

**National and regional capacity  
for biotechnology research;  
Indian experience**

# Biotechnology research by LMIC's

- Why invest?

  - Affordable, locally relevant service products

  - Manufacturing

  - Bio and clinical services

- Long term

  - New and novel products

  - Bio-economy

# Developing countries vaccine manufacturers

**39 members spread over 15 different countries; 12 members are WHO prequalified bold**

Argentina	National Administration of Laboratories and Institute of Health Anlis Dr Carlos G. Malbran
Bangladesh	Incepta Vaccine limited
Brazil	BioManguinhos/Fiocruz Instituto Butantan
China	Beijing Minhai Biotechnology Co., Ltd, Changchun BCHT Biotechnology Co. China National Biotech Corporation, Hualan Bio, Liaoning ChengDa Biotechnology Co., Ltd , Sinergium Biotech, Sinovac, TiantanBio,Walvax Biotechnology Co., Ltd, Xiamen Innovax Biotech Co., Ltd
Cuba	Finlay Institute, The Center for Genetic Engineering and Biotechnology
Egypt	Vacsera
India	Bharat Biotech International Limited, Cadilla Pharmaceuticals,Biological E Ltd,Haffkine Bio-Pharmaceutical Corporation Ltd, Indian Immunologicals Ltd, Panacea Biotec Limited, Serum Institute of India Ltd
Indonesia	Bio Farma
Iran	Razi Vaccine & Serum Research Institute. Pasteur Institute of Iran
Korea	Greencross Corporation, EuBiologics Co., Ltd, LG Life Sciences, SK Chemicals
Mexico	Birmax
South Africa	Biovac
Taiwan	The National Institute of Infectious Diseases and Vaccinology
Thailand	BioNet-Asia Co., Ltd, Queen Saovabha Memorial Institute. The Government Pharmaceutical Organization
Vietnam	Institute of Vaccines and Medical Biologicals, Vabiotech

# DCVMN and future pipeline of vaccines

Vaccines	Country
Pneumococcal conjugate	Brazil, China, India, Cuba
Rotavirus	India, Brazil, China
Meningococcal (Includes polysaccharide and conjugate vaccines)	India, China, Cuba, Brazil
Japanese encephalitis	Vietnam, India
Seasonal and Pandemic influenza vaccines (also includes vaccines with oil in water adjuvants)	Vietnam, Thailand, Brazil, China, Mexico
Malaria	India,
Typhoid	Cuba
Dengue	India, Brazil
Yellow fever	Argentina
Hepatitis A	Brazil
Leishmaniasis	Brazil
Leptospirosis	Brazil
Human papillomavirus	India, Cuba, China
Chikungunya	India
Anthrax	India

# India vaccinology enterprise has vibrancy

## Recent licensure

Japanese B Encephalitis  
meningococcus – A conjugate

Rotavirus vaccines  
*Neonatal strain*  
*Bovine reassortant*

Pandemic flu

Vi Conjugate antityphoid

Combination (Pentavalent)

Oral cholera vaccine

## Early clinical development

Dengue virus

DSV4 (Dengue, HepB, Chimera)

Tetravalent, Live attenuated

Zika virus

ONCO-BCG

## Candidates

Chikungunya

## Affordable products manufacture

HPV

Pneumococcal conjugates

# Key drivers of India's vaccinology effort

India started the twenty-first century well behind Russia, France, Italy and Canada in terms of yearly publications and it now leads them all by healthy margins. It is quickly closing in on Japan.

## **Our aspiration**

Significant discovery

Mid or high level innovation

Impact

# A coherent institutional framework for vaccine regulation and introduction is taking shape

## DCGI

- Licensure
- Post marketing surveillance

## NTAGI

- Technical basis of public health use
- Disease burden
- Cost effectiveness
- Safety

## MoHFW and Technical support unit

- Vaccine procurement
- Delivery
- AEFI surveillance

## Academic institutions

- Impact evaluation

## Innovation promotion and R&D support Global partnership

- BIRAC, TDB, DBT, ICMR
- WHO, NIH, CDC, PATH, BMGF  
global academia

# National Technical Advisory Group on Immunisation (NTAGI); a game changer

- No new vaccines nationwide from 1986 (measles) to pentavalent (started in 2011 to nationwide rollout, with HepB in some states prior to 2011)
- Subsequently, recommendations made by NTAGI
  - JE in adults
  - Inactivated Polio
  - Measles-rubella
  - Rotavirus
  - Pneumococcus
  - Tetanus-diphtheria
  - Human papillomavirus

