CEPI

Coalition for Epidemic Preparedness Innovations

CEPI's Fourth Scientific Advisory Committee (SAC) Meeting

August 24, 2017

Radisson Blu Plaza, Oslo

Committee members:		Non-voting members:
• Mark Feinberg (Chairperson) • Alan Barrett • Amadou Sall • Gagandeep (Cherry) Kang • Connie Schmaljohn • Daniel Brasseur • David Kaslow • Gunnstein Norheim • Helen Rees • James Robinson • Jesse Goodman • Kathleen Neuzil • Maharaj Kishan Bhan • Michael Kurilla • Penny Heaton • Peter Smith • Subash Kapre • Stanley Plotkin	***Apologies*** • Bernard Fanget • George Fu Gao • Jean-François Delfraissy • Kenji Shibuya • Martin Friede • Gary Disbrow • Kathrin Jansen	***MNC representatives*** • Ali Alloueche • Jean Lang • Johan Van Hoof ***World Health Organization*** • Vasee Moorthy ***Secretariat*** • Richard Hatchett • Carolyn Clark • Dimitrios Gouglas • Johan Holst • Frederik Kristensen • Hinta Meijerink • Elizabeth Peacocke • Benedicte Skutle • Nora Indrehus • Neil Cherian • Klara Henderson • Karianne Johansen • Georges Thiry • Joseph Simmonds-Issler • Amrita Sekhar • Solomon Yimer • Simone Blayer ***Others*** • Josie Golding • Ralf Clemens

Objectives for the meeting:

1. To define next steps in CfP1 review and award selection process
2. To define next steps in CfP2 launch
3. To discuss any updates on Chikungunya
4. To discuss any updates on Ebola
5. To discuss key decisions made by the Board
6. To discuss updates on CEPI Working Groups

CfP1 conclusions and next steps

In previous deliberations, the SAC decided to invite **16** applications (18 vaccine candidates) to submit proposals for Step 2: 6 MERS proposals, 6 Lassa proposals, 3 Nipah proposals and 1 multiple-antigen proposal (Lassa & Nipah). The SAC review process was as follows: applicants were invited to submit and the submission portal hosted by the Research Council of Norwas was closed on 12 July 2017. Each application was reviewed by: 3 Independent reviewers assessing the overall application to provide text based evaluation and scores to support a decision analytic framework; Topic specialist reviewers including 1 preclinical, 1 clinical and 1 CMC/manufacturing expert to provide text based evaluation and scores to support a decision analytic framework; 1-2 affected country experts for evaluation of capacity building aspects of proposals; CEPI Secretariat team for a preliminary budget and cost analysis; and 1-2 Non-conflicted SAC reviewers.

The CEPI Secretariat presented analysis of results to SAC for final recommendations based on a voting process. The outcomes of the Step 2 review process were: from the total of 18 candidates assessed at the SAC meeting, the following recommendations were made by the SAC: 8 proposals were recommended for award; 6 proposals were advised for the CEO to further review and deliberate on; and 4 proposals were rejected. The distribution of recommendations by platform technology included a broad mix of viral vectors, nucleic acid technologies, and recombinant proteins, and at least two different platforms by disease.

It was agreed that the CEPI CEO and Secretariat would present SAC recommendations to the Interim Board in a Board teleconference planned for 21 September, following which, applicants would be contacted to initiate the Due diligence process.

Key points raised in discussion:

- Funding for projects should be based on milestone achievements
- Partnership agreements should be flexible, but be based on robust technical performance standards and monitoring
- A “Pathogen X” may require CEPI funding to be reprioritized
- SAC members questioned if some of CEPI’s budget should be allocated to capacity building and encouraging developing country manufacturers. CEPI should aim to achieve capacity building and civil society goals via collaboration with other funders, such as the EC and World Bank

CfP2 on Vaccine Platforms

In its second call for proposals, CEPI aims to encourage the development of vaccine platform technologies that can be rapidly deployed against known and newly emerging pathogens, to limit or prevent future outbreaks of known or new diseases.

The SAC was presented with recommended specifications (scope, eligibility criteria, platform performance metrics, target product profile for platform technologies, etc) to be included in the call for proposals. In discussion it was noted that given that time use metrics requested by CEPI are aspirational, it is the implicit message to the applicants that carries value, and CEPI should ask applicants to demonstrate claims made with regard to achieveable timelines. However, CEPI should push beyond established status quo. Given the broad nature of the discussion and time constraints, SAC members agreed to further reflect and provide their comments and feedback via e-mail to the Secretariat. The CEPI Secretariat also invited interested SAC members to participate in the CfP-2 review process including a face to face meeting on 16-17 Oct and the Step 2 review in February-March 2018.

Chikungunya update
A Chinkungunya Workshop being planned for 1QY2018 was presented to the SAC, and it was noted that:

- The objective is to identify bottlenecks and opportunities to Chikungunya vaccine development, and stimulate potential partnerships for vaccine development by providing a platform for vaccine developers/ researchers, funders, public health specialists/governments and academic institutions to discuss their interests in a vaccine.
- Expected outcomes are producing a meeting report, special issues/journal article, and publish the summary of the meeting. Then, follow up on any potential partnerships/insights relevant to CEPIs mandate after the meeting.
- The meeting will be organized primarily by CEPI and DBT with support from ICMR, PATH and NIAID for about 100-120 participants
- A scientific advisory committee for the meeting has been constituted and will provide guidance

Ebola update
The SAC discussed the objectives and outcomes of a Regulatory science meeting "Challenges in understanding vaccine-based protection against Ebola," which took place in 22 March 2017. The formation of two task forces (one on assays and standardization, and another on non-human primate models and correlates of protection) was discussed. The SAC highlighted that Interactions with industry before and after Calls for Proposals was crucial to capture and represent industry thoughts and insight to ensure success of the task forces.

Key decisions from CEPI Board Meeting
The SAC discussed the implications of key decisions from the most recent CEPI Board Meeting (Berlin, 11-12 July 2017). These included the SAC's permanent arrangements and roles and repsonisbilities, and how the SAC will evolve in future.

Update on CEPI Working Groups

a) Regulatory Working Group – its mandate and further work plans were presented. The SAC commented that AVAREF might be better positioned and able to make observations with regard to Ebola.
b) Stockpiling and Procurement Group – the objective is to outline and envision a clear pathway for stockpiling and procurement, manufacturing quantity and management of investigational stockpiles. The scope covers vaccines in the proof of concept to 'Phase 3 ready' space to be used for investigational purposes and outbreak response. The SAC noted the need for clarity on scope.
c) Biological Standards Group – support the various vaccine development projects with common reagents, validated assays and animal model work where necessary. The SAC noted the importance of this work integrating with CFP1 applications