Participants: Adriansjah Azhari (AA), Ben Pierce (BP), Benoit Hayman (BH), David Kaslow (DK), Katharina Hartman (KH), Kelvin Lee (KL), Laura Viviani (LV), Lingjiang Yang (LY), Maureen Dennehy (MD), Nora Dellepiane (ND), Patrick Tippoo (PT), Rajinder Suri (RS), Ray Prasad (RP), Sivashen Cunden (SC), Sonia Pagliusi (SP), Steve Jarrett (SJ), Tana McCauley (TM) Tiago Rocca (TR), Sonia Villaseñor (SV).

Excused: Jong Ho Park (JH)

Meeting started at 16h00 CET and adjourned at 17h35 CET

PT chaired the meeting and welcomed all participants. PT thanked MD’s invaluable contributions for the last 5 years.

Training program (for advice/decision): SP presented the training program for 2021 for approval.

- SP proposed to establish a clinical/medical affairs Working Group to foster dialogue on best-practices for clinical trials design, data collection, analyses, interpretation and reporting, based on the members that have completed the NUS clinical/medical affairs certification. Secretariat will seek an expert consultant (with PATH support) and will need to add an intern to support the group activities. Ca. 50K USD.
- DK confirmed PATH support to this initiative.
- PT asked if the budget 50K will be mainly for the consultancy costs. SP confirmed the budget would be from the grant that was transferred from Gates Foundation to PATH, so it is within the planned budget. SP clarified that the consultant may start with a survey within members as to the clinical/medical affairs operations. There is ca. 650K USD available from BMGF/PATh grant for 2021, including carryover, without considering other sources (NIIMBL/FVMRH).
- The initiative and budget were approved. RP suggested to direct this effort to candidates for pandemic, so it would be great that the consultant has experience in the approval of EUL vaccines. DK agreed. RP added that expansion of the budget can be considered, if needed. Particularly for WHO PQ, however DK mentioned that the route to get to EUL is through EMA. SP added that EMA scientific opinion pathway is available, if requested by manufacturers.

FMVR Hub Collaboration (for advice/decision): BP summarized the FVMRH support since December 2017, with 50K £ for fixed costs that support training and general activities and up to 400K £ for variable costs (workshops, consultancy, third party programs, awarding). Large portion of that was allocated to provide on-site QC training at NIBSC in 2020, but it was not possible to do it due to travel restrictions. So, we need to decide how to use the ca. 300K £ before Sept 30, 2021.

- The proposal is to extend the support for existing DCVMN member collaborations that have already received third party consultancy support, for activities that can be concluded and invoiced by Sept 2021.
- BP also requested accessing 32K £ to support a researcher at Imperial College. DCVMN would still have access just under 300K £ for activities until the end of September. This research would be completely independent from DCVMN activities.
- SP mentioned that DCVMN is contacting the 6 companies now, and suggested to wait the 6 replies, and if ca. 50K £ in average each, it would correspond to 300K £.
- RP asked if the call could be open to all members, not only the selected 6. BP clarified we are running against time, so ongoing collaborations are the best solution, as the average time to select and sign new agreements is 3-4 months. RS asked if it is open for any project or if there are any criteria. BP said it is open to any DCVMN project, though not COVID-centered.
- SP suggested to work towards getting written suggestions of the 6 ongoing collaborations for the next 6 months and in the next DAC meeting of see how much is left over to decide upon the support of the researcher. BP agreed.
- In parallel, BP will try to apply for no-cost extension of the grant, but there is no precedent that this has ever been granted. RS suggested to clearly communicate the action plan but not give them the hope, at the beginning, that the grant extension might come through. The DAC agreed.

Supply Chain Traceability project (for advice/decision):

- SJ presented an update on the Supply Chain WG activities with the traceability pilots of barcode labelling in primary and secondary packaging. A consortium has been created with potentially 8 members: 3 with
ongoing traceability projects, Biofarma and 5 others. The WG has also started discussions on stockpiling.

- Regarding the barcoding initiatives 100K USD had already been granted, the request is to increase additional 200K (total 300K) to support members with local high-level and junior-level consultants for the design and implementation of piloting projects. SP confirmed it is within the budget.
- DK asked about the connection with CEPI and COVAX within this project. SP said that when the project started, members decided to focus on the secondary stages of the supply chain\(^1\), while CEPI is now looking on the primary stages of the supply chain (raw materials), so it is complementary to DCVMN supply chain efforts. RS added that he has had discussions with CEPI, who has been involved on R&D manufacturing and scaling up and would soon take some projects with CEPI and our members for 2021.
- The DAC members were in agreement.

**Regulatory convergence (for advice/decision):** ND proposed the joint Risk Management Project with the PV WG to strengthen the capacity of DCVMs to develop Risk Management Plans for vaccine registration and PQ submissions to meet ICH, EMA GVP GL with company multidisciplinary teams. The project will support companies to write a RMP for a real vaccine being prepared for submission.

- The project would involve contracting 3 experts to support the roll-out of the project and additional 3-4 experts for independent review and feedback of the final plans.
- The project will be an open invitation to members and there won’t be a limitation on the number of companies that could be accepted into this project. The ideal number of representatives per company would be 3-4 from different areas relevant to the development and implementation of RMP.
- KH estimated that 10 companies and 3 consultants for the first part and 6 for the second part, would be around 200-300 consultancy hours for the project. SP confirmed budget availability.
- DK confirmed PATH support for experts for this project.
- LV updated on the activities related to the 3Rs WG. Training sessions are being carried out. No requests.

**Access to expertise update:**

- MD announced that the access to expertise will be taken over by Sivashen (Webinars and DCVMN portal) Webinars are on track and organized for the first 4 months. MD requested DK for assistance in populating the portal. AA added that Sinopharm is collaborating with Kimia Farma, Indonesia.

**Technology adoption trough AGM (for advice/decision):** PT reminded that Biovac has offered to host the 2021 meeting in Cape Town. He asked the DAC if we could still consider the face-to-face meeting as an option. Biovac team is evaluating the proposals sent by SV and will check on venue availability and will come back with a proposal to be approved by the EC and DAC.

- RP said that a face-to-face meeting is always better, he suggested to keep the option open until we are able to decide by June-July upon the travelling conditions. DK suggested to consider also the restrictiveness of the host country and to consider a couple of back-up countries having less restrictions.

**Pharmacovigilance (for advice/decision):** KH proposed, in collaboration with COVAX, to create an open and closed forum to address PV needs from DCVMN members as well as IFPMA. This is under discussion.

- PV monthly training plan with PATH in PV from Mar-Nov 2021, as outlined above under training.

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**Nyon, March 1st, 2021**

\[\text{Notes taken by S. Villasenor, edited by Sonia P.}\]

**Patrick Tipoo, Vice-president DCVMN**