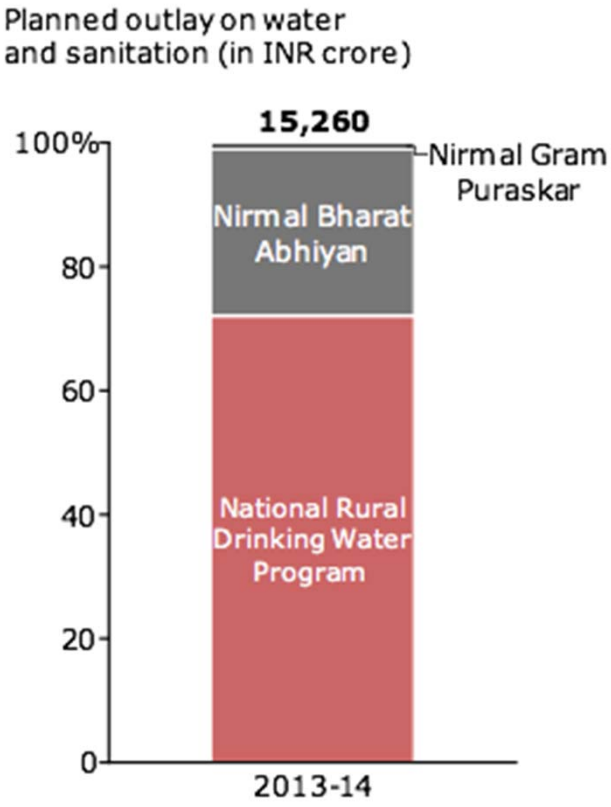
Note: All coverage rates are WHO estimates, may differ from NFHS/DLHS figures, DPT3 – Penetration of 3rd dose of Diptheria, Pertusis, Tetanus vaccine
BCG – Penetration of Bacillus Calmette Guerin (anti-tuberculosis) vaccine
Source: WHO coverage estimates 2007; UNICEF statistics

List of initiatives

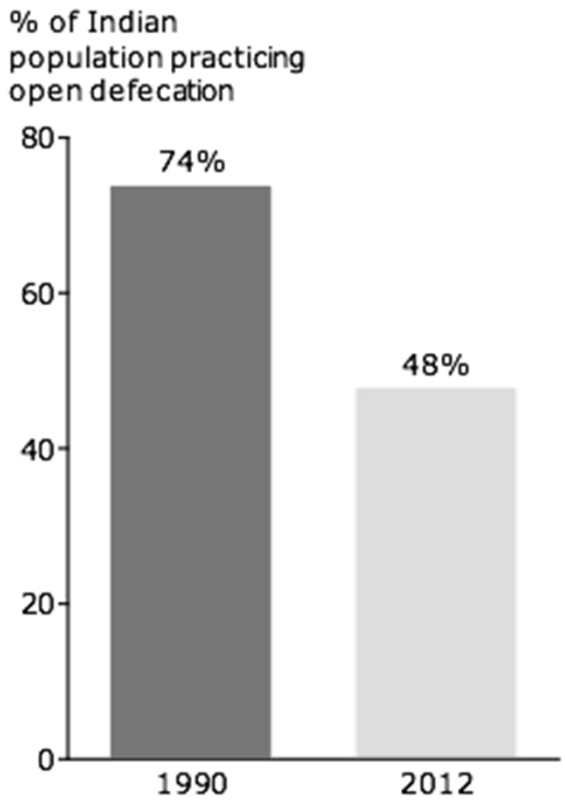


Currently, India carries a huge burden of open defecation; this is despite significant improvement in last 2 decades

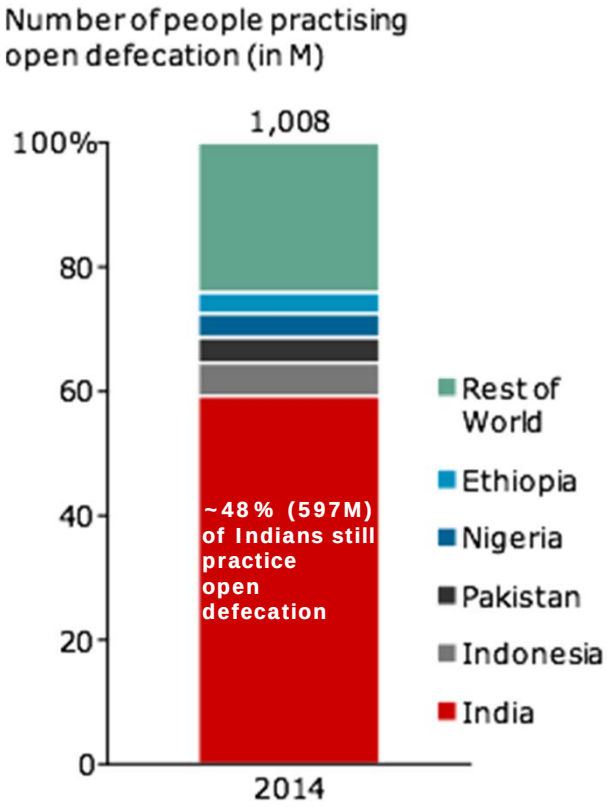
Multiple flagship programs aim to tackle the sanitation challenge



SIGNIFICANT PROGRESS HAS BEEN MADE...

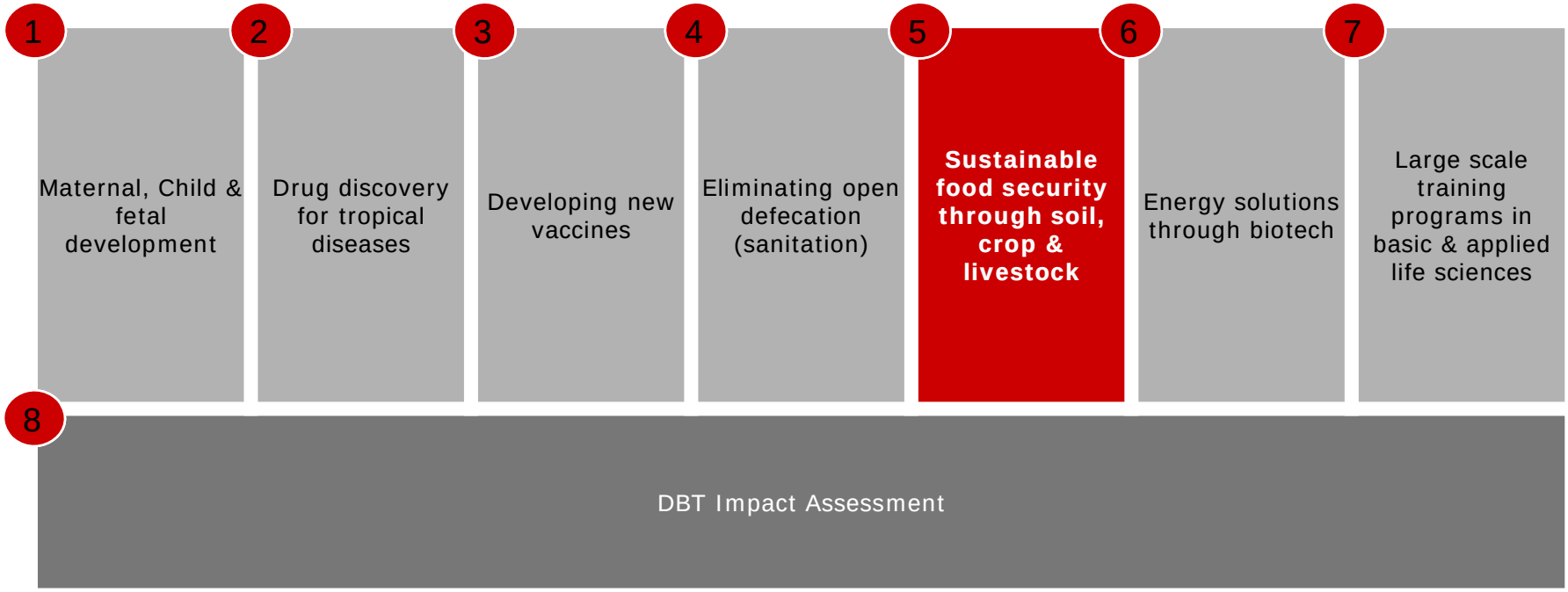


..yet ~60% of ALL people practicing open defecation reside in India...



