Cross learning experience human and animal vaccine licensure based on technology platforms

A Joint CEPI/IABS/ZAPI Workshop

March 16 & 17th, 2020

Palais de l’Académie Royale des Sciences
Brussels, Belgium

AGENDA – FEBRUARY 2020

Scientific Committee

Daniel BRASSEUR, co-Chair Scientific Committee
former CHMP-PDCO-VWP chair at the EMA; CEPI consultant

Murray LUMPKIN, co-Chair Scientific Committee
former Deputy Director, FDA; Bill & Melinda Gates Foundation

Dr. Barney GRAHAM NIH, Deputy Director and Chief, Viral Pathogenesis Laboratory
Dr. Mélanie SAVILLE Director, Vaccine Development, CEPI
Prof. Dr. Johan NEYTS Rega Institute Louvain, Belgium, specialist of DNA vaccine PLLAV
Dr. Marion GRUBER FDA, Director, Office of Vaccine Research and Review – CBER
Dr. Ivo CLAASSEN EMA, Head of Veterinary Medicines Division
Dr. Marco CAVALERI EMA, Head of Anti-infectives and Vaccines
Prof Dr. Jeffery ALMOND Oxford University; Chairman of the Board, Osivax
Dr. Jean-Christophe AUDONNET Senior Director, Vaccines R&D; ZAPI Project Coordinator; Boehringer Ingelheim Animal Health
Dr. Emmanuel HANON Senior Vice President, Head of R&D, GSK Vaccines
Dr Ajoy CHAKRABARTI Bill & Melinda Gates Foundation Vaccine Development
Dr Steve BLACK The Brighton Collaboration, Task Force for Global Health
MONDAY MARCH 16th

08:00 Welcome
9:00 Opening

9:00 1. Welcome and Introduction - CEPI & IABS
     Dr. Joris VANDEPUTTE, International Alliance for Biological Standardization (IABS)
     CEPI representative

Chairpersons:
Dr. Dean SMITH, Health Canada
Dr. Nicholas Jackson, CEPI

2. Focus/Objective
9:15 Vaccine Technology Platforms: What are we talking about?
Dr. David VAUGHN
Senior Program Officer, Integrated Clinical Vaccine Development
Bill & Melinda Gates Foundation (Seattle, Washington - USA)

3. Scene setting
   Experience with emergency situations: success & failures
9:30 Animal: state of the current licensing situation: regulatory requirements in force and currently licensed vaccines
Ivo CLAASSEN
Head of Veterinary Medicines Division
European Medicines Agency, EMA (Amsterdam, The Netherlands)

9:45 Human: influenza past experience success & failure
Dr. Ralf WAGNER
Senior Scientific Officer for Viral Regulation and Research
Federal Institute for Vaccines and Biomedicines, PEI (Langen, Germany)

10:00 Emergency preparedness: Lessons learned in the development of an Ebola vaccine
Dr. Jayanthi WOLF
Executive Director, Global Regulatory Affairs
MSD (North Wales, Pennsylvania - USA)

10:15 Discussion

10:30 Coffee break

Chairpersons:
Dr. Carmen JUNGBÄCK, IABS
Dr. Ralf WAGNER, PEI

4. New Technologies
11:00 Animal vaccines: ZAPI project
Dr. Jean-Christophe AUDONNET
Senior Director, Vaccines R&D; Coordinator ZAPI IMI Project
Boehringer Ingelheim Animal Health France (Lyon, France)
**Experience with technology platforms in animal vaccines - US regulatory approach**  
*Dr. Carol GIBBS*  
Senior Staff Microbiologist  
USDA Center for Veterinary Biologics - Policy, Evaluation & Licensing (Ames, Iowa - USA)

**Advanced human vaccines in the pipe-line (Viral vectors, VSV-Measles-ChAd...) and RNA, DNA technologies**  
*Dr. Mark VAN OOIJ*  
Scientific Director  
Janssen Vaccines (Leiden, The Netherlands)

**The CEPI portfolio : Examples of vaccine candidates based on platforms**  
*Dr. Nicholas JACKSON*  
Head of Programs & Technology  
Coalition for Epidemics Preparedness Innovation, CEPI (London, UK)

