

15th DCVMN International AGM

Vaccines, Our Shared Responsibility

(October 27-29, 2014)

” Partnerships for Vaccine Development “

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Senior Adviser

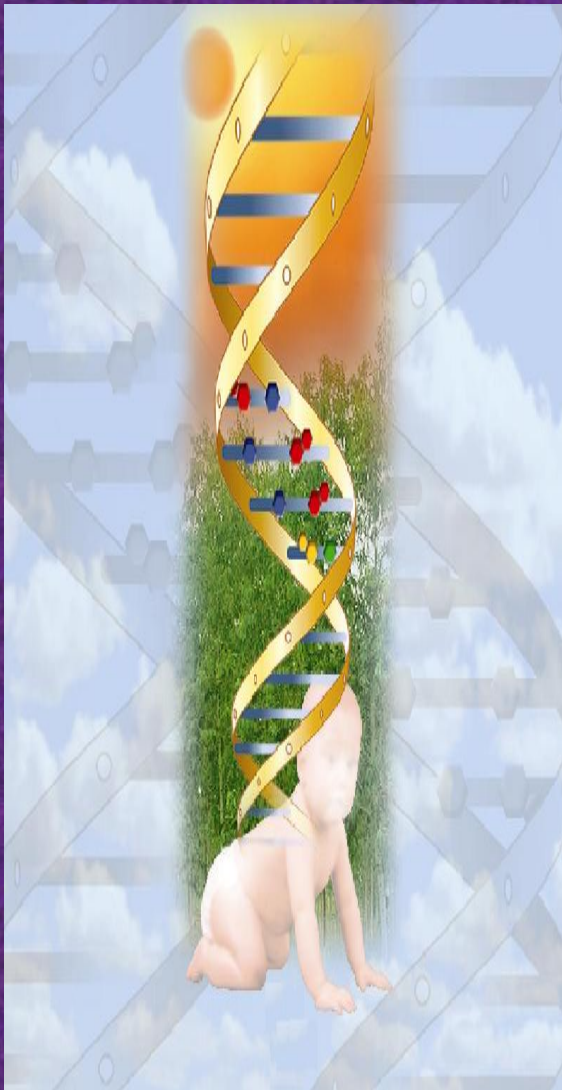
Department of Biotechnology

Ministry of Science & Technology

Government of India, New Delhi

OUR VISION

“Attaining new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice – specially for the welfare of the poor”.





Advances in Vaccinology

- Vaccines are the fastest growing biotech area with the entire pharma/biological sector and India is considered a global hub in this sector.
- To design better and more effective vaccines .

Need Newer Techniques to design novel vaccines

- Genomics, proteomics, bioinformatics, computational tools, reverse vaccinology, microarray technology, signature tagged mutagenesis and *Invivo* expression technology

Vaccine Development and Demand

- Till 1980 vaccine requirements for immunization programme has been made through the public sector vaccine manufacturers.
- Due to increase in demand of vaccines, the private sector entered in the vaccine manufacturing business to produce new and improved vaccines.
- **High Demand** - GAVI supported by multiple donor, purchase through UNICEF for the entire developing world.
- India itself is a large consumer for its immunization programme.
- The global vaccine market expected to reach about \$1 billion by 2015.
- Expected product innovations and global recognition of the benefits of immunization with new and improved prophylactic, therapeutic and adult vaccines.

- **Major vaccines produced in India**

- DPT,
- DT,
- Tetanus Toxoid,
- BCG,
- Oral Polio (formulation)
- MMR
- Penta
- Rubella,
- Hepatitis-B,
- Rabies
- Typhoid etc.

*Now Rotaviral Diarrhoea Vaccine : **ROTAVAC** - BBIL*

SII & others

The VISION 2025 of Department of Biotechnology, Govt. of India envisages

No one should suffer from Vaccine Preventable Diseases

- To make available of affordable, safe & effective vaccines for Children, Adolescent, Adults and Geriatric population.
- To accomplish the strategy comprises of strengthening :
 - ❑ Fundamental tools for vaccine development (Basic and applied R & D)
 - ❑ Product Development, Manufacturing, Regulation & Marketing capabilities
 - ❑ Human Resource
 - ❑ Effective partnerships with National/International Scientists and Organizations.

