CENTER FOR RESEARCH AND PRODUCTION OF VACCINES AND BIOLOGICALS (POLYVAC, VIET NAM)

http://polyvac.com.vn
VIETNAM

- In Southeast Asia, 331,690 km², 63 provinces, 100 mil. peoples, ~1.5 mil. babies born yearly
- Disease burden: both infectious (30-40%) and non-infectious diseases.
- Endemics: Dengue fever, HFMD, etc.
- Vaccine manufacturers: 4, not yet mRNA technology
  - POLYVAC (Hanoi): Measles, MR, Rota, bOPV
  - Vabiotech (Hanoi): Hep B, JE, Cholera
  - IVAC (Nha Trang): DPT, TT, BCG, Td
  - Davac (Da lat): Typhoid
PROGRESS OF VACCINE DEPLOYMENT IN EPI

- BCG, - Diphtheria, - Pertussis, - Tetanus, - Polio - Measles

- 1985
- 1997 - Hep B, - JE, - Cholera, - Typhoid,
- Measles (2nd dose)
- 2007 - DTP, - Hep B - Hib
- 2010 - Measles - Rubella
- 2014 - IPV
- 2018 - Td*
- 2019 - IPV2*
- 2022

Roadmap to introduce vaccines into EPI:
- Rota vaccine : 2023
- Pneumonia vaccine: 2025
- HPV: 2026
- Flu: 2030
POLYVAC

➤ Center for Research and Production of Vaccines and Biologicals

➤ State organization directly under Vietnam MOH

➤ Established in 1994

➤ Facilities:

  ✓ LO-DUC, Hanoi

  ✓ VINH-HUNG, Hanoi

  ✓ CAM-PHA, Quang Ninh
MISSION

R&D and production of vaccines and biologicals with high quality for prevention of infectious diseases.
MAIN BUSINESS SECTORS

1. R&D and production, including QC, QA and QMS/GMP
2. Trading: exporting, importing, wholesale and retail business, etc.
3. Application and technology transfer
4. Breeding experimental animals
5. Provision of technical services: vaccination, consultation, equipment calibration, training, etc.
Staff number in total: 142
LICENSED VACCINES

1. Measles vaccine
2. Measles-Rubella combined vaccine
3. Rota vaccine
4. bOPV
IN VITRO DIAGNOSTICS KITs

IgG/IgM antibody diagnostic ELISA Kit

COVID-19 IgG/IgM Rapid Test

Polyvac Rota Ag Rapid Test

Flu, Dengue Rapid Test: under development
VINH-HUNG FACILITY
(MVVAC & MRVAC)

- 2002-2009: built up; technology of MVVAC was transferred from KDSV- Japan
- 2013-2018: technology transfer of MRVAC
- Marketing license: 2009 for MVVAC, 2017 for MRVAC
- 2017: GMP certification in Vietnam
- Max capacity: 10 mil. doses/year, (domestic demand and exportation)
- MVVAC is submitted for WHO-PQ and in process
VINH-HUNG FACILITY
(SPF rabbit breeding)

- Meeting SPF rabbit breeding requirements
  - Rubella vaccine production
  - QC tests
  - Non-clinical trials and others
## LO-DUC FACILITY
(.OPV & Rotavin vaccines)

### POLIO
- 1960s: tOPV R&D
- Max capacity: 40 mil. doses/year.
- Polio eradication in 2000.
- 2017: bOPV was produced to replace tOPV (WHO’s requirements)

### ROTA
- 1998-2006: Vaccine Strain (G1P[8]) R&D (support from US CDC and WHO).
- 2008-2009: safety and high immunogenicity (3 phases of clinical trial)
- 05/2012: marketing license of Rotavin-M1,
- 2022: stabilizers changes: storage at 2-8oC instead of -20oC (support from PATH)
QUANG-NINH FACILITY
(Monkey breeding center)

- Two isolated islands in Quang-Ninh.
- Established in early 1960s
- Monkeys meeting criteria for:
  - OPV production
  - QC
  - Non-clinical trials, and others.
Quality management system

WHO-cGMP

ISO 9001

ISO 13485
R&D PRODUCTS

- **Sabin-IPV (sIPV):**
  - Produced in pilot scale with technical support from JPRI, Japan.
  - 3 phases of clinical trial were approved with good results

- **In vitro diagnostics test kits:**
  - Rotavirus Antigen Rapid test kit
  - Dengue Rapid test kit
  - Flu A/B Rapid test kit

- **Backbone of measles vector for viral rescue**
INTERNATIONAL COLLABORATION

- Daiichi Sankyo Biotech, Japan and JICA: transferred technology for Measles vaccine and MR combined vaccine production.
- Japan Poliomyelitis Research Institute (JPRI): developing OPV and sIPV;
- US CDC R&D and production of rotavirus vaccine;
- PATH: technical support to modify formula of rotavirus vaccine, conduct clinical trials and improve PQS, PV activities, etc.
- Developing Countries Vaccine Manufacturers’ Network (DCVMN): vaccine production, GMP, clinical trial, pharmacovigilance and WHO PQ procedures.
PROSPECTS FOR COOPERATION

- Technology transfer of mRNA vaccine production
- Exportation and importation of bulk and final products
- Supply of SPF rabbit and monkey for vaccine production, QC tests and non-clinical trial.
APPLICATION FOR mRNA TECHNOLOGY

Development of new vaccines:

- COVID-19 vaccine
- Emerging/Urgent threat(s)
- HPV, Dengue and others
APPLICATION FOR mRNA TECHNOLOGY

- Legal ground
- Experience in vaccine R&D and technology transfer
- Trained and experienced personnel

- Assigned by the government to receive the mRNA technology transfer
- Access to high technology in vaccine production
- Development of new vaccines
- Collaboration with partners

- mRNA vaccine GMP facility: not built up, yet
- Not experienced in mRNA vaccine production.

Resolution No. 104/NQ-CP
Resolution No. 36-NQ/TW
Decision 1286/QD-TTg
INTEGRATION OF AFIGEN’S TRAINING

• Receive lab-scale mRNA technology (package 1).

Doing:
• Set up the research area to meet the requirements of the mRNA vaccine research laboratory
• Make a list of materials and equipment in need to seek investment

Will do
• Participation in Hub's scheduled training courses
• Consultation from MoH on vaccine candidates in line with vaccine development strategies and epidemic situation of Vietnam.
• Collaboration with other partners
Thank you for your attention!