Present: Ben Pierce (BP), David Kaslow (DK), Jongho Park (JP), Patrick Tippoo (PT), Ray Prasad (RP), Sonia Pagliusi (SP), Lingjiang Yang (LY), Tiago Rocca (TR), Benoit Hayman (BH), Katharina Hartmann (KH), Laura Viviani (LV), Maureen Dennehy (MD), Nora Dellepiane (ND), Sonia Villasenör (SV), Steve Jarrett (SJ). Apologies: Adriansjah Azhari (AA).

TC started at 4.00 pm CET and finished at 5.00 pm CET.

PT chaired the meeting and welcomed all participants.

- **Administrative/logistic queries:** Update. MD reported that AC member Shaozhong Dong has agreed to step aside for a member with more availability. Two recommendations to the EC for AC membership are (i) invite a member company representative to fill the position and (ii) invite an additional NIIMBL representative once the funding contract is signed, as discussed last meeting. **ACTION PT.**

1. **FVMR Hub (for information).** Update: The FVMH award to 16 DCMVN members for training at NIBSC in 2020 has been disrupted by COVID. BP confirmed that a no-cost extension from end March to end September 2021 is intended, but formal confirmation is pending. **ACTION:** Once formal confirmation is received, communicate and plan with NIBSC and award recipients.

2. **Training.** Update: in the context of COVID, training has been focused on self-learning and e-workshops since early 2020. As agreed at the last AC TC, DCMVN signed a collaboration with NUS/CoRE, to enable staff of DCMVN members to follow a graduate regulatory. SP reported that 7 members were accepted for the first two NUS lecturer-led, online Regulatory courses, running this month. One delegate resigned from their company and, thanks to immediate communication of the member company, DCMVN, in consultation with NUS/CoRE was able replace the delegate with another qualified DCMVN applicant. Total number of applications is unknown (they were made directly to NUS selection committee), but members’ emails queries to DCMVN suggest 10-20 - more than expected. The initial NUS contract was for 10 applicants over 2 years of courses.

- **Proposal:** two self-tutored e-courses are also available at NUS in Medical Affairs (MA) and Clinical Affairs (CA; 3 modules/course x [module]). SP proposed that unused training budget from cancelled face-to-face workshops be redirected to offer 30 MA/CA courses (15 certificates x 2 courses @ [budget]).

DK noted the logos associated with the courses and requested that SP assure with the university that the courses are appropriate for low-resource settings. RP added that relevance to WHO PQ be checked. If appropriate, the AC provided mandate to go ahead immediately. **ACTION SP.**

3. **Supply Working Group.** Following on from the priorities of the DCMVN Supply Chain WG set and agreed last year, SJ’s primary packaging case study with Bio Farma was pre-circulated.

- **Proposal:** in the context of fostering implementation of traceability standards, SJ proposed to allocate unused funds (DCVMN up to [amount]) to provide support, with member co-financing, to assess requirements for (1) adoption of GS1, (2) related packaging line modifications. LY supported this, AC approved. **ACTION SP, SJ.**

- **Proposal:** following Supply Chain working group discussions in November 2019, SJ and Biofarma drafted a case study. It is suggested that this be submitted for publication to enhance awareness in this area (given the appropriate permissions from Biofarma and other contributors to the report). DK asked whether to share with CEPI, VIPS, etc., noting that limiting circulation ahead of publication is no longer standard. A query was received from VIPS before this meeting. The AC recommended parallel submission for publication and sharing/advocacy. **ACTION SJ.**

- **Proposal:** with DCVMN members, countries in parallel to publication by taking the report and proposals to
vaccine pillar at COVAX. DCVMN WG to share report with VIPS once completed and cleared by co-authors/data owners. **ACTION SP, SJ, DK.**

4. **3Rs WG and PSPT project.** Update: LV reported that the NIIMBL award agreement was in progress.
   - **Decision:** coating antigen, necessary to the ELISA testing of potency, the quote from a second CMO was pre-circulated. It has been discussed and approved, in principle, by the EC. DK queried the qualification / fitness for purpose and risks. LV clarified that risk is mitigated by CMO company experience with pertussis, use of Intravacc’s existing procedures, Intravacc-CMO collaboration on process controls, and independent characterization of antigen by Intravacc. Multiple formulations (7) will be pursued initially, with selection of the best for the final 2000 vials. There is also time to run a second batch should something still go wrong. AC endorsed supplier selection and quote, with congratulations to LV. **ACTION LV.**
   - **Decision.** LV: Intravacc has multiple roles as resource member, service provider to PSPT and expert members of steering group. They would also like to be part of the consortium (although not doing the batch testing). DCVMN needs to be transparent and ensure no perception of conflict of interest. LV requested waiver for them to serve as service provider, covered by funds from NIIMBL for the characterization, and permission for them to sign the consortium agreement and officially join the group. AC concluded that Intravacc activities are well-known and roles are accepted. Both actions can go ahead. **ACTION LV.**
   - RP queried if LG, as major manufacturer of pertussis-containing vaccines, had been invited to join. LV: they were invited but are intending to observe rather than participate due to testing differences. LV to re-send information to JP, who will follow up, if needed. **ACTION LV, JP.** SP noted that non-member vaccine manufacturers and National Control Laboratories are also engaging with the consortium-led validation study through WHO.

5. **Virtual AGM.** Update SV: 6 providers of event virtual platforms, event services and technical support were evaluated. One that has experience in UNICEF and GAVI meetings was selected. EC has approved. Currently investigating options for partners to display materials and hold virtual meetings during the event. Agenda is almost finalized: 3 hours x 3 days 11 am – 2 pm CET, with general assembly as part of day 1. SP: as previously, the service provider will be paid with Foundation funds. USD50K for this event. DK: COVID has resulted in more flexibility on work times. SP: recorded presentations are an option if the timing is unworkable.

6. PT noted that Initiatives 3 (Regulatory Harmonization), 4 (Access to Information) and 6 (Pharmacovigilance) presented Updates (see slides) but did not require any decisions or discussion. Should there be any additional queries, attendees were invited to engage via email.

The meeting was adjourned by PT.

10/09/2020