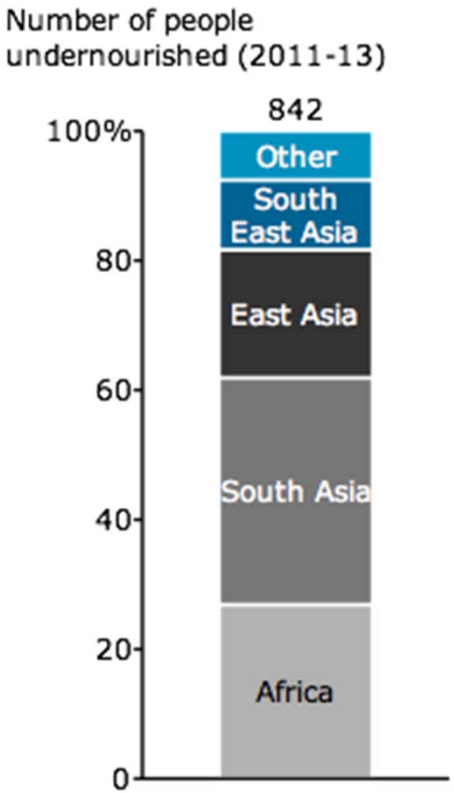
Note : Unimproved sanitation includes shared, open defecation & other unimproved facilities
Source: Progress on Drinking Water and Sanitation (2014 Update)

List of initiatives

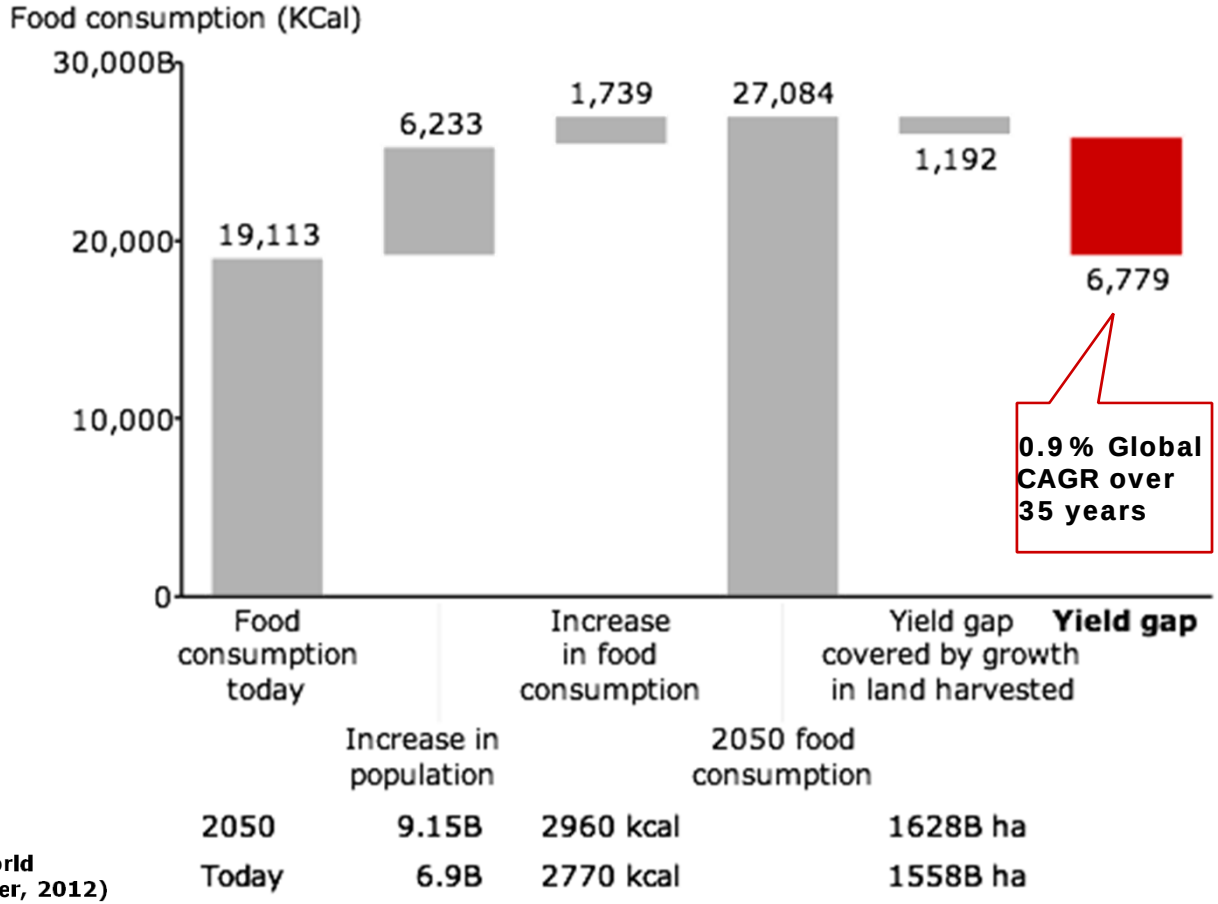


Globally, improvements in yield are crucial to closing the food security gap as population increases drive demand

Much of the planet does not have access to optimal nutrition



with an increasing population, improved crop production is required to meet demand

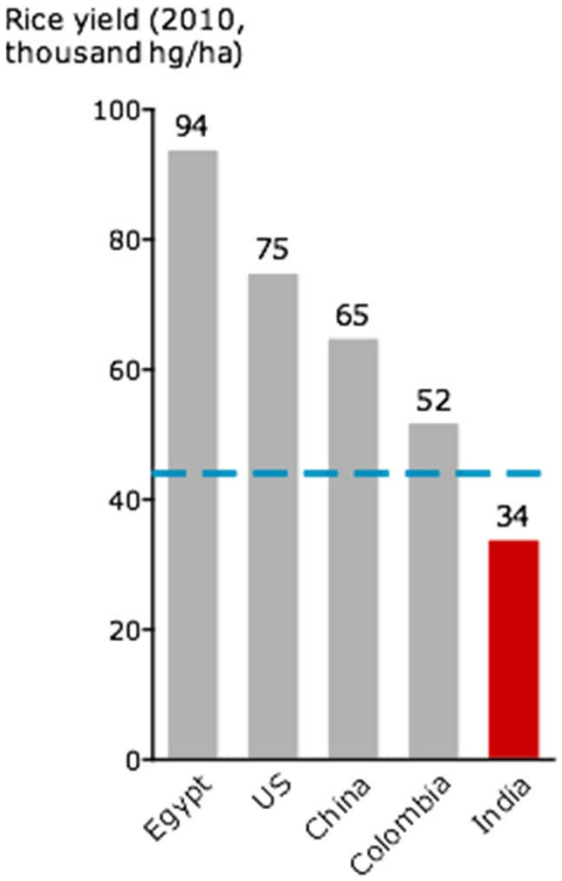


Source: FAO Food Security Indicators Database, World Agriculture Towards 2030/2050 (FAO Working Paper, 2012)

