dcvmn
Developing Countries Vaccine Manufacturers Network

RMP Project Kick-off Meeting
May 17th, 2021

Attendees: Bharat: Smita Singhania (SS). Bio-Manguinhos/Fiocruz: Renata Pedro (RP), Eliane Santos (ES), Cleyton Lage (CL), Claudia Miranda (CM). BioNet-Asia: Librada Fortuna (LF), Porntip Wudtisun (PW), Woranut Suksotkhiao (WS), Walalee Khantaviti (WK). Butantan: Beatriz Lucchesi (BL), Monica Cintra (MC), Marcelo Koike (MK), Cleber Gomes (CG). Cadila Pharmaceuticals: Vipin Sethi (VS), Mona Gogia (MG), Sankar Babu Thanniru (ST), Rashmi Attrai (RA). Polyvac: Thuy Huong Nguyen (TN), Quoc Hung Le (QL), Thu Nga Le (TL). Serum Institute of India: Chetanraj Bhamare (CB), Santosh Bahirat (SB). Sinergium: Sebastian Comellas (SC), Agustina Litterio (AL), Maximiliano Macario (MM). Vabiotech: Luu Anh Chien (LC), Le Thi Thanh Tuyet (LT), Mac Van Trong (MT). Walwax: Annie Chen (AC), Cecilia Cai (CC), Rui Min (RM), Qiuzhenping Lu (QL). Zydus Cadila: Jaimin Bhatt (JB), Madhusudhana Reddy (MR), Mayur Patel (MP), Subhodeep Chakraborty (SC).
Anne Hepburn (AH), Paul Willems (PW), Bernadette Hendrickx (BH), Nora Dellepiane (ND), Katharina Hartmann (KH), Sonia Pagliusi (SP), Rajinder Kumar Suri (RS), Laura Viviani (LV), Sivashen Cunden (SC), Tana McCauley (TM) minutes

ND started the meeting at 12:02 by welcoming all the participants.

The project managers (ND and KH) and the consultants (BH, AH and PW) introduced themselves. Then followed introductions of the project participants from the participating companies.
ND presented the project to all participants. The project's objectives are: to increase understanding of risk and risk management, inform about international guidelines on RMPs and increase understanding of RMP structure and development. The expected outcomes are developing a robust RMP that meets EU and WHO PQ standards and creating a multidisciplinary team with representation from different RMP development and implementation areas.

Project schedule:

Activity	Quarter											
	Q1			Q2			Q3			Q4		
	1	2	3	1	2	3	1	2	3	1	2	3
Inform DCVMN members of proposal												
Development RMP e learning course												
RMP webinar												
E learning course conducted.												
Project kick off Meeting.												
RMP e workshops												
Participants finalize RMP preparation												
Participants submit their RMPs.												
RMPs review and feedback by experts												

ND then presented the way of working: learning by doing. The webinars will not be based on presentations by trainers or facilitators. Each webinar will cover a specific part of the EU RMP. In between webinars, it is expected that participants will develop the requested section of the RMP and will come to the workshop with their challenges and questions. The teams should develop together the part of the plan that is expected to be completed for the upcoming workshop. It is essential to understand that the project participants will need to invest time and effort into the project. During the webinars, the expert consultants will answer questions. Questions asked during the workshops are expected to be general (not disclosing confidential information). Participants can send confidential questions to KH and ND through

email, who will then forward them to the most suitable consultant. ND added that in case of complex questions, it is possible to set up a TC with the consultant and the company's team.

Workshop schedule:

Activity						
KOM	17th May 2021					
Part I Part II (modules S1 and S2)		31st May 2021				
Part II (Modules SIII to SVIII)			14th June 2021			
Part III Part IV				28th June 2021		
Part V Part VI					12th July 2021	
Part VII						26th July 2021

ND opened the floor to the consultant's comments on the challenges of RMP development.
Inputs from the consultants included the following:
BH advised never to hide something that is a real risk in the dossier. It is essential to know what is the risk that has been identified and how to manage it. SAEs, even if they are rare, need to be identified and commented on. There are also different behaviours among different authorities. It is critical to understand what is the risk and benefit. Sometimes the risk is minimal with a considerable benefit, and sometimes the benefit/risk ratio is different. What is essential is to have a clear position on this and to be able to present arguments.
AH approaches RMP development from the perspective of the medical writer. The biggest challenges are getting consensus within the company, receiving feedback and comments on time and deciding who makes the final decision. One of the other challenges is that the guidelines do not specifically describe what to do and are open to interpretation. When working with the team, there will be multiple different opinions and viewpoints. The job of the medical writer is to make sure everybody agrees on the data and information that goes into the document. Also, if there is something unclear or the company deviates from the guidelines, the Regulatory Agencies (RAs) will come back with comments.
PW noted that one of the first and very operational aspects is to have clear PV concepts, such as risk (potential, identified), safety concern and adverse events. When it comes to the planning within the companies, this should not be underestimated, especially if companies need to perform additional measures like post-authorization safety studies (PASS). These involve different stakeholders within the company, and the biggest challenge may be that the PV department may have to discuss with people in other departments and get them aligned on strategies. At the licensure stage, companies should be able to come up with relatively advanced planning. That can be one of the most significant issues for the RMP at the licensure stage.

ND and KH opened the floor to questions and comments.
RS suggested calling the meetings, workshops rather than webinars as the way of working is to learn by doing. RS also highlighted the need to focus on skilling, reskilling and upskilling. Every participant should notice the change that she or he is bringing into her or his skillset. RS encouraged all participants not to come to the meetings as good listeners only but to bring value addition.
BL asked a question regarding the choice of vaccine. The product they chose is in early development and will probably not have the full safety data. PW advised going towards a product at a more developed stage, with different risk categories. If the product is in early development, there would only be the

potential risks anticipated because of the product's properties but no clinical data. If the product is more advanced in its clinical development, there will already be clinical data and perhaps some identified risks. There will also be more missing information.
LF asked how much time the participants will have to do the revisions to the RMP (after the reviewers have given their comments). KH answered that there would only be one round of corrections, and it will be up to each company to integrate the expert comments into the RMP.
AH gave some practical tips on writing the RMP. The team needs to know that they should put time into the RMP. There should be an identified leader who will make the ultimate decisions. The most common way of writing the 1st draft of the RMP is to have a discussion (TC) with the team, where the writer will take notes, which will then be translated into a first draft. It is important to know the first draft is not the last draft. AH also suggested using Microsoft Word to write the RMP. Some companies use their own template. The 1st job of the writer would then be to prepare the template.
RS noted that different people are involved in RMP development, and different subjects can be selected, e.g., drug products, drug substance, commercialization, and supply chain. It could benefit the participants to have a variety of RMPs. KH answered that it is helpful to have a broader perspective. In PV, this is a regulatory document to submit to RAs for applying for authorization.
VS asked if the participating companies are expected to share part I and II (modules S1 and S2) before the workshop on May the 31st. ND answered that companies should only bring questions, challenges and doubts to the workshop and do not need to send their work beforehand. VS also enquired if companies should communicate the team lead to DCVMN. ND said that it is essential to have a team lead. However, it does not need to be communicated to DCVMN. VS asked if during the project there will be a discussion on templates for different countries. ND replied that there is a lack of alignment between authorities, which makes things complicated. The objective of this project is to develop a plan that meets EU and PQ requirements. KH added that if you have local requirements, it is easier if you have a core RMP and add these local requirements and not recreate the whole RMP.

ND and KH closed the meeting at 13:39 by thanking all participants.

2.6.2021