OVERVIEW ON THE DEVELOPMENT OF ROTAVIRUS VACCINE IN BIO FARMA

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Global Situation

• Rotavirus is estimated to cause >500,000 deaths among children aged <5 years
• Rotavirus infection causes 2.1 million hospitalizations, 25 million outpatient visits, and 111 million episodes of diarrhea worldwide annually

(source : Soenarto et al. 2009)
Rotavirus cases in Indonesia

• Rotavirus infection accounts for 60% of hospitalized children with acute gastroenteritis
• Rotavirus infection most common among children 7-23 months of age
• Rotavirus infection was more common during the dry season (July – August)

(source: Soenarto et al. 2009; Wilopo et al. 2009)
Recommendation for the introduction of a particular vaccine into the Indonesian immunization programme is made by the Indonesian Technical Advisory Group on Immunization (ITAGI)

– Independent body appointed by the Minister of Health
– Group of experts (pediatricians, policy makers, etc)
ITAGI Recommendation

- Rotavirus vaccine be introduced into the national immunization program taking into account several factors such as:
  - Epidemiological status
  - WHO position paper
  - Cost effective analyses
  - Etc.
Bio Farma in brief

- Established in August 6, 1890
- State-owned Enterprise
- Only producer of vaccines and immunosera in Indonesia
- The number of employees approx. 900 people
- Integrated Pharmaceutical Quality System
  cGMP, ISO 9001, ISO 14001, OHSAS 18001
Bio Farma covers 2 sites

- **Animal breeding** on the outskirts of Bandung covering an area of 282,441 sq meters

- **The main campus** is sited in No 28 Jalan Pasteur covering an area of 96,210 sq meters
  - Production, QA and QC activities
  - Marketing and distribution activities
  - Administration
HISTORY OF BIO FARMA

August 6, 1890: Parc Vaccinogen or Lands Koepok Inrichting in the military hospital Weltervreden

1895 - 1901: Parc Vaccinogen Instituut Pasteur,

1902 - 1941: Landskoepok Inrichting en Instituut Pasteur
(1923 located in Bandung)

1942 – 1945: Bandung, Boeki Kenkyushoo

1946 – 1949: Lands Koepok Inrichting en Instituut Pasteur activities migrated to Klaten – Jogja (RM. Sardjito)

1955: Perusahaan Negara Pasteur


1997: PT. Bio Farma (Persero)
List of Products

- TT Vaccine
- DT Vaccine
- DTP Vaccine
- DTP-HB Vaccine
- BCG Vaccine
- Td Vaccine

- Polio Vaccine (Oral, m/b/trivalent)
- Measles Vaccine
- Hepatitis B Rec.
- Seasonal flu vaccine

Immunosera: Tetanus, Diphtheria, Snake anti venom
## Milestones of WHO PQ vaccines

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<tr>
<th>No</th>
<th>Vaccine</th>
<th>PQ Date</th>
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<td>1</td>
<td>OPV, Measles 10 ds</td>
<td>9 April 1997</td>
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<td>2</td>
<td>TT, DT</td>
<td>11 March 1999</td>
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<td>3</td>
<td>DTwP</td>
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<td>4</td>
<td>TT (Uniject)</td>
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<td>5</td>
<td>Hep B (Uniject)</td>
<td>13 May 2004</td>
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<td>6</td>
<td>DTP/HepB</td>
<td>7 Oct 2004</td>
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<td>7</td>
<td>Measles 20 ds</td>
<td>4 Sept 2006</td>
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<td>8</td>
<td>mOPV1</td>
<td>3 Nov 2009</td>
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<td>9</td>
<td>bOPV (1,3)</td>
<td>26 May 2010</td>
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<td>10</td>
<td>Td</td>
<td>6 July 2011</td>
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Rotavirus vaccine development in Bio Farma

• In collaboration with Murdoch Childrens Research Institute (MCRI), Australia

• Goal:
  – To develop and subsequently commercialize attenuated oral rotavirus vaccine in Bio Farma
Rotavirus Vaccine Strain

- RV3 strain with Serotype G3P[6]
- Isolated in an obstetric nursery in Melbourne, Australia
Vaccine Development Pipeline

**Exploratory**
- Understand the disease
- Epid. Data
- Identify antigen

**Vaccine Candidate Design**
- Seed history
- Presentation
- Route of administr,

**Vaccine Characterization**
- Bulk manuf.
- Formulation
- Identity
- Purity
- Standards
- Stability

**Preclinical studies**
- Safety
- Toxicology
- Teratology
- Etc.

**Pilot scale manufacturing**
- Clinical lots
- cGMP
- QC
- QS

**Clinical Development**
- GCP
- Phase I
- Phase II
- Phase III

**Regulatory Approval**
- Documents/Data (CTD)

**Commercial manufacturing**
- Regulatory compliance
- cGMP
- QC
- QMS
Milestones

- **Process Development**
  - Process optimization
  - Experimental lots

- **Production of clinical lots**
  - Comply with cGMP standards
  - Approved by NRA

- **Preclinical and clinical trials**
  - Anticipated 2014 - 2016

- **Commercialization**
  - Functional according to WHO standards
  - WHO accredited
THANK YOU