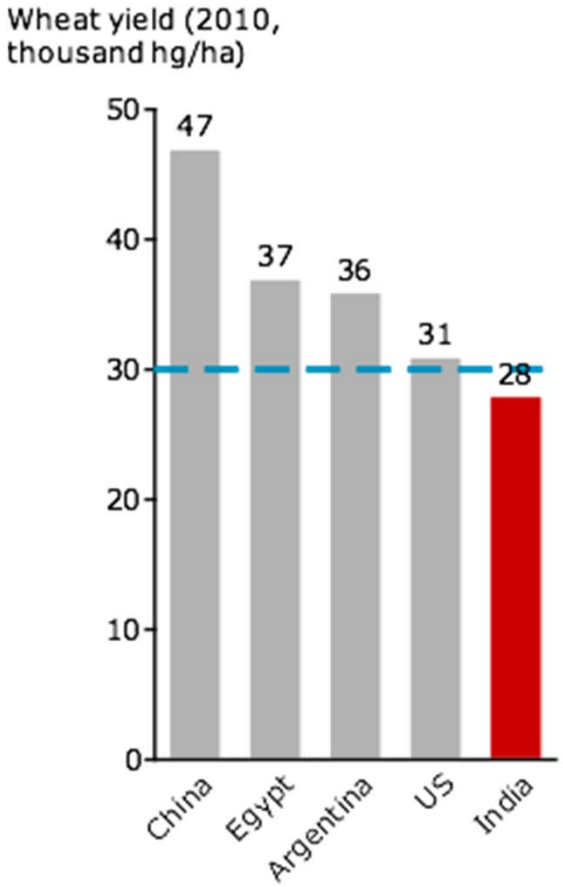
India lags behind most other nations in terms of yield (1/2)

Preliminary

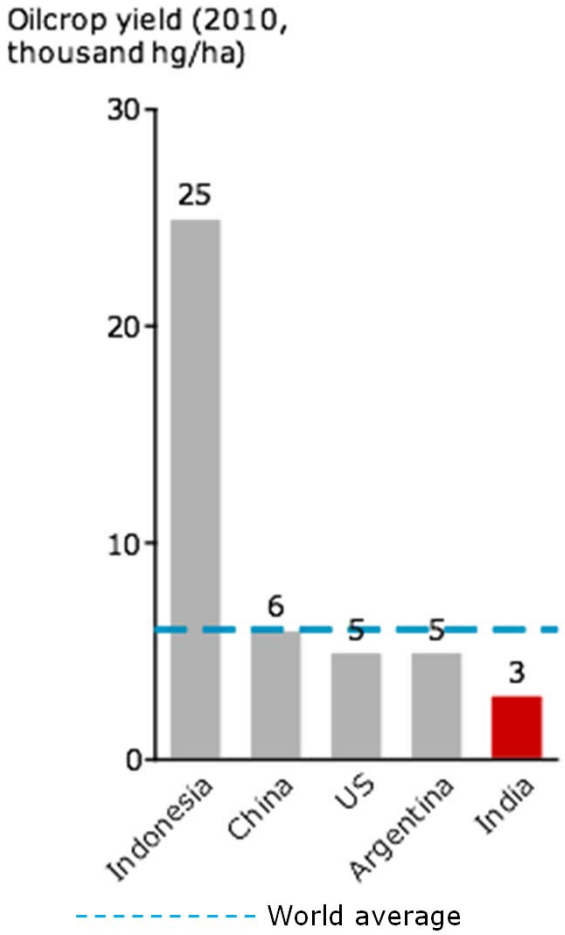
rice



wheat



oilseeds

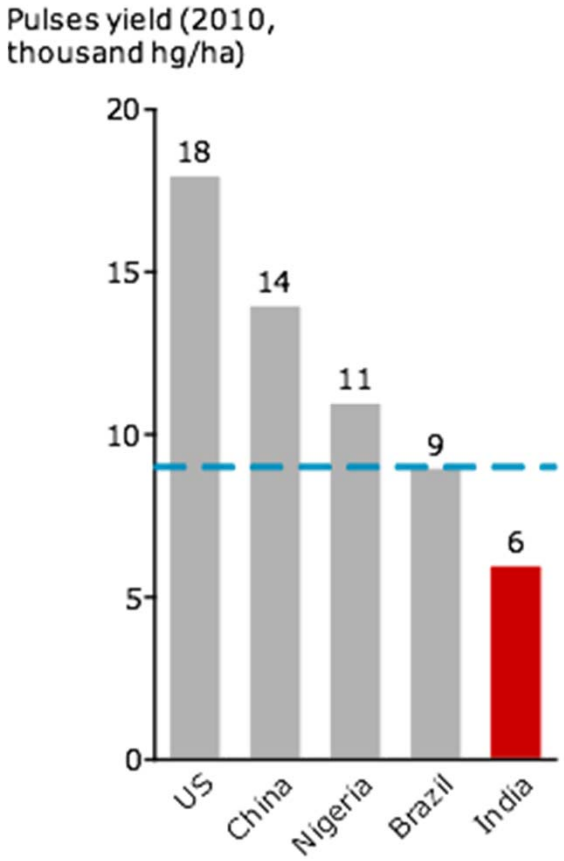


Source: FAO

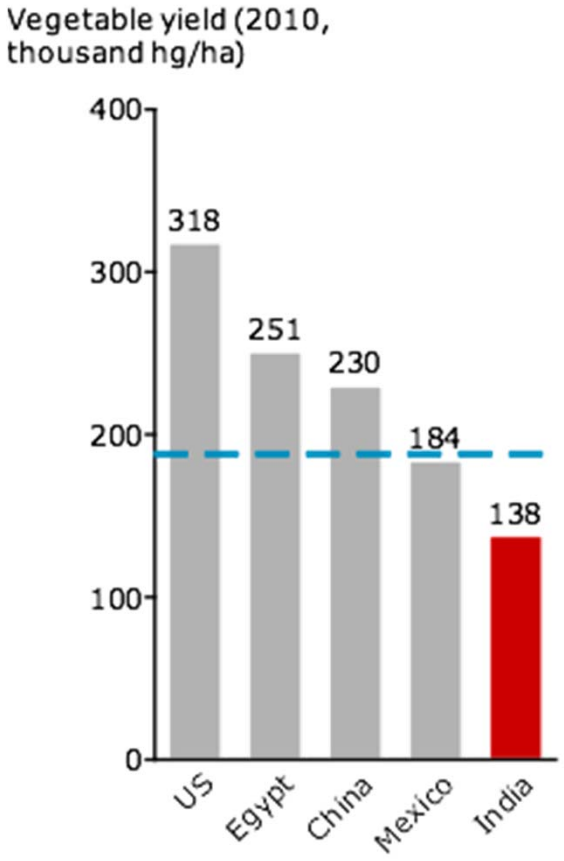
India lags behind most other nations in terms of yield (2/2)

