CEPI | New vaccines for a safer world

Joint Coordination Group Meeting

February 13, 2018

London, Wellcome

Summary of proceedings

Attendees

Member institutions represented by

- Peggy Hamburg (JCG Chair)
- Charlie Weller (Wellcome)
- Emanuele Capobianco (IFRC)
- Emer Cooke (WHO, and Chair of Standards and Assays WG)
- Jordi Llinares (EMA)
- Marion Gruber (FDA)
- Mark Page (NIBSC)
- Michael Thomas (Gavi, and Chair of Stockpiling WG)
- Myriam Henkens (MSF)
- Shanelle Hall (UNICEF)
- Wilson Mok (Gavi)

Regulatory working groups represented by

- Daniel Brasseur (Regulatory WG Chair)
- Murray Lumpkin (BMGF, Regulatory WG Co-Chair)

Other invitees

- Mark Feinberg (Outgoing SAC Chair)

CEPI Secretariat

- Dawn O'Connell
- Frederik Kristensen
- Gunnstein Norheim
- Johan Holst
- Joseph Simmonds-Issler
- Karianne Johansen
- Nicki Lurie
- Ole Kristian Aars
- Per Etholm
- Richard Hatchett
- Simone Blayer

Document Administration

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

1. Opening remarks and Introductions

Points discussed under this item:

- Welcome to members
- Objectives for the meeting

2. Introduction to CEPI

Points discussed under this item:

- Key milestones achieved

3. Duties of the JCG

- The JCG is designed to be a coordinating as well as a horizon scanning entity. The JCG will not have a set of pre-defined tasks to be accomplished, but rather operate as a dynamic entity focusing on problems that emerge and harnessing the opportunities in vaccine R&D.
- The members of the JCG are institutions, who select individuals to represent them in meetings. It is however foreseen that the JCG meetings will benefit from having the same people attend on a regular basis.
- The JCG is not intended to duplicate nor add another layer of bureaucracy. This implies that some issues might be passed on or embraced by other bodies and institutions where appropriate. This is especially important in the case of the WHO, whereby there has to be close communication as to what is best handled by which institution.

4. Updates on CEPI

- CEPI is funding 14 candidates through its first CFP of which CEPI aims to finalise the first contract in the near future. The awardees range from biotechs, academia to industry.
- In order to work alongside on the preclinical and clinical phases of the CFP1 projects, CEPI is aiming to expedite its work on the biological program.
- For regulators, it is important to have more information on the types of candidates in question before making an assessment of the best regulatory pathway to be applied.

- **Updates from Scientific Advisory Committee In recommending pathogens, the SAC looked at feasibility of producing the vaccines as well as public health impacts that were also highlighted in the WHO Blueprint Action Plan.**

- The work on Ebola has not seen a lot of progress, and there are many developers that have scaled down their ambitions. The experience has identified a number of issues that need to be tackled, and CEPI should be a strong advocate for being an entity solving these problems. The JCG will also be an important platform to inform this discussion and provide guidance for future improvements.
- Industry participation in the SAC was contentious at first, but their non-voting presence has proven to be a real value added in terms of getting the necessary expertise on vaccine manufacturing and development.
- Crucial for the SAC and the JCG to work closely together. CEPI's end-to-end approach does not imply a "unidirectional" approach, but that the SAC must be informed about the downstream challenges identified in the JCG and vice versa.
- In order to drive meaningful change, a sense of urgency must be conveyed – especially outside of crises.

5. Ongoing working groups

6.1. Regulatory working group

- When working in LMICs, we do not want to be in a situation where we impose protocols that are unfamiliar to the recipients. Will therefore be key to keep local regulators and ethics boards involved in the early parts. The JCG will have the opportunity to do so, including by inviting non-permanent members and by CEPI.
- Information sharing will be important. CEPI shall have the opportunity of hosting sequential presentations with industry/awardees and regulators under a "safe harbour" with NDAs. Defining the "pre-competitive space" will thus be important. A similar option of 2 NRA's working closely together and sharing results with a broader network should also be explored. Current regulators have good experience with this approach. Lastly, seeking parallel advice does not necessarily imply advice in silos – communication and breaking down preconceptions is key.
- CEPI may want to do a mapping of emergency use provisions available in different NRA's in LMICs.
- Given the multifaceted reality of vaccine development, regulatory advice should preferably be disease and vaccine candidate specific.

