

# CEPI

## Coalition for Epidemic Preparedness Innovations

CEPI Interim Scientific Advisory Committee (SAC) Teleconference

February 27, 2018

Teleconference

### SUMMARY FROM SAC PROCEEDINGS (CEPI/SAC TC Feb 2018)

The following Scientific Advisory Committee members participated:

Committee members:	Non-voting members:	
<ul style="list-style-type: none"> <li>• Helen Rees (Chair)</li> <li>• Jim Robinson (Vice Chair)</li> <li>• Alash'le Abimiku</li> <li>• Alan Barrett</li> <li>• Daniel Brasseur</li> <li>• Christian Bréchet</li> <li>• Paula Bryant</li> <li>• Inger Damon</li> <li>• John Edmunds</li> <li>• Christian Happi</li> <li>• Penny Heaton</li> <li>• Tom Kariuki</li> <li>• Phil Krause</li> <li>• Myron Levine</li> <li>• Kathleen Neuzil</li> <li>• Stanley Plotkin</li> <li>• Connie Schmaljohn</li> <li>• Peter Smith</li> </ul>	<p><b><i>MNC representatives</i></b></p> <ul style="list-style-type: none"> <li>• Ali Allouche</li> <li>• Jean Lang</li> </ul> <p><b><i>World Health Organization</i></b></p> <ul style="list-style-type: none"> <li>• Vasee Moorthy</li> </ul>	<p><b><i>Apologies</i></b></p> <ul style="list-style-type: none"> <li>• Delese Mimi Darko</li> <li>• George Fu Gao</li> <li>• Yves Lévy</li> <li>• Kathrin Jansen</li> <li>• Johan von Hoof</li> </ul> <p><b><i>Unknown</i></b></p> <ul style="list-style-type: none"> <li>• Ralf Clemens</li> <li>• Kenji Shibuya</li> <li>• Michel De Wilde</li> </ul>

***CEPI Secretariat participants:*** Richard Hatchett (CEO), Eirik Bakka, Carolyn Clark, Theo Grace, Karianne Johansen, Nicole Lurie, Hinta Meijerink, Gunnstein Norheim, Melanie Saville, Joseph Simmonds-Issler, Nadia Tornieporth, Frederik Kristensen, Mike Whelan

#### Objectives for the meeting:

1. To introduce new SAC members to one another and to the CEPI governance structure
2. To give an overview of CEPI's 4 Strategic Objectives and 7 Working Streams
3. To update the SAC on Cfp1
4. To update the SAC on Cfp2 and define next steps
5. To discuss CEPI's work on Lassa in the context of the ongoing outbreak in Nigeria

### **New SAC and CEPI governance structure**

Members of the SAC were introduced to one another and to the [CEPI governance structure](#). The roles of the SAC were defined as set out in the SAC Terms of Reference. Conflicts of interest overview was circulated with meeting documents in advance of the teleconference. No additional conflicts were raised by SAC members during the teleconference.

### **CEPI Strategic Objectives and Workstreams**

SAC members were presented with the 4 CEPI Strategic Objectives (preparedness, response speed, market predictability, and equity) and the 7 workstreams:

- Biological Standards & Assays Working Group
  - The working group is aiming to define the needs for standardization for tools used for assessment of vaccines, to identify sources of critical reagents and undertake procurement, and facilitate a dialogue to standardize key SOPs
- Finishing the Job on Ebola Vaccines
  - A Board subgroup is leading work
- Chikungunya
  - A meeting was held in February in India. The CEPI pipeline for Chikungunya was presented, and suggested there were over 35 vaccines in development and 9 in clinical phase trials. The workshop brought together actors and highlighted a need for coordination. Areas to consider included R&D opportunities, gap-filling roles, opportunities for cross-sectoral and cross-location collaborations
  - The SAC agreed further discussion on the outcomes of the workshop should be taken forward by interested SAC members
- Diagnostics
  - CEPI and FIND signed an MOU in 2017, and CEPI has been working to drive development and delivery of “companion in vitro diagnostics” for vaccines against new and re-emerging infectious diseases with epidemic potential, and define CEPIs strategy on diagnostics
- Regulatory Working Group
  - Currently focused on guidelines for vaccine platform technologies
- Rapid Response Strategy
- Collaboration with the WHO).

### **Update on CfP1**

As discussed in previous SAC meetings, 14 CfP1 applicants were invited to submit full proposals for Step 2 of the application process. These applicants would comprise a portfolio of 4 MERS, 6 Lassa, and 4 Nipah vaccines. The SAC was informed about the three main areas of the due-diligence process (technical due diligence, financial due diligence, and legal & business development negotiations). The end-product of due diligence is to draw a partnership agreement, including: project governance, integrated product development plan, budget and work package components. The aim is to have all partnership agreements signed by the end of 2QY2018.

### **Update on CFP2 and next steps**

As discussed in previous SAC meetings, the [call for CfP2](#) was launched. 38 applications were submitted to Step1 and **33** were deemed eligible. The applications comprised a broad range of vaccine platforms (8 nucleic acid, 9 protein-based, 12 viral vector, 4 other/multiple platforms).

All 33 applications were reviewed through a series of experts. The review included an initial read through and review of proposals by 4 experts. Following this, a 2-day consultation of experts and CEPI Secretariat looked each proposals and at crosscutting issues on CMC, preclinical and clinical proposals. Each application was reviewed by an expert on CMC, preclinical, clinical and 2 secretariat

members as well as others. The review criteria are described in [the CfP2 call](#). After this initial review, **18** applicants were invited to submit applications to Step2 of the process, requiring applicants to submit the following document templates:

- Project description (30 pages)
- Detailed budgets
- Milestones and Gantt chart
- CMC details
- Evidence to date on platform
- Immunological assays
- Animal welfare
- Biosketches and Letters of Support

The review process and timelines were presented to the SAC. SAC members were invited to attend the expert review and they were reminded to update their Conflict of Interest forms for transparency. The SAC also decided that compensation for attendance of expert reviews should be reviewed.

### **Lassa Update and context**

The SAC was informed that, given the ongoing and significant outbreak in Nigeria, CEPI was reassessing its current strategies in order to align with the WHO led initiative to propose a single national research agenda for the Nigerian government.

Areas of potential work include:

- Strain identification and characterisation
- Gauging likely protection against these strains by the vaccine portfolio
- Clinical data collection
- Determination of the immune response related to recovery
- Biobanking
- Capacity building, for clinical trials
- Diagnostic development
- Mapping actors and stakeholders
- Bringing together this varied data
- Working with coordination mechanisms
- Development of Standards/ Panels
- Sample access
- Epidemiological studies

The SAC discussed that CEPI must consider how it can work with global lab networks and how it can accelerate development to meet needs in circumstances like these. The SAC decided that Gunnstein Norheim, CEPI's Director of Vaccine Sciences, would convene a separate teleconference on Lassa plans and needs.

Next SAC meetings planned:

- 26-27 April 2018: CfP2 review meeting in London (voluntary)
- 1 June 2018 (tbc): SAC meeting (CfP2 step 2 decision)