Also discussed hepatitis A, cholera, typhoid





# Department of Biotechnology's (DBT) critical role in nurturing India's bioscience and biotech

Interdisciplinary Science

Translational Research

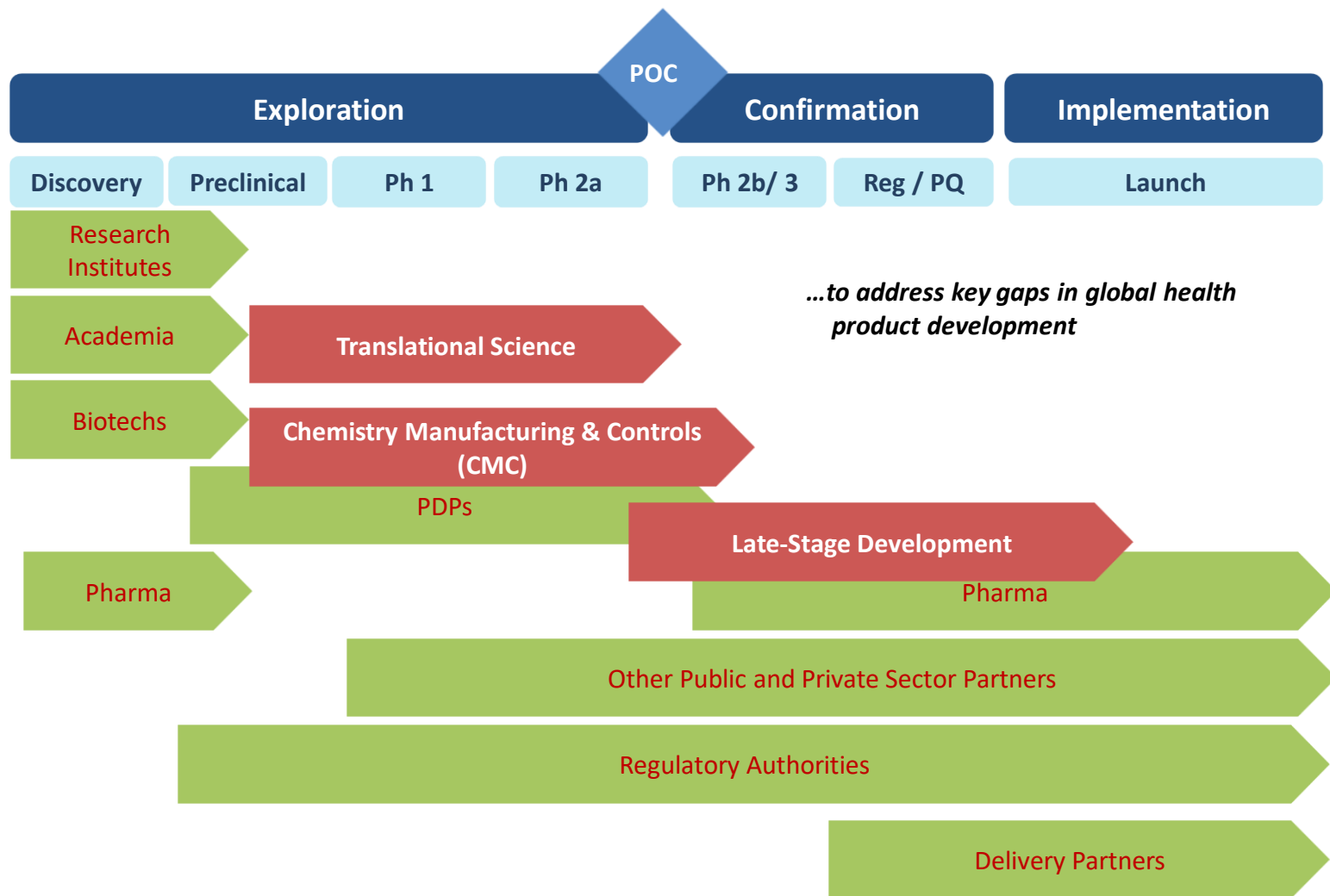
De-risking Industry product development

Nurturing human talent

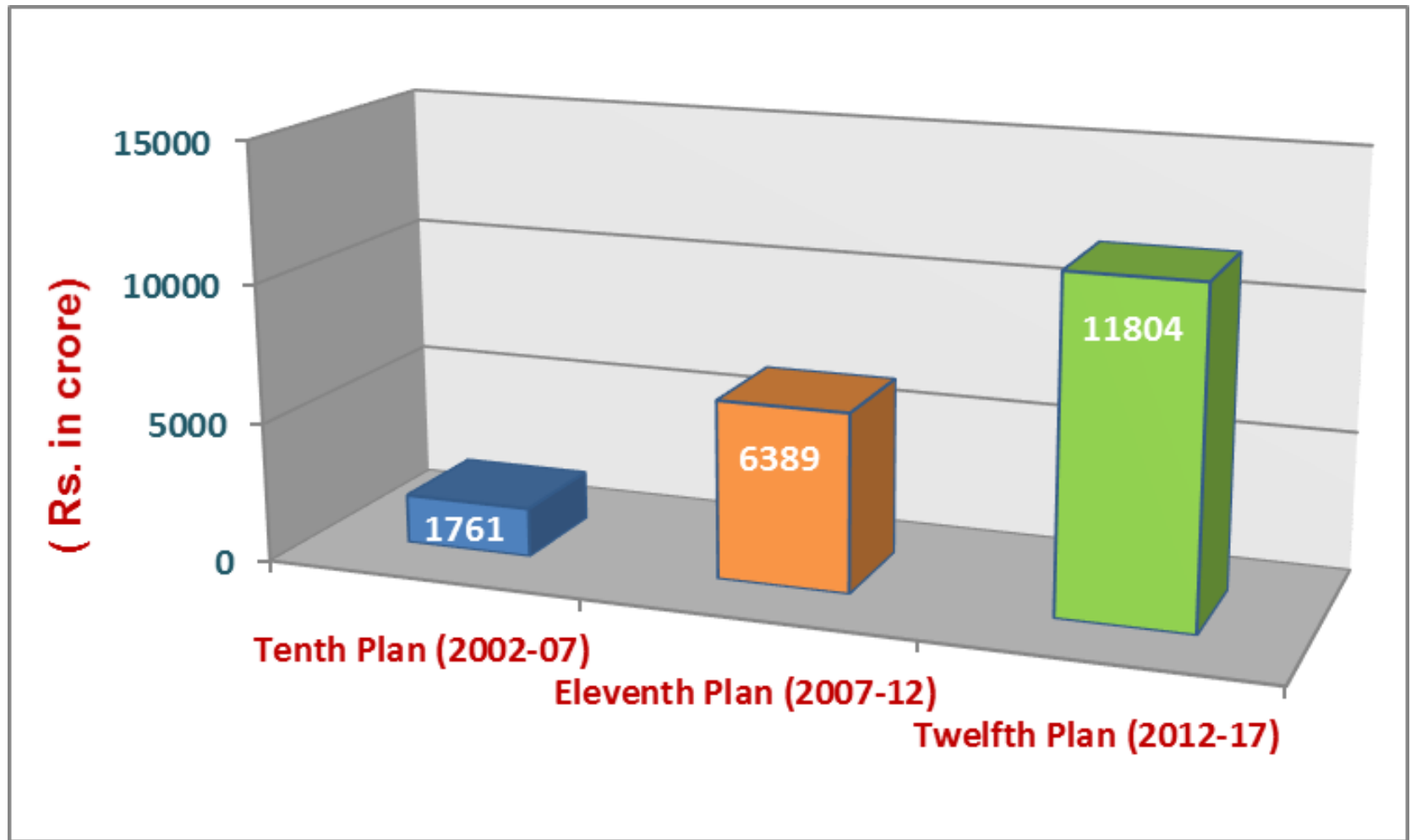
Connecting nationally and globally

Supporting Health Ministry and DHR in Policy, regulation, and standards

# DBT and BIRAC addressing strengths and weaknesses of India's Vaccinology through national and global collaboration



# Department of Biotechnology



DST, CSIR and ICMR support biomedical research

# Institutions with novel designs for innovation



**International Centre For Genetic Engineering And Biotechnology (ICGEB)**

**The Translational Health Science And Technology Institute (THSTI)**



**Indian Institutes Of Science Education And Research (IISER)**

# India's international collaboration is growing

<b>Papers collaborative with India</b>			
	<b>1999-2003</b>	<b>2004-2008</b>	<b>% Increase</b>
USA	6,725	10,728	62.6%
Germany	2,667	4,284	62.3%
UK	2,137	3,646	58.6%
Japan	1,908	3,017	63.2%
France	1,393	2,402	57.9%
Canada	927	1,590	58.3%
Italy	822	1,309	62.7%
China	674	1,665	40.4%
Australia	643	1,338	48.0%
Netherlands	563	874	64.4%
South Korea	558	2,074	26.9%
Taiwan	540	1,102	49.0%
Switzerland	493	1,067	46.2%
Russia	482	940	51.2%

India–US Vaccine Development Program is an ‘exemplar’

