

Coalition for Epidemic Preparedness Innovations

CEPI Interim Scientific Advisory Committee (SAC) Teleconference

January 13, 2017

Teleconference

SUMMARY FROM SAC PROCEEDINGS (CEPI/SAC TC 3)

The following Scientific Advisory Committee members participated:

| Committee members elect: | Non-voting members: |
|---|---|
| <ul style="list-style-type: none"> • Mark Feinberg (Chairperson) • Alan Barrett • Daniel Brasseur • Gary Disbrow • Heinrich Feldman • Jesse Goodman • Penny Heaton • Gagandeep (Cherry) Kang • Subash Kapre • David Kaslow • Michael Kurilla • Kathleen Neuzil • Gunnstein Norheim • Stanley Plotkin • Amadou Sall | <ul style="list-style-type: none"> • Connie Schmaljohn • Kenji Shibuya • Peter Smith • Yazdan Yazdanpanah (delegate) <p>Apologies</p> <ul style="list-style-type: none"> • Maharaj Kishan Bhan • Jean-Francois Delfraissy • Bernard Fanget • George Fu Gao • Helen Rees • James Robinson |
| | <p>MNC representatives</p> <ul style="list-style-type: none"> • Ali Allouche • Kathrin Jansen • Jean Lang <p>World Health Organization</p> <ul style="list-style-type: none"> • David Wood <p>Secretariat</p> <ul style="list-style-type: none"> • Dimitrios Gouglas • Frederik Kristensen • John-Arne Røttingen <p>Apologies</p> <ul style="list-style-type: none"> • Johan Van Hoof |

Quorum: 19 out of 25 Committee members participated by TC. 8 non-voting members, including 3 members from Secretariat, were present.

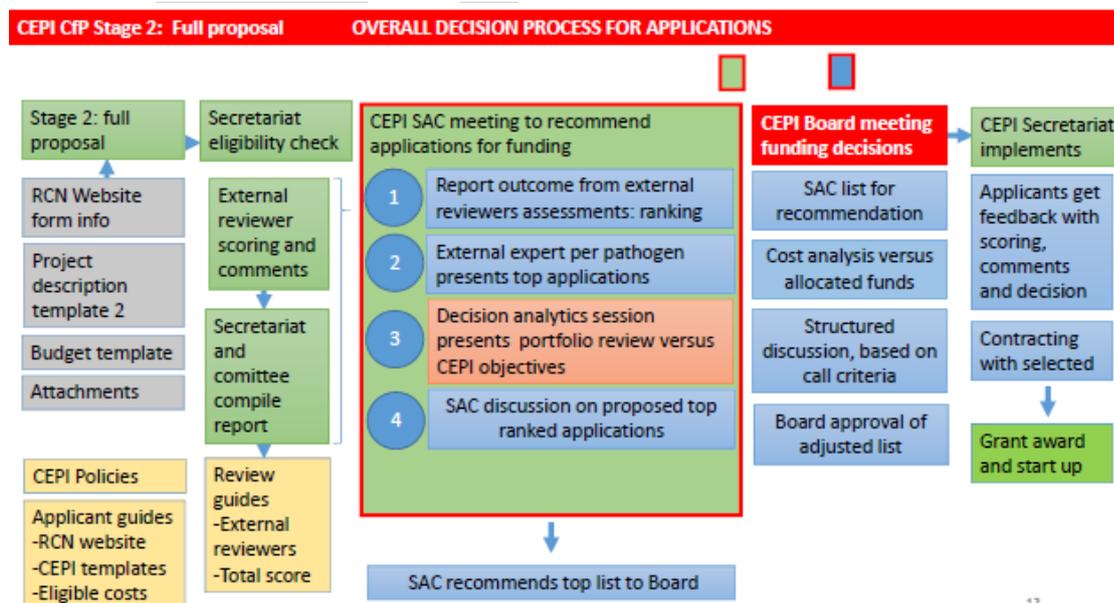
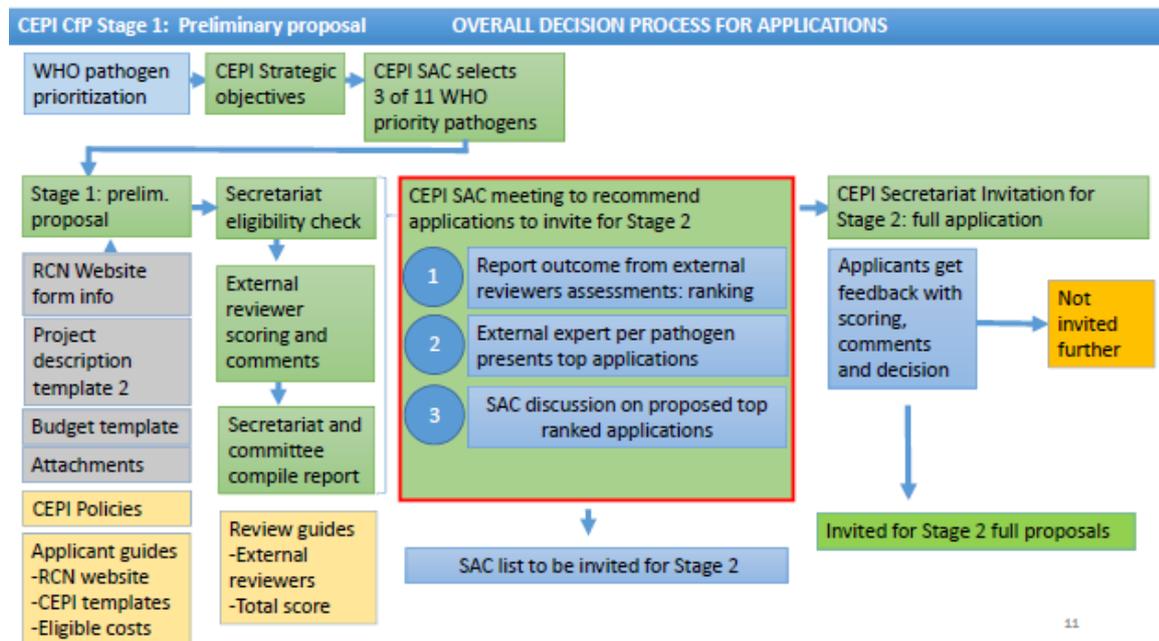
Objectives for the meeting:

