

DCVMN COVID-19 Committee Meeting Minutes

Attendees: Sonia Pagliusi (SP), Sonia Villasenor (SV), Adriansjah Azhari (AA), Anand Kumar (AK), Sai Prasad (SDP), Mahima Datla (MD), Suresh Jadhav (SJ), Harshet Jain (HJ), Raches Ella (RE), Marcus Freire (MF), Yuri Vasilev (YV), She Guangbio (SG), Ladda Suwitruengrit (LS), Dat Do (DD), Martin Rees (MR), Rachel Park (RP), Sekar Thangaraj (ST), Young Baik (YB), Weijuan Wang (WW), Tianjia (TJ) and Apoorv Kumar (AP), Valeria Brizzio (VB).

TC started at 1.10 pm CET and finished at 1.30 pm CET

AA, appointed as committee Chair, welcomed all members and observers inviting introductions by all participants.

SP provided an overview to COVID-19 epidemiology status as of today: Deaths are highest in Europe, North America, and emerging in South America; Cases highest in North America. Asia has moderate cases and deaths. Oceania and Africa have low cases and deaths. Number of active cases may suggest high incidence and urgent need for vaccines. DCVMN R&D manufacturing capabilities for COVID are now important to protect people against COVID-19, and specified in a recent publication. Cf. https://www.sciencedirect.com/science/article/pii/S0264410X20307957. More resources available at DCVMN-webpage created on COVID-vaccine resources for member's information. Cf. https://www.dcvmn.org/COVID-19-Resources

SDP introduced the ACT- Accelerator program led by WHO, that includes three pillars: Vaccines, Therapeutics, and Diagnostics, also geared for regulatory and health system strengthening support.. The COVAX Facility and COVAX AMC are within the Vaccines pillar.

MD provided an overview of the COVAX pillar and Facility. This is a mechanism governed by GAVI and CEPI, where GAVI is responsible for pull funding (procurement), and CEPI is responsible for push funding (R&D). MD said that an independent R&D evaluation and Investment committee reviews the grant applications sent to CEPI. Request for proposals is open Cf. https://cepi.net/get_involved/cfps/ MD added that there are 2 new additional committees: Technical oversight committee & Regulation and QC technical committee, seeking nominations from industry.

MD will share the ToRs with this group.

AA asked, since CEPI is also investing directly on other manufacturers and also via COVAX Facility, how will they distinguish investment and funding source? MD clarified that CEPI is developing a standard for evaluating the funding source and ensuring that there is a clear distinction of investment sources. Donors funding is primarily for LICs, however the facility is not limited to only Gavi countries. MICs and HICs can sign up for access to vaccines provided they self-financing and an AMC.

RE asked about path to licensure. Are there any guidelines available? MD added that UNICEF EOI is collecting information from manufacturers as to needs and NRAs approaches or government concerns; they hope to reach a solution. Indeed, UNICEF and Gavi will prioritize & evaluate vaccine candidates based on efficacy and safety data, first to market, COGS, manufacturing volumes, etc.

SDP brought up conversations with WEF and potential partnership with ACT. DCVMN'spublic communications with the objective that all manufacturers become part of a solution for COVID19, no matter if as innovator or manufacturer. Cf. https://www.dcvmn.org/DCVMN-joined-Global-leaders-



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<u>call-for-a-new-collaboration-to-accelerate</u> & <u>https://www.dcvmn.org/DCVMN-united-with-the-EU-at-the-Coronavirus-Global-Response-international</u>

MD brought up on a call with World Bank that it will be good to fund facilities for manufacturing purposes as grants, not loans. If innovators are willing to share IP, there should be funding allotted for out-manufacturing of vaccines.

SDP indicated that DCVMN is in conversation with ACT, Gavi, CEPI, WEF, and maybe with the EU. He mentioned that DCVMN is made up of small and large companies and that funding should be opened for all manufacturers.

MD added that there is concern about the allocation of vaccines post-licensure. WHO is responsible for developing an allocation system, where population vulnerability and disease burden is taken into account. However, several countries due to this uncertainty are approaching manufacturers directly.

SJ cautioned regarding the push & pull financing mechanisms, that depending on these mechanisms for funding should not be our priority and that manufacturers should actively look for other sources.

SDP agreed that CEPI's funding is for innovators, who have limited to no manufacturing experience. Partnerships between a large and small companies may lead to a solution.

SP says the allocation would most likely based on disease burden and mortality.

AK asked how long the COVID-19 situation may extend; SDP said that the evolving situation is very uncertain, as limited knowledge on the virus and epidemiology. AK requested to pursue ideas that companies with advanced stage candidates should consider out-manufacturing.

Due to time constraints AA requested to move to next agenda item.

AP presented ToRs for this committee and requested for comments from members. (next mtg)

AA moved on to selecting co-chair by asking for volunteers among members. RE volunteered. No other volunteers expressed interest and no-objection was voiced. Thus RE was elected Co-chair of the DCVMN COVID-19 committee.

SP suggested that due to the evolving situation a weekly call may be suitable.

AA closed the meeting.

Notes taken by Sonia Villasenor and Apporv and edited by Sonia Pagliusi

Nyon 20 June 2020