

**Attendees:** Adriansjah Azhari (AA), Apoorv Kumar (AP), Ladda Suwitruengrit (LS), Lingjiang Yang (LY), Linsen Du (LD), Marcos Freire (MF), Martin Reers (MR), Sunil Gairola (SG), Suresh Jadhav (SJ), Valeria Brizzio (VB), Yeong OkBaik (YO), Yuri Vasilev (YV), Sonia Pagliusi (SP), and Sonia Villasenor (SV).

TC started at 12.05 CET and finished at 12.59 CET

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AP gave an epidemiological update; Europe has emerged as the region with most active cases; Asia as the second place, then North America and the rest of the regions. Mortality is increasing. A study around the genomic variations of SARS-CoV-2, suggested mutations of the virus, c.f. [SARS-CoV-2 genomic variations associated with mortality rate of COVID-19 | Journal of Human Genetics \(nature.com\)](#)

AA gave updates on the activities of CEPI SWAT team. In the SWAT team there are three groups: Enabling sciences, Clinical Development and Operations, and Manufacturing (CMC). Main discussions were focused on the vials of the vaccines: Glass vials are preferred, CEPI has secured vials for 100 M vials for vaccine developers that can be used up to 45 doses/vial. Plastic vials and 200 dose bags can also be used to replace glass vials, but maybe not for mass vaccination. Multi dose vials without preservative shall be discarded after 6 hours. WHO is working on its position on labelling and barcoding.

SP asked if the use of plastic vials will require clinical trials to validate the different container. AA said that using plastic containers is a concern, however it also depends on the NRA.

SG asked if there have been discussions about a change from non-preservative product to preservative product, on which compatibility studies will have to be performed, which remains to be clarified. SG also asked if there is a consideration on the requirement of VVM for freezing temperature vaccines (-60 to -80°C). There is an option in this pandemic suggesting that for the pandemic use the use of VVMs may be waived at this stage. Maybe within 6-8 months companies may go for VVM, when applying for PQ.

YV updated on the P&M sub-group activities; they are updating the management table so that different companies can find each other to communicate. YV asked about the results on manufacturing survey. SP said AP help design the survey, the results were gathered by secretariat and are not available to individual members because it could be seen as individual advantage. The results of 26 respondents have been analyzed and B. Hayman (BH) is working on the report with anonymized compiled information. Results are formatted as graphs in a ppt presentation. ACTION: SP suggested the chair of this meeting to invite BH to present the survey at the next meeting.

AP clarified this information is intended to be published. He requested BH an update on when the publication is intended to be submitted to the journal through the secretariat. SP added that because the data has been provided by members, it is fair that the members see the data before the submission, so if there is anything is incorrect, they have an opportunity to express it. It will be useful to have a presentation by BH to all DCVMN members and to circulate the paper, drafted as confidential, for comments. They should be careful not to circulate or show the slides publicly outside, because journals would not agree to publish something that has been already publicly circulated.

AA agreed to inform the members on a confidentiality basis. SP will ask BH if there is an abstract that can be circulated along with graphs labeled as confidential. A short update from BH will be beneficial (one pager just to show advances). SP will follow up with BH and circulate.

SG updated on QC sub-group activities, particularly the preparation of international standards for antigen and antibodies by NIBSC. It has been announced that the international reference standard for ECBS have announced the report for establishment of international reference standard for SARS-CoV-2. NIBSC code 20/136, is established as the WHO International Standard for SARSCoV-2 antibody, based on 15 to 16 labs who participated. The draft report was circulated to all participating labs only. Internal 250 IU/ampoule can be assigned to this international standard and once available can be harmonized 1 unit can be assigned on the Clinical samples to be analyzed. He added only 3000

ampules were made and it is preferred to transport them in frozen conditions. All manufacturers have to have their in-house preparation of the reference. These reference standards will be discussed at the ECBS.

SG also updated on sera panels of three types: High, medium and low antibody levels; another panel is the spike protein, from sera from patients who recovered. These sera panels are aimed to validate the assays. Only 2000 freeze dried vials will be made.

SG also gave a small update on animal models. One recent publication suggests that animal models like rats, mice, hamsters, are not showing disease symptoms and also there is a lot of variability. There is a transgenic mouse model in US (publication to be shared) which has a matching receptor and reproduces the disease, so it has become a disease model and has mortality.

AA suggested a webinar for DCVMN members, focusing on updates for Covid vaccine development, to highlight the landscape of candidate vaccines on clinical trials and updates on Covid facility. He invited CEPI and the webinar was held on 08<sup>th</sup> December at 10 am CET to all the members. The objective was to understand the clinical trials design, the end points, and efficacy calculations made. The people from CEPI are knowledgeable to present on that.

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*Notes taken by SV, edited by SP and SG*



Adriansjah Azhari  
Chair of DCVMN COVID-19 Committee  
Nyon, November 26th, 2020