Preliminary

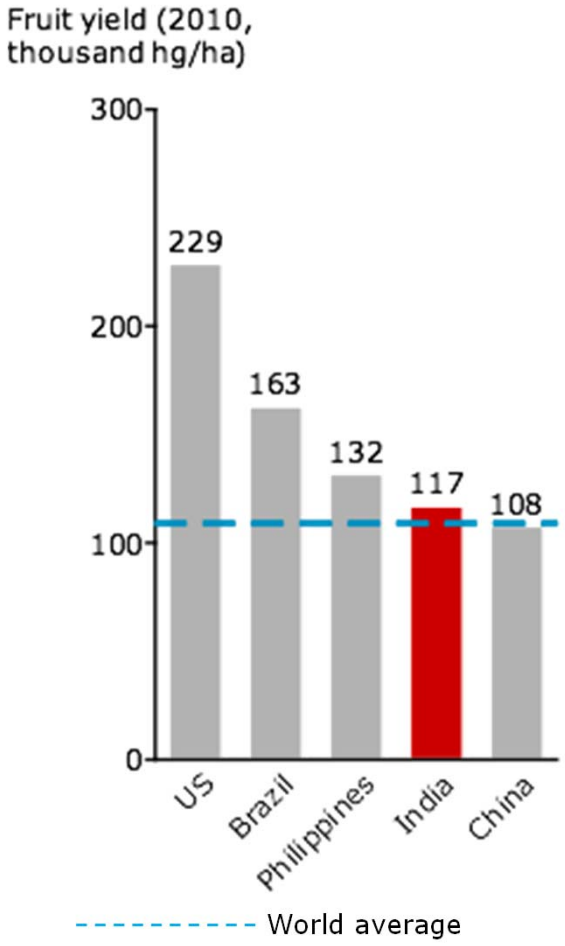
pulses



vegotables



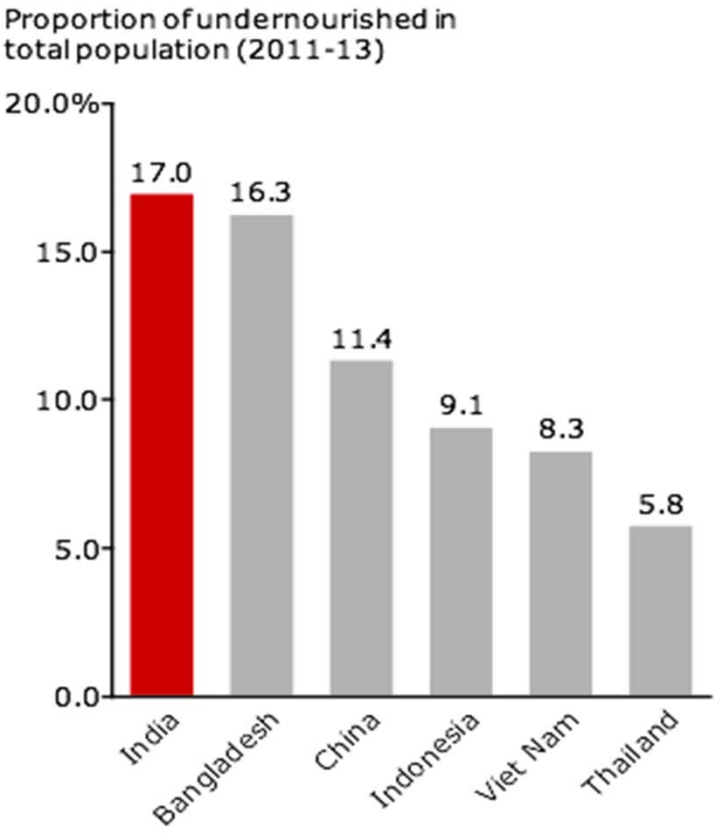
fruits



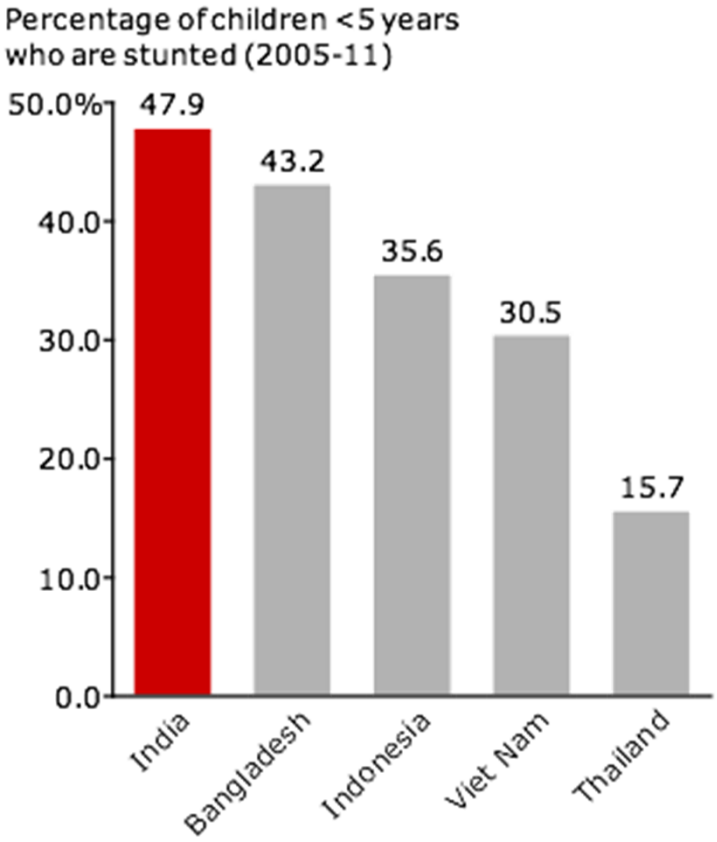
Source: FAO

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…

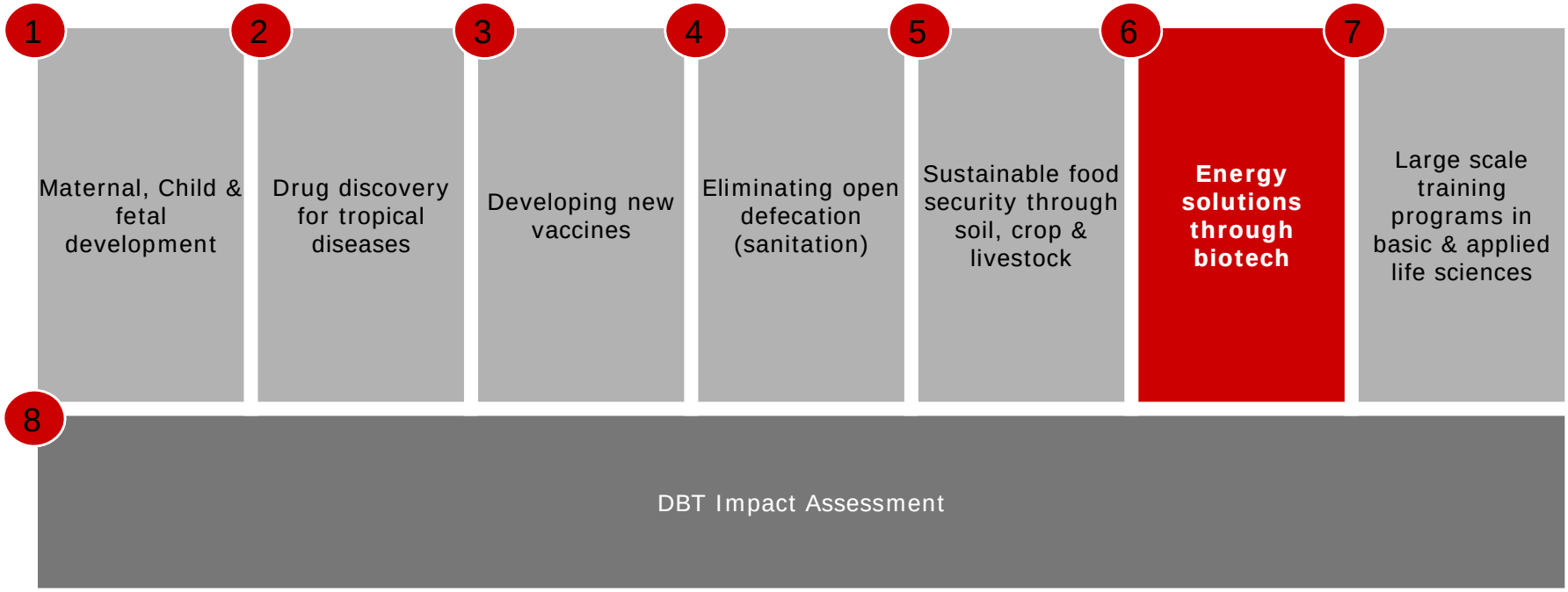


