Participants: Adriansjah Azhari (AA), Ben Pierce (BP), Fernando Lobos (FL), Hannah Kettler (HK), Jongho Park (JP), Patrick Tippoo (PT), Tiago Rocca (TR), Katharina Hartman (KH), Laura Viviani (LV), Nora Dellepiane (ND), Benoit Hayman (BH), Rajinder Suri (RS), Sivashen Cunden (SC), Sonia Pagliusi (SP), Steve Jarrett (SJ), Tana McCauley (TM), Sonia Villaseñor (SV).

Excused: Kevin Lee (KL), Ray Prasad (RP). Meeting started at 15h00 CET and adjourned at 16h12 CET

PT chaired the meeting and welcomed all participants.

SP gave an overview of the financial implementation status of grants DCVMN has received from January 2019 through 30th April 2021. The table showed the 4 major wards received in cash so far: Gates Foundation, Imperial College, PATH and NIIMBL, around 2.2 million USD. The Gates Foundation grant and the PATH grant are linked, and we aim to finalize the Gates funds by Q3, before using the PATH funds. As previously discussed, the Imperial College grant, after 6 months no-cost extension, will wind up on 31st July 2021, and funds allocated will go directly to 2-3 members who voluntarily engaged with the Hub, because of the time pressure. The PSPT grant implementation is on target, at ca. 50% implementation, as planned.

1. **Training program (for advice/decision):** SP gave an overview of the 4 training programs: Workshops, academic NUS-Core regulatory courses, Moodle e-learning courses and Virtual Reality (VR) courses. Implementation statistical details are available on attached slides. SP asked advice on VR project. A link has been shared to the DAC members to look at the 30 sec VR video on pipetting steps to the MAT test, in collaboration with Laura Viviani and ISSI, made by experts at the University of Luzern (Switzerland), which costed around 4,000 USD. She asked the DAC members if we should finalize the VR, which may be used next year, if we gather for in person meetings with members, and it can be uploaded on YouTube. KL provided his support (cf. attached email) and HK expressed support as well. There were no objections to finalize the VR for future training. SP will follow up with the University experts to finalize the 30 min VR in Q3. PT acknowledged SP’s work and dedication to the training program.

2. **Supply Chain WG /Traceability project (for information):** SJ informed that the Traceability Consortium group is advancing, the first meeting will take place next week with four member companies that are actively engaged in traceability pilots and GS1 service providers already selected for each. There is a 5th member working on traceability but has not yet decided if they will join the consortium. It was noted that there may be some delays due to the Covid pandemic. By June-July the pilots can start moving.
   - A workshop on stockpiling was held on 31st March with +50 participants (cf. https://dcvmn.net/Supply-Chain-Stockpile-workshop), 5 members presented their views on stockpiles, and a report has been prepared and is expected to be sent for peer-reviewed publication. The WG will continue with traceability and other activities related to supply chain.

3. **Regulatory convergence (for information):** ND updated on the two main objectives:
   - To expand the use of the Collaborative Registration Procedure (CRP); this year 1 additional vaccine was registered in 4 additional countries, while the objective is 16 countries for this year the procedure is already used in 12 countries.
   - The group will pursue the work on variations within the CRP procedure; we need to help WHO improve how the variations are managed in this context. A task force has been established within the Regulatory WG to accelerate work in this respect, called “PACs task force”, constituted by representatives of 3 companies that have products approved by the CRP (BBL, BioE and SIIPL).
   - In collaboration with the PV WG, the RWG established the Risk Management Plan Project (RMP). A Moodle course in RMP has been developed and is already successfully running. 10 companies have joined the RMP project to develop a real-life RMP between May and December 2021. The project was launched on the 17th of May and the first technical workshop has taken place on 31st May. 3 PV expert consultants have been engaged, with slightly different expertise (Regulatory, R&D and writing) and will be involved in all the meetings at the same time. ND then gave some details of the next steps for these projects to continue advancing.
• ND announced that she will stop supporting DCVMN at the end of July. She has been working with the Regulatory WG for them to take ownership and to continue working on these projects. The RMP project will continue with KH support until the end of 2021. PT thanked ND support over the past years.

• HK asked which actions are being taken to ensure the members take ownership of the projects before ND leaves. HK also asked if there is a variety of member companies involved in the different projects or if there are always the same companies benefitting from the projects. ND said the manufacturers understand that the CPR will bring advantages to members, regulators and WHO; so they are engaged. Few manufacturers in the group are stronger and can take the lead of the RWG. Having a facilitator would be very helpful. Regarding the RMP it is a more diverse group, and the challenge is that they have to work and bring questions to the workshops. SP added that the CRP applies for the manufacturers that have PQ vaccines and share their experiences to others, while the RMP group is broader with 10 member companies engaging (cf. https://www.dcvmn.org/Project-Participants-List).

• RS thanked ND for her work. He agreed that a facilitator will be required for the Reg WG, which is one of the most critical fields. HK supported the idea of having a facilitator.

• LV updated on the 3Rs WG activities and discussion of some successful case studies from some members in the implementation of 3R or refinement opportunities. The group has now 3 new members. The group has drafted the results of the 3R survey, which was shared with the DAC, confirming the priority areas of interest for the different manufacturers to adopt 3Rs tools.