1. To define the steps leading up to the publication of the Call for Proposals (CfPs)
2. To define a path for a second CfP related to vaccine technology platforms
3. To revisit "Finishing the Job on Ebola"
4. To define steps for the next face-to-face meeting

Call for Proposals:

The SAC discussed the draft text for the 1st CfP, highlighting, among other things, that it wished to limit entry criteria to applicants with pre-clinical data on a candidate, and that would be important to have agreements with awardees based on transparency between CEPI, regulators and product development partners.

The proposed decision process and role of the SAC in recommending applications for funding was presented by Gunnstein Norheim as a two-step process: Step 1 (Preliminary Applications) and Step 2 (Full Proposals), as illustrated below:



The SAC also agreed on critical timelines for the CfP call on Lassa, MERS and Nipah vaccines, and discussed criteria:

- Call for Proposal launch: 19 January
 - To be included in a press release
 - Launch on CEPI website – with a link directly to the call from the cepi.net home page
 - To include links to the policies and Research Council of Norway
 - SAC members invited to make suggestions on distribution of the call for proposals
- Deadline for preliminary applications (Step 1): **8th of March 2017**
- Deadline for full applications (Step 2): **24th of May 2017**

During discussion, it was noted previous experience indicated it is important to have (in agreements with awardees) transparency between regulators, CEPI, and product development partners.

Second Call for Proposals related to Vaccine Technology Platforms

The SAC decided to postpone this discussion until the next face to face meeting in Paris.

Revisiting the “Finish the Job on Ebola” issue

Mark Feinberg presented on the outcome of the Ebola discussion at the Interim Board meeting on December 16, 2016, where the Board agreed:

1. CEPI organise a regulatory science meeting in 1Q17 with key regulatory agencies (including EMA and FDA), the WHO, vaccine companies engaged in Ebola vaccine development and other stakeholders, to:
 - Definition of criteria for expedited licensure, clinical data needed to support vaccine licensure as well as essential CMC information, for both
 - Ebola Zaire vaccines (including those for which efficacy data are not available)
 - Vaccines targeting other Ebola species and Marburg virus (no human efficacy data available for any candidate)
 - Develop a common understanding and shared solutions to enable timely licensure of vaccines against filovirus infections targeted by CEPI, also as a pathfinder approach for other pathogens where efficacy data may not be available/feasible in advance of a large outbreak
2. Prepare a comprehensive assessment of current funding initiatives supporting the development, licensure and procurement of vaccines targeting Ebola Zaire and Sudan and Marburg virus.
3. Organise a meeting to develop consensus preferred product characteristics that will help inform and expedite the development of vaccines that can have the greatest public health impact as well as the greatest probability of technical and regulatory success, product development feasibility and program affordability.
4. Gaps or inadequacies will be defined in light of recommended regulatory science strategies and used to provide the focus on a targeted CFP(s) to be issued by CEPI (potentially in collaboration with other funders) to support R&D efforts needed to complete the job on Ebola vaccine licensure. This CFP(s) will be targeted for 2Q2017.

Next steps:

- The Scientific Conference will take place in Paris, France 21-22 February 2017. It will be jointly hosted between CEPI and INSERM.
- A draft agenda for the SAC meeting will be circulated prior to the meeting.