DBT

ICMR

NIH, USA

# India based efforts showing impact

## India ROTAVAC® Story

**A small experience about learning to walk to the end**

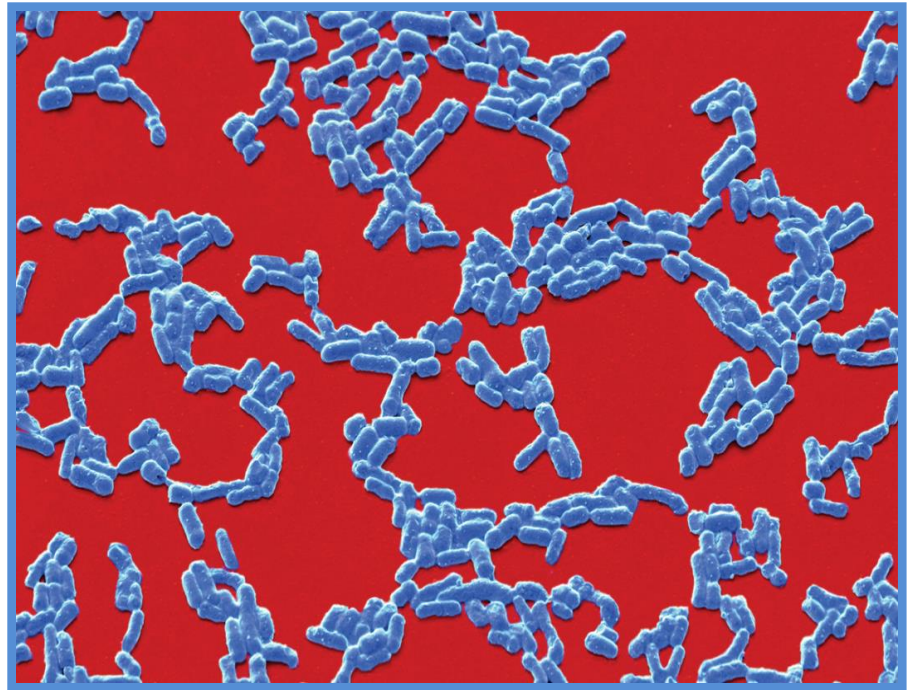


Team Science

Academia, industry, science agencies, global partners, philanthropy

# Typhoid vaccine development with a human challenges model

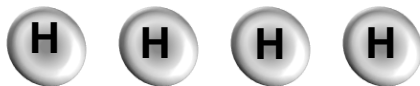
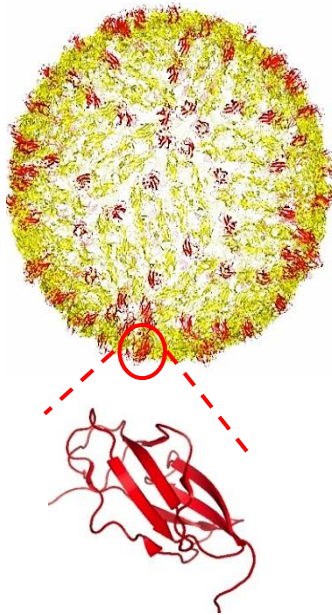
Vi-TT is a highly immunogenic vaccine that significantly reduces typhoid fever cases when assessed using a stringent controlled model of typhoid infection. Vi-TT use has the potential to reduce both the burden of typhoid fever and associated health inequality