• LV reported the progress of the PSPT project, now at a stage of shipping the coating antigen to all 11 laboratories, so that they can start testing in June (cf. https://dcvmn.net/-PSPT-consortium-57-). The project not only assesses the feasibility of this specific refinement test now, but will also allow the continuation of the future testing activities, and the validation of this methodology in the future. DCVMN paid for the production, characterization and distribution of this critical reagent. The group is exploring options on how to manage this reagent in the future. Results will be presented on Q3 to discuss and decide the option to handle the available antigen material.

4. **Access to expertise update:** SC took over the scientific webinars from Maureen, and reported the attendance of members to 4 webinars taking place in Q2, noting an increase with respect to Q1, the number of companies attending has remained the same. There is one webinar scheduled for Q3 and 3 for Q4.

• PT asked if we have some feedback of the value derived to members from these webinars and if there is a request for specific topics? SC said that attendance appears higher when there are large organizations presenting, like CHAI and CEPI; for the post-webinar surveys we don’t actively seek attendees’ inputs. HK asked if there is an agenda of contents we want to cover. SC said it is more on the line of what partners want to share to members manufacturers.

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

• BH updated on the assessment of the needs of all the manufacturers on technology platforms, regulatory, supply chain, and quantify what support mechanisms they require, e.g. tech transfer, funding, training, etc. in order to create a strategy. Results highlight interest in COVID-19 vaccines, RNA technology, formulation, and Phase III trials as key areas for which manufacturers need support. The report was submitted for peer reviewed publication 2 weeks ago, and should be out in the coming weeks. HK commented that it will be helpful to have it in the public domain.

• SV updated on the advances of the AGM organization. The dates have been established for Oct 19-21 for a 100% virtual event. Biovac will be co-host. The focus will be on Africa. The draft agenda is being finalized. The proposal includes 3 days, and 4 hours session per day with a 30 min break. Platform vendors are being evaluated and selection will be finalized in June to start registration; important features to look are polling, booths and networking.

6. **Pharmacovigilance (for information):** KH updated on the PV WG activities, including telecons, RMP project, follow-up on COVAX support to DCVMN PV needs, COVAX/WHO vaccine safety PV webinar
planning. 3 PV training workshops have taken place in Q2 (see training initiative slides for details). The COVAX/WHO RMP webinar took place in April with a total of ca. 300 attendees and ca. 20 DCVMs attending. Next steps include the monthly PV training until Nov 2021, pursue the RMP project and the continuation of implementation of the open and closed forum to support DCVMs needs, with COVAX support. There are plans for activities to cover further PV needs, to be presented in Q3.

7. **FMVR Hub Collaboration (for information):** BP had left the meeting at this point. SP updated that the grant from the Hub has provided support to 6 companies and to 4 international workshops on technologies and supply management. Their funds (ca. 170K GBP) need to be disbursed until the end of July 2021, and the need for support was explored with members already voluntarily engaged with the Hub; only 2 manufacturers sent adequate proposals (Incepta and Vabiotech) and will be funded directly by the Hub, to speedup disbursements (e.g. 80K and 95K GBP). CNBG proposed an extension of their project for ca. 40K GBP, and is under discussion with the donor.

- SP mentioned about the project of establishing a Clinical Affairs WG, approved by the advisors at the Q1 meeting. SP is in contact with two clinical expert consultants, waiting for their proposals. They will start by making an assessment within the membership to identify the gaps and needs in this field, as a basis to create a WG and agree on priorities to be tackled in this area. The assessment will be designed by these consultants. Will be applied by secretariat in July and results will be available in August.

Nyon, June 1st, 2021

Patrick Tipoo, Vice-president DCVMN

Notes taken by S. Villasenor
2. Sharing Best Practices: Supply Chain

Overview:
Transparency
Stockpiling
Packaging Innovations

Update Q2:
- Transparency: Four companies have signed up to the Transparency Consortium. Three transparency pilots are in the planning stage, with GS1 service providers already selected for each.
- Stockpiling: The supply chain group held a 2-day virtual workshop on stockpiling 30-31 March with presentations from 3 manufacturers and UNICEF Supply Division and with 46+ participants.

Decision/discussion points:
- No decision required.
- Next: TSC to review experience in vaccine stockpiling. Hold regular meetings of the group to continue to identify solutions affecting the supply chain.

3. Regulatory Convergence - Regulatory

Overview:
- Next steps:
  1. Continue to foster CIIP implementation toward the targeted number of countries adopting CIIP
  2. Increase the number of countries registering CIIP through CIP from more manufacturers
  3. Improved CIIP management for CIIP registered countries
  4. Collect information from manufacturers and share with WHO, the opportunity to discuss CIIP gaps
  5. Avoid DCVMN to improve their capacity to prepare Risk Management Plans for vaccine safety and efficacy
  6. Start project proposal writing workshops: smoothly until end of the year

Decision/discussion points:
- No decision required.
- Next Q3: analyzed data on use of CIP, implementation of CIP, partnership, and recommendations for collaboration initiatives.

Update Q2:
- No decision required.
- Next: Work on the draft.
- TSC to discuss the paper.
- Revised draft should be ready for submission to regulatory authorities.
- Work on the draft should be completed by end of June.
- All TSC members to review the draft and provide comments.