Coalition for Epidemic Preparedness Innovations

CEPI Interim Scientific Advisory Committee (SAC) Meeting
SUMMARY FROM SAC PROCEEDINGS (CEPI/SAC 3)
May 11, 2017
Wellcome Trust, 215 Euston Rd, London NW1 2BE, UK

The following Scientific Advisory Committee members participated:

Committee members:

- Mark Feinberg (Chairperson)
- Alan Barrett
- Daniel Brasseur
- Maharaj Kishan Bhan
- Bernard Fanget
- George Fu Gao
- Gagandeep (Cherry) Kang
- Subash Kapre
- David Kaslow
- Michael Kurilla
- Helen Rees
- Connie Schmaljohn
- Kenji Shibuya
- Peter Smith
- Yazdan Yazdanpanah

Apologies

- Gary Disbrow
- Jesse Goodman
- Penny Heaton
- Kathleen Neuzil
- Gunnstein Norheim
- Stanley Plotkin
- James Robinson
- Amadou Sall

Non-voting members:

MNC representatives

- Ali Alloueche
- Jean Lang
- Johan Van Hoof
- Kathrin Jansen

World Health Organization

- Vasee Moorthy

Secretariat

- Richard Hatchett
- Carolyn Clark
- Dimitrios Gouglas
- Johan Holst
- Frederik Kristensen
- Hinta Meijerink
- Elizabeth Peacocke

Objectives for the meeting:

1. To discuss the state of the 1st Call for Proposals (CfP1) and decide next steps
2. To discuss the state of the second call (CfP2) and decide next steps
3. To revisit Ebola vaccine development issues
4. To discuss the role of CEPI in facilitating dialogue about Chikungunya vaccine development

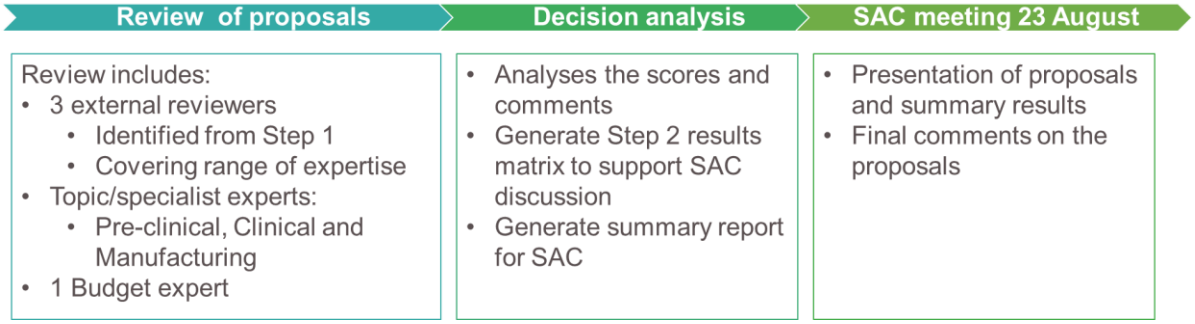
CfP1 on Lassa, MERS & Nipah

CEPI received **33** applications, which were first screened under Eligibility criteria (coherence, relevance, consistency and completeness). 5 applications were excluded, as they did not meet the minimum requirement (preclinical immunogenicity data in any animal model), resulting in **28** remaining applications eligible for scientific review.

A discussion was held on each of the 28 applications to decide on whether to recommend for further review (Step 2) or not, with dedicated focus to applications with mixed positive/negative review.

The SAC decided to invite **16** applications to submit proposals for Step 2: 6 MERS proposals, 6 Lassa proposals, 3 Nipah proposals and 1 multiple-antigen proposal (Lassa & Nipah). The platform technologies represented among those invited for Step 2: were viral vectors, nucleic acid technologies, and recombinant proteins. It was decided that the Secretariat would engage with applicants and provide advice on proposal/ grant shaping for Step 2.

For Step2, the SAC approved the submission templates, including the descriptions of the review criteria, which may be found here. The SAC also approved the following review processes for further evaluation:



CfP2 on Vaccine Platforms

The CEPI Secretariat together with the Bill and Melinda Gates Foundation performed a landscaping of vaccine technology platforms to inform the revision of the CfP2 process documents.

The platform call (CfP2) seeks to identify applicants with a vaccine technology platform and capabilities able to meet the following criteria:

a. Target a 16-week timeframe to product release clinical trials after identification of antigen
b. Take 2-3 years to completion of phase II trials demonstrating clinical proof of concept
c. Rapidly produce sufficient vaccine doses (e.g. >1,000,000) to impact an emerging outbreak
d. Target at least one or more pathogens on the WHO priority pathogen list
e. Demonstrated immunogenicity and likely protective immunity for the platform

The funding call for vaccine technology platforms was postponed given a number of platforms were under consideration as part of CFP1. The SAC discussed new timelines, and agreed to aim for launch of the call by 3QY2017, for review of applications by 1QY2018 and for a recommendation to the Board by 2QY2018.

Ebola Vaccine Development

A Regulatory science meeting on Ebola in Washington D.C. on March 22nd, 2017 was organized by CEPI with active participation of FDA, EMA, BARDA, WHO and European Commission. Key objectives were:

a. To clarify current gaps in scientific knowledge that make it challenging to use non-traditional regulatory pathways for the approval of Ebola vaccines, i.e., when licensure may need to be based on data other than those derived from efficacy studies with a clinical disease endpoint
b. Develop a joint action plan to define remaining research and funding needs.

Main conclusions

Given the different modes of action, characteristics, and the varying degrees of data on vaccine performance:

- Extrapolation of efficacy and safety determinations from one current Ebola vaccine candidate to another is not currently supported.
- Each vaccine candidate is thus "on its own;" i.e., the efficacy, safety, and manufacturing quality data needed to support regulatory approval need to be accrued and programmatic use determinations made (especially with respect to correlates/surrogates of protection) for each vaccine candidate separately
- Methods to bridge immunological data between human and NHP studies have been developed; however, successful bridging could not be achieved as the antibody responses in humans vs. NHP were very different.

The meeting recommendations were to develop time-limited task forces for describing the refined research needs for

1) Non-human primate models for viral challenge and study of correlates of protection
2) Standardization of neutralization assays

A full meeting report is available here.

Facilitating dialogue on Chikungunya vaccine development

There are over 20 Chikungunya vaccines candidates in preclinical stages, with 4 now progressing into phase I trials. However, it is unclear what the vaccine demand would be. CEPI has initiated a process to get a clearer view on the challenges, roadblocks and opportunities within Chikungunya vaccine development.

The SAC approved a plan to conduct a Chikungunya workshop between PATH, NIAID, DBT, CEPI. A two-day meeting was foreseen for early 2018, in India, targeting the following participants: Disease burden experts (epidemiology, surveillance, clinical trial sites), vaccine developers, regulatory, policy experts/programs, funding agencies.

The Workshop objectives would be:

- To highlight the unmet medical need for a Chikungunya vaccine, focusing on selected high burden countries
- To identify the disease burden of and potential vaccine demand in "case study countries" (such as India, Brazil)
- To perform Pipeline analysis and engagement for interest in vaccine development
- To collect and analyse market analyses
- To stimulate innovation in partnerships between stakeholders