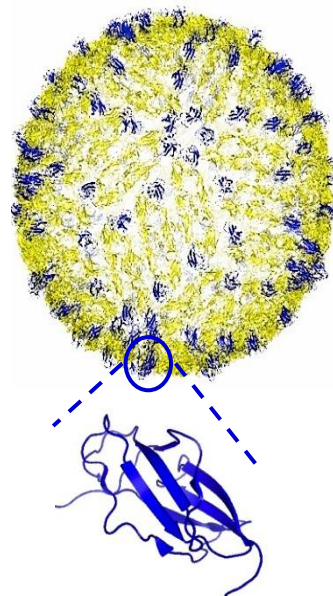


# Dengue HepB, Chimera-DSV4 shows preclinical proof of concept

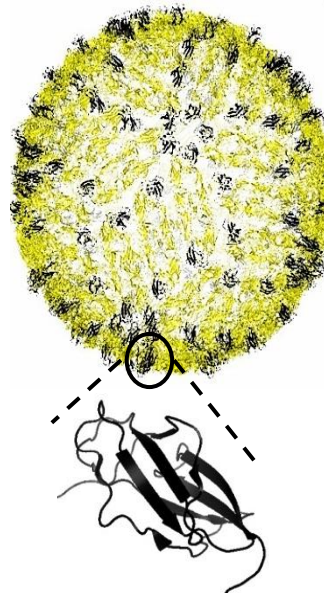
DENV-1



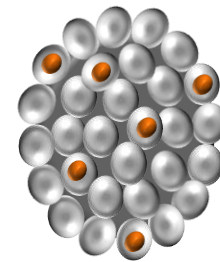
DENV-2



DENV-3



DENV-4

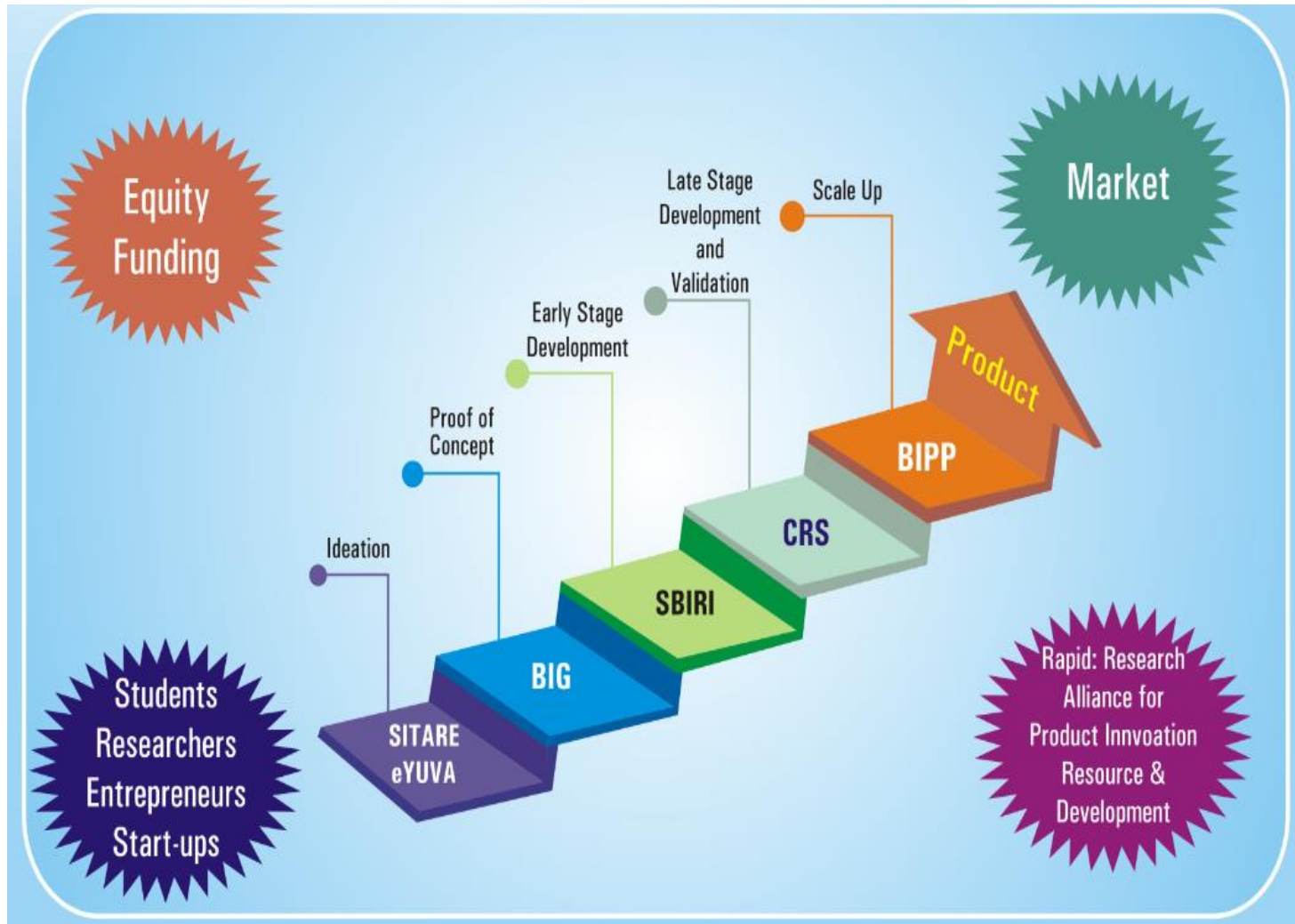


# **DBT established BIRAC as a section-8 company to accelerate biotech innovation**

## **Mission**

Facilitate and mentor the generation and translation of innovative ideas into biotech products and services by the industry, promote academia – industry collaboration, forge international linkages, encourage techno entrepreneurship and enable creation and sustainability of viable bio enterprises

# De-risking innovation



# Department of Biotechnology and World Bank Alliance

**Industry-Academia Collaborative Mission For Accelerating Research To  
Development For Biopharmaceuticals**

**Development  
of specific  
products**

**Establishment  
of Shared  
Infrastructure**

**Building and  
strengthening  
skills**

**Creating and  
enhancing  
technology  
transfer  
capabilities**

Product development  
Novel platforms and tools  
Early translational R&D  
Access to services  
Validated assays  
Animal models  
Clinical trials

**Bringing together Isolated Centers of Excellence**

**Strengthening existing infrastructure, capacities and technical know-how**

**Establishing linkages with global and national experts**

**Enhancing India's contribution to the global community**

# The BIRAC Team



# Redesigned approach to soliciting participation by academia/industry

- A clear definition of;
  - Scientific challenge to be solved
  - Solutions to be enabled
- Innovation cluster sentinel programs
  - Interdisciplinary
  - High level innovation
  - linked to services
  - Sustainable
- Innovation service hubs

# Invest in vaccine platform technologies for epidemic/pandemic preparedness

Rapid host response, single or two doses, adaptable to multiple pathogens, ease and rapidity of manufacturability – scalability.

