Participants: David Kaslow (DK), Kelvin Lee (KL), Bernadette Hendrickx (BeH), Nirav Chokshi (NC), Linda Nesbitt (LN), Laura Viviani (LV), Benoit Hayman (BH), Rajinder Suri (RS), Svivashen Cunden (SC), Sonia Pagliusi (SP), Steve Jarrett (SJ), Sonia Villaseñor (SV), Prerna Kumar (PK).

Excused: Patrick Tippoo (PT), Adriansjah Azhari (AA), Tiago Rocca (TR), Ray Prasad (RP), Ben Pierce (BP), Lingjiang Yang (LY), Katharina Hartman (KH). Meeting started at 15h00 CET and adjourned at 16h22 CET.

RS chaired the meeting in the absence of PT and welcomed all participants. RS thanked DK and PATH for having cleared the grant due for renewal up to June 2022 and the agreement was reached.

SP acknowledged the secretariat team and expert consultants’ group for their support to DCVMN members. SP announced 2 new interns have joined the secretariat this year: Tietoja Baroroh and Aila Marini (AM).

1. Training initiative: Regarding the collaboration with NUS, in 2022 we have already 53 registrations for the NUS e-learning courses, which shows that the interest of the members is increasing.
   - MeDRA support initiative: The expression of interest was launched on the 13th Dec, attracting 12 applications, of which 9 fulfilled the eligibility criteria. 7 have already applied and have been paid.
   - The Clinical & Medical Working Group was established. A first meeting between the Chair, Co-chair and consultant, along with RS and SP was held on Feb 16th to establish the goals & objectives. The Terms of Reference are being drafted. The WG Kick off meeting is scheduled for March 22nd.
   - SP showed an update on the use of the donors’ funds as of 01st March 2022 (BMGF/PATH). She also mentioned that there is a 500 K approval until June 2022.

2. Supply Chain WG /Traceability project: SJ summarized that 6 companies have joined the Traceability Consortium. In total 6 pilot studies, 3 for primary packaging and 3 for secondary. 2 pilots are self-financing and 4 with DCVMN financial support. BioFarma, has been the lead implementing primary barcoding at national level on COVID-19 vaccines.
   - The warehouse system innovation project was introduced by CNBG. The objective is to increase the traceability of the flow of materials throughout the production process, from first input (e.g. raw materials) until dispatching final products. The question to the DAC members is whether DCVMN should support some of the member companies moving into this kind of modernization for more efficiency in the production process, which ultimately could lead to savings.
   - The plans for Q2 are to continue with the meetings of the Traceability Consortium until June and to document and publish the lessons learnt. The idea is to add 2 additional pilots of barcoding in primary packaging over Q2, if relevant. SJ requested the additional support for these up to US$100K. RS clarified that the 2 additional traceability pilots had already been approved and SJ can move ahead.
   - Regarding the warehouse management innovation pilots, it was proposed that DCVMN provide support to up to 4 member companies with consultancy, training and software support for the selected companies initiating their integrated warehouse management innovation up to $100K. RS clarified that these pilots could start in H2 and requested the approval of the DAC.
   - A workshop on new packaging technologies is scheduled for member companies in early May with a focus on VIPE recommendations involving PATH, CEPI, GAVI and WHO as invited speakers, to inform DCVMN members on the technologies being developed.
   - DK asked if these financial requests were already in the budget. SP explained that there are US$200K in the budget for the warehouse management pilots, however as the warehouse management could take some time to be launched and signed, it may be too short in time to do all by end June, so the idea was to use 100K to support the traceability pilots on primary packaging for those companies who successfully completed the secondary packaging (potentially Innovax and Sinergium) if desired. DK suggested SP to have a discussion with Cindy on this budget flexibility. RS mentioned that the warehouse management project does not appear on the approved budget, whereas it is part of the Supply Chain. This was clarified and will be discussed with Cindy so that everything is clear.

DK asked if there are other VIPE recommendations that will be incorporated in the workshop. SJ said in the
workshop we will look at all potential new packaging technologies.

