Clinical Development & Medical Affairs Working Group Meeting Minutes

Tuesday,04th, June 2024 |13:00 CET. Online, via Zoom

Participants:

Rajinder Suri (RS), Sajjad Desai (SD), Eliane Santos (ES), Elvira Alonso Lago (EAL), Manish Mahajan, (MM), Michelle Singleton (MS), Sai Krishna (SK), Prerna Kumar (PK), Sonia Villaseñor (SVB).

Meeting started at 13:06 CET and adjourned at 13:35 CET.

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1. Welcome

SD welcomed as chair of the WG and thanked for being appointed as Chair of the CDMA WG. RS welcomed SD and mentioned that PATH has offered the support from Dr. Tushar Tewari and Dr. Niraj Rathi. Unfortunately, they were not able to attend the meeting.

2. Adaptive Clinical Trials manuscript progress

MM provided an update on the manuscript development to create a position paper on adaptive clinical trials design, noting that he had shared a detailed table of contents with the group previously, and now he has elaborated further, so that when the medical writer starts writing, he has a fair amount of information to start with. Further input from the regulatory affairs group on the regulatory stance to be included. The final objective of this paper is to create an environment in which Regulatory Agencies can open to accepting Adaptive clinical trials, so for the moment MM has left blank the section about the suggestion DCVMN is going to make to the Regulatory Agencies. Based on the final journal selection we will identify the number of words.

RS suggested to share this document for inputs also from Regulatory WG, Pharmacovigilance WG, PATH consultants, CEPI, and IFPMA to provide input and make the manuscript a robust, co-authored publication. This should not be a concept note or white paper; it needs to be a value addition document. RS requested al members to take this objective seriously.

3. Proposals for medical writers.

The group discussed the potential role of a medical writer, RS said the medical writer can be brought once we have the outline ready and requested the members to suggest various names of competent professionals who can add value. SD said he could suggest a name of a medical writer. RS said the group needs to have clarity on what exactly shall we ask to the medical writer e.g. to write, to review, to add value, etc. MM said some editors like Elsevier have their own medical writers we could approach. RS said that if the internal team has the necessary writing and editing capabilities, a medical writer may not be required. The focus first should be on gathering input from various stakeholders to enrich the content before finalizing the manuscript.

4. Vaccine hesitancy publication

RS emphasized the group needs to have clarity on the purpose of this publication, the group should have content in order to write a publication. One should be a matter expert when writing a paper for a journal. RS requested the group to define what is the information base that we have today in the WG and who are the other stakeholders who can add value.

RS offered to call a consultant on vaccine hesitancy to organize a workshop together with the L&D WG. RS will explore with her, the dates available. RS emphasized the need to thoroughly learn, research and address the barriers and challenges around vaccine hesitancy before attempting a publication.

5. Upgrade the skills of DCVMN members' staff

SD expressed the importance of the role of a statistician in clinical trials design. It is important provide training to DCVMN members' staff on topics such as clinical trial statistics and adaptive trial design methodologies. SD offered to connect the group with a statistician who could conduct the training.

MM requested SV to share with SD the list of questions that were sent to Dr. Pieter Neels for the training requirements (target audience, training duration, module, etc.).

6. Discussion on the interest of exploring AI for clinical trials

SD offered to prepare a short document on the role of exploring AI in conducting clinical trials and we can take it forward from there.

Notes taken by SVB 04 June 2024

sajjad desai

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Sajjad Desai
Chair of the CDMA WG

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