Collaborative Vaccine Development

- Vaccine development, clinical trial and commercialization is very complex and requires many steps with involvement of multi-partners.
- The partners will bring prospective, resources and unique skills
- Academic institutions will develop candidate vaccines and conduct clinical trials.
- Industry provides expertise in product development, manufacturing and commercial launching.
- The Government will facilitate through financial support and regulatory clearances.
- Most currently available as well as those in the developmental stage resulted from successful collaborations between partners from academic institutions, government, private sector including support from global organizations and non-governmental organizations.

Vaccine Research and Development Programme of DBT

- The Department is implementing the programme since 1987-88 through:
 - ❑ Technology Mission on Immunization – Development of new and improved vaccines and production of some of the EPI vaccines (polio, measles etc.)
 - BIBCOL (IPV, Moscow)
 - IVCOL (PMSV, France)
 - ❑ Indo – US Vaccine Action Programme – **a model bilateral programme under implementation for the past 27 years** - *“Value Added Programme”*
 - ❑ Medical Biotechnology Task Force
 - ❑ National Jai Vigyan Mission programme for S&T on generation of new and improved Vaccines
- **Vaccine Grand Challenge Programme – A new governance model**
- The VGCP is being implemented with an overall objective to accelerate development of candidate vaccines for which earlier leads are available and to take them through pre-clinical and clinical development and commercialization.
- Potential candidate vaccines developed
 - Rotavirus, Cholera, Typhoid, Rabies (DNA based), Malaria, Dengue, Tuberculosis, Japanese Encephalitis, HIV, chickenguniya etc.**

Key features envisaged under VGCP for granting mechanisms :

- Preliminary grant for nascent ideas followed by full grants for those that show promise.
- Planning grant for proposal writing as a team with consultant support.
- Centre of Excellence and programme support as per existing DBT schemes but through the vaccine grand challenge apex committee.
- Research strengthening grants for retaining key team members on contract hiring basis, extendable every 5 years.
- Engagement of consultants for problem solving as per Government of India norms.
- Public Private Partnership projects strictly according to SBIRI and BIPP and pharma fund rules.
- Cooperate grants, where R&D is jointly managed by investigators and by a professional team engaged by the programme on a part time basis.
- Subcontracting of work to not for profit organization, public institutes and industry through an open, competitive process.
- Consortium projects with other ministries or agencies in the country and internationally.

Current Status of DBT Vaccine Projects

➤ Rotaviral vaccine development (116E)

- ☐ Developed first indigenous rotavirus vaccine called ROTAVAC® - \$1 per dose.
- ☐ Under a unique social innovation public private partnership model.
- ☐ Recently approved to pilot introduction of the vaccine in EPI programme of Govt. of India.

➤ Malaria vaccine development

- ☐ Phase-I completed
- ☐ Established MVDP (DBT, EMVI, MVI, Bill & Melinda Gates Foundation)

➤ Dengue vaccine development

- ☐ Tetravalent vaccine against DENV-1 to 4] - ICGEB, New Delhi
- ☐ International Vaccine Agency - GlobeVac
- ☐ Technical Consultation – NIH

➤ **Cholera vaccine development**

- ❑ Phase III

➤ **JE vaccine development**

- ❑ Transferred to Panacea Biotech- due to various reasons not progressed further.

➤ **Typhoid vaccine development**

- ❑ Transferred to USV Ltd.
- ❑ Efforts made to make V_i polysaccharide vaccine (THSTI-BBIL)

