Coalition for Epidemic Preparedness Innovations

CEPI Scientific Advisory Committee (SAC) Teleconference
Roundtable Discussion
September 20, 2018

SUMMARY FROM SAC ROUNDTABLE PROCEEDINGS (CEPI/SAC *TC 20.09.18*)

The following Scientific Advisory Committee members participated:

Committee members		Invited and CEPI
Present • Helen Rees (Chairperson) • James Robinson (co-chair) • Alash'le Abimiku • Connie Schmaljohn • John Edmunds • Michel De Wilde • Myron Levine • Peter Smith • Stanley Plotkin • Michael Levin • Daniel Brasseur • Paula Bryant ***Apologies***: • Inger Damon • Phil Krause • Christian Bréchot • Christian Happi • Delese Mimi Darko • George Fu Gao • Kathleen Neuzil • Kenji Shibuya • Penny Heaton • Thomas Kariuki • Yves Lévy • Ralf Clemens	**Non voting members** • Vasee Sathiyamoorthy, WHO **Apologies:** • Kathrin Jansen, Pfizer • Ali Allouche, Takeda • Jean Lang, Sanofi • Johan van Hoof, J&J •	***Invited:*** • none ***CEPI Secretariat***: • Richard Hatchett • Gunnstein Norheim • Melanie Saville • Carolyn Clark • Frederik Kristensen • Tung Thanh Le • Nora Indrehus • Allison Adele Bettis • Raul Gomez Roman • Joseph Simmonds-Issler

Notes to readers

- Pre-read slides for the telecon were shared ahead of the meeting. Slides are found here.
- This meeting was a telecon to follow up on the previous meeting held one week before to discuss potential areas of investment.
- Meeting rapporteur: Raul Gomez Roman, CEPI Secretariat

1. Declaration of Conflicts of Interests

Upon question from the CEO if attendees had additional COIs to declare beyond those previously on records of CEPI, none were declared.

2. Discussion about potential areas of investment

2.1 Should CEPI invest in more vaccine candidates for CfP1?

Points considered:

a) Clarification required – whether CEPI should invest in further pathogens on the WHO Blueprint for R&D priority lists, or in more candidates for the three priority diseases. Response: the question related to three priority diseases.
b) Clarification on conditions for EC funds - these cannot be allocated to existing agreements in place, and are required to be allocated to new projects.
c) Could the funding be used for epidemiology studies? Response: consider focusing first on vaccine development projects.
d) CEPI's Nipah vaccine pipeline is very limited, which may warrant investing in further Nipah candidates
e) CEPI may not be ready this early to answer the question on need for more candidates, may be useful to pose the question in 3 years' time
f) Could current vaccines in the pipeline be assessed against the WHO TPP? For example, there may be a potential disconnect between one of the Nipah candidates funded and the WHO TPP for reactive use (1 dose-schedule). Also, keep in mind 1-dose indication for medical personnel. Clarified: as part of due diligence, CEPI has asked applicants to meet at least the minimum requirements in the WHO TPPs
g) What about animal vaccines, e.g. camel vaccines vs MERS where proof-of-concept has been demonstrated. However, it would take a Board decision to reverse the prior decision of not supporting animal vaccines.

Decision: In the short term, SAC opted to **not** support further investment in more vaccines against MERS, Lassa and Nipah and follow the progress of the current portfolio. Open to further investment in the long term and to explore wider scope areas.

2.2 Should CEPI invest in Chikungunya clinical vaccine development?

Questions raised and points considered:

a) Unclear if there would be a market for a CHIKV vaccine. Market may not exist in some countries.
b) Difficult to conduct Phase III, and unclear if any role of human challenge studies.
c) CEPI was never intended to fund large phase III trials, but it is in our remit to determine and finance vaccines to reach the final stages.
d) Demonstrating safety is a major challenge for a CHIKV vaccine.
e) Should CEPIs focus be on reactive vaccines or on vaccines against life-threatening disease?
f) RVFV is another easy target, but CHIKV is more widespread.

g) Instead of limiting to CHIKV vaccines, why not open a call for all WHO priority pathogens not currently funded? Responses: the SAC was divided in its views on whether or not to fund CHIKV vaccine development: on the one hand, CHIKV ranked 4th in the interim SAC's priority assessment and a vaccine is likely to be feasible to develop; on the other hand, does a CHIKV vaccine have a place in an outbreak response? Does it really have a place in the market? Is it like the yellow fever vaccine?

