Participants: Patricia Mouta (PM)- Bio-Manguinhos, Aminata Diagne (AD)- Institut Pasteur de Dakar, Ana Paula Loch (APL)- Butantan, Arani Chatterjee (AC)- Cadila Pharmaceuticals, Beatriz Lucchesi (BL)-Butantan, Beauty Moloto (BM), Beverly Cowper (BC)-Biovac, Charlotte Cheng (CC)-Innovax, Chetarnaj Bhamare (CB)-SII, Devi Sahoo (DS)-Indian Immunologicals, Eliana Barros (EB), Leticia Lignani (LL) Bio-Manguinhos, Linda Nesbitt (LN)-Biovac, Renata Saravia (RS)- Bio-Manguinhos, Reza Bosman (RB)-Biovac, Rini (R)-Biofarma, Rui Wang (RW), Shuyan ZUO (SZ)-CNBG, Sunil Gairlola (SG)- SII, Tainá Pereira (TP) Bio-Manguinhos, Mila Triana R (MTR)-BioFarma, Varun Sharma (VS)-PATH, Vijay Yerroju (VY)-Biological E, Viska Indriani (VI)-BioFarma, Katharina Hartmann (KH)-Consultant, Sonia Villaseñor (SV)-DCVMN. **Meeting started at 13:00 CET and adjourned at 14:24 CET.**

PM, chair of the PVWG, welcomed the participants. KH, consultant for Pharmacovigilance,
LN, former chair of the PVWG, gave some background of what has been done with this AVSS project and the way forward.

- The objective of the project is to strengthen the understanding and capacity of the member companies on AVSS. This has been identified as a need by the members. It is also necessary to meet the ICH E2E requirements (PV/RMP) & EMA GVP Module VIII/ Module VIII Addendum I, and EMA PAES.
- Timelines by phases were shared in the slides presented. So, the final phase will be finalized in May 2024.
- Phase I was a workshop training in theoretical aspects, given in February 2023 in Geneva. Materials are available at DCVMN website, c.f. https://dcvmn.org/avss-pharmacovigilance-workshop/
- Phase II was a questionnaire & landscape analysis that 16 member companies interested in the project responded. This showed a mix of various levels of expertise.
- Phase III is to learn by doing: How to prepare and implement an AVSS program for a **product of their choice**.
- Members will receive guidance with the preparation of the mock protocol.
- Based on the findings the group will write and publish a paper on the challenges in performing AVSS in LMICs.
- AVSS is a multidisciplinary work, so each member is expected to include in their team 3 or 4 participants. Typically, an AVSS team would include PV, epidemiology, regulatory, quality, and clinical teams and medical teams within the company.
- Two small groups will be formed to actively discuss study questions (one for COVID-19 and one for Rabies vaccines)
- The outcomes of the discussions will be taken to the Barcelona meeting in 20-21 October 2023.
- Groups will help member companies to create their protocols with the guidance of KH
- Member companies will then submit them for review with technical experts.
- LN asked the participants on how they want to deal with confidentiality and conflict of interests, e.g., have confidentiality agreements signed, or use a code for their vaccine, not to disclose sensitive information. Members will be able to approach the consultant on a 1-1 basis if some sensitive information is to be discussed. Members are requested to give their feedback on this. KH mentioned that for the RMP only with experts that looked at real world data. SV will try to share a basic template for confidentiality agreement.
- The two groups will have leaders; for the COVID-19 group will be PM and VI; and LN for the rabies group. KH will support both groups. The focus is on and limited to the understanding of AVSS tools and development of AVSS protocol.
- The meetings will be for having clarity of the questions, partners sources of data, optimal

design methodology, settings for safety investigation and others as appropriate.

- Examples of topics for discussion are: What is the research question? Which research design is most appropriate to answer the research question? What is the most appropriate study design- prospective/retrospective; type of specific design? Is a comparator required, and if so, what is an adequate control group? Governance constraints and partnerships?
- Phase IV is the final study protocol by the end of February 2024 and review within 2 months. To be completed with a final workshop in May 2024 and results published.

PM opened the floor for discussion.

- Even though each member company is free to work with the vaccine of their choice, the 2 groups were formed thinking on the target population, the kind of platform, the kind of safety question to guide the discussions with a concrete example. Members can have the discussions having in mind another vaccine and explore options of safety questions and safety issues that may arise.
- SZ raised a concern on the new COVID-19 strains that are now being recommended. The inactivated COVID-19 vaccines containing index strain which were widely used in developing countries may not update the component timely. That will eventually result in no supply of inactivated COVID-19 vaccines containing new variants. KH said this is a good example. Here it would help to think what kind of safety issues we expect with this new strain? Would it be the same? What is the population that will use the new strain? What is the difference in population between the old and new strain? The same with any other vaccine. LN added we also need to think what the authorities want to see with the new strain.
- PM added how can we verify if there is a knowledge gap with our product. What kind of information and databases are we going to use to explore this gap.
- Participants without experience will be guided by the most experienced to cover the gaps, as well as by the consultants. The member companies will write their protocol with the knowledge they have and will receive feedback.
- Templates for protocols already exist, but the ones to be used will depend on the research question and methodology to be used.
- The discussions will be centered in post-authorization scenario, where AVSS activities focus.

Each member company decided in which group they wanted to participate. The groups were formed as follows:

Covid-19 group **Leader: VI and PM**	**Rabies** **Leader: LN**
Biological E (VY) Bio-Manguinhos (RS, LL, TP) Butantan (BL, APL) Bio Farma (MTR) Innovax (CC, RW) Institut Pasteur de Dakar (AD) Institut Pasteur Dakar (Billo Tall) CNBG (SZ)	Biovac (BM, RB, BC) Cadila Pharmaceuticals (AC) Serum Institute of India (CB) Indian Immunologicals (DS) Institut Pasteur de Dakar (Awa Ly and or Antoine Diatta)

SV will send doodles to establish the next meetings per group ideally on the last week of September (Tue, Wed or Thu). PM asked the participants to be prepared for these online meetings with some questions they would like to discuss.
SV said that only 2 persons per company will be sponsored to Barcelona. Nominations are required at the earliest possible. The meeting will be hybrid so that those members not being able to travel will be able to join virtually.

Patricia Mouta
Chair of the PV WG