3. **Regulatory convergence**: RS mentioned that all WG had been reorganized and introduced NC as the new Chair for the Reg Affairs WG.
   - NC informed that the group had a first call on January 11th. They will also have a meeting with CEPI to discuss on opportunities and challenges for collaboration.
   - The group set 3 main priorities: WHO CRP, CEPI 2.0 and DCVMN training opportunities.
   - There is a need to revitalize the connections and engagement of the WG members, thus NC is having 1-1 calls with the WG members to receive feedback on processes and challenges. NC reported that some members updated that it is very easy to approach NRAs or going for the CRP, however they are not involved in the recent CRP procedure so their experience was having little older applications. The South African members are very excited about the CRP and feel that they are going for the initial application which will probably be lengthier than the CRP, and would be a great idea to go for the CRP.
   - On a broader level, most members agree that there is a need for more clarity, awareness and communication on the topic and there should be collaborative training programs amongst the members and industry participants; there is a need of WHO and leading regulatory agencies conducting training programs and they feel that if there is a better coordination amongst the regulatory agencies, the CPR may emerge amongst the best options.
   - BeH offered to keep the team updated on the important regulatory meetings she participates in.

**Regulatory convergence: 3R WG**: LV highlighted the importance of ensuring that DCVMN members get involved in the various international discussions in USA and EU on implementing alternative methods to animal testing. DCVMN was able to support to get some of the members into some of these discussion groups. There is also the project of collaborating with other industry associations to delete obsolete testing that have already been removed by EU, Canada, USA, but still requested by the majority of the countries where DCVMs operate, and DCVMN will contribute actively on that.
   - It is important to share information on the different opportunities for QC for batch release, and the data collected up to now, there is the possibility for saving from 1 to 2-digit figures (few dollars per batches till hundred depending on the test and the personnel and materials used for the test) per batch in replacing animals by other in vitro lab testing. The data will be published.
   - There is another project for deleting the Single Dilution assay for TD containing products; around 9-10 DCVMN companies could participate in this project, collaborating with 2 NRAs. RS clarified that funding for this project has been approved for H1.
   - DK observed that it seems to be a great progress on the developed countries but not so much in the other ones and asked if there is a need to have WHO engaged more to help the other National Regulatory Authorities (NRAs) to come along. LV said WHO is engaged in another project to get the NC3R to do a complete review of the WHO Technical Report Series.
   - s to introduce 3Rs opportunities. We have 2 DCVMN members participating in these WGs. With these updates, after 2023 we could expect some NRAs to follow. However, sometimes the issue is that in some countries the GMPs are not followed and that is why some NRAs are not open to these changes. DK said that WHO’s updating the technical series is a critical path. RS said that this project requires very high visibility so that we are able to create this sense of urgency required, DCVMN will participate with WHO in whatever is required.
   - **PSPT project**: LV mentioned that the no-cost extension requested to NIIMBL has been approved, and in the last months the statistician has advanced in the review of the data received. At the end of the month, they will have a dedicated workshop to discuss the preliminary finding and in the same time they will have 1-1 interview with some of the laboratories, because there are some complexities and challenges. Any recommendation to the SOPs will be implemented so that laboratories have a clear guidance on how to implement it in their laboratories.
   - The additional samples of the coating antigen have started to be shipped to the different laboratories.
for in-house validation studies, although it is not part of this project.

- There is a possibility of carrying out the final meeting in a face-to-face mode in India, but there are still some participants that don’t feel comfortable to travel. RS suggested that Singapore could be an alternative destination for the meeting as they have very careful COVID protocols.

- KL invited LV to reach to her project manager in NIIMBL and to himself to talk about the next steps beyond the period of performance of the NIIMBL funding and whether additional funding as a separate project could be useful to accelerate these next steps.

4. **Access to expertise update:** SC reported the attendance of members to 2 webinars which took place in Q1. The average number of connections was 45 members, more than Q1 of last year.

- The webinar plan for 2022 is being scheduled with 8 sponsors, however they are responding very low. There is already one webinar scheduled for May and maybe another one for VR.

