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

Venue
Palais de l'Académie Royale des Sciences
rue Ducale, 1
B 1000 Bruxelles

Tentative Programme for Joint CEPI/IAB/ZAPI Workshop in Brussels on March 16 & 17th, 2020

Monday March 16, 2020

Welcome 8.00 am
0pening 9.00 am

1. Welcome and Introduction (15 min)
   CEPI & IABS
   Richard Hatchett and Joris Vandeputte

2. Focus/Objective (2 speakers, 15 minutes each = 30 min)
   a. Vaccine Technology Platforms: What are we speaking about?
      David Vaughn, BMGF
   b. Emergency Preparedness:
      A very specific public health situation with a different risk/benefit perception
      Lessons learned in the use of an investigational Ebola vaccine for outbreak response".
      Jayanthi Wolf, Merck
   c. Questions 15 min

3. Scene setting (2 speakers, 15 minutes each = 30 min)
   Past Experience with Emergency situations: success & failures

   a. Animal : state of the current licensing situation: regulatory requirements in force and currently licensed vaccines **Ivo Claassen, EMA**
   b. Human: influenza past experience success & failure
      Prof Klaus Cichutek, PEI
   c. Questions (15 min)

Coffee Break 10.45-11.15 am

4. New Technologies (3 speakers 15 minutes each = 45 min)
    a. Animal vaccines: ZAPI project **Jean-Christophe Audonnet**
    b. Experience with technology platforms in animal vaccines - US regulatory approach
    Dr Carol Gibbs, US Center for Veterinary Biologics Policy, Evaluation & Licensing
    c. Advanced human vaccines in the pipe-line (Viral vectors, VSV-Measles-ChAd…) and RNA, DNA technologies
    Dr Mark van Ooij, J&J awaiting confirmation

Questions (30 min)

Lunch Break 12.30-13.30pm

5. Commonalities and Particulars & Challenges of Platforms (3 speakers, 15 min each = 45min)
    a. Manufacturing & quality control – what is platform generic, what is vaccine specific?
    TBC
    b. Vaccine Platforms: pre-clinical package, how far can we go?
    Kaat Smits, FAMHP Belgian Drug Agency
    c. To what extent can Clinical trials be Pre-designed?
    TBC

Discussion (30 min)

Coffee 3.00- 3.30 (speakers 15 min each= 45 min)

    d. 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?
    Steve Black, Global Vaccine Data network
    e. What kind of risk taking in emergency situation?
    J-M Dogné Member of the PRAC, EMA
    f.
    Challenges regarding the way proof of Efficacy/Protection can be demonstrated
    The design of a 'responsive' antigen likely to elicit a immune response and the way to demonstrate clinical protection would be considered here (mechanism of action, surrogacy, field trial.) Animal rule
    Speaker, pending

General discussion 4.15 – 5.00pm

March 17, 2020

Welcome 8.00am
Start **8.30am**

6. Regulatory issues (5 speakers – up to 10.00am)
    a. Introduction of Challenges to date, the CEPI portofolio
       Melanie Saville, CEPI
    b. Potential use of Platform Master Files
        a. EU approach **Marco Cavaleri, EMA**
        b. Facilitating vaccine development through the use of platform technologies: US FDA perspective **Dr Marion Gruber, FDA**
        c. Avaref, Asian Regulators **Dr Mimi Darko, Avaref**
        d. WHO perception in the PQ process
           Emer Cook *or* Carmen Rodriguez Hernandez, WHO

Break 10.00-10.30am

Panel Discussion 11.00 – 11.45am

    c. How can "tried and true" vaccine platform streamline vaccine development and gain regulatory acceptance?
       Panel Discussion asking each panelist one slide for a personal statement
       FDA (Marion Gruber), EMA (Marco Cavaleri) and VWP (Mair Powell), WHO (Emer Cook), BMGF (Ajoy Chakrabarti), PEI (Klaus Cichutek) + Industry Member TBC

General discussion 11.45-12.30am

All

Conclusions/Recommendations
The way forward…..

End 01.00pm