Live and live attenuated vector (measles, VSV)

Non-replicating (Ch-adenovirus, MVA)

Subunit

mRNA

DNA

# Investment in disease burden estimates, molecular epidemiology of vaccine preventable diseases

Cohorts in several sites also become vaccine trial sites  
(Phase III, IV)

TB

Flaviviruses

Respiratory viruses



# Support people rather than projects only strategy

- Ease re entry into India fellowships
  - Ramalingaswami
  - Ramanujan
- Built top talent
  - Wellcome-DBT
  - Inspire(million fellowships)
- Niche-Biotech skills

## Nurturing talent in Biomedical Research

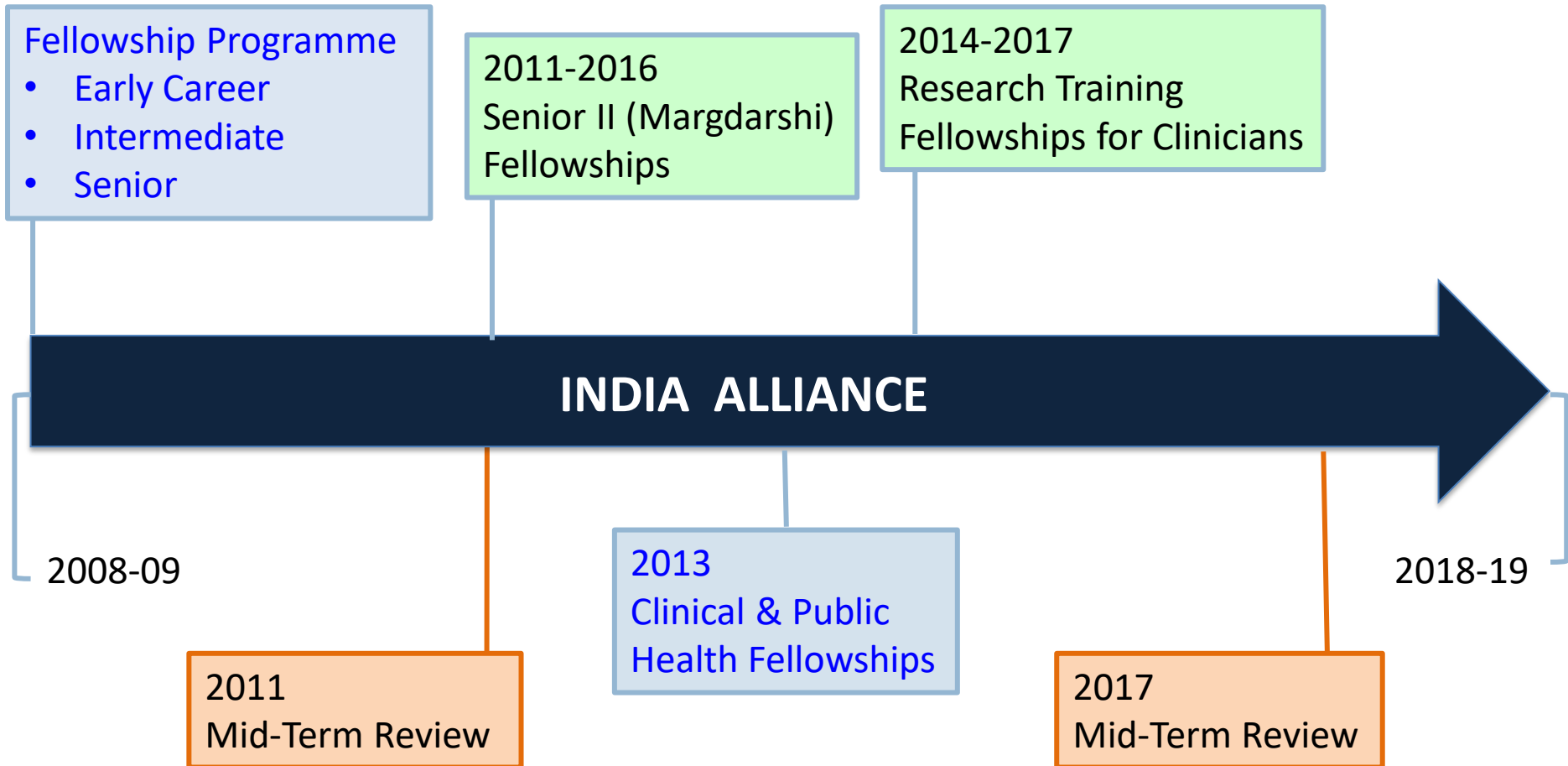
- **Basic**
- **Clinical**
- **Public Health**

