DCVMN Donors Advisory Committee minutes
TC of Thursday 25 June 2020

Present: Adriansjah Azhari (AA), Ben Pierce (BP), Benoit Hayman (BH), David Kaslow (DK), Harmony Chartier (HC), Jongho Park (JP), Katharina Hartmann (KH), Laura Viviani (LV), Nora Dellepiane (ND), Philippe Gilbert (PG), Ray Prasad (RP), Sara Chumbley (SC), Sonia Pagliusi (SP), Sonia Villasenor (SV), Steve Jarrett (SJ), Maureen Dennehey (MD). Excused: Patrick, Dr. Dong.

AA chaired the meeting and welcomed all participants.

1. Administrative/logistic queries (for advice/decision):
   - DCVMN was awarded a grant from NIIMBL, would it be appropriate to include a NIIMBL representative on this committee? RP supported the idea as NIIMBL is looking for initiatives that help solve issues unique to developing countries. NIIMBL is now expanding outside US. Perhaps can join these meetings. SP clarified that to be eligible to NIIMBL grants, organizations have to be a NIIMBL member and DCVMN is already a member of NIIMBL.
   - The challenge for some members to follow the committee TCs was mentioned by MD and one AC member only join 1 out of 6 meetings so far. Thus we seek your agreement to considered seat vacant to be filled by another member with availability. It was agreed that all the AC members should actively participate in the meetings, so that decisions can move forward. ACTION: Advise the member if there is somebody from the organization who could fill the seat, otherwise seek another member company, for EC approval on a 2-step process.
   - Grant transfer (for information): HC informed that PATH can move grant to DCVMN, within the grant already in place with BMGF; funds were added by the foundation for the grant management as a supplement. DK clarified that PATH has a broad award with gates foundation. On sustainable manufacturing and this was added as an 11th objective to support DCVMN and including Pharmacovigilance (PV) capacity building, in 2 phases, with support of PATH staff, The target is to get approval by 1st week July. So that period of amendment goes from 1st July 2020 to December 2021. RP approved the proposal. DK added that an agreement between PATH and DCVMN will be signed on the scope of work to be signed once the foundation gives the award. SP sent the outline of activities and budget to PATH, on 24th June, for discussion. Feedback is awaited.

2. Training (for information/advice):
   - Query for advice on training policy (agreement): DCVMN/CoRE/NUS collaboration was signed on 17th April 2020 for the graduate program on regulatory affairs, having 8 training modules over 12 months. Each module costs about 2500 USD/person and the agreement covers for 10 participants over 12 months for any of the 8 modules. For the first module, DCVMs had 5 voluntary. Our concern is that if one member has 3 seats in one course, other members may also like 3 seats for their staff. Registrations are on the hands of NUS on each course, first served basis, including registrations from all over Asia (in high demand). AC members agreed to allow a balanced and equitable approach we could renew contract and increase budget. The aim is to benefit as many people and companies as possible for the good for vaccine systems, and donors are open to consider additional budget. SP added that funds from F2F workshops are available, to expand contract to another 10 seats. We need clarity and consistency for all the DCVMN members. AA suggested allowing 2 persons per member company. DK suggested no more than 2 seats per member, if there is significant interest, then increase. RP added, he is glad to see interest and funds available. ACTION: SP contact CoRE/NUS to increase DCVMN participants quote.

   - Virtual reality (VR) training (for information): needs a new “champion”, as budget available. Three short hands-on VR

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courses were planned, we had one last year. BH is exploring with Partners, majority based in Europe, to introduce VR but it has been postponed because of Covid. DK volunteered to get more information and explore within PATH. ACTION: DCVMN secretariat (SP) to share VR documents with DK. (materials shared with PATH on 25th June)

3. **Supply Working Group (WG) for information**: SJ reported that 2 papers were published on supply road map and Covid R&D and on manufacturing and fill- finish capabilities.
   - The agreed WG main focus is traceability standards, due to increasing concerns on counterfeiting and potential diversion of products to parallel markets. Biofarma has presented their work in “biotrakcing and biodirect”. DCVMN will build a “case study” based on their work, including critical processes, hardware, software, and investments in innovation. Potentially we will come with an investment plan for traceability for all DCVMN members to implement traceability with barcode in primary packaging, also important for Covid 19 vaccines on huge demand and limited supply over the next year or two. RP suggested a dialogue with CEPI. DK suggested making the WHO CTC group aware of the needs. SP added that the WG members are concerned about implementation costs for equipment, training, i.e. around 1 or 2 million per company. DCVMN cannot fill that gap but provide clear ideas for them to fundraise. ACTION: DK to allow visibility and funding. ACTION: DK to connect with SJ to find solutions.

4. **3Rs WG and PSPT project for advice/decision**: LV asked for endorsement of a strategy to selecting CMO to produce the coating antigen for the Pertussis Serological Potency Test (PSPT).
   - One CMO has no previous experience with B. Pertussis and quotations changed significantly over time (from Feb to June) getting to [redacted] raising some discomfort. Another CMO quotation, received today, is [redacted] USD. The final budget to NIIMBL needs to be submitted in 24 hours: Shall we go with the first quote as a base, and see if we can find a better solution? RP understands that it is a very critical reagent for the success of this project and quality will be key. RP agreed that it is important to move forward and submit costing, while seeking a reasonable agreement, and advised to check other options from a company in China that does antigen coating and monoclonals (contact details to be shared). SP asked if perhaps one of our members could produce this antigen for the study, if agreeable for AC to ask a member to produce antigen for a cost? It was agreed that all members will benefit, thus not unreasonable to support this project. The AC agreed to the strategy. ACTION: LV to submit the budget to NIIMBL on 26th June, with the high quote, while seeking lower alternatives.

5. **Virtual AGM for information**: BH exploring options for virtual AGM in October 2020, with SV, who found great options for large number of participants with booths and interactions. Costs seem less significant than an in person meeting. ACTION: prepare an excel spreadsheet for inputs form AC and DCVMN partners who had been fed from their booths.

6. Pharmacovigilance (for information): KH mentioned that PATH will take over PV training for next 12 months as DK said. The DCVMN PV WG agreed to the PATH plan. DCVMN is thinking about strengthen monitoring capacity for the safety of COVID vaccine rolled out.

7. **FVMR Hub for information/agreement**: Imperial College awarded funds to DCVMN for hands-on training.
   - BP reminded that FVMH awarded 16 applicants from DCVMN members to NIBSC in the UK in 2020 to be conducted in Q3-4 2020 [redacted] However COVID situation may not allow travel. No cost extension will be possible, thus we seek agreement to sign the contract with NIBSC to work on a financial and contractual proforma arrangement with DCVMN, to have the training deferred to 2021. DK said the no-cost extension would be best. ACTION: We will update in one month.

The meeting was adjourned by AA.