CEPI

Coalition for Epidemic Preparedness Innovations

CEPI Interim Scientific Advisory Committee (SAC) Meeting
February 22-23, 2017
Institute Pasteur, Institut Pasteur, 25-28 Rue du Dr Roux, 75015 Paris, France

The following Scientific Advisory Committee members participated:

Committee members elect:		Non-voting members:
• Mark Feinberg (Chairperson) • Alan Barrett • Daniel Brasseur • Jean-Francois Delfraissy • Jesse Goodman • Penny Heaton • Gagandeep (Cherry) Kang • David Kaslow • Michael Kurilla • Kathleen Neuzil • Gunnstein Norheim • Stanley Plotkin • Helen Rees • Connie Schmaljohn • Kenji Shibuya • Peter Smith	***Apologies*** • Maharaj Kishan Bhan • Gary Disbrow • Bernard Fanget • Heinz Feldmann • George Fu Gao • Subash Kapre • James Robinson • Amadou Sall	***MNC representatives*** • Ali Alloueche • Jean Lang • Johan Van Hoof ***World Health Organization*** • Bernadette Murgue ***Secretariat*** • Dimitrios Gouglas • Klara Henderson • Johan Holst • Frederik Kristensen • Hinta Meijerink • Elizabeth Peacocke ***Apologies*** • Kathrin Jansen

Objectives for the meeting:

1. To discuss the state of the published Call for Proposals (CfP1)
2. To discuss the vision for the CfP related to vaccine technology platforms (CfP2)
3. To discuss impressions from the Scientific Community meeting
4. To discuss the CEPI pipeline
5. To discuss Biological Standards, Assays and Correlates of Protection
6. To revisit the “Finishing the Job on Ebola” issue
7. To review the market potential for priority pathogen vaccines
8. To obtain an update on the WHO R&D Blueprint

CfP1 on Lassa, MERS & Nipah

1. The SAC noted that the Board endorsed the *CEPI Procedure for Calls for Proposals* that outlines the evaluation process to be followed by the CEPI Secretariat, independent expert evaluators and SAC members.
2. Based on new Conflict of Interest (CoI) declarations, and depending on applications received, SAC members were appointed to review Lassa, MERS and Nipah CfP1 applications. Non-voting SAC members did not have access to proposals and would instead receive a summary report of the proposals that includes non-confidential information.
3. The SAC approved the step 1 decision support framework, including criteria descriptions, three-level rating scales (A-B-C), rules and groupings for shortlisting proposals that should be advanced to step 2 of the proposal submission process.
4. For the step 1 review – the SAC agreed to focus on applications with divergent opinions
5. The SAC decided that, on receipt of applications, and *before* circulating to reviewers, the CEPI Secretariat would complete a ***screening*** of proposals against a number of eligibility criteria, including whether the candidate showed any immunogenicity and safety data in relevant animal models.

In discussion it was noted that the Secretariat should push speed and output, be clear that funding is stage gated, and that contract management processes will be important.

CfP2 related to Vaccine Technology Platforms

The SAC decided to limit CfP2 to vaccine platform technology related investment and to establish a working group led by CEPI, in partnership with Bill and Melinda Gates Foundation (BMFG), to map "most promising technologies" available to ensure appropriate investment portfolio.

During discussion the following key points were raised:

- This call should advance vaccine development for EID relevant priority pathogens (WHO priority plus key categories of emerging pathogens)., rather than a generic platform call, and bring these vaccine candidates to phase II
- Define whether the scope of the vaccine platform technologies call will also include funding to support R&D related to adjuvants, formulation, delivery, BSL4 testing, manufacturing and clinical trials enabling rapid vaccine development.
- Leverage ongoing efforts in R&D on vaccine platforms by emphasizing the chance of technology being applied to commercial products as a criterion for funding.

Scientific Community Meeting

The SAC discussed its impressions from the Scientific Community Meeting, including: the need to define a clearer output of meeting; the need to add community engagement, social sciences, implementation topics; the need to include regulators, and the importance of partnerships to ensure efforts are not duplicated. In addition, panel chairs commented on their session, with the main response being that this was a useful meeting and that the set of speakers was excellent.

The CEPI Pipeline

The SAC discussed how, in supporting/choosing candidates, it was critical to:

a. Understand protective immunity and relevant approaches, suitable animal models (neutralizing antibodies for Nipah, cell mediated immunity for Lassa, etc).
b. Define extent of preclinical data wanted/desirable/lower bar: up to NHPs if relevant
c. Assess cross protection (Lassa, Nipah)
d. Coordinate BSL4 use for animal challenge models (limited number of facilities)

Biological Standards, Assays and Correlates of Protection
The SAC discussed the existing players & system to be utilized. It proposed to invite NIBSC to come to SAC to present their work. The NIH was mentioned, as it has the BEI standards resource facility, plus experience from FANG Ebola group.
Several views were expressed:

a. CEPI should enable others to fulfil the needs, facilitate and fund the doers
b. Head-to-head comparisons of preclinical candidates could be a facilitated/mandatory step in CEPI product development. Collaboration across projects, BSL facilities, standardised testing
c. Experience from Ebola vaccine response assays standardisation highlighted need for international coordination and standardisation of assays down to protocols
d. The recommendation to focus on antibody assays first, as CMI assays are challenging to standardise
e. The recommendation that this should be initiated quickly, as it takes time to standardise and source reagents
f. The need to define scientific needs, action plan, milestones, budget estimate

The SAC ***recommended*** that a **working group** be initiated in close collaboration with WHO (potentially co-chairing) including/sponsoring NRAs from LMIC countries. The group should include regulators (in their capacity as experts) for likely pathway.

Revisiting the "Finish the Job on Ebola" issue
Dr. Michael Osterholm presented the latest report from Ebola Team B. See slides from the meeting for the presentation.

The SAC discussed how the possibility for a licensed Ebola vaccine was a key unresolved issue. The gaps and the path from current state to licensure were still unclear. Further, it is difficult to maintain the level of urgency once there is a change to the risk and benefit of a vaccine such as Ebola. It was unclear who has/had the responsibilities for remaining gaps, and there may be a need for an advocacy group engaging high-level politicians in affected countries to mobilise support for future use. The issues with Ebola are similar to H1N1, and need to build capability, not only vaccine specific development.

The SAC recalled that the CEPI Board made several recommendations related to this topic on December 16, 2016. However, the SAC noted there was a need to check "perceived or real gaps." Views were expressed regarding how the Board could develop expected timelines for when vaccines should be licensed, and appoint resources to work on this, linked to CfP formation, and perhaps work closely with WHO SAGE to ensure progress.

Market potential of priority pathogen vaccines – Chikungunya case study
Presentations from industry representatives described limited market potential for a Chikungunya vaccine. The SAC proposed that CEPI contact endemic countries, such as India, Brazil, Colombia to explore vaccine demand and linkage to developers with promising vaccine candidates. The discussion included views on how development and manufacturing costs and potential market are closely connected.

- **Update on WHO R&D Blueprint**
  The WHO provided an update on the annual pathogen prioritization process for 2017, which can be consulted here. SAC members were also invited to provide input into the draft WHO MERS TPP to the CEPI Secretariat by COB 28 February. The MERS TPP was later published in May 2017 and be consulted here. CEPI is interested to understand more about the development of the WHO long-list, and asked the WHO if this list could be shared with the CEPI SAC.