DCVMN
Developing Countries Vaccine Manufacturers Network

3rd Working Group meeting of Clinical Development/Medical Affairs (CDMA) – 15th December 2022 - Started at 12 noon and finished at 1:30 pm

Participants: Ravindra Mittal/Zydus Cadila, Interim Chair, Long Xu/Bravovax, Daniela Lazzarini/Sinergium, Beatriz Luchesi/Butantan, Pieter Neels/ consultant, D.P.Sahoo and Sai Krishna/Indian Immunologicals, Sonia Pagliusi/secretariat and Sonia Villasenor/secretariat. Absent: Richard Chawana, Katharina Hartmann.

Ravindra Mittal chaired the meeting, welcomed all participants and announced that the WG structure/organization may change in the near future. He reminded participants that in the last meeting of 06-07 June 2022, he had proposed a list of "must to have SOPs" as tool for knowledge sharing and basis for consideration. He acknowledged Sonia Pagliusi for complementing the information on the list circulated to all on 05th and 07th December 2022.

- **Review of the list of SOPs**: Ravindra recognized that the list is not exhaustive, as different companies may have different needs, and invited all to deliberate on the proposed list of SOPs. Sonia Pagliusi provided information on the context and content of SOPs, and indicated that a series of 23 papers published by Wiley, describing contents of SOPs, is openly available online, which may correspond to the WG needs. In addition, Johns Hopkins University also has a webpage with SOPs and templates openly available[1] , as well as detailed guidance from EMA is available online[2]. However, Ms. Katharina Hartmann, who is interested in this area, has mentioned that SOPs from academic institutions may differ from those of corporations. P. Neels commented that indeed, academic SOPs are sometimes not fully recognized by regulatory authorities. Documents based on ICH, FDA and EMA guidelines are more acceptable. Ravindra agreed that academic documents are perhaps not fully aligned to clinical development of new vaccines, as they may be used for other kind of studies, however such documents may help manufacturers understand the context, and can be supportive to understand the subject and to prepare the own SOPs, while ICH guidelines are the top priority when preparing such documents. Beatriz Luchesi agreed that available information is useful and can be used as support, and shared her experience over five years in building the SOPs: she searched websites and realized many of the academic SOPs are focused on clinical site and principal investigators processes, but do not specifically describe the processes of the company when developing a product, therefore cannot be just "copied"; at Butantan they developed their own SOPs from "scratch", as such industry documents are not publicly shared. PN suggested that manufacturers share their SOPs, and wondered why members do not share their SOPs, in order to improve trust in public health, as it is the case for corporate risk-management plans. Ravindra Mittal explained that SOPs are approved documents, but from a corporate point of view can only be shared with a limited number of stakeholders, because it is a "controlled document" for execution of a trial in a specific context, and therefore cannot be shared broadly with the public at large. Sonia Pagliusi added that the list and the elaboration on content are a learning tool for members, and asked the participants to comment on how to go forward to finalize the list, if useful. Daniella L. agreed to have a list and compilation of information displayed as resource, with links, for those who do not have inhouse expertise or previous experience. Devi Sahoo noted that while sharing information would be ideal, within his experience in industry it is not possible to share the specific SOPs, and there are good reasons for that, as it was also experienced during the COVID pandemic, e.g. cyber-attacks; still he agreed that the list and

[1] https://www.hopkinsmedicine.org/institutional_review_board/about/compliance_monitoring/researchers_tool_kit/standard_operating_procedure.pdf

[2] https://health.ec.europa.eu/system/files/2022-02/guidanceclinicaltrials_covid19_en_1.pdf

content can be helpful, and the WG is a good forum for sharing knowledge (rather than sharing the documents). He agreed to have a list of SOPs to supplement each other's knowledge. He mentioned that some SOPs are aimed at tackling specific issues that arise during clinical trials: thus, a list with a brief synopsis with 1-2 links to help members understand can provide some support. Beatriz Luchesi added that some areas are missing here, e.g. Pharmacovigilance (PV) SOPs. P. Neels added that a PV SOPs list is already available for DCVMN members (cf. https://dcvmn.org/wp-content/uploads/2020/09/pv_sop_masterlist_with_explanations.pdf). Sonia Pagliusi asked if she should complete the synopsis of the list, and circulate to the group, then have a 2-day virtual workshop with interested members to discuss and finalize, so that large companies, e.g. Zydus Cadila, can help smaller ones to advance faster, as it was the case within the DCVMN Supply Chain WG, to create a stronger network, with larger manufacturers. Ravindra mentioned that the list and content is appropriate and agreed to continue the work, circulate it for members to provide views and decide about "must to have SOPs" versus "good to have SOPs". Beatriz L. agreed to review the list, populate it with comments and discuss. Daniela L. agreed that it is a great help to have this list handy, and transparency would improve trust. Devi Sahoo thanked for compilation of the list agreed, and suggested some amendments in headings/subheadings, once the list is discussed; one concern of his was to have SOPs that can be followed, not just have a list, e.g. SOP no. 29 to decide how to deal with it. Xu Long agreed that this list is very helpful, for new R&D companies with few staff in clinical development, as sometimes even some CROs do not share their SOPs. S. Krishna agreed and suggested to divide the review of the 55 SOPs among the group, to facilitate the work: Part A (Beatriz L.), B (Devi), C & D (Xu Long), E & F (Ravindra M.). Ravindra agreed and requested the secretariat to finalize populating the list with contents/links, and organize the workshop, depending on budget.

- **Training needs**: Ravindra suggested to plan GCP training, and Pieter N. suggested adding a training in NGS, if possible (though this is CMC area). Other suggestions can be sent by email.
- **Conclusions**: Ravindra reminded that over the discussions the main agreed points of action included: The list will be finalized shared by mid-January to collect feedback by end January.

1. Provide feedback if all SOPs listed are essential (or some can be excluded)
2. Provide feedback as to whether the preamble/synopsis to each SOP is appropriate, or is missing something or goes beyond (so can be shortened)
3. Provide feedback as to whether references/links are relevant (or not) or be added, if missing
4. A virtual (or F2F) workshop could be scheduled in early March 2023.

Ravindra acknowledged all participants for interactive discussions and adjourned the meeting.

Notes drafted by S. Pagliusi

Acknowledged by meeting Chair

RM Date: 27-01-2023

Ravindra Mittal