➤ **Rabies vaccine development**

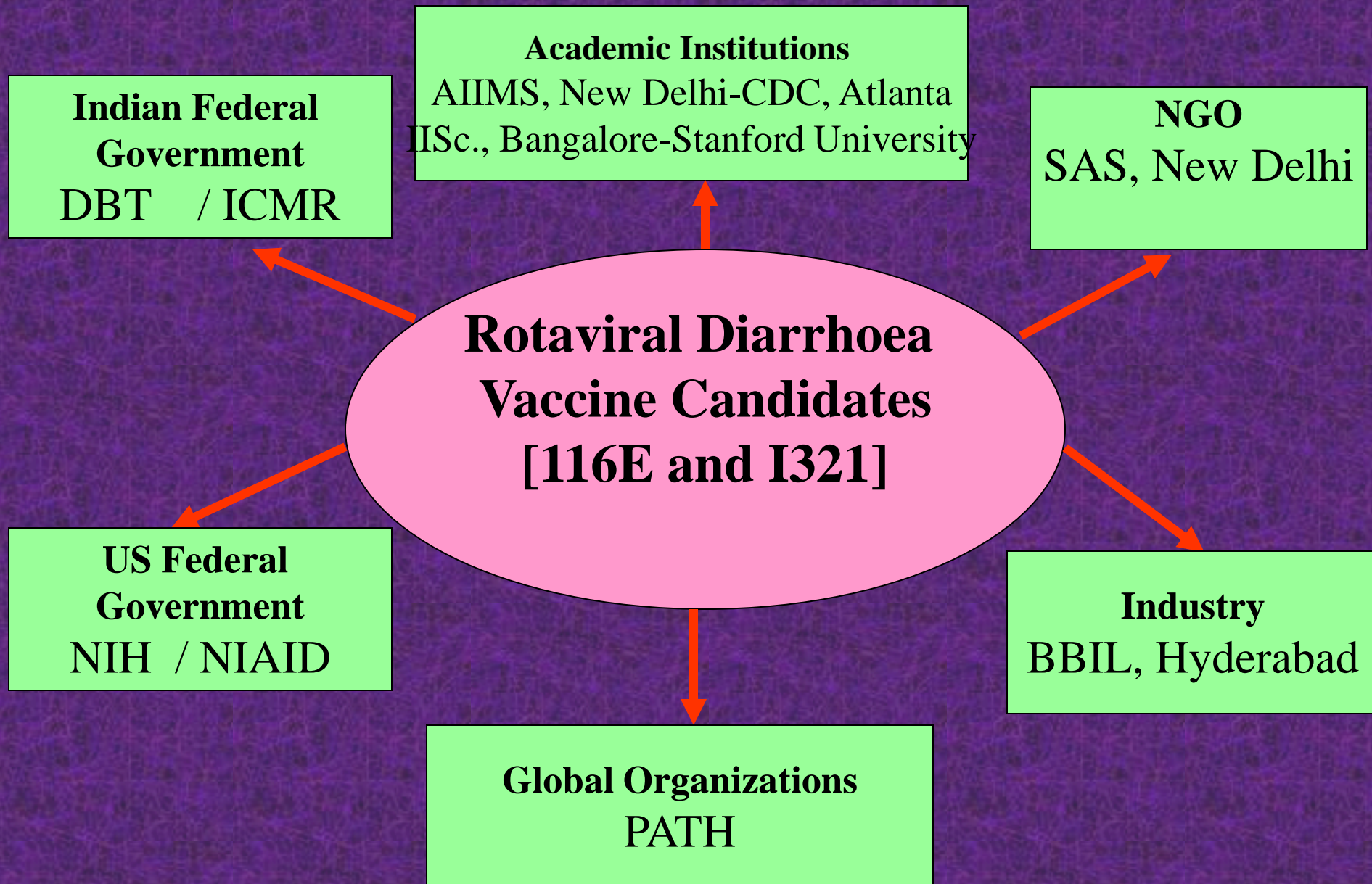
- ❑ Animal studies completed
- ❑ Human studies not pursued

➤ **Chickengunya -**

Immunological studies

- ❑ ICGEB, AIIMS, New Delhi
- ❑ Emory Vaccine Centre

Effective Global Partnership Rotaviral Diarrhoea Vaccine Development



Low-Cost Rotavirus Vaccine



Developed in partnership between



Bharat Biotech puts the cost as under Rs. 54 a dose for children.
Affordable health care at its best!