…Leading to major impact on population especially children

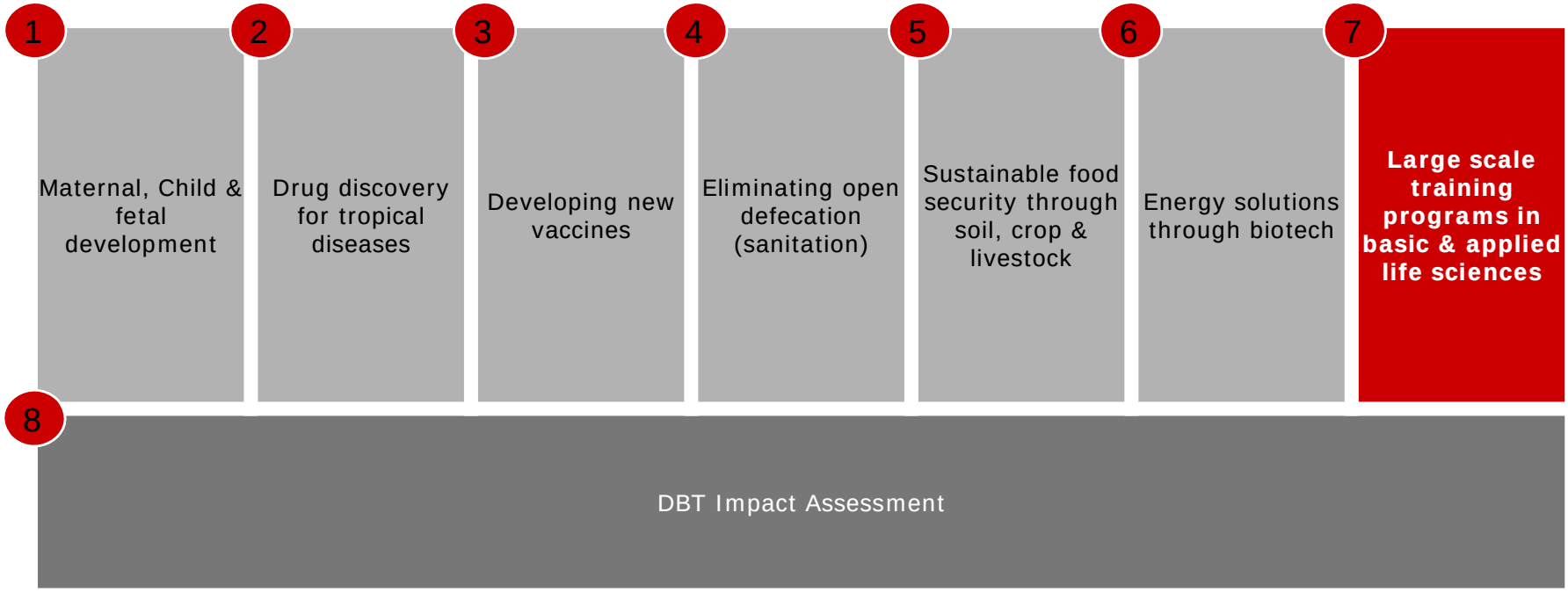


Source: FAO

List of initiatives

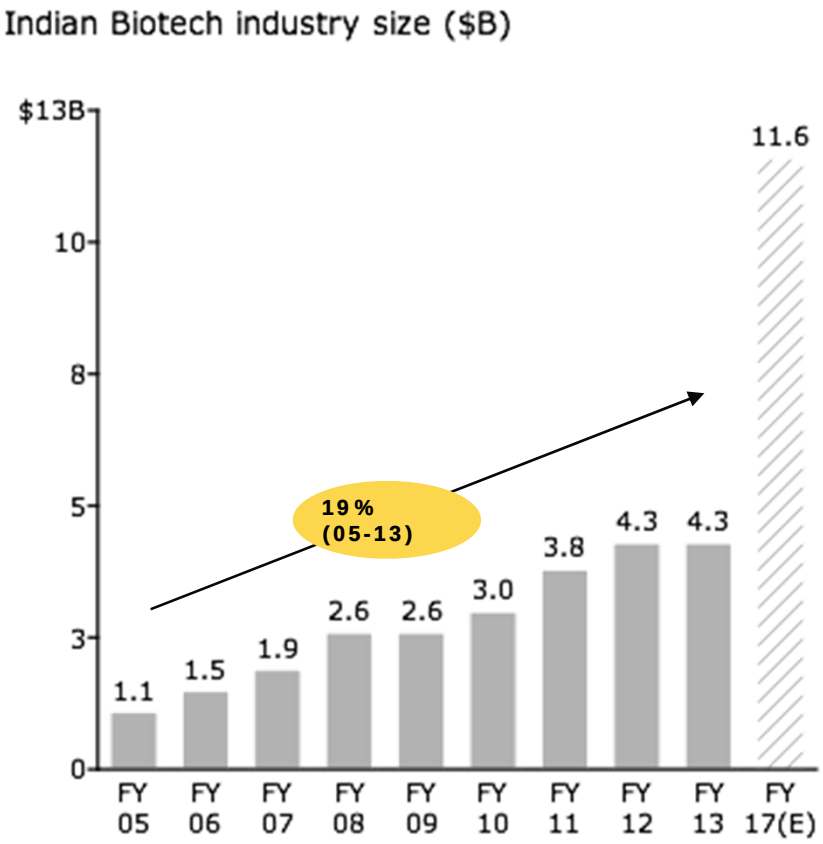


List of initiatives

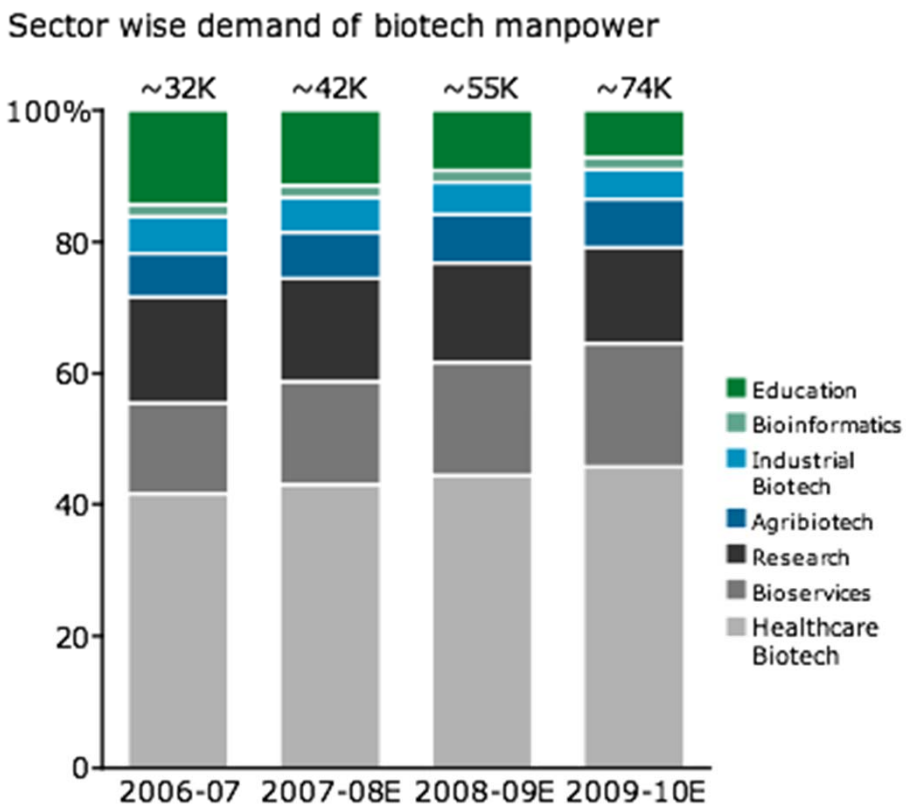


Rapid increase of biotech industry has driven demand for biotech professionals across years

