DCVMN COVID-19 Committee
Meeting Minutes
September 17, 2020

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

TC started at 12.05 CET and finished at 12.50 CET

- AP provided an epidemiological update: This month there is a resurgence of the disease in the EU. Although the total number of cases is lower than Asia and Americas, the active cases are increasing, so EU might have a potential second wave, mainly Spain, France, Portugal and UK.
- YV mentioned that in March a D614G mutant strain emerged from Europe, being only a single amino-acid mutation, which is now the predominant strain; but so far it does not represent any critical issues regarding vaccine research.

- RPG informed that COVAX scheduled on September 24th, between 3 and 6 pm CET, a workshop regarding clinical trials and statistics. As soon as the public advertisement is available, RPG will share it so that interested DCVMN companies can attend.
- RPG also informed that the COVAX regulatory advisory group is open to receiving general questions from any of the members (not for a specific case, but on issues that could affect several manufacturers). RPG or AA can receive the questions from DCVMN manufacturers and direct them specifically to one of the 3 sub teams in COVAX structure: clinical development and operations, manufacturing or enabling science. The group meets every month and they can provide some feedback publicly available. It is possible they will not take all the questions, but it might be useful for our members.

- YV mentioned that on partnerships there is not much to mention apart the CEPI grant that has already been mentioned. The deadline is 28th of September.
- Regarding the partnership & manufacturing sub-group, they will have the kick-off meeting on 24th of September at 07:00 GMT. Invitation will be sent out later. The goal of that meeting is to work out the goals and roadmap, the first short-term deliverable will be the weekly digest of relevant information.
- AP asked, regarding COVAX facility and partnership if the deadline for countries to partnering in the COVAX agreement is this Friday. YV said that was the original plan, but some informational meetings and updates from WHO have been canceled last week because of the situation of the severe side effects from the vaccine from Oxford- Astra Zeneca; so schedules will be adjusted.
- RPG commented that this last topic of the adverse event of the AZ vaccine has been raising discussions in the Clinical operations team. The lesson to be learnt is that one of the main issues was communication. Even though the procedures followed were correct, there were lapses and gaps in communication. Therefore, in order to prevent rumors or misleading information in any similar situation in the future, it is necessary to address and work as a group to improve communication strategies.

- RE updated on the clinical development subcommittee mentioning that some discussions have been raised regarding large scale phase 3 efficacy studies. There are some guidelines from WHO and FDA on how phase 3 trials shall be developed, what kind of assumptions shall be made, etc. It is clear that a large phase 3, event driven efficacy trial is mandated for any Covid 19 vaccine to be licensed. Based on these guidelines, PATH created generic protocol SP has provided the details in earlier communication, RE can re-send the links. There have been some discussions on the assumptions to be made for conduction the clinical studies, such as the minimum efficacy reported at 50% with a lower 95% confidence limit of 30%. Having this extra lower limit criteria inflates sample sizes. Many manufacturers have preferred to conduct the trials in high endemic countries like America, Brazil or India. It is also advisable to generate data generalizable implying that the eligibility criteria should be broad enough to include

various regions, demographic backgrounds, comorbidities, diverse regions, races and ethnicity. There are also discussions on the case definition; as Covid-19 causes not only symptomatic diseases, but also many asymptomatic infections. When developing a vaccine, the goal is to prevent infection, disease and further transmission. It is important to understand how efficacious are these vaccines to prevent symptomatic Covid and asymptomatic Covid. There is a lot of confusion on that. That is something that will be talked about on 24th of this month. It is necessary to discuss what is an appropriate symptomatic case definition and a severe case definition to get a better understanding on it as we go along on the process.

- RPG added there has been a lot of discussions and disagreement in this regard in the clinical development and operations sub team. There is a variety of definitions for different developers in later stage, such as the number of participants, the frequency of collection of samples or how restricted will it be to moderate and severe cases (without taking mild cases), which will imply a huge increase in sample size. This is a subject of discussion and a huge problem for the pioneer vaccines which may probably provide some guide for the ones coming later by next year. These last ones will have the advantage of having a correlate of protection, which will probably be by families of vaccines (inactivated, subunit, etc). Also, establishing a correlate of protection with different case definition changes the meaning. RPG will share some more information with the group led by RE and will share some ideas on Butantan-Sinovac's development.
- AA asked if there is any progress on WHO vaccines solidarity. RPG mentioned there is a protocol lead by Ana María Restrepo from WHO, who mentioned several manufacturers have approached WHO and they are setting up meetings with potential clinical sites around world, but there is not yet a concrete starting date nor names of companies involved. He suggested SP may approach A. Restrepo to invite her to give an update on this regard.

- SG briefed the group on the QC sub-committee advances. He prepared a document with the main objectives of the group based on three main subjects (QC testing of vaccines, Animal models for COVID vaccines and Bioanalytics of vaccine- clinical evaluation of Covid-19 vaccine) and circulated with the members of the group, receiving responses of agreement but also requesting to add a broad variety of items, which would be difficult to cover in a short span time; therefore, he proposed on concentrate on the Bioanalytics for clinical samples as per the published data and also discuss about resources of reference reagents. Another aspect is to discuss about the platforms being used by DCVMN manufacturers and give them a chance to present on what they are doing. However he did not receive any comments to this communication sent twice to the members; therefore SG asked the committee members to give some guidance on how to move forward with this sub-committee and also requested to know one of the basic aim of formation of this sub-committee and which could be one of the basic bullet points they think this sub-committee should move forward and prioritize.
- AP said that the agenda of these subcommittees is to gather as much information available regarding the development of Covid-19 vaccines and provide information to the Chair, AA, so that he can advise the DCVMN's EC on the decisions they are making. The EC is involved in talks with the WEF as well as COVAX facility for various indemnification forms and MOUs. It is important for them to have all the information the network is taking when vaccines are developed and distributed and all factors to be taken in consideration. This was meant to be tripled down in these subcommittees. He also suggested that maybe the advice from secretariat SP may be very helpful in addressing the fact SG received no response to his two emails.
- SG said he will move forward with the agenda. Include things that need to be discussed, and will let the group decide on the priorities, topic by topic. AP suggested SV to forward the ToR for SG.
- The next Covid Committee meeting is scheduled for October 8th at 12:00 CET.

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Notes taken by SV

Adriansjah Azhari
Chair of DCVMN COVID-19 Committee
Nyon, September 17, 2020