Participants: Bernadette Hendrickx (BeH), David Kaslow (DK), Jongho Park (JP), Kelvin Lee (KL), Linda Nesbitt (LN), Lingjiang Yang (LY), Patrick Tippoo (PT), Ray Prasad (RP), Samir Desai (SD), Laura Viviani (LV), Benoit Hayman (BH), Sivashen Cunden (SC), Sonia Pagliusi (SP), Steve Jarrett (SJ), Sonia Villaseñor (SV), Tana McCauley (TM).

Excused: Adrianzjah Azhari (AA), Katharina Hartman (KH), Rajinder Suri (RS), Tiago Rocca (TR).

Meeting started at 15h05 CET and adjourned at 16h26 CET

PT chaired the meeting and welcomed all participants.

SP acknowledged the growing secretariat team and expert consultants’ group for their support. SP welcomed BeH, who introduced herself.

SP then showed an interim financial draft (not yet audited). From BMGF, DCVMN received over 1 M USD in 2019 and up to date there are 80 K available now, which are already committed for pending invoices. The Imperial College grant ended on 31st July 2021 of which the non-used funds were returned to the donor and the report was sent on 30th July, the final approval from the donor is being awaited. Regarding PATH funds, the whole grant will be approx. 900 K, and DCVMN received already 446 K, which is still available because DCVMN has not used any funds yet. The PSPT grant from NIIMBL, is 60% implemented. From the PATH side, SP said that the 400 K may not probably be disbursed before the end of the year (perhaps only 100 K?), and there are other 500 K scheduled for next year. SP asked the DAC members advice/suggestions for using these funds for identified needs. PT opened for comments. RP asked if there were any proposals for spending the remainder of this year. SP said there was a proposal for 300K reallocated to supply chain traceability pilots, but only 3 proposals were received, of which only 1 was approved for 50K. There is room for new ideas and activities suitable for DCVMN, because in principle DCVMN, from the fiduciary point of view so far, should be focusing in training and capacity building, and is not suitable to provide consulting to members. She asked if BMGF and PATH have the same kind of limitation. RP encouraged to pursue the virtual reality training activities. DK said PATH is not restricted as DCVMN.

DK mentioned there is a lot of activity on regional Hubs, which will be needing a significant amount of training and proposed that some of these funds could be used by DCVMN for a training component. SP said that if there is a proposal, it could be allocated. PT said that traditionally DCVMN uses the resources received for training activities for their own programs given to its members. In terms of the way the Hub is set coordinated by WHO with the support of the Medicines Patent Pool this would imply a donation from DCVMN to that program. DK then proposed the funds could be used to sponsor the attendance of DCVMN members to these trainings organized by the Hub, to which they wouldn’t have had access to, because they are not part of the groups being trained. PT said this could work but we need to keep in mind the timing, as it is not yet clear.

1. Training program (for advice/decision): TM mentioned there is a new Moodle course on Monocyte Activation Test, which will be released by the end of this week. TM also showed the data of the 2 courses added this year which are doing good, and a steady increase in the participation of the other modules. Regarding the 3 PV workshops from PATH held in Q3, there has been >30 participants.

• SP showed the 3 programs in collaboration with the National University of Singapore (NUS): Medical Affairs, Clinical Affairs and Health Products Regulation (which is a graduation program). 29 people from 18 DCVMN companies enrolled in the Medical Affairs and Clinical Affairs. The courses are self-paced, so very convenient for the members. The courses cost between 225 and 335 USD/participant. The Health Products regulation graduation is a program in which each participant needs to go through four different courses or modules but they are online live lectures. This course costs now 5800 USD per person, and requires more logistics as it needs people to be available. 3 participants are expected to graduating by the end of 2021. SP recommended to continue with the e-learning but she asked whether or not to continue with the Health Product graduation.

• The feedback received from the participants is very good. Only 2 have dropped due to time constraints.

• RP endorsed the proposal for continuing with the programs as long as members show interest. RP suggested one more round survey to see how many people would be interested, and if there is a similar number as on the first round, we should continue. KL and DK also endorsed the proposal.
• SP gave an update that the Clinical Affairs Survey has been launched and received 88% members’ participation rate and the results are being analyzed and will be presented in a webinar on October 6th.

2. Supply Chain WG /Traceability project (for information): SJ informed that the Traceability Consortium group with 4 members, and 2 more who are reviewing joining the consortium. In total 6 pilots, 2 of which have not requested support. DCVMN has given support to 1 company and 2 are under review by the independent committee, which may represent 100K. Another proposal still needs some details to be clarified. In addition, another proposal has been received which is related to Warehouse Management Systems. If these other 2 proposals are approved, they might represent additional 100K. The pressure on COVID-19 is delaying these projects. In 2 to 4 weeks, we will have a better view in terms of resources needed. SJ will follow up on a date for the independent committee to convene.

• In terms of stockpiling, the peer-reviewed paper was revised and resubmitted in August and it is expected to be published soon.