Indian market is growing…



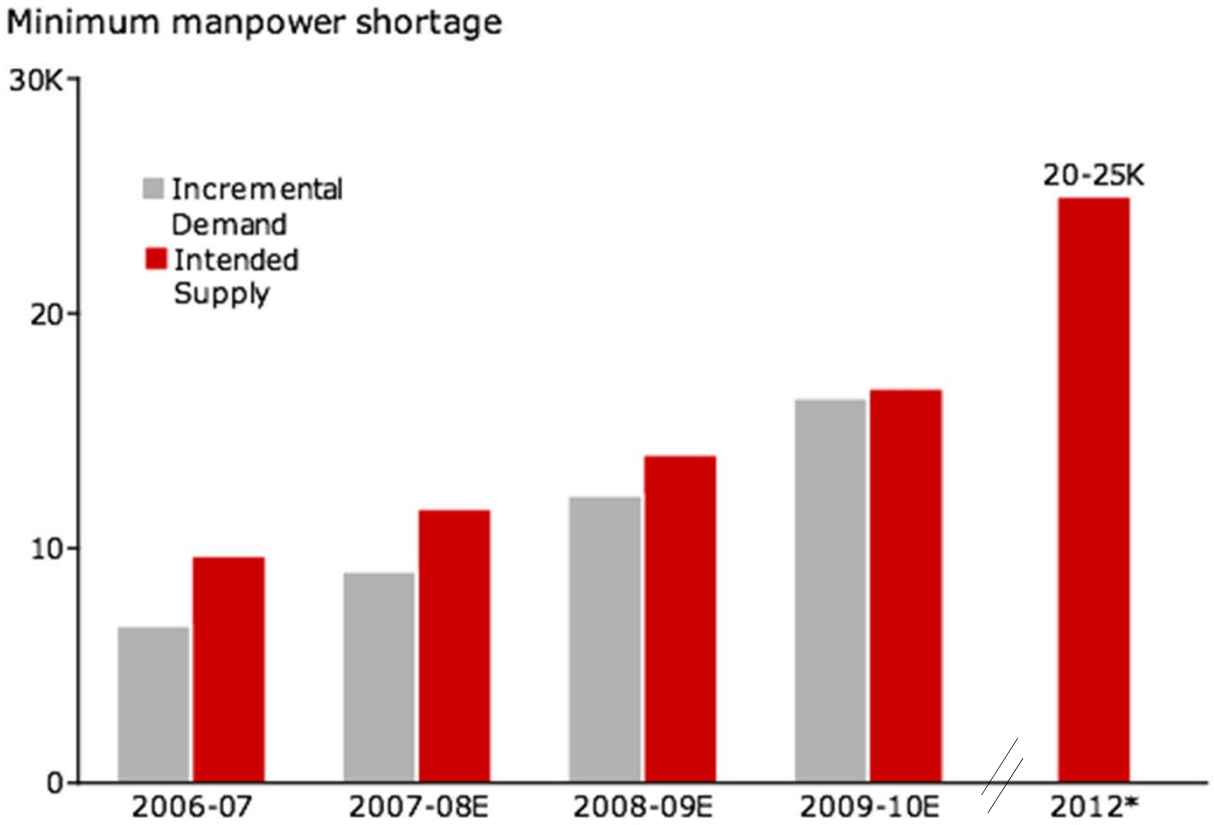
… fueling demand for biotech professionals



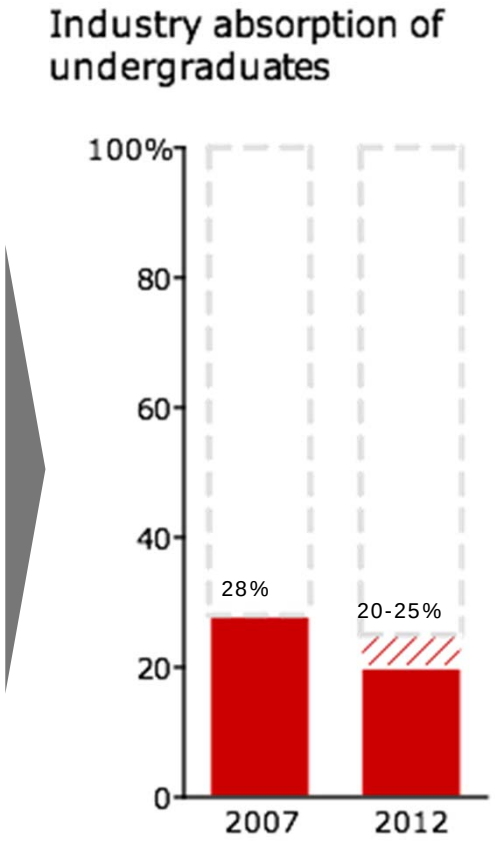
Source: IBEF, Biospectrum survey (2007)

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.

Gorillas in the Room

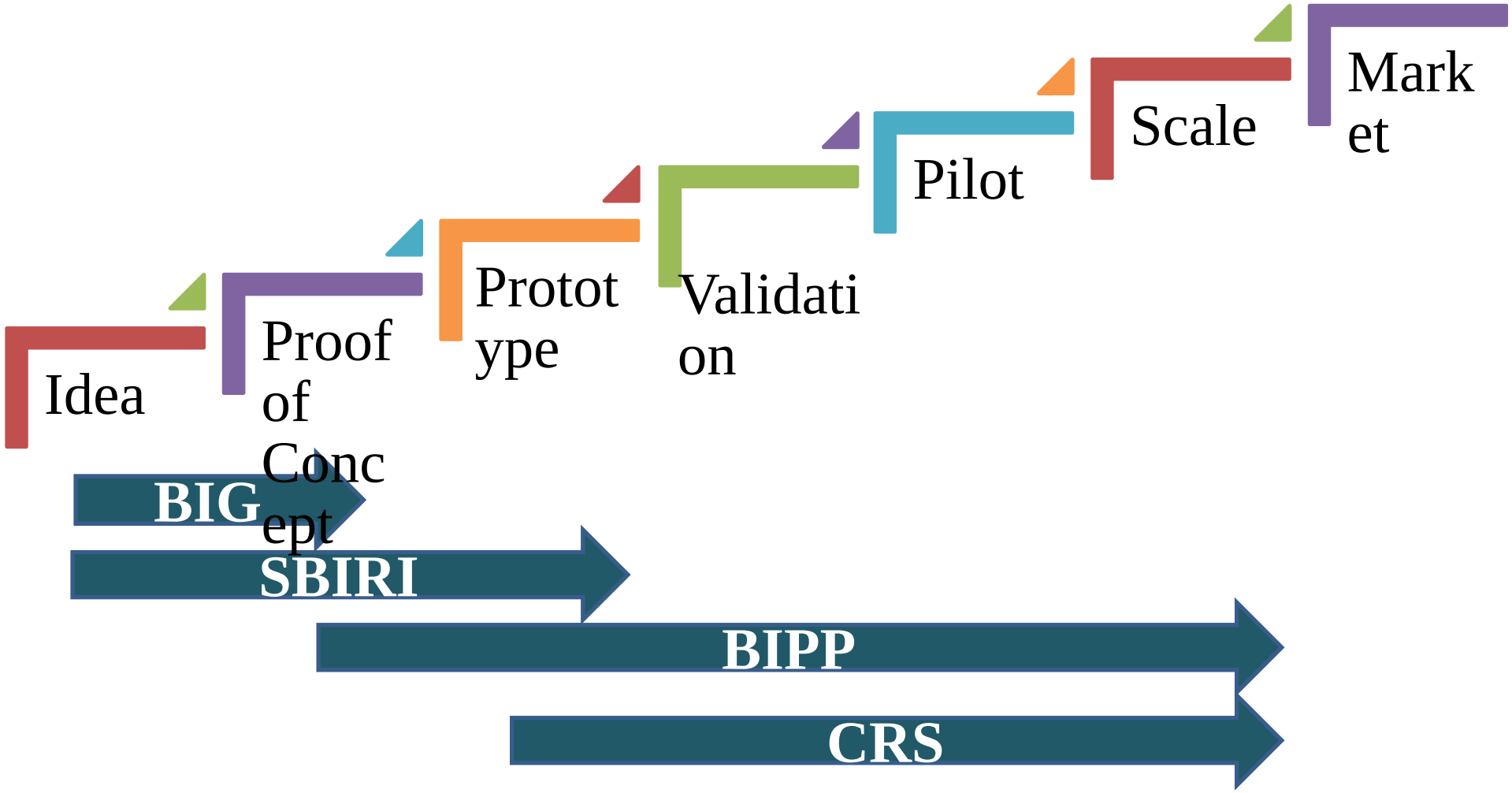
BIRAC Role in Medical Technologies Sector