5. **Technology adoption trough AGM (for information):**

- BH said that in January he made an assessment within members on their level of familiarity with VR as a training tool, and their level of interest. Few responses were received, but it was clear that there is no current use with VR as a training tool, but a high level of interest. LV will guide SC and AM to collaborate with these members to identify the most suitable topics to develop the VR training tools.

- We are going to be collaborating with CEPI to increase the members’ engagement in their calls. On March 4th there will be a call with CEPI so that all manufacturers interested in the call, know how to submit it. DK mentioned that maybe part of the issue is that some of DCVMN members have applied to CEPI calls and it is so difficult to go through the process. He asked if there is some feedback on that, it would be good if DCVMN gives it. RS said he had started talking to the top team of CEPI in these aspects.

- The AGM report has been submitted for publication.

- SV said the AGM organization has not started but the aim is to make a face-to-face meeting in Cape Town. If it is not possible to do so, then a hybrid mode will be adopted. Regarding the VR, RS suggested BH to start looking at the Regulatory front as virtual regulatory inspections will be the norm.

- DK asked if we are aware of what are MNC’s doing in VR. BH said we have had a look and haven’t found much available and we have discussed the possibility of reaching out to some of these companies, like Merck (our sponsor) to see what they are doing. DK suggested to contact BIO or IFPMA to see what they are doing in this area. RS offered he could also contact Sanofi to see what they are doing. KL suggested also to approach some vendors or suppliers.

6. **Pharmacovigilance:** LN, the new Chair of PV WG said they had their first meeting on the 25th of February where they discussed their 5 priorities for the WG and was accepted as shown in slide 16.

- Regarding the RMP from last year, the comments from 1:1 feedback sessions were submitted on the RMP to the consultants and awaiting for their response.

- The next steps are to organize a high-level RMP workshop in early March. Also, to work on the workshops for the active vaccine safety surveillance. They will engage more with the Reg WG and with the COVAX vaccine safety WG on aspects of safety and challenges DCVM developers face and what are the actions to take and feedback their suggestions to the COVAX WG.

- RS thanked PATH for nominating Varun Sharma to this PV WG who has been giving very valuable inputs.

- DK questioned who’s the donor for post-licensure vaccinovigilance work and who is really engaging in it. He suggested to engage CEPI, as it seems a bit out of scope for CEPI currently. RS said CEPI is one of the candidates who should be supporting the active vaccine safety surveillance and we are working on a project but have not yet reached CEPI. However, RS asked DK if PATH would have the appetite for this project, this would be a multi-centric regional project and will involve various LMICS and maybe PATH could add this into their portfolio for the clinical part, we could route it through PATH so that there is a centralized action plan. CEPI is working very actively in the active surveillance. BeH said KH and herself work as consultants at CEPI and there is a huge PV WG having the most experts in it and are funding. DK acknowledged CEPI’s contribution in pre-licensure safety but said that the gap is on post-licensure PV
Nyon, March 2nd, 2021

Signed by: RAJINDER KUMAR SURI
Reason: MOM-DAC 2nd March 22
Location: Delhi, India
Date: 12-Mar-2022 (02:25 PM)
Rajinder Suri, DCVMN CEO

Notes taken by S. Villaseñor

DCVMN Donors Advisory Committee
Quarterly Meeting: Q1 2022

Funding. RS will check on this and come back to DK.

DCVMN Donors Advisory Committee

Acknowledgment to DCVMN secretariat & consultants

VR training program development, MedDRA software finalized ready for hands-on “testing” in Q1

Clinical Affairs survey analysis completed

Access to MedDRA training and data:

VR for MedDRA and MedDRA software finalized ready for hands-on “testing” in Q1 2022

Planning for 2022:
1. Pursue development of additional VR training in 2022
2. Establish a Clinical Working Group for DCVMN, led by an expert consultant
3. Sponsor MedDRA subscription access for “first learners”

Rajinder Suri, DCVMN CEO

Developing Countries Vaccine Manufacturers Network

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