Example of effective global partnership

Case Study-II : Malaria Vaccine Development

**Indian Federal
Government**
DBT, ICMR

MVDP
Independent Society

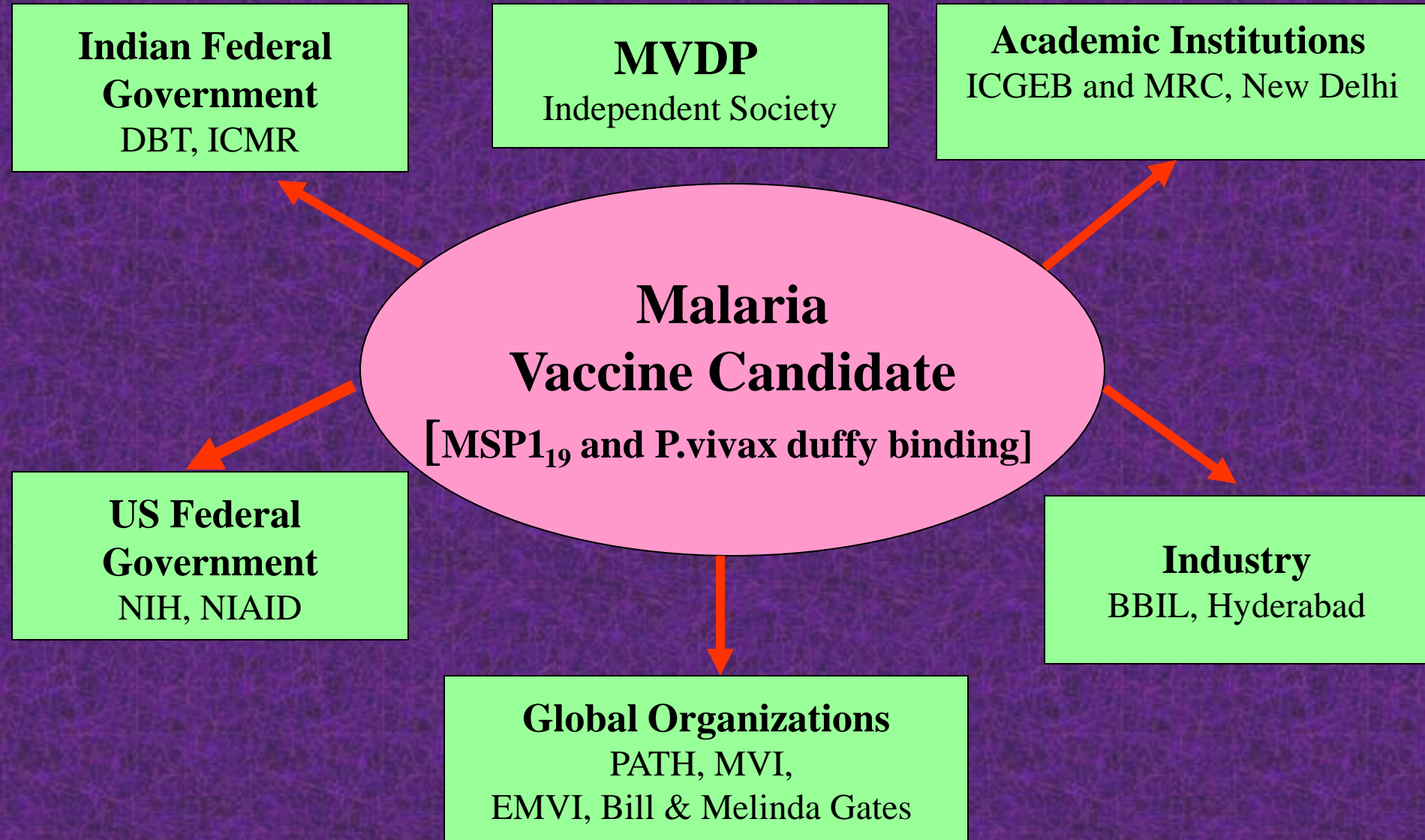
Academic Institutions
ICGEB and MRC, New Delhi