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**

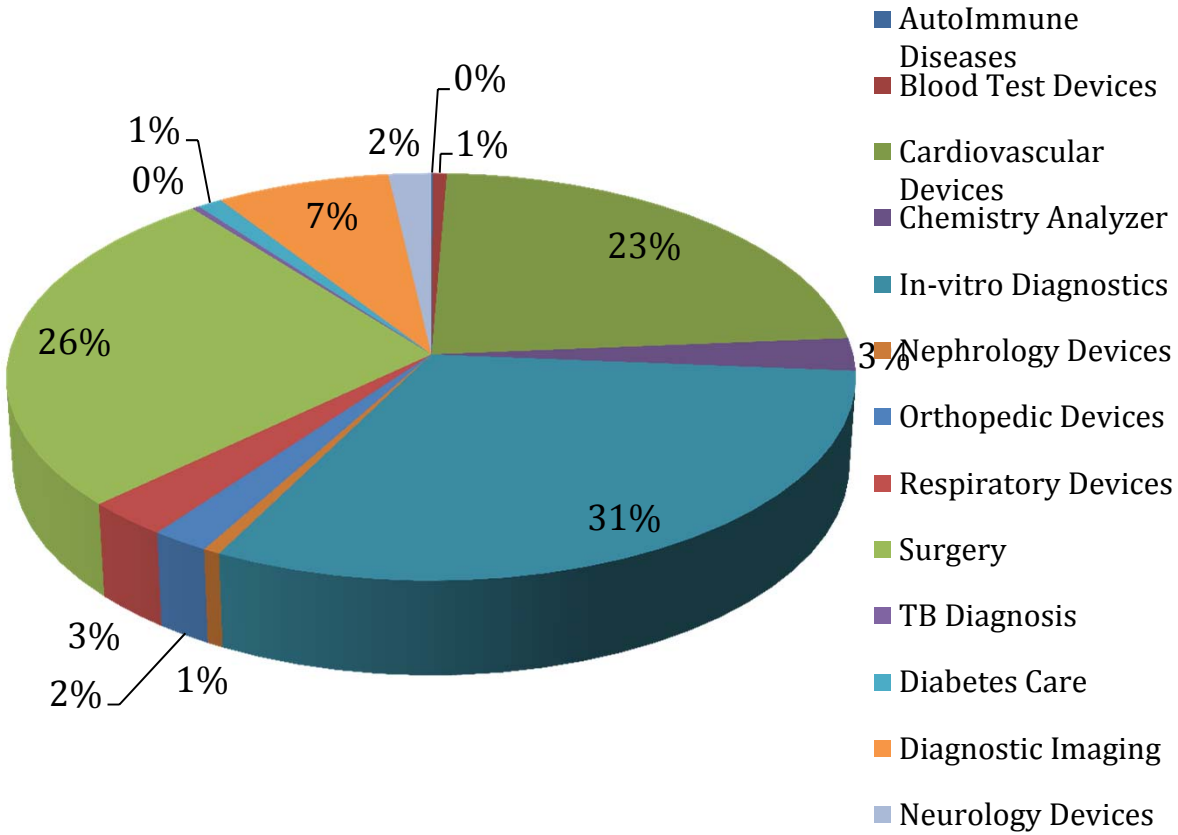
BIRAC Medical Technologies Investment Portfolio

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

सत्यमेव जयते

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

AIIMS, New Delhi

IIT, Delhi

Stanford University, CA

Indo-US
S&T
Forum

BCIL

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*

Aim:	**To create medical technology innovators and entrepreneurs to foster & promote medical technology innovation in India**
Focus:	**Implants & devices**
Unique features:	**Multidisciplinary team; national level selection;** **Training in biodesign process at Stanford; clinical immersion in India;** **Platform to work together for end to end processes (*idea generation & selection, IP protection, prototyping, validation, testing, tech-transfer and commercialization);***
PPP:	**Collaboration with med-tech industries;**
Challenge :	**Ability to walk the last mile**

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(IO) 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.

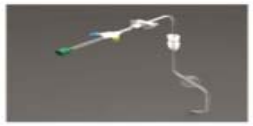
Darshan Nayak, Pulin Raje

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, Mridusmita Choudhury, Chinmay Deodhar

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, Shitij 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..

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

Brün - A cost effective solution to assess fetal wellbeing to reduce intrapartum stillbirths.

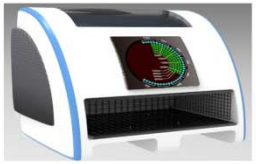
Anirudh Chaturvedi, Prashant Jha, Abhinav Ramani, Balaji Teegala

NeoCap - A novel cost effective way to prevent neonates from environment induced damage.

Aanan Khurma, Saurabh Bag, Akhilesh Gupta, Monika Singh

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



Hanitizer-A intuitive way to increase compliance to WHO prescribed hand hygiene guidelines in health care settings.

Aanan Khurma, Saurabh Bag, Jagdish Chaturvedi, Neeraj Jasmathiya

Needs Manager- A mobile application to assist innovators to manage their observations and translate them to meaningful need statements.

Aanan Khurma, Jagdish Chaturvedi

Handy - Simplifying hand hygiene in hospitals with improved accessibility and functionability.

Aanan Khurma, Neeraj Jasmathiya, Saurabh Bag Ripunjay Chachan

Uthishtami -An uplift device to help elderly rise independently from a sitting position.

Deepali Chandratre, Sneha Venkat, Rahul Das, Chetan

AccuFeed - An accurate way to insert Nasogastric tube in patient with neurological dysphagia.

Neha Shetty, Medha Tyagi, Himanshu Gupta , Ageyeya 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

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

iWe - A Transillumination device for peripheral vein detection in pediatric patients.

