DCVMN INTERNATIONAL
Developing Countries Vaccine Manufacturers Network International

Clinical Development & Medical Affairs Working Group Meeting Minutes

Wednesday, 7th, February 2024 |12:00 CET. Online, via Zoom

Participants:
Fernanda Boulos (FB), Daniela Lazzarini (DL), Manish Mahajan, (MM), Sai Krishna (SK), Sajjad Desai (SD), Lorraine Hill (LH), Rini Mulia Sari (RMS), Rajinder Suri (RS), Prerna Kumar (PK), Sonia Villaseñor (SV).
Meeting started at 12:00 CET and adjourned at 12:53 CET.

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1. Welcome

RS welcomed the participants and invited them to establish SMART objectives which are quantifiable, crystal clear, measurable and achievable through at the same time stretched; something that will help benefit the member companies, e.g. regulatory harmonization, solidarity trials, preparedness for future pandemics, Nagoya protocol, etc. He advised to follow the approach of 'Think global, Act local'. And based on the objectives, to define clear deliverables. RS invited them not to go for mundane problems, but something achievable like reducing timelines, cut costs, how to approach regulators, to harmonize regulations etc.

2. Objectives

FB as the Chair of the CDMA WG welcomed the participants and invited them to collaborate with ideas. FB shared the first draft of the objectives of the WG for discussion. One of the deliverables expected would be to issue a publication.
SD asked if it would be only Clinical Trials issues or also everything related to the vaccines, including Regulatory approval, harmonization regarding regulatory approvals.
SV clarified that there is a Regulatory WG that is working in Post-Approval Changes (PACs) looking for harmonization in this field. She suggested to focus on the pre-approval part of the vaccine life-cycle, covering whatever is needed, of course knowing that CDMA is part of regulatory.
RS endorsed the fact of approaching regulators with several things and do not limit themselves. But rather focus on real problems that the manufacturers are facing and how can we help to resolve them.
MM suggested to work in two ways: one could be to work on how to Fast Track the Clinical Trial process, e.g. having adaptive clinical trial design (Combining Phase I and Phase II) while the second part is to educate and create awareness in the population to improve vaccine hesitancy.
RS intervened to say that there is "Trust Deficiency" in the general public in certain populations leading to Vaccine Hesitancy, so he suggested to work on ways to mitigate this challenge; think global but include several ramifications (regulators, industry, population, etc.) and they should be doable.RS further guided to draw conclusions on what to do and how to do.
RMS supported the idea to work on accelerating the clinical trial process, like doing Phase I II and III in parallel instead of sequential or Phase I and II in one protocol and then do the Phase III trial. This could be a learning from the pandemic to accelerate the clinical trials while still fulfilling the requirements.; this could also be addressed by using adaptive design. In addition, RMS identified another obstacle which is how to address the statistical method to calculate the sample size and how to do the statistical calculation to make the report of the clinical trial, fulfilling the international and national guidelines.

DL proposed setting goals understanding and identifying common projects with shared goals for mutual growth; e.g. research strategies of each country, the burden of disease that each country has. In Argentina they are concerned about possible resurgence of a new pandemic because of the low rates of vaccination. She invited all the participants to express the challenges that they are facing, because each country may be facing different problems.
FB supported the idea of establishing the objectives beforehand, discuss the problems faced by each country, in order to make sure we are establishing objectives of common interest. She proposed to create a survey to understand the most common issues in each country and based on the results, establish the prioritization of the objectives (What are the two major issues that you have … something quick to respond and to analyze).

RS referred to a meeting he attended last week in London including discussions with many regulators. A common concern, ideal to take up, is vaccine hesitancy. He also talked with the head of Regulatory at WHO to follow up on workshops on CRP (Collaborative Registration Procedure). He suggested to address this issue during the next week Joint Working Group Workshop. So that we can know how to move forward.
SV mentioned that for next week meeting it would be necessary for the group to prepare some slides to promote discussion on what is the situation, what are the gaps/ barriers and proposals, so it is important for all of the members of the Working group to participate in the creation of the slides even if they will not participate in the Workshop. The slides were uploaded on the shared drive and shared to all the members of the CDMA WG.

FB agreed that vaccine hesitancy is indeed an important topic to address and discuss on how it is impacting developing countries and we can perhaps make an evaluation and issue a publication; however, our power to move that needle is maybe less of what we can do for the adoption of adaptive design trials or statistical support. So, we can establish some draft objectives, but with the result of the workshop, we can establish more clear objectives and prioritize them with more clear action plans. RS supported this idea and suggested that the prioritization could be:

1. Adaptive design trials to shorten the development time (One of the derived outcomes could be reduction in costs, though this would not be listed as an objective).
2. Development of statistical calculation tool for refining Statistical analysis
3. Addressing the challenge of trust deficiency to counter Vaccine hesitancy

FB will draft the objectives document and will share it with all the participants. FB insisted that the participants should not only edit the slides but must add value about their specific issues in their countries.

The group then agreed to meet every 15 days at the beginning (until March) and then once every month. She also invited the participants to participate in the AGM in October in Sao Paulo and maybe have a WG meeting there. RS thanked the group and closed the meeting.

Notes taken by SVB 07 February 2024

DocuSigned by:
Fernanda Castro Boulos
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Fernanda Boulos
Chair