**Malaria
Vaccine Candidate**
[MSP1₁₉ and P.vivax duffy binding]

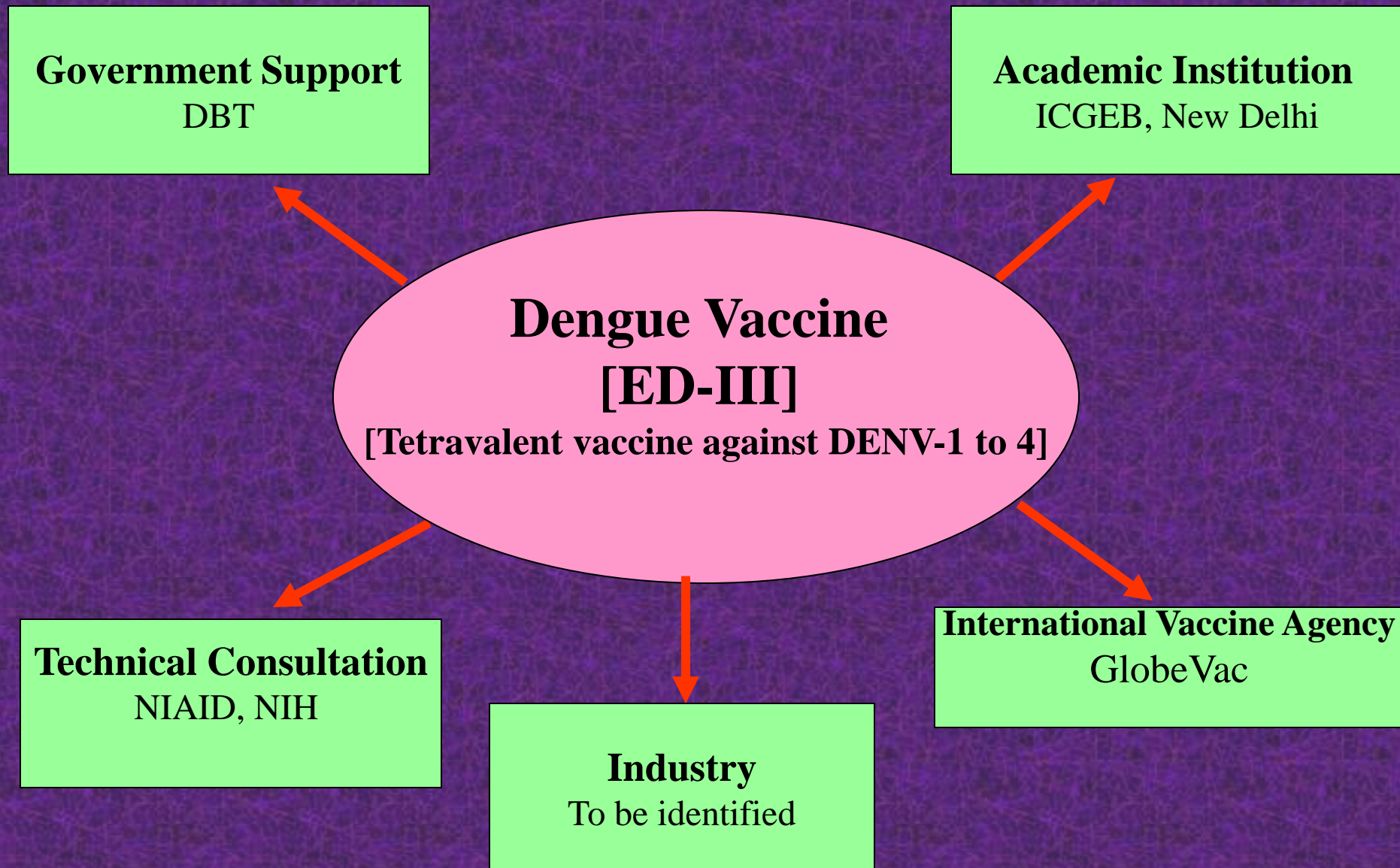
**US Federal
Government**
NIH, NIAID

Industry
BBIL, Hyderabad

Global Organizations
PATH, MVI,
EMVI, Bill & Melinda Gates



Dengue Vaccine Development



- ❑ National immunization programme of Government is the best example of policy makers regulating the prices directly, so that the vaccines should reach the masses at affordable cost.
- ❑ Government has to look at various options to make the vaccines affordable.
- ❑ For example **Polio Vaccine** was made available to masses at negligible price through the public programme.
- ❑ Without compromising the quality of vaccine, we have to work towards achieving the affordability, healthy competition is a necessity for the companies and at the same time the Government too has social responsibility.

