

**Participants:** Linda Nesbitt (LN), Viska Indriani (VI), Katharina Hartmann (KH), Varun Sharma (VS), Paulo Takey (PT), Hongde Xie (HX), Rajinder Suri (RS), Sonia Villaseñor (SV)

**Meeting** started at 1pm CET and adjourned at 2:20 pm CET.

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LN chaired the meeting and welcomed the team and went through the agenda and started the discussion of the topics.

1. LN gave an overview of the WHO-DCVMN CRP (Collaborative Registration Procedure) Joint Workshop held on 26-27 September 2022.
  - a. WHO indicated that Pharmacovigilance Reliance needs to be discussed separately, thus it was not discussed during the workshop
  - b. To the request of LN, SV will search if WHO slides are available for the group and will also follow up with WHO on the meeting minutes comments.
  - c. WHO added that PV will change brutally, and a WHO board will take place in Dec 22 to outline the changes on PV. After that meeting it will be known better about the impacts this will have on the manufacturers. The changes will most likely impact the way WHO works.
2. It was clarified, as a response to LN question that the DAC is composed by the donors that give funds to DCVMN, like PATH, BMGF, NIIMBLE, and some representatives of the members (Biovac, Biofarma).
3. VI presented the key learning & activities that she presented in the AGM.
  - a. The PV WG creates ad hoc projects. This was done through 1 to 1 meetings with the members.
    - i. Risk Management Plan Project. The final result is already published [RMP project - General Comments \(dcvmn.net\)](#)
    - ii. PV post-licensure training (PATH)
    - iii. Pre-licensure period: Clinical Safety Management
    - iv. Clinical development & Medical affairs WG collaboration. This was a FtF workshop held in June 2022. The result is a specific PV SOP master list with explanatory notes that was also published.
    - v. Active Vaccine Safety Surveillance. Ongoing project that will have training, members will prepare a protocol and will receive feedback from consultant. Results will be published.
    - vi. Electronic Safety Data Management. Ongoing project
  - b. Feedback received to the WG from Tiago Rocca at the AGM is that they have so many projects. VI emphasized that the learnings and results have been very valuable. The results are available at DCVMN webpage, specially from the RMP project.
4. LN informed the group about the WHO workshop held on October 20<sup>th</sup> about pharmacovigilance during the COVID-19 pandemic. “Leveraging the learnings and maintaining the momentum” and the topics addressed in it.
  - a. Feedback from WHO regional offices (PAHO, AMRO, SEA and Western pacific regions) on 3 topics: What infrastructures did they establish for PV during the

- COVID-19 pandemic. What changes that you worked on that they have maintained after the pandemic, and Are you ready for the next pandemic?
- b. Cohort event monitoring for safety signal detection after COVID-19 vaccines in Iran. 30K people enrolled for each vaccine (4 vaccines) to rate the incidence of SAE for each vaccine brand to estimate the incidence of AESI, reactogenicity and of COVID-19 infection for each brand. It is a prospective study, expensive and work intensive.
  - c. KH mentioned about the EU-M4all cooperation with WHO so that manufacturers can get scientific opinions on their vaccines intended to be marketed outside the EU. It replaces EU Article 58 ([Medicines for use outside the European Union | European Medicines Agency \(europa.eu\)](#)). It has not yet been defined if this approval will replace PQ. It now includes the post-licensure life cycle safety review of the project. Having the approval of a stringent NRA makes it easier to get approval in other countries.
  - d. AU Smart Safety Surveillance (AU-3S). 2 key success factors for their pilot were: a high level of sponsorship and engagement from the country NRA, they showed the value of the program by interacting directly with the EPI heads; managing to break down all the historic silos between EPI and NRA. Use of digital health tools with real time tech support.
- EMA has commissioned the ACCESS study (vACCine covid-19 monitoring readinESS) to obtain background rates for the identified AESIs ([Background rates of AESI - VAC4EU](#))
    - e. . This will be used on our Active Vaccine Surveillance project.
5. Lessons learned from the pandemic PV: Monthly safety summary reports (MSSR) and ADR reporting/ surveillance networks. There is a need to improve surveillance networks (e.g., TTS report cases).
  6. Active Vaccine Safety Surveillance (AVSS) project.
    - a. There is a training ready to be used on AVSS. Send out by 1<sup>st</sup> December a comprehensive outlook of this project, similar to what was done with the RMP.
      - i. Quantify interest of member companies.
      - ii. Propose face to face (hybrid) workshop in Q1 2023.
      - iii. Training, Discussion and a 3 months implementation exercise.
    - b. RS suggested to do it in Jan or Feb, but not beyond Feb.
    - c. RS requested to have an estimated cost of for the program in excel to separate the budget. Include: Suggested venue, number of people required in person and from which countries. Then SV can help to get the final numbers
    - d. It is important first to assess the interest of the members
  7. Maternal Immunization WG- IMmunizing PRegnant women and INfants neTwork (IMPRINT) (Nov 22)
    - a. Network of stakeholders aimed to provide assistance regarding vaccination in mothers and infants. Raise funds for prioritized challenges., post-doc fellowships for LMICs
  8. The group discussed on how to encourage more participation in the PV WG.
    - a. VS suggested 1 to 1 meetings to check with the most absent members if their absence has to do with the time of the meeting, and engage them with the WG and



- project (after they see the proposal of the AVSS project).
- b. Agenda can be shared few days in advance
  - c. Create updates to be shared with the WG members (newsletter). Invite short articles from the members with regional updates.
9. Rotation of Chairperson. RS informed all the WG will be reconstructed for 2023. Nominations will come from the companies and from the current members, who can continue if desired.
10. RS requested KH to check with Alexander the status of our proposal. KH suggested to ask also the CEPI EPI group for support for the AVSS project.

**Linda Nesbitt**  
**Chair of the**  
**DCVMN PV WG**

*Linda Nesbitt*

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