Vishal Agale, Megha Agrawal, Ramakant Beesetty, Chandni Kabra

Technologies licensed

'Stanford India Biodesign' Licensed Technologies

Fecal Incontinence Device

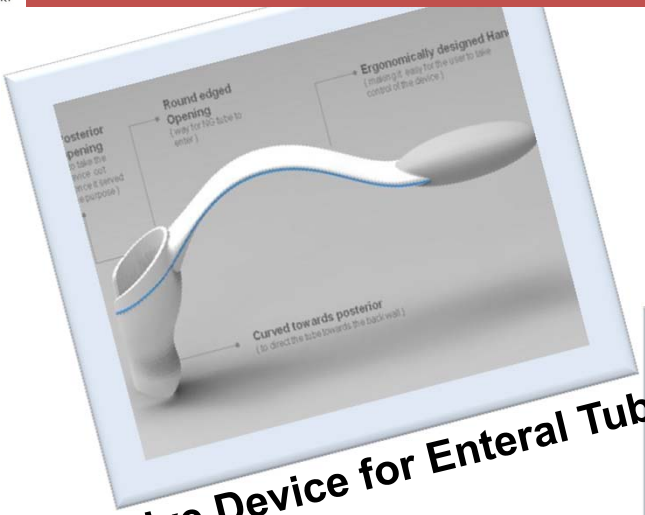
Soft Tissue Biopsy Device

Limb Immobilization Device

Neonatal Resuscitation Device

Auditory Impairment Screening Device

Technologies licensed cont……

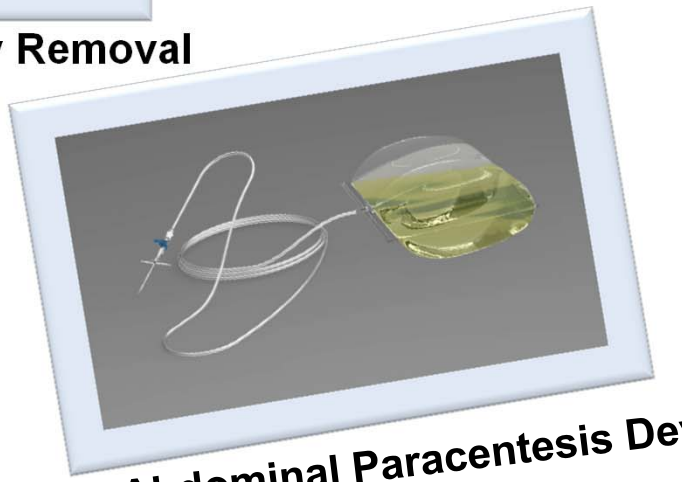


Assistive Device for Enteral Tubes

Nasal Foreign Body Removal

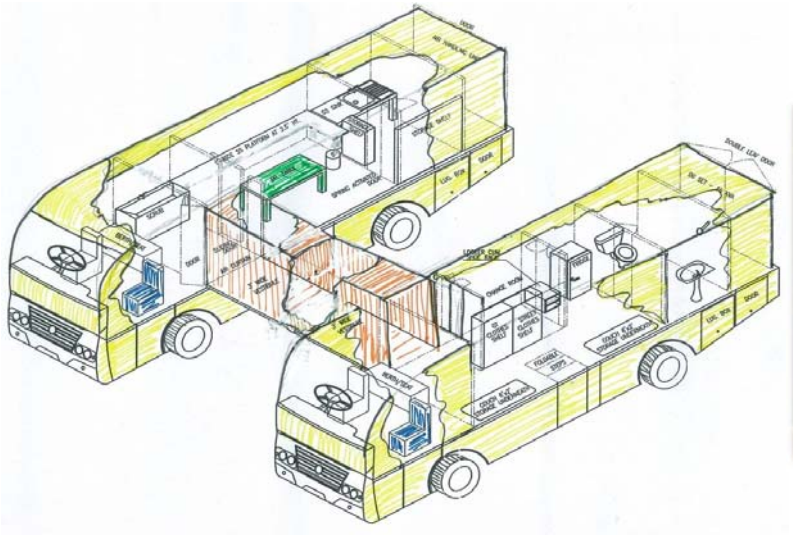
Aspiration Device

Patient Transfer Device



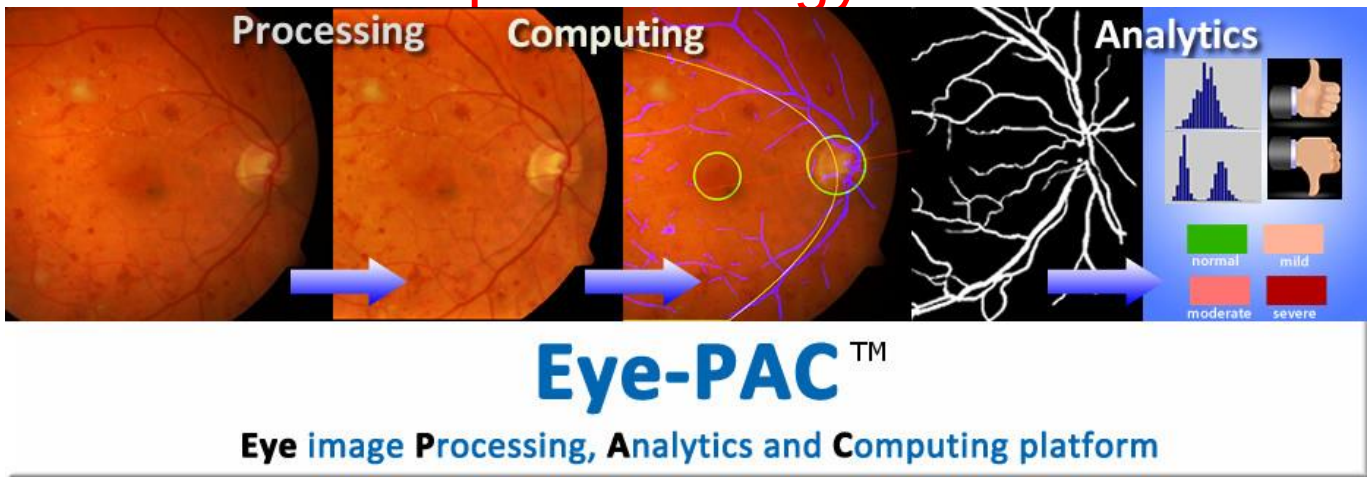
Abdominal Paracentesis Device

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

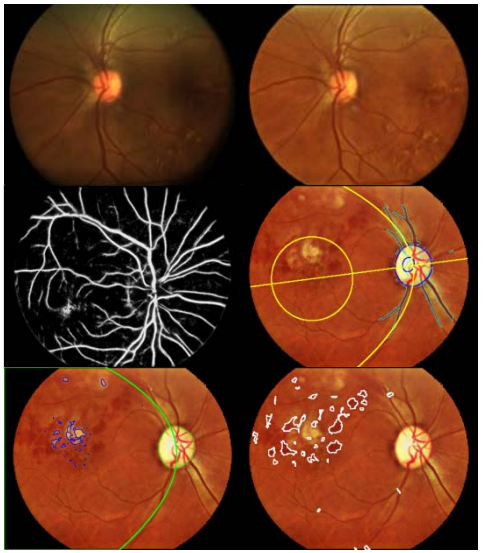


- **Ophthalmic image computing**
  - **Computational extraction of quantitative information from eye images**
  - **Visual information present in images: anatomical, neuro-vascular, pathological**
- **Capabilities**
  - **Disease screening:**
    - **High scalability**
    - **Timely identification**
    - **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**



Forus

Healthcare Technology Innovation Centre
collaborate ▸ innovate ▸ impact

Powered by Eye PAC technology's computing intelligence,

Developing affordable diagnostic instrumentation in India

Healthcare Technology Innovation Centre

— A joint initiative of —

Indian Institute of Technology Madras

Department of Biotechnology
Ministry of Science and Technology

J. Mitra & Co Pvt. Ltd
a vision to serve mankind

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

Develop diagnostic equipment

Market leader in rapid test kits

Develop quantitative 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**