CEPI | New vaccines for a safer world

Joint Coordination Group Meeting

May 30, 2018

Telephone Conference

Summary of proceedings

Attendees

Member institutions represented by

- Peggy Hamburg (JCG Chair)
- Freya Hopper (Wellcome)
- Emanuele Capobianco (IFRC)
- Emer Cooke (WHO, and Chair of Standards and Assays WG)
- Marco Caveleri (EMA)
- Marion Gruber (FDA)
- Mark Page (NIBSC)
- Aurelia Nguyen (Gavi)
- Els Torreele (MSF)
- Shanelle Hall (UNICEF)
- Wilson Mok (Gavi)

Regulatory working groups represented by

- Daniel Brasseur (Regulatory WG Chair)

CEPI Secretariat

- Carolyn Clark
- Dawn O'Connell
- Frederik Kristensen
- Gunnstein Norheim
- Johan Holst
- Joseph Simmonds-Issler
- Karianne Johansen
- Melanie Saville
- Nicki Lurie
- Ole Kristian Aars
- Per Etholm
- Richard Hatchett
- Sidra Shami

Document Administration

Version number	Approval process	Date
1.0	Prepared by: CEPI Secretariat	16.02.18

1. Brief updates

CFP1 and CFP2

An overview of CEPIs portfolio was provided; 5 agreements in CFP1 have been signed to date, and another 7 are expected to be finalised in the next month. For CFP2, 6 candidates are moving forward with contract negotiations, to be finalised by end of 2018.

Questions & Comments

- 16 weeks from identification to clinical trial product in CFP2 was found to be an ambitious timeline. CEPI justified this, together with other objectives for the calls, on the basis of wanting to be aspirational. Depending on the project in question, timelines might be either delayed or expedited and therefore should be understood as targets rather than something that will be completely demonstrated.
- CFP2 is intended to be complementary to CFP1. Although CFP1 applicants were not excluded from participating in the platforms call (CFP2), the purpose of the latter is to diversify the types of pathogens CEPI can respond to in the future.
- CFP2 contains a mix of projects with both novel and previously tested platforms.
- CEPI expects to be below the budget approved by the Board for CFP1. Although vaccine development in innately unpredictable, there will likely be room for expansion of the current portfolios and possibly extend funding for platforms for as long as the data takes us.

Standards and Assays Update

Separate task forces have been established for the three priority diseases Lassa, Nipah and MERS. Deliverables include providing recommendations on key assays and advice on product characterisation. The overall objective will be, by doing things differently, to apply assays for effective and rapid development and licensure.

Questions & Comments

- Animal models can mean different things, and CEPI is therefore looking into what types the different developers are using. Through this mapping exercise, CEPI will seek to harmonise as much as possible. For example, applying the same challenge strains is vital. A desired outcome will be to determine the best conditions for predicting protection in humans.
- Experience from working with developers so far suggests that there is a strong willingness to share notes and information, as well as apply findings from the different task forces into their own development.

2. Update on Finishing Ebola To-Do List

Having gone through the to-do list in more detail, it was the Secretariat's assessment that there were two issues that stood out as particular important to dig deeper into as the others were either covered by other entities or of less priority. The two issues are; i) human survivor data and ii) sustainable manufacturing.

Human survivor data

- The point of departure is that one might look at either the i) immune profile at large or ii) use a booster to see whether it triggers correlates of protection.
- CEPI is investigating whether it is possible to leverage current efforts on the Ebola outbreak in the DRC to begin data collection on survivors. WHO has deployed a team that will assess the plausibility of implementing protocols for specimen collection, but it is unlikely that data will be collected during this outbreak. CEPI is thus trying to learn from the experience without adding complexity to the response itself.

- There is a hope that standards that are made for Ebola can be made available for relevant countries. CEPI's assistance in getting this done would be very helpful.

Sustainable manufacturing proposal

- The manufacturing model for EIDs is not a sustainable solution given the types of diseases and challenges the world is facing. The CEPI Secretariat is therefore looking into how different manufacturing solutions using public-private partnerships can help making vaccines available when they're needed.
- As a point of departure, the manufacturing solution should be independent from CEPI partners to allow for more agility in building and maintaining a stockpile. Two important criteria are i) lead time and ii) cost of goods.
- It is important to assess whether we should focus on manufacturing a finished product or bulk that can rapidly be converted to a finished product.
- The solutions currently under consideration are i) contract manufacturing organisations (CMOs) and ii) innovative solutions that are being explored together with BMGF.
- The benefits of establishing a centralised solution relates to creating economies of scale, and reducing capital expenditure due to being able to turn the solution on and off. CEPI may play a key role contracting the solution and the technology may be shared with others if successful.

Other issues

- After the Ebola outbreak, it will be useful to assess the cold chain requirements that are currently imposed on the Merck vaccine. It was suggested that lyophilisation may be a topic to consider.
- The fact that there is not a licensed vaccine is complicating the current Ebola intervention. There is a lack of greater clarity on how to solve the bottlenecks. It was suggested therefore that CEPI should look at the to-do list again, to ensure that it is not incorrectly assuming topics are resolved when they may not be.
- Gavi is currently working with WHO and UNICEF to model stockpile needs. Any work that CEPI or JCG members are doing that could feed into this work is welcome.
- There should be a collective responsibility of JCG members of solving the bottlenecks of finishing the job on Ebola, and in doing so addressing difficulties that have surfaced from the Merck vaccine.

3. Equitable Access discussion

- CEPI is in the process of revising its policy on equitable access. The background for doing so relates to the feedback received from partners of CEPI and the experience gained in establishing a portfolio.
- A number of partners have been engaged in one-on-one discussions, as well as a workshop that was recently held in Geneva in conjunction with the World Health Assembly.
- A revised draft of the policy will be prepared by June and placed online in July/August for comment; and the final policy will be presented to the CEPI Board in October.
- JCG colleagues should let the CEPI US office know if they would like to discuss the policy
- A summary will be made of the main issues identified during the public comment period

4. Additional topics

Confidentiality issues

- Language is now included in all contracts regarding the sharing of information with regulators.
- CEPI will be present when there are discussion between companies and regulators, but will not share confidential information without written approval

Upcoming Meeting

- The next meeting will take place on September 17th in DC; a calendar invite will be distributed from the CEPI Secretariat
- September 17th Meeting Topics
    - Presentation of outstanding systems issues for the portfolio
    - How we can address the problems? Regulatory and clinical challenges, stockpiling, etc.

AOB

- The Secretariat was asked how the JCG will be engaged in between meetings in order to make an effective body. In response it was clarified that work will be delegated to working groups or task forces on specific issues, but that the Secretariat would work on a plan to better involve members to ensure sufficient input.