

Participants: Ravindra Mittal/Zydus Cadila, Interim Chair, Long Xu/Bravovax, Beatriz Luchesi/Butantan, Pieter Neels/ consultant (left at 1:30 pm), D.P.Sahoo and Sai Krishna/Indian Immunologicals, Sonia Pagliusi/secretariat and Sonia Villaseñor/secretariat. **Absent:** Richard Chawana, Katharina Hartman, Daniela Lazzarini/Sinergium.

Ravindra Mittal chaired the meeting, welcomed all participants and reminded participants that this meeting aims to finalize the proposed list of SOPs as tool for knowledge sharing. He invited participants to go over the list and discuss each SOP, recognizing that the list is not exhaustive, as different companies may have different needs. PN commented that from a regulatory view point, SOPs are needed for any clinical operation, and would not consider segmentations among “must haves” and “good to have”. SP added that as a network of manufacturers, the group may not be in a position to establish which SOPs are to be followed or not: the list is just a tool for information of members to share, without grading the importance of each SOP. The information collected on the list is not authored by any WG members, is just a compilation of information available on multiple websites, as indicated in the list. Beatriz agreed, and stressed that the document should include this disclaimer, and the list be used as a tool for reflection. PN added that processes may vary as well, from country to country, or even local to local.

Review of the list of SOPs:

Participants agreed to the table of contents, as proposed by Ravindra, and to keep the helpful references, for information. Some wording was discussed, to keep “soft language” avoiding “must”, and to avoid any potential conflict with local regulations that this group may not be aware of. Clarification of further wording was agreed, and many comments on the document were resolved upon open discussion with the WG meeting participants. It was also agreed to remove too many details, to avoid stating any confusing or contradictory information, and combine some SOPs, so that the list was summarized to 46 SOPs in total, clarifying that the list is not yet exhaustive.

The goal of the WG of providing a list of general SOPs for clinical trial operations, agreeing on their usefulness and general content, was achieved, as discussed and proposed initially at the outset of this WG, in its meeting of March 2022 (to share a list of SOPs for clinical trials), and more specifically in its meeting of June 2022, held in Geneva. The meeting participants agreed to post the edited and reformatted list on the webpage of the CDMA WG, as a resource for reflection/ information for those who so wish, with a disclaimer on any liability by neither the network nor any of the WG participants about the accuracy, completeness or relevance of the list and its content.

It was concluded that the aim of this list may represent a living document, to be reviewed, extended, complemented, or reduced as proposals are received from members, and agreed upon. Ravindra was warmly acknowledged for supporting this project, providing the first draft of the list, and supporting all discussions. The WG hopes this list will be helpful for manufacturers to initiate new clinical trials of new vaccines in the near future. The meeting was adjourned.

Notes drafted by S. Pagliusi

Acknowledged by meeting Chair



Date: 21-02-2023

Ravindra Mittal