DCVMN
Pharmacovigilance WG Minutes

February 25th 2022

Attendees: Linda Nesbitt, Viska Indriani, Maria Beatriz Lucchesi, Paulo Roberto Gomes Takey, Chetanraj Bhamare, Phan Honghoa, Hongde Xie, Dr. Yuvraj, Varun Sharma, Katharina Hartmann, Rajinder Suri, Sivashen Cunden
Apologies: Lei Zhang

Welcome and AOB

- Linda Nesbitt (LN) welcomed all new members to the WG and new members introduced themselves and provided their organization affiliation.

1. Pharmacovigilance WG Project and Priorities 2022 — All

Reminder of topics of interest

- LN introduced the tentative project list developed in 2021 which will be the topics of discussion for potential projects in 2022.
    1. Pre-licensure period: Safety Management in Clinical Trials
    2. Active Vaccine Safety Surveillance – introduction and tools
    3. Assessment of Benefit – Risks in the product life cycle
    4. Continuation of PV post-licensure training with PATH
    5. Implementation of Safety Governance

- LN stated that members of the PV WG should reflect on the proposed topics and determine which would be of benefit to the DCVMN membership
- LN stated that definitive and obtainable goals for the projects will be required.
- LN handed over to Katharina Hartmann to introduce a tentative project proposal which has been discussed by the PV WG leaders (Linda Nesbitt, Viska Indriani and Katharina Hartmann)

Tentative project proposal

- KH introduced the tentative project - Active Vaccine Safety Surveillance (AVSS). AVSS has become a topic of interest in the light of the COVID19 pandemic and post-authorization studies which some regulators have been requesting from DCVMN members.
- KH introduced the outline of the project which intends to provide comprehensive training on the subject of AVSS via a series of online webinars, similar to the Risk Management Plan Project that was conducted in 2021

Basic outline of project

1. **Importance of establishing safety governance**
2. **Basic introduction to AVSS**
3. **Guidance on implementation of AVSS**
    - Methodologies
    - How to address common knowledge gaps in the AVSS
    - AVSS as post-licensure commitments included in the RMP / Pharmacovigilance Planning:
        - Safety studies which could be implemented and when – i.e., Cohort study, Case control study etc.
        - Post licensure safety studies
        - NRA engagement
4. **Provide support on submitted AVSS plans –** Similar to the RMP exercise

- KH stated that one of the major focuses of the project will be how to navigate the interaction between the DCVMs and NRAs. This is due to a majority of AVSS projects being conducted by NRAs without industry/DCVM input.
- Varun Sharma (VS) stated within PATH AVSS has become a topic of interest which the organization is looking to gain more experience.
- VS added that within PATH a generic protocol for a COVID19 Vaccine cohort study has been developed and can be shared with the DCVMN members.
- Viska Indriani (VI) stated that this generic COVID19 protocol would be of value to the members as it can serve as a template that can be adapted for COVAX vaccines in production at Biofarma.
- Maria Beatriz Lucchesi (MBL) stated that Instituto Butantan has utilized the generic COVID19 protocol and it has been very useful for their AVSS for COVID19 vaccines after consultation with their NRAs.
- KH added that there are many generic AVSS protocols available through the WHO and a Dutch organization known as "NCEP".
- LN stated the proposed project also aligns with the efforts made at the Global Vaccine Safety Group who will be writing a paper on the methodologies employed during the COVID19 pandemic, of concern to DCVMN members within this paper, is the AVSS capacity and readiness to respond to future pandemic originating in LMICs – in identifying signals, access clinical safety data and do LMICs have the pathways needed to significantly respond.
- LN stated that DCVMs will be able to support and inform this paper and potentially receive funding.
- VS queried that captured within the AVSS project will specific tools be developed for Passive Vaccine Safety Surveillance – e-module, manuals etc.
- KH stated that there will be material developed for AVSS and PVSS material can be developed.
- RS supported the development of this material and excused himself from the meeting.

2. E-Pharmacovigilance Safety data Management Systems – White Paper **LN/KH**

- LN introduced the whitepaper which was written in 2021 on E-Pharmacovigilance Management Systems.
- Paper covers why a safety data management system is needed, general requirements-resources, budgetary, regulatory, training and identifying type of product is suitable for your needs.
- LN asked for endorsement of the paper from all members to reach 1 objective for 2022 (publication of 2 papers) and identification of where this paper should be published – DCVMN website or elsewhere.
- MBL asked if the paper covers cross-system aspects such as clinical systems, as for channels of distribution MBL stated that the DCVMN website requires proactive engagement from industry and perhaps other channels can also be used.
- VS stated that this paper of great interest and relevance, but many manufacturers may not be at the stage to adopt a E-PV safety data management system and rely on Microsoft and Excel tools
- VS further stated that a point of support, the DCVMN can provide is how to effectively use Microsoft Excel and Access tools so that those who are not ready to adopt a E-PV safety data management systems are still compliant with regulatory standards and WHO good documentation practice.

- KH added that this maybe a good initiative to consider but many regulators in high-income countries will not accept the excel and access tools as they are not validated but for those members operating locally this remains an option.
- KH also expressed that the development of a custom system E-PV safety data management system was discussed within the DCVMN and it maybe worth revisiting this idea.
- Paulo Roberto Gomes Takey (PT) added that a training or RFP template which members could use to acquire E-PV safety data management system may be of value to members as aspects of the safety data management system parameters were difficult to define when Bio-Manguinhos Fiocruz were looking at safety data management system acquisition.
- KH and LN in agreement that this would be of value and that safety data management system needs to be discussed with management ahead of time of need due to the high costs.
- MBL stated within this RFP tool a need to address data migration should also be captured.
- Rajendra Kasi (RK) seconds the statement by VS and KH that a common electronic data base would be beneficial to encouraging the smaller companies to submit their AEFIs.
- LN stated given the interest in the topic the whitepaper can be seen as a jumping platform to other projects such as a common electronic data base but would need the support of the companies and be developed in consultation with an electronic supplier to address security and validation.
- VS queried if the next stage would be to develop from scratch a database within the DCVMN or contact a supplier to lower prices for members.
- KH stated an existing provider would be best with a tailored system as they are established.
- VS stated that a system developed from scratch could bring some benefits that an established system cannot such as lack of licensing issues. Additionally, to be considered is the migration of the data as MBL pointed toward.
- RK added that any developed systems would need to be validated.
- KH and LN stated that the pros and cons can be discussed at the next meeting.

3. Actions before next meeting + AOB **LN**

- VS stated that for the next meeting the DCVMN will be conducting individual meetings to discuss the AVSS project to identify the individual needs and discuss the regions requirements.
- LN asked the PVWG if they were in agreement to hold these 1-1 meetings.
- Majority of members agreed to hold 1-1 to discuss the PV topics and no objections were voiced.
- LN added that while there is a wealth of knowledge within the PVWG if from the interviews any topics which required expertise are discovered a consultant could be contacted to inform the group on best direction etc.

Actions

- Members to receive an email to arrange 1-1 meetings.
- DCVMN to summarize the 1-1 meetings to provide regional overview
- Members to receive the E-Pharmacovigilance Safety data Management Systems – White Paper.
- Members to bring pros and cons on E-Pharmacovigilance Safety data Management Systems to next meeting.

Linda Nesbitt

31/05/2022