DCVMN COVID-19 Committee Meeting Minutes, July 09th, 2020

Attendees: Apoorv Kumar (AP), Anand Kumar (AK), Dat Do (DD), Harshet Jain (HJ), Ladda Suwitruengrit (LS), Linsen Du (LD), Marcus Freire (MF), Martin Reers (MR), Rachel Park (RP), Raches Ella (RE), Ricardo Palacios Gomez (RPG), Sekar Thangaraj (ST), Suresh Jadhav (SJ), Valeria Brizzio (VB), Yuri Vasilev (YV), Sonia Pagliusi (SP) and Sonia Villasenor (SV).
Excused: Adriansjah Azhari (AA), Sai Prasad (SDP)

The meeting started at 12:10 with an epidemiological update by AP.

Three sub-groups were agreed upon: preclinical/clinical (led by Raches), QC, and Partnerships & Manufacturing (led by Yuri). SJ proposed someone from SII to coordinate the QC subgroup. SP suggested to create a registration form for members to sign up on the different sub-groups. The subgroup lead can organize TCs with its subgroup by Skype or other communication tool. List of sub-groups will appear in DCVMN's Covid site.

RE presented Bharat's advances with three vaccine candidates: BBV150 with Wisconsin University, BBV151 with Thomas Jefferson University, and BBV152 with ICMR, whole virion inactivated vaccine. The first two will enter Phase 1 clinical trials by Q4-2020. The ICMR candidate is initiating Phase 1/2 trials, is based in Vero cells manufacturing platform, aimed at liquid 0.5ml dose vaccine. It will have 2 dose regimen with 2 weeks space in between. It is intended for pediatric and geriatric population, aligned with WHO TPP. A large scale Phase 3 clinical trial will be in the magnitude of 10,000-30,000 subjects. For Phase 1 sample size is small, below 100 subjects.

RPG from Butantan mentioned the collaboration with Sinovac, on an inactivated Covid-19 vaccine. Butantan is sponsoring the phase 3 clinical trials in Brazil, scheduled to start in 2 weeks. RP is joining CEPI Technical Review Group discussions and joined this TC to be aware of DCVMs Covid activities. RPG explained the CEPI COVAX structure, as the vaccine arm of the ACT accelerator, to provide vaccines. The other 2 pillars are diagnosis and treatments. COVAX issued call for proposals and received 60 proposals under review. CEPI call may extend deadlines. The Technical Review Group focuses on science of vaccines. Another group focuses on clinical development and operations, aiming to meet the needs of the companies, regulators and stakeholders and define needs for harmonization. Covax is willing to learn from the participants about concerns to find solutions, not to impose standards. RPG said Anamaria from WHO Solidarity program mentioned the US is running independent efforts through NIH to support any manufacturer selected by the US government, working independently to WHO Solidarity. RPG added that the perception is that Solidarity is another trial in the world, not within any special category. WHO is acting as one group in charge of clinical development, but not yet ready to start. Solidarity trial was discussed at the WHO R&D Blueprint meeting in Geneva 12-13th February; however the standardization of protocols may not allow creative research that could lead to a variety of vaccines towards higher success rate. RPG agreed that Butantan and Sinovac cannot wait to start next phase. There are still many doubts and concerns among regulators and developers.

SP mentioned IFPMA has issued a statement about commitment to help stop Covid and perhaps DVCMN could consider a joint statement for the public, so that public knows that emerging manufacturers are working hard and trying to collaborate as far as possible to have a vaccine available ASAP. The group agreed RE and AA could draft something with DCVMN specific elements, for the committee to agree upon and approve by the EC. RE closed the meeting at 13:15 CET.

Next meeting will be (20-24th) July at 12:00

Notes taken by Sonia Villasenor and edited by Sonia Pagliusi

Nyon 12 July, 2020