Participants: Adrianzjah Azhari (AA), Benjamin Pierce (BP), David Kaslow (DK), Eunjung Kim (EK), Fernando Lobos (FL), Kelvin Lee (KL), Lingjiang Yang (LY), Patrick Tippoo (PT), Bernadette Hendrickx (BeH), Katharina Hartman (KH), Laura Viviani (LV), Benoit Hayman (BH), Rajinder Suri (RS), Sivashen Cunden (SC), Sonia Pagliusi (SP), Steve Jarrett (SJ), Sunil Gairola (SG), Sonia Villaseñor (SV).

Excused: Tiago Rocca (TR). Meeting started at 15h05 CET and adjourned at 16h32 CET.

PT chaired the meeting and welcomed all participants.

SP acknowledged the secretariat team and expert consultants’ group for their support throughout the year.

1. Training initiative: SP summarized the outcomes of the Training initiative, including the e-learning programmes. There were 4 e-Workshops in Q4, with high participation of member companies. E-workshops will continue in 2022. Regarding the ongoing collaboration with NUS, 19 certifications were completed, 8 are pending and 2 dropouts, from 15 companies. The NUS graduation program on the Regulation of health products, there were 10 enrollments from 6 companies, obtaining academic certificates in Q4. There is continued interest for 2022. SP then presented the results of new VR tools for QC lab assays: 4 sets of VR we developed and shared through links (included in the slides). VR tools are now available for implementation and further development, which will be led by LV and SC in 2022.

MedDRA support initiative (for advice/decision): SP informed that the Clinical Affairs survey, initiated in Q3 was completed and analyzed in Q4 with the support of a consultant. The results are to be discussed with a new group of members, forming a Clinical Working Group. One of the proposals is to facilitate the use of MedDRA (Medical Dictionary for Regulatory Activities), for companies to learn more about. It is a mandatory tool for submissions in ICH countries. SP proposed to facilitate the subscription for 1 year for ca. 10 of the member companies, which expressed not having access to it and interest in knowing it. Eligibility criteria is to have a revenue of less than 500 million USD annually. Estimated budget is ca. 47,000 USD. No objections were received, the proposal was approved.

7. Hilleman initiative. RS presented the initiative “hands-on” training program for Tech-Transfer, by Hilleman’s Lab in Singapore. The program is aimed for 15 people from DCVMN members (5 companies and 3 members from each company) in a 10 days program in tech transfer for viral and bacterial vaccines. The budget proposed was of 160,000 USD (100,000 USD to Hilleman + 60,000 for travel/lodging for participants). A demonstration of mRNA will be sought, but it is not yet confirmed. The program will be carried out in May, 2022 and depending on the success, a similar project may be proposed for Latin American companies. RS said the ideal would be to repeat it, for LATAM and Africa, and then in 2023 replicate it in a larger scale, but it would be subject to budget approval.

AA encouraged to look for the training for mRNA technology. RS said that was the original aim, but since Hilleman is not expert in mRNA for the moment, it may be added in the future.

DK asked how this fits in a larger landscape, where WHO has launched the mRNA Hub in Africa. RS said mRNA Hub in South Africa is likely to be ready for training in Q4 2023. These 2 years to go could act as precursors for those advanced training programs. However, this has to be an integrated approach.

KL asked if there is a plan to see how the contents and curriculum will be developed, if it would be based on pre-existing programs and on how will the program be assessed. RS said that Hilleman has been training people from developed countries, but it seems they have the content and curriculum, but at the same time, we would like to ascertain the facilities and program so to evaluate if the content and curriculum can be improved. Maybe PATH could help us find out if there are other similar programs in other parts, and see if there is a curriculum available so that we compare and see which are the best practices to be deployed and integrated in this program.

PT endorsed the program and the idea to evaluate and measure the success of the training program. He also asked if as preamble of this proposal we should do a landscape analysis of some of the players active in this domain, e.g. BIO, IVI, Korea, mRNA Hub in South Africa to understand who is doing what, and find the differentiation, and based on that refocus the Hilleman’s proposition. Finally, DK asked on how is going to be decided in terms of selection in case we receive more than 15 submissions. RS said that the invitation will be
circulated to all DCMVN members with a fixed criteria for selection, in consultation with experts, particularly with PATH and based on it, decide how many of them are qualified. Then, based on the level of maturity of the company, the ones less developed will be prioritized over the more mature ones. Based on that a merit list will be prepared and the first 15 will be selected. The rest of them will be put in waiting list for future programs. The DAC gave the approval to proceed.

**Linksbridge initiative:** RS mentioned a proposed data management course, launched by Linksbridge, together with CHAI. They collect information and do the landscape analysis of various vaccines in different marketplaces. This could be a very useful input, particularly for LMICS, who have no idea of criteria used in these markets, nor what kind of market is available for a particular vaccine, and what kind of information is required to succeed. The training would be on how to read, interpret and use this information. It is the entire spectrum of information including demographics, kind of product and presentation, pricing strategy adopted, quantity used in the public and private markers. It is an analytical tool for vaccine in particular countries. DK questioned as he considered this gets out of DCMVN charter, being competitive market data. RS confirmed that even though it is purely marketing information, he requested the DAC to start expanding the scope, as it ultimately helps bring a range of vaccines at affordable prices.