• In terms of packaging Innovations, SJ has been in contact with Debbie Kristensen at PATH who has agreed to help with the workshop, but it is likely to be done early next year.

• In addition, from a survey done earlier by BH, there was some concern by a number of members about the new shipping packaging and shipping guidelines of WHO, and were requesting training. SJ has been in contact with WHO in order to try to push that these on-line trainings provided on this by WHO should be open to all DCVMN members and not just those with pre-qualified vaccines, as it will not represent additional cost to WHO. RP asked if there is need for intervention with WHO. SJ will follow up and if there is a need of high-level intervention, he will point it out.

3. Regulatory convergence (for information): SD presented the activities of the Regulatory WG:

• There is a follow up with WHO on ways to foster increased CRP implementation and improvements on PACs management.

• The group recognizes that with COVID vaccines new regulatory opportunities are opening up with regulators being open to more innovation, which could benefit other vaccines.

• 8 vaccines have been registered using CRP in 14 countries so far. Target of 16 has almost been met.

• There is also a RMP project ongoing. The e-learning RMP has been completed by 38 members.

• The target forward is to continue fostering CRP implementation to duplicate the number of countries adopting CRP. BeH pointed out that some efforts need to be made to expand it beyond Africa to other continents.

• DK suggested to take to the Board the issue of finding a way to drive the CRP through the distribution of COVID vaccines by DCVMN. PT noted that the Board shall discuss on how can we capitalize on the gains that we have made in certain areas in the way of working, recognizing that not all of them can be extrapolated to peace times. RP suggested that it could be quite useful if a similar process could be applied to EUL.

• LV updated on the 3Rs WG activities and discussion of 2 interesting case studies shared by some members; one on the implementation of Tetanus-Diphtheria dilution assay and one for the Hepatitis B potency assays. 2 Workshops will be created to go more in depth in the implementation of these two assays. Closer collaboration will be sought with the Regulatory WG for implementing these assays as part of the batch release tests. There is also the objective of having business cases demonstrating that the implementation of non-animal testing can reduce costs and time frames. This information will be added to the paper being prepared.

• LV updated on the progress of the PSPT project, now at a stage of implementing the test to see if this test is able to detect sub-potent lots. Raw data from all laboratories will be collected towards the end of the
year. 60% of the budget has been spent; discussions are being held on how to use the remaining budget because in-person meetings scheduled were not held due to COVID. LV is managing a no-cost extension of the grant with NIIMBL. An option is to develop VR trainings for this test. The members have been fully engaged with the project. RP and PT congratulated LV work.

4. **Access to expertise update:** SC reported the attendance of members to 6 webinars which took place in Q3; noting slight decrease in the number of participants with respect to Q2. The average number of companies attending remains the same and the average number of countries increased. There was a decrease in the Portal Consultants views and in the Portal member collaborations views with respect to Q2.
   - For Q4 there are 4 webinars scheduled.
   - SP added that for the webinar initiative, the fact that the webinars are now being managed by SC, who is staff, the funds form the grant originally assigned for this activity need to be reallocated. Face-to-face workshops have not been happening and thus are also leaving funds to be reallocated. PT said that this will be an ongoing issue.

5. **Technology adoption through AGM (for information):**
   - BH updated on the advances of the AGM organization. The team has been closely working with the platform supplier, and everything is progressing in the right direction. 70% of speakers have confirmed. Several VVIPs are still awaited, for their confirmations. Sponsors are working on the booths. The agenda will be released today. SV added that the registration link has been shared and up to this morning 189 persons had registered.
   - BH mentioned that two articles have been accepted for publication in Vaccine, mainly about the involvement of the DCVMs in the COVID-19 capacity; hoping this can create some value for the network and draw some attention to our members.

6. **Pharmacovigilance (for information):** LN updated on the PV WG activities. The group had 2 telecons. The feedback received from the PV training is excellent as they have been focused on vaccines PV and the standards required for a robust PV system (3 workshops were held in Q3). There is a challenge for COVID vaccines for which many adverse events have been reported for almost all vaccines. Safety apps for AEFI reporting have been created in some developing countries and policies have been created to encourage people on reporting AE; a white paper is being prepared on these. 4 members have shared their experiences on their PV systems.
   - 6 RMP workshops were held and are preparing a Q&A document and for the final project to be reviewed by an independent regulatory expert.
   - PV monthly trainings will continue until Nov 2021, and will continue with the implementation of open and closed forums to support DCVMN’s PV needs with COVAX support.
   - DK asked if crisis communication at all was addressed as a need or is that downstream from this work. And also asked if there is a gap in having access to subject matter experts in that specific adverse event and if it is something that the DCVMN can provide to all of its members. LN said this gap is trying to be addressed with the COVAX support as it has open and closed forums for companies to have quick access to consultants to address their needs. In this context LN added that there is some need for training on Brighton case definitions and PV governance.
   - Next DAC meeting will be held on December 1st and each activity holder is expected to propose work plan for 2022 with budget.
   - PT closed the meeting by thanking the hard work of the initiative holders in spite of COVID-19 challenges.

