

**Attendees:** Alexander Precioso (AP), Viska Indriani (VI), Linda Nesbitt (LN), Sonia Pagliusi (SP), Katharina Hartmann (KH), Tana McCauley (TM) minutes.

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**AP started the meeting at 13:03** by welcoming all the participants.

**1. Approval of the minutes of the PV WG meeting on December 16, 2020**

The WG approved the minutes of the previous PV WG meeting. SP suggested circulating the draft meeting minutes for comments 24 hours after the meeting. Participants should then be given one week to comment on the minutes. After one week has passed, and a final 24-hour no-objection clearance, the WG Chair can sign the minutes, which can then be uploaded on the DCVMN webpage.

**ACTION:** signature of the December 16 meeting minutes and upload them on the DCVMN website.

**2. Follow-up information on the COVAX Vaccine Safety WG to support DCVMN needs, based on the outcome of the December meeting**

AP updated the WG on how the COVAX VS WG could further support DCVMN members in their COVID vaccine safety efforts. COVAX support would help DCVMN members with their overall PV issues. Over the last 2 COVAX meetings, a proposal has come up where the COVAX VS WG would be open to supporting members through 2 types of forums: an open forum and a closed forum. These 2 forums would allow DCVMN members to bring up their issues/questions and show what they need in terms of support. In the open forum, general issues can be discussed that are not confidential. The closed forum will be based on confidentiality agreements and would be an opportunity for members to address specific safety and PV issues. AP underlined that it would be important that DCVMN members develop a list of their needs, which could guide these two forums' organization. With this list, open forums could be organized first and then a more specific agenda for the closed meetings could be established. KH added that the closed forum would be strictly confidential, with access to specific experts. These forums would also be open for everyone, not just COVID vaccine producers.

LN gave the example of a vaccine where the neurological effects would need to be categorized and asked if that would go to the closed forum. KH responded that it would go to the closed forum. AP added that other members could have similar questions.

As COVAX is a specific entity of ACT for COVID vaccines, SP asked if COVAX would discuss vaccines that are not COVID vaccines. KH replied that the goal is to help manufacturers in low and middle-income countries to get up to speed with the vaccines they are developing. AP recommended asking for further clarification on this subject.

AP noted that the idea to have an open and closed forum was first discussed in a previous DCVMN PV WG meeting. COVAX found the idea interesting and would like to make the forums available to members.

AP asked SP for her opinion on engaging DCVMN members in this project. SP replied that engaging members is easier when there is a project on a topic that would be a priority. For COVID-19 vaccines, there is a need regarding handling the data, as safety statistics are not implemented in some companies. The offer from COVAX could help the whole network in handling safety, efficacy, and quality data. KH agreed this is a concern that can be discussed in the closed sessions. Getting the safety data out of the trials that they can be analyzed in a systematic manner can be difficult and setting up the clinical trials' integrated safety database is a difficult task.

SP noted that closed consultations might be more interesting than the open forum for DCVMN members. KH said that the format for monthly safety reports (discussed during the last meeting) would be an example of a question for the open sessions. SP suggested starting with this issue, as it is more engaging if the sessions focus on a specific issue. Manufacturers with specific needs would attend if specific issues are being addressed at the forum.

LN explained that South Africa is getting the AstraZeneca vaccine via the COVAX facility and asked if this could be discussed with COVAX. KH stated that for COVAX health data management, however, in this case

be looking into safety issues as they are doing the training for regulators in the countries where COVAX is distributing vaccines.

The WG members agreed on the usefulness of the COVAX's support. LN noted that it would be an excellent potential environment to discuss safety issues regarding clinical trials. LN also suggested sending out a general email asking people to bring back their questions. The WG agreed to send an email to the members. ACTION: LN and AP agreed to send an email to members about COVAX's support

**3. Presentation and discussion of an RMP e-learning course and a following interactive program training plan in cooperation with the DCVMN Regulatory Working Group**

KH shared the proposed initiative on risk management planning in collaboration with the DCVMN Regulatory WG. KH explained that mainly people working in regulatory affairs respond to risk management, and it may not get back to PV. KH asked the WG for their comments on the initiative.

AP believed that the initiative would benefit many members. LN agreed on the usefulness of the collaboration with regulatory colleagues and the practical aspect of the training. VI noted that getting feedback on the RMP will be very useful.

The PV WG endorsed the proposal. KH will liaise with Nora to communicate the approval of the endorsement.

**4. AOB**

AP suggested the WG have more frequent meetings. The WG decided to organize monthly calls. LN noted that it is essential to meet regularly to discuss the response to COVAX. The next call was set for March 2 at 11:00 CET.

**AP closed the meeting at 14:10** by thanking all participants.

*Alexander Munnich*