DCVMN INTERNATIONAL
Developing Countries Vaccine Manufacturers Network International

Clinical Development & Medical Affairs Working Group Meeting Minutes

Friday,19th, April 2024 |14:00 CET. Online, via Zoom

Participants:

Fernanda Boulos (FB), Daniela Lazzarini (DL), Manish Mahajan, (MM), Michelle Singleton (MS), Sai Krishna (SK), Rini Mulia Sari (RMS), Rajinder Suri (RS), Prerna Kumar (PK), Sonia Villaseñor (SV).

Meeting started at 14:00 CET and adjourned at 14:46 CET.

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1. Welcome

FB welcomed as chair of the WG and summarized that in the previous meeting the WG finalized the objectives for 2024. She mentioned there are some topics in which the WG would need support in order to accomplish the objective.

2. Update on support offered by PATH

RS said that PATH had identified two expert consultants in clinical trials who will be operating from PATH office in India. We will receive the details by tomorrow.

RS clarified that the consultants will help refine objectives and provide guidance where there is a bottleneck, however, should not be relied on as the sole drivers of progress. Working group members need to take ownership and contribute based on their Attitude, Skills and Knowledge (ASK) and leverage their strengths.

All the members of the WG are expected to contribute and RS suggested to define roles and responsibilities in this meeting according to the objectives.

FB expressed her concern on the time constraint of the WG members. She suggested to benchmark what other WG are doing to reach their objectives and learn from them.

3. Discussion on action plan to attain objective number 1. To upgrade the skills of DCVMN members staff by training them on Basics of Adaptive Clinical Trial Design, Statistics and Methodologies for Designing Adaptative Clinical Trial Protocol

FB invited the WG members to brainstorm on how can we proceed in upscaling the knowledge of the WG members in this topic without the use of an external support. How to identify if we have the resources inside.

MM suggested there are many resources and guidelines available for public consultation to learn about Adaptive Clinical Trial Design. He identified statistical design as the biggest bottle neck in terms of critical designing part of the Adaptive Clinical Trial. He said that probably the people of CDMA WG are not the right people to use Adaptive Clinical Trial Design but rather statisticians are. This requires very specialized people. He suggested if any of the member companies has a statistician in terms of models of adaptive digital design, then they can teach as a trainer for the member companies on how it can be done.

RS suggested the group to work upon one single vaccine that the whole working group agrees upon as an example. Identify the protocol, challenges faced and then propose a mitigation strategy. And then he suggested to identify if there are statisticians who can support. First look inside the WG members, if not, look within the network, and if not, then reach out to CEPI, PATH or other organizations, and finally look for and external statistician. This has to be written down and then define the responsibilities, and finally monitor the progress.

FB mentioned that this will imply reviewing again the objective and redefining it, as it is something different to what the group had identified as a need and objective which is to upgrade the group's skills on statistics. RS suggested rather to defer this objective as number 2 and work first in objective number one which is to develop a protocol for adaptive clinical trial and then it can be followed by training.

4. Discuss the outline proposed for the publication on Adaptive Clinical Trial Design in order to start writing content. MM proposed an outline that was shared with the group for comments. One next step is to identify a medical writer. He can suggest some. RS said that if they have published in international journals of repute, we can evaluate them, and suggested not to focus only on Indian Medical Writers rather look worldwide. The group agreed to suggest 2 or 3 medical writers by 30th of April. The goal would be to have at least one suggestion from each of the members, so as to have one from each country. SV will send a note on the timelines for members to share their suggestions on medical writer with coordinates.

5. Brainstorm on ideas on how to framework a paper on how to counter vaccine hesitancy.

RS shared that two expert female advisors on Vaccine Hesitancy have been identified, and we are looking for their availability to organize a training session on vaccine hesitancy, as they have done a lot of research in the field. In the meantime, he suggested to put resources together, in order to prepare the background and questions to be ready to discuss with them whenever they organise the session, and share experiences and ask questions to refine our thinking process and reach some kind of publication. RS added that they have an online short course and a mix of lectures and interactive sessions basically around four pillars framing the vaccine confidence, measuring and monitoring vaccine confidence, responding to and addressing vaccine confidence and rebuilding trust.

FB emphasized on the need of more members to contribute with ideas and suggested that we could create a doodle to schedule a specific meeting for this brainstorming ensuring more participation of the different WG members to enrich the brainstorm process and preparation session for the meeting with the advisors.

MM suggested that the people who will be really contributing in the paper, should be present in all meetings and contribute with comments on the documents shared. We could invite participants from PV and Regulatory WGs.

Out of the 13 members of the CDMA WG, most of the participants have not joined, only 4 or 5 join. RS suggested to reach out to all the members individually to see if they are interested in participating and contributing with the WG, otherwise we will search for replacement who can contribute with other senior participants.

Notes taken by SVB 19 April 2024

DocuSigned by:
Fernanda Castro Boulos
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Fernanda Boulos
Chair