Pharmacovigilance Working Group Meeting Minutes

Thursday, 4th, April 2024 | 13:00 CET. Online, via Zoom

Participants:
Patricia Mouta (PM), Chetanraj Bhamare (CB), Devang Patel (DP), Shuyan Zuo (SZ), Vijay Yerroju (VY), Katharina Harmann (KH), Sonia Villaseñor (SV), Prerna Kumar (PK).
Meeting started at 12:00 CET and adjourned at 12:53 CET.

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1. Welcome

SV welcomed the participants and invited them to follow up on the pending task as per the objectives set during the workshop in February.

2. Update on status of review of the AVSS projects

KH updated that AVSS project is at the last phases. 2 protocols and 5 synopses were submitted. Mark Kuepens is supporting KH in reviewing the protocols and synopses. 1 to 1 Meetings to discuss the proposals will be scheduled for end of April-beginning of May'24.
The first draft of the manuscript and tables of the publication has been prepared by KH and is being circulated amongst the members who have participated in the project for their feedback.
The ideal, if RS approves, would be to wait for the conclusion of the analysis of the protocols to integrate these conclusions at the end of May, to submit the publication to the journal by the end of June'24.
KH has requested RS to contact Anne Hepard, a medical writer, to give the final review and formatting before it could be submitted.

3. Survey on PV maturity level

SV updated that 20 responses have been received so far. SV sent a reminder yesterday, extending the deadline to April 10th.

4. Update on status of objective to set up/Improve effective processes between the 3 areas (PV/CD/REG) to ensure the product safety life cycle

- PM mapped some points that could integrate a series of documents or policies that could guide the best practices in this process to flow between these three areas and with it improve the work for all of them.
- Regarding interaction with Regulatory, the first proposal is to try to define standard minimum timelines for the different kind of requests from regulatory. 8 main areas of interaction were identified: Regulatory submission, Signal detection and management, post-marketing safety reporting, labeling updates, Risk Management Plan (RMP), Inspections and audits, change management, training and awareness.
- KH reminded the team that some years ago the PV team had put together a master list of SOPs which could serve as a basis, as they are multifunctional, which is on DCVMN website. It could be a good idea to review it and update it. https://dcvmn.org/wp-content/uploads/2020/09/pv_sop_masterlist_with_explanations.pdf

- KH said that Simonetta Viviani conducted a survey and analysis on clinical development. SV will search for it.
- DP suggested to include the liaison with the clinical and non-clinical team. Also, we could include the points of the notification of the protocols or the planning what they are planning into quarter one and quarter two, which gives the insight to the PV when they provide certain information.
- DP also suggested to set a certain mechanism and minimum timelines on safety management; establish the flow of the safety data, which is essential for the PSUR or the annual reports, from the clinical trial team along with the R&D.
- For the interaction with CDMA, PM identified 8 main areas of interaction: Safety planning in clinical trials, safety data collection and reporting, risk management, safety monitoring committees, protocol amendments, adverse event management, training and education and post-trial safety follow-up.
- PM suggested the team to work on a template of the PSMF (Pharmacovigilance system master file).
- KH reminded that in 2020 Varun Sharma gave an intensive training on the Pharmacovigilance system master files, suggested to have a hands-on training on that.
- KH developed a training on safety and clinical development and will share it with the PV WG for the team to elaborate more on the topics of their interest and start the discussion with the CDMA WG.
- CB said this list presented by PM is complete, but we need to find out certain deeper aspects of each point so that we could have a better understanding amongst ourselves.

Next steps

- PM will elaborate in depth the points discussed and propose some flows to start with.
- SV to address with RS the need of the team to have hands-on training on Pharmacovigilance Master File and on Data Safety Monitoring from Clinical Trials.
- KH will share the training she developed to PM to pick the sections that would be of interest to the team.
- SV suggested turning this training also into an e-learning module.
- Schedule the next meetings in advance, ideally for the rest of the year. PM will send proposal of dates.

Notes taken by SVB 04 April2024

Patricia Mouta
Chair