11:30 | 11:45 | 12:00 | 12:30
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Advanced human vaccines in the pipe-line (Viral vectors, VSV-Measles-ChAd...) and RNA, DNA technologies | The CEPI portfolio : Examples of vaccine candidates based on platforms | Questions | Lunch

**Chairpersons:**  
*Dr. Carol GIBBS*, USDA Center for Veterinary Biologics  
*Dr. Svein Rune ANDERSEN*, CEPI

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**5. Commonalities and Particulars & Challenges of Platforms**

**Manufacturing & quality control – what is platform generic, what is vaccine specific?**  
*Dr. Dean SMITH*  
Head and Senior Scientific Evaluator of Vaccines  
Health Canada (Ontario, Canada)

**Vaccine platforms : pre-clinical package, how far can we go?**  
*Dr. Kaat SMITS*  
Nonclinical Assessor  
Federal Agency for Medicines and Health Products (Brussels, Belgium)

**To what extent can clinical trials be pre-arranged?**  
*Professor Stephen LUBY*  
Professor of Medicines (Infectious Diseases and Geographic Medicine)  
Director of Research, Center of Innovation for Global Health  
Stanford University (Stanford, California - USA)

**Discussion**

**Coffee break**

**Chairpersons:**  
*Dr. Nicholas JACKSON*, CEPI  
*Professor Pieter NEELS*, IABS

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**How can use of platform technologies influence the size of the safety database needed to support product safety? Can the risks of the antigen and the platform be dissociated?**  
*Professor Steve BLACK*  
Emeritus Professor of Pediatrics, Cincinnati Children’s Hospital  
SPEAC Workpackage lead, The Brighton Collaboration (Berkeley, California)
What kind of risk taking in emergency situation?

Professor Jean-Michel Dogné
Member of the Pharmacovigilance Risk Assessment Committee PRAC
European Medicines Agency, EMA (Amsterdam, The Netherlands)

Challenges to proof vaccine efficacy for outbreak vaccines

Dr. Jakob Cramer
Head of Clinical Development
Coalition for Epidemics Preparedness Innovation, CEPI (London, UK)

General Discussion

Short conclusion & End Day 1

TUESDAY, MARCH 17th

08:00 Welcome
8:30 Start

Chairpersons:
Dr. Mimi DARKO, Ghana-FDA
Dr. Debra Yeskey, CEPI

6. Regulatory issues
Facilitating vaccine development through the use of platform technology

8:30 EU approach
Dr. Marco CAVALERI
Head of Anti-infectives and Vaccines
European Medicines Agency, EMA (Amsterdam, The Netherlands)

8:50 Facilitating vaccine development through the use of platform technologies: US FDA perspective
Dr. Marion GRUBER
Director, Office of Vaccine Research and Review - CBER
Food Drug Administration, FDA (Silver Spring, Maryland - USA)

9:10 AVAREF, Asian regulators
Dr. Mimi DARKO
Chief Executive Officer at Food Drug Administration (Accra, Ghana)
African Vaccine Regulatory Forum, AVAREF (WHO office Brazzaville, Congo)

9:30 WHO Regulatory preparedness activities to facilitate access of emergency vaccines
Dr. Carmen RODRIGUEZ HERNANDEZ
Group Lead Vaccine assessment
World Health Organisation, WHO (Geneva, Switzerland)

9:50 Coffee break
10:15  Panel Discussion

How can « tried and true » vaccine platform streamline vaccine development and gain regulatory acceptance?

Dr. Marion GRUBER, FDA
Dr. Marco CAVALERI, EMA
Dr. Carmen RODRIGUEZ-HERNANDEZ, WHO
Dr. Ajoy CHAKRABARTI, Bill & Melinda Gates Foundation
Professor Klaus CICHUTEK, PEI
Dr. Jean LANG, EFPIA Infectious Disease SGG & Vaccine Europe R&D Industry Chair

11:00  General Discussion

11:45  Conclusions & Recommendations
The Way Forward....

Dr Mac Lumpkin
Deputy Director Integrated Development
Lead for Global Regulatory Systems Initiatives
Bill & Melinda Gates Foundation (Seattle, Washington - USA)

12:00  End of meeting