[www.wellcomedbt.org](http://www.wellcomedbt.org)  
[info@wellcomedbt.org](mailto:info@wellcomedbt.org)



Knowledge grows  
where roots run deep  
Wellcome to science in India

# India Alliance – A Visionary Partnership

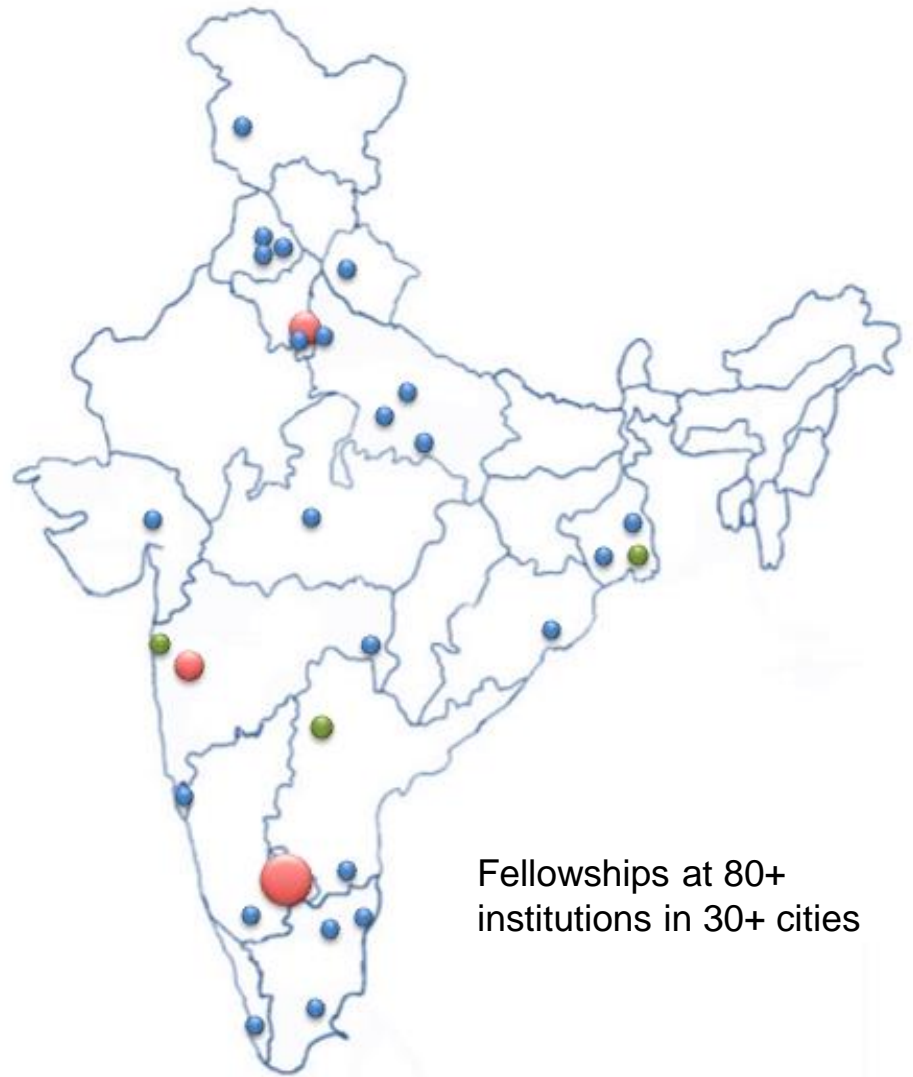


# Mandate for biomedical research

- Internationally accepted practices
- Develop, attract and nurture best in class human resources
- Best Indian scientists working overseas to return to India
- Increase the number of locations (in India) where world class biomedical research can be performed
- Devise suitable systems to support basic, clinical and veterinary research

# Fellowships (2009-17)

Fellowship Scheme	Awards
Early Career	87
Intermediate	152
Senior	42
Margdarshi	05
RTF	16
Total	302



*~3000 applications; funding rate ~6.5% – 18%*

# India | EMBO Symposia



Meetings on frontier, pioneering and interdisciplinary areas of life sciences. Designed to bring together basic scientists, clinicians, public health researchers, engineers, etc.