PT suggested that in terms of procedure, it might be worth examining and investigating if it should fit within DCMVN mandate and then escalate it to the DCMVN board for confirmation.

- **Supply Chain WG /Traceability project:** SJ summarized that 6 companies have joined the Traceability Consortium, one more has signed. In total 6 pilots, 2 por primary packaging and 4 for secondary. 3 are self-financing and 3 with partial DCMVN support. The pandemic has caused implementation delays in due to travel restrictions and, so it was decided to extend the Consortium through to June’22 in order to finalize the pilots, plus time to assess the lessons learned in the implementation of barcoding, looking forward to publishing them.

- In terms of stockpiling, the peer-reviewed paper came out in Vaccine earlier in December. Cf. [https://www.sciencedirect.com/science/article/pii/S259013622210003X](https://www.sciencedirect.com/science/article/pii/S259013622210003X)

- In addition, the group is looking at warehousing system innovation, which is looking at the traceability of the flow of materials throughout the production process, looking at intermediaries, semi-finished products, final products so there’s and integration in the traceability of all those steps. And make a position paper.

- The other aspect is having PATH to give a workshop by end of Q1 or beginning of Q2 for our members to have a better understanding of where some of the innovations in packaging will be coming and get their feedback and interest on that; e.g., blow fill seal, prefilled devices. DK supported these initiatives.

2. **Regulatory convergence 3R:** LV updated on the 3R WG:

- In order to increase the active participation of the members in the 3R WG, LV will launch a new project in Jan 2022 for the DT-containing vaccines single dilution potency assay. This will reduce the number of animals for potency testing, as well as the time needed. The project will start with a workshop and from there she will evaluate if there will be enough members committing into this implementation project.

- The idea is to ensure that the members are as much active as possible, not only with the network but participating in external endeavors, with a lot of activities, projects and discussions ongoing.

- **PSPT consortium:** LV mentioned that she has requested a no-cost extension to NIIMBL, and still waiting for the response, in order to complete some of the pending activities in 2022, as a couple of laboratories had issues with some critical reagents’ supplies. Within the no-cost extension activities are to secure a bit of support to laboratories that would like to do validation studies of this assay. Although these validation studies will not be supported by DCMVN, we can follow their activities. A face-to-face meeting is planned for the end of Q2-2022. The results of this meeting will be extended to our stakeholders.

- **Regulatory convergence:** BH explained that even though the CRP is a priority, and there is a lot of goodwill from the members, it is difficult to have feedback from WHO. There is a need to have a meeting with the RSS team and seek an agreement on how to proceed swiftly, and according to what they want. This will be discussed also with IFPMA and then think about an extension of the CRP to PV as a next step.
• BH also mentioned other topics that will be addressed, like manufacturing, quality and COVID-19.
• They are also working on the risk management plan (RMP), which was asked for the members to submit. 7 dossiers have been received and one more is expected. They will be reviewed together with KH and Peter Niels; but BeH considers they give a good picture of on how companies work and tackle RMP.

3. **Access to expertise update:** SC reported the attendance of members to 4 webinars which took place in Q4. The average number of connections was slightly lower than in Q3.
• For 2022 the plan is to increase attendance by inviting the attendees with the relevant background, so the relevant questions are asked and can be taken further to focus the content of topics that members are interested in. The plan is to have 30 webinars in 2022, so to have a sponsor’s webinar each month and also relying on partners like PATH, CHAI, ICH, HIS, NC3Rs holding bimonthly webinars.
• PT questioned about having so many webinars, as it might cause webinar burnout. SC assured that is the reason for having targeted invitations per area of expertise within the member companies.

4. **Technology adoption through AGM (for information):**
• BH updated on the results of the AGM as shown in the slide. The feedback received was very positive.
• BH said a survey is in process to be conducted to assess on sustainable manufacturing. DCVMN wants to identify the current capabilities and the gaps existing, so to match with international organizations who can help reduce these gaps.
• A workshop with CHAI is planned for Q1 2022 on opportunities in MICs and developing commercial case.
• Support from CEPI on a regional workshop for match making.
• SV presented the workplan for the AGM. Still to be defined if it will be hybrid, if there will be a host, define the dates. PT said it is maybe too early to think on a hybrid or face-to-face meeting.