**Nyon, September 1st, 2021**

Patrick Tipoo, Chair of DAC and Vice-president DCVMN
DCVMN Donors’ Advisory Committee Quarterly Meeting: Q3 2021

Three main goals:

1. Training program
   - Virtual/remote courses
   - Hybrid live/virtual courses

2. 6th DCVMN Hub Collaboration
   - Global COVID-19 Vaccine Global Hub

3. Technology adoption through AGM
   - 7th DCVMN Hub Collaboration
   - Virtual acceleration of vaccine development

DRAFT interim Financial Updates - Q3-2021 (tbc)

DCVMN Summary of 8 grants from January 2019 to 23rd August 2021

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Update @ Q3:

- Virtual/remote courses
- Hybrid live/virtual courses
- Global COVID-19 Vaccine Global Hub
- Virtual acceleration of vaccine development

Decision points:

- Approval of the final report and accounts by donor

Overview:

- 2019-2021 6th DCVMN Hub Collaboration
- Virtual/remote courses
- Hybrid live/virtual courses
- Global COVID-19 Vaccine Global Hub
- Virtual acceleration of vaccine development

Next steps Q3:

- Virtual/remote courses
- Hybrid live/virtual courses
- Global COVID-19 Vaccine Global Hub
- Virtual acceleration of vaccine development

Acknowledgment to DCVMN secretariat & consultants
Training (3): E-learning programmes NUS

- E-learning on Clinical & Trial site visit
- E-learning on Regulatory
- E-learning on Clinical Studies
- E-learning on Clinical & Trial site visit
- E-learning on Regulatory
- E-learning on Clinical Studies

Health Products Regulation and Licensing Administration.
- E-learning modules on CLA.
- E-learning on MRA.
- E-learning on Clinical & Trial site visit
- E-learning on Regulatory
- E-learning on Clinical Studies

DCVMN Clinical Affairs Survey

Following a proposal from clinical trials resource network members, with the support of clinical trials, DCVMN discussed the inclusion of a new module on clinical trials and regulatory affairs.

Survey launched on 1st July, inviting all 45 members to respond, extended to 14th August 2021.

88 companies (48% responded to the survey; 88% participated) or 30% of all members who had ATP/field experience. The feedback received from ATP companies did not consist of 88% of all survey participants.

- Response rate is considered good; a higher percentage of members are encouraged to participate.

- Report of the survey to be submitted as open access after discussion in November by the DCVMN.

Webinar to discuss results with DCVMN members scheduled for 12th October 2021.

DCVMN Clinical Affairs Survey

Overview @ Q3 - 2021: Regulatory

Next steps:
1. Establish a CSEP implementation and management
2. Increase number of members in CSEP through engagement and outreach
3. Improved CSEP management for CSEP through engagement and outreach
4. Share with NACs and CSEP data collected by CSEP

3. Regulatory Convergence

Decision/description points:
- No dangerous agent
- Clinical evaluation of resources used will be given
- No draft guidance
- Strategic plan will be given
- No draft guidance
- Strategic plan will be given
- No draft guidance
- Strategic plan will be given

Planning Rest of 2021:
- Translational
- Member 6 feasibility plans
- Host regular meetings of the Consortium to exchange experiences
- Document the experience of the first year
- Co-organize a networking event
- Update the Q4 of 2021 paper

Updates @ Q3 - 2021: Regulatory

- Eight countries are represented in the CSEP: 34 countries. Target reach: 30 countries. (Up from: 30 countries)
- PM-linked to develop a robust framework for CSEP implementation and management of CSEP.
- DCVMN CSEP will publish a draft on 15th November 2021
- E-learning on Regulatory
- E-learning on Regulatory
- E-learning on Regulatory

2. Sharing Best Practices

- Translational
- Development
- Packaging innovations

Update @ Q3:

- Four companies have signed up to the transatlantic consortium.
- Two additional feasibility plans are in the pipeline
- DCVMN will share the details of the consortium on the DCVMN website

3. Regulatory Convergence

Overview @ Q3 - 2021: Regulator

- Focused on regulatory issues
- No draft guidance
- No draft guidance
- Strategic plan will be given
- No draft guidance
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- No draft guidance
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Planning Rest of 2021:
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Discussion & Next steps

- Budget is not aligned with implementation, e.g. supply chain 100K USD was approved for traceability, one 50k proposal approved by independent review group, and 50% (25K) disbursed, but 27Kx VR pending.
- Budget reallocation to new initiatives/activities?
- In Q4 present 2022 plans for approval per initiative:
  - Training (EF workshops?)
  - Regulatory
  - Industry
  - Webinars
- AGM (hybrid)

*Update Kristofer, SL@Techno, Ben, Piers, KB&I