6.2. Standards and Assays

- Although in its start-up phase, it is clear that the working group will need to find ways to engage LMIC scientists more than it does at present.
- Platforms cannot be seen in isolation, as there are challenges unique to specific diseases. We do not however want to end up in a situation with multiple assays trying to solve the same problem – uniformity and harmonization is important.
- Since the WHO and others are already doing a lot within this space, the working group needs to be focused around gaps, as well as ensure close collaboration with other entities.
- CEPI should look into the possibility of working on assays for its diseases under a set of confidentiality agreements with relevant parties (CEPI, WHO, NIBSC) to ensure an expedited process.

6.3. Stockpiling

- Financial risk sharing mechanisms have to be established well in advance – the same goes for roles and responsibilities of different entities. This will also differ depending on the disease and vaccine candidate in question. The Secretariat would welcome one-to-one discussions with members of the JCG on different perspectives around this. Industry expertise will be important when this work is carried forward.
- CEPI's current mandate does not include all necessary components of the vaccine development pathway. CEPI is therefore trying to expand the collective ownership of the downstream issues to ensure that necessary push and pull mechanisms are in place to conduct phase 3 trials – and when feasible – bring products to licensure.

6. Updates from WHO

- WHO has done extensive work in the context of the WHO R&D Blueprint and many of these activities will facilitate the implementation of CEPI projects. Clear roles and responsibilities need to be continually defined and there is a need to continue to work on mutual awareness.. CEPI is better resourced to look at concrete solutions to concrete disease targets, which can then be applied to a broader suit of problems. For example, the WHO

created the first Target product profiles (TPPs), which was subsequently incorporated by CEPI into its CFPs.

- CEPI will need better standards and samples to develop vaccines and has to work closely with WHO and leverage its leadership to carry this work forward.
- Capacity building is a broad term that needs to be thoroughly defined. It is however clear that there are gaps when it comes to health systems and regulatory strengthening that need to be tackled for there to be an effective R&D environment. Within CEPI, the JCG will be the right entity to take the lead in further clarifying this.
- Everybody must be aware that outbreak response is not limited to vaccines R&D, but also includes aspects related to delivery.

7. Reflections from Members

- More pull funding is needed.
- The JCG will have to make case-by-base decisions on where it seeks to drive activities versus be a catalyst for implementation.
- Early discussions and collaboration with regulators will be key. The Ebola experience can serve as point of departure when looking at how we can develop safe standards.
- Engagement with the private sector will be important in better understanding how their commercial model works and what challenges the JCG can help tackling.
- Approval of products does not necessarily mean availability amongst populations in need.
- CEPI should take a role as an influencer and look at challenges beyond stockpiling of investigational vaccines. This should also be reflected in the contracts CEPI enters in to.
- The involvement of countries at risk in the JCG is fundamental
- The list of challenges identified in the Ebola update should serve as point of departure for scoping out the next set of activities for the JCG.
- An appropriate level of confidentiality is a prerequisite for information sharing. CEPI must ensure that it has appropriate mechanisms in place in order to capitalise on the information generated through its portfolio, as well as in engaging regulators and industry in workshops.
- Although outside of CEPI's financing scope, it must take necessary steps to ensure that capacity building resources from other institutions are galvanized.
- Diagnostics cannot be seen as separate to what CEPI is doing.
- CEPI needs to be clear with partners, and especially WHO, on roles and responsibilities. There is especially a need to define who drives the activities when there is a potential overlap in missions and mandates.

8. Next steps

- The Secretariat should take a look at appropriate ways of including representation of LMICs and industry (including developing country manufacturers) in the JCG.
- Should consider convening future JCG in-person meetings in countries that are at-risk to CEPI priority diseases. Moreover, consideration should be given to members' ease of travel and general likelihood of participation when choosing location.
- The initial focus of the JCG requires a cross-cutting focus, but disease specific deep-dives should be considered in the future.