5. **Pharmacovigilance:** KH said in Q4 there were the last 3 workshops of 9 on PV training with PATH.
• A survey was conducted and a discussion in COVAX vaccine safety group to stress on PV systems with COVID-19 vaccines. The challenges are similar within companies, mostly for manufacturers than for only distributors.
• The items to tackle in 2022 are safety management in clinical trials, active vaccine safety surveillance, benefit risk-assessment, and also continue with PATH training, who has joined the WG.
• PT asked KH about the level of interest and engagement from DCVMN members. KH said it would be desirable that companies collaborate more with each other and interaction.
• DK mentioned that international conversations are appointing towards immunobridging for new COVID-19 vaccines and most importantly the commitment for post-licensure of the vaccine effectiveness. KH said the idea is to get first this concept to understanding of the members and then do it continuously. DK asked on how urgent is an issue for DCVMs in this second wave to get support to work on vaccine effectiveness. RS said this is an area we would need to work a lot as it is going to be a big challenge particularly with variants emerging, and requires full attention from the manufacturers and from DCVMN and consultants to provide the right information and training available to respond to this challenge. DK suggested conducting a survey with the manufacturers asking how big is this going to be an issue or barrier for them, if they decide to go to the immunobridging regulatory pathway and if this is something DCVMN could help.
• RS shared the budget for 2021 and up to June 2022. The disbursements from 2021 will be very close to the budget. The revised SOW will be shared on Monday. By the end of January, we will enlist the activities for the second half of 2022.
• SP presented a cascade chart showing how the grants spent, per activity and per year.

**Nyon, December 10th, 2021**

**Notes taken by S. Villaseñor**

Patrick Tipoo, Chair of DAC and Vice-president DCVMN
DCVMN Donors Advisory Committee
Quarterly Meeting: Q4 2021

Welcome:
Welcome to the DCVMN Donors Advisory Committee meeting.

Three main goals:
1. Development of a new training module on a specific topic.
2. Updating of existing training modules.
3. Development of new training initiatives.

Support available to secretariat:
Support available for implementation of training initiatives.

DCVMN Donors Advisory Committee
Quarterly Meeting: Q4 2021

Acknowledgment to DCVMN secretariat & consultants

Training [1] - eLearning Moodle platform updates


DCVMN-NUS collaboration on Clinical & Medical Affairs training:
- 29 enrolled from 15 companies.
- 19 completed certifications.
- 8 still ongoing.
- 2 dropout: left company (BoM) no follow up possible.

Conclusion & Proposal
Acknowledging that MedDRA is a mandatory coding tool for all AEFI submissions in ICH countries:
- DCVMN international secretariat proposes to facilitate the MedDRA access by sponsoring the subscription for members to explore its relevance, enabling access to professional training for 1 year for companies.
- Please do not delay in application, and
- A minimum of 600 million USD annually.

This proposal seeks the endorsement of the Donors’ Advisory Committee

Thank you for your consideration.
Sonia & Katharine
7. New initiative! "Hands-on" training programme for tech-transfer, by Hilleman's Lab in Singapore

- On April 2021, a Hilleman Laboratories Centre of Excellence for Vaccines and Biologics was established in a partnership with the Economic Development Board, that uses Hilleman's art laboratory facilities and leverages access to a strong and expert talent pool of scientists and engineers and a rich network of local partners and collaborators that will enable Hilleman to deliver on its commitment to the Government of Singapore while continuing to fulfill its mission of developing novel vaccines and biologics for developing countries.
- The programme developed by Hilleman will provide hands-on training to 15 DCVMN participants for 10 days, focusing on procedures for fermentation.
- Budget: $18,000 USD ($180,000 USD to Hilleman for materials/tutors + 60,000 for travel/looding for participants)

3. Regulatory Convergence

4. Access to expertise

5. Technology adoption through AGM
DCVMN Donors Advisory Committee minutes
TC of Friday December 10th, 2021

5. Technology adoption through ASM

Planning End 2021/2022

Decision/Discussion points:

- What are the key barriers/limitations to DCVMN entering ASM markets?
- How can DCVMN support increased adoption in other ASM markets?

Implementation of NPIs

6. Pharmacovigilance

Update @ Q1 2021

- P42/decision with WHO
  - Regular updates
  - Signal and risk management
  - Risk management
  - Health Risk Assessment
  - P42/decision with WHO
  - Final draft of the report
  - Review of the current P42 by independent regulatory expert
  - Some “temp” on the P42

- 5 th P42 (15th Dec. 2020):
  - Discuss the challenges encountered by P42 due to the high workload of this pandemic
  - Discuss the next steps for support to safety pharmacovigilance

Discussion and Conclusions

Realisation of PATH funds for pandemic

Most figures in this document in no allocations

For approval: carryover to ’22

Opening the PATH grant

- Reimburse 1st instalment: 11/16/15 USD
- Reimbursement of funds as per budget
- Reimbursement of funds in accordance with USD by which
- Reimbursement of funds in accordance with USD by which
- Reimbursement of funds in accordance with USD by which

From PSPT [IMB] grant

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Expenditure as at 10.11.2021

| Expenses as at 10.11.2021 | -121755.45 |

Thank you