Source: Biospectrum (edition February, 2013)
statement given by Dr.T.S.Rao, Adviser, DBT

INDUSTRIAL PROMOTION AND DEVELOPMENT

- Major policy goal to promote R&D in SME's and to provide enabling mechanism to build in-house company technology capabilities
- Continuation and expansion of Small Business Innovation Research Initiative - SBIRI
- Public partnership with large scale companies encouraged and supported in areas vital to the national development from scientific, economic or social perspective and development of technologies and products.
- Establishment of incubators by consortia of small and medium enterprises : Biotechnology Industry Research Assistance Council (BIRAC) for monitoring, supporting and nurturing R&D in small and medium biotechnology companies.
- Biotech clusters : Institutions, parks, incubators with large space for new start-ups – NCR, Bangaluru, Mohali, Kolkata, Pune .

Challenges

- New and improved vaccines need to be developed for a variety of infections of public health importance against which no effective preventive intervention measures are available or practical.
- A new paradigm needs to be established among all stake holders of immunization this includes research institutions, industrial partners, funding agencies in public-private partnership mode including global partners.
- Since vaccine R&D is an expensive and high risk enterprise. Normally it takes more than 10-15 years to bring a vaccine from research to commercialization with an approximate cost of US\$200-500 million per vaccine.
- The uncertainty of research outcomes makes the pipeline necessary with a portfolio of vaccine candidates for each of the targeted diseases.
- The prospects of new formulation technologies specially for new conjugate vaccines and production under GMP conditions revolutionized production of international standard quality vaccines.
- **Not having effective vaccine adjuvants** – Need to establish Vaccine Adjuvant Centre for new and novel adjuvants

Major hurdles faced by vaccine industry

- Technological capacity and access to know-how
- Lack of generic pathway for vaccines
- High capital investment in manufacturing infrastructure with lack of demand
- Gap in the need and accessibility of vaccines
- Need to add new vaccines in expanded program in immunization (EPI)
- High cost of R&D, long and complex clinical trials result in longer time to licensure
- Entry barriers to emerging suppliers in competition

Clinical Trial by August, 2014

Global

173,388

Korea

5,634

China

8,276

Taiwan

3,672

India

5,496

Thailand

1,567

(source : ClinicalTrials.gov)

(Published in : Biospectrum – Volume 12)

Opportunities and Challenges of International Cooperation in S&T with development of Vaccines and Pharmaceuticals : The DBT Experience

Opportunities

- Model for national programmes
- Institutional strengthening & Capacity building
- Access to international networks
- Frontier research in areas of mutual interest
- PPP with international partners
- Develop products/processes: global standards

Challenges

- Harmonization with national/regional priority areas – avoiding duplication of work
- Clinical trial issues (SC order) & adoption of global best practices
- Increased administrative time & effort – review, IP, agreements etc
- Collaboration in strength to strength; not just transfer of biological material

Translational Health Science & Technology Institute (THSTI)

Intramural Centers

Vaccine & Infectious Disease
Research Centre

Pediatric Biology Centre

Centre for Biodesign &
Diagnostics

Centre for Human Microbial
Ecology

Policy Centre for Biomedical
Research

Drug Discovery Research
Centre

Partnership Centers

Population Science
Partnership Centre

Intl.Centres (USA)

IAVI – HIV
Pre Term Birth

Extramural Centers

Clinical Development
Services Agency

Biotech Science Cluster, Faridabad

**Vaccine & Infectious
Disease Research
Centre (VIDRC)**

**Clinical Research
Centre for
Paediatric Diseases
(AIIMS)**

**Paediatrics
Biology Centre
(PBC)**

**Plat form
Technology
Centre**

**Translational Health Science &
Technology Institute (THSTI)**

**Centre for
Animal Model
for Clinical
Advances**

Biotech Park

POLICY UNIT

Incubator

**Centre for Biodesign
and in vitro
Diagnostic**

**UNESCO Regional Centre for
Biotechnology (RCB)**

**Clinical Development
Services Agency
(CDSA)**

**Cancer
Nano Centre**

**Clinical Research Centre
for Neurological Disorder
with NBRC & Gurgaon
Civil Hospital**

**Drug Discovery
Centre**

**Molecular Breeding
(NIPGR)**



- ❑ Based on the experiences so far, we in the Department re-defining the Vaccine Research and Development Mission to translate the product development process upto commercialization in accelerated mode.
- ❑ The same is under consideration by the Government of India

**How do we deal with this
exciting but uncertain future**

with

**Courage
Core Values
Innovativeness
Togetherness**

Thanks