Recommendation: **launch an RFP** for vaccines against all WHO priority diseases not currently funded, including CHIKV. Include criteria such as, but not limited to: "a vaccine against a widespread infection for which a product is feasible by 2021".

2.3 Should CEPI invest in gene-encoded monoclonal antibodies (mAbs)?

Questions raised and points considered:

a) This technology is still relatively new, hence CEPI should not invest in the short-term, but also not exclude from future funding.
b) There are challenges related to regulatory approval even for a single administration.
c) Propose seed funding for existing targets and for Pathogen X. Consult with e.g. DARPA to understand gaps.
d) Discussion with WHO on how this can be taken forward?
e) This technology could potentially stop an outbreak, but what can CEPI do so that a product is ready for Pathogen X?
f) mAb production could be helpful for analytical development (potency and release assays?)
g) What would be the added value for CEPI involvement?

Recommendation: In general, there was no opposition voiced to the proposal, but also no strong support given the early stage of technology and suggest to let the technology mature a bit and consider for a 2020 call. SAC concluded to **not** support investments now; but to conduct consultations with colleagues at NIH, Gates Foundation, DARPA, etc. and then CEPI positions itself for a future call.

2.4 Could CEPI invest in sustainable manufacturing in the short term?

Questions raised and points considered:

a) Constructing and maintaining a stockpile is extremely important. For example, who is going to manufacture a Lassa vaccine if we have one? As we ask people on CfPs what they can do, there is reluctance to commit as they are afraid on how it may affect their portfolio. We may have solutions from CfP2.
b) Sustainable manufacturing will vary from vaccine to vaccine.
c) SAC should give its advice to the Working Group on manufacturing and sustainability.

Recommendation: **not** to support investments in the immediate term; continue to have this item on the agenda and wait for conclusions and recommendations from Working Group.

2.5 Should CEPI invest in adjuvants?

Questions raised and points considered:

a) Don't invest in development of new adjuvants, but perhaps on the ones that CEPI can obtain.
b) Focus on a toolbox of adjuvants that could be made available to applicants?
c) Under CfP2, there are potentially 2 adjuvants included among the applicants in due diligence

Recommendation: **not** to support investments in development of new adjuvants. Support approaching manufacturers under two scenarios: 1) see how to make a toolbox of adjuvants available to partners – this refers to already developed adjuvants (licensed in the context of a vaccine product); 2) approach manufacturers who have sufficient data on safety, including clinical data, to gain confidence on the safety of the adjuvant and then perhaps make it available.

Recommendation: **not** to support investments in the immediate term; continue to have this item on the agenda and wait for conclusions and recommendations from Working Group.

2.6 Should CEPI invest in addressing gaps in the WHO Blueprint?

Questions raised and points considered:

a) In this context, CEPI should focus on vaccine development/immunological preventive measures and on being careful to not step out of scope and take on WHO's role.
b) Prepare a list of activities not currently funded by WHO to consider allocating resources
c) Biological standards and enabling research, correlates of immunity are important for vaccine development
d) Animal Models, though these are already part of iPDPs, particularly for MERS and Nipah,
e) Monoclonal antibodies – part of potency assays and release assays
f) Support targeted Epi studies within CEPI scope, relevant to vaccine development – not intended to replace WHO epi studies, but important to link to WHO and national health agencies to build capacity.

Recommendation: Further consultation needed with WHO prior to revisiting in future SAC meetings

2.7 Other issues that should be considered? Questions raised and points considered:

a) Diagnostics are important; though not on CEPI's remit, they are important to fulfil its mission. Is there a special gap needed that CEPI can fill?
b) Vaccination and pregnant women – the PREVENT initiative: is there something that we can do now that is going to allow us to make informed decision in pregnant women in the future? Standing questions raised by PREVENT could be applied as applications come in through new RfPs.

3. Closing and next steps

Next meeting: Feb 7th 2019.