<http://wellcomedbt.org/event-support>

## EMBO Research Leadership Courses

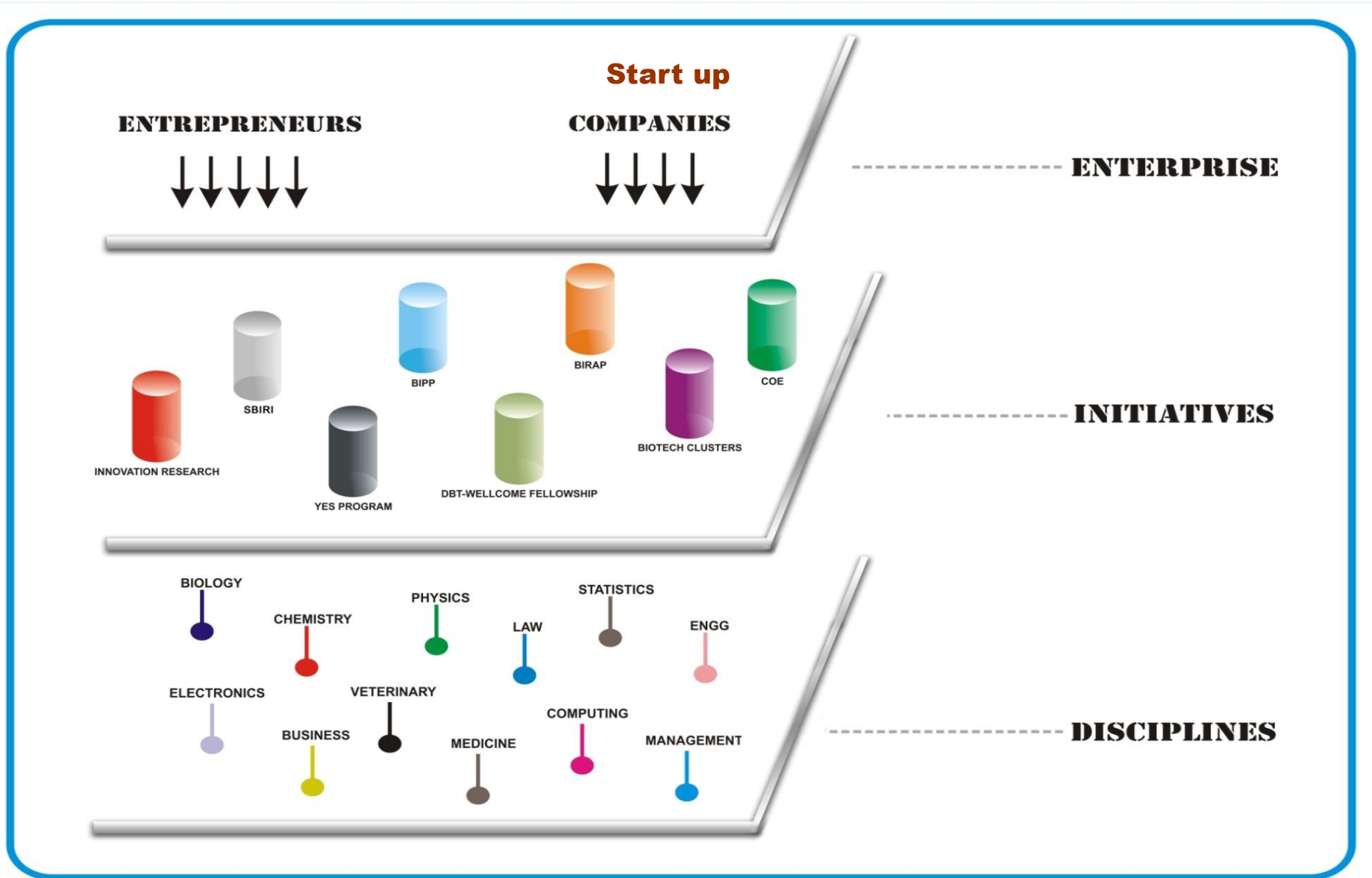


GESELLSCHAFT ZUR  
FÖRDERUNG DER  
LEBENSWISSENSCHAFTEN  
HEIDELBERG GMBH

**To turn the best scientists of today  
Into effective leaders of tomorrow**

- Leadership
- Communication
- Negotiation
- Conflict solving
- Problem solving
- Team development

# Universities and research institutes as part of innovation clusters



- Countries must share and learn together and from each other the art and science of making and delivering vaccines equitably
- A collaborative purpose driven global and regional innovation program can deliver affordable preventive and therapeutic vaccines against many communicable and chronic diseases
- And exciting journey awaits us all