

Attendees: Sunil Gairola (Serum Institute of India) chair, Pradip Kumar Das (Biological E) co-chair, Sunil Goel (Serum Institute of India), Rajanathan Chozhavel (Zydus Cadila), Taehyun Kim (LG Chem), Deepak Mahajan (Panacea Biotec), Zebun Nahar (Incepta Vaccine), Irma Riyanti Hidayat (BioFarma), Shri T. Sekar (Pasteur Institute of India), Ganesh Dubey (Bharat), Hassan Ahmed (Amson), Sonia Pagliusi (DCVMN), Laura Viviani (DCVMN), Sivashen Cunden (DCVMN), Tana McCauley (DCVMN). Excused: Adhir Chaubal (Indian Immunologicals), Indrajeet Poredi (Bionet Asia), Li Yi (IMBCAMS), Vu Tien Dung (Vabiotech).

1. DCVMN Survey on Animal Use and 3Rs Implementation

L. Viviani presented the results of the DCVMN survey. The results were collected based on the following categories: respondents were divided based on the WHO regional classification; answers were divided by animal use (and species) for vaccine's production and in-process control; animal use (and species) for potency and safety test; 3Rs opportunities already implemented by members (or planning to be implemented); pyrogenicity test and knowledge about its replacement. The survey highlighted again that the focus of the WG should be the promotion of the implementation of 3Rs opportunities for Tetanus, Diphtheria, Pertussis and Rabies vaccines. Currently, a project for Pertussis vaccines is already underway, however, the 3R WG should discuss how to further promote opportunities for the other vaccines. The WG also highlighted the opportunity to replace the monkey neurovirulence test. The 3R WG will pursue further in-depth discussion of identified opportunities during the next WG meeting (May 5th, 2021). The chair and co-chair asked DCVMN to verify the information presented on potency tests for Haemophilus Influenza type B and Japanese Encephalitis vaccines. Another request on how the final survey report will present the data was advanced by S. Pagliusi: to guarantee the anonymity of the respondents. Additional comments came from various members of the WG highlighting major barriers in the implementation of 3Rs they experience: the lack of global harmonization of regulatory requirements and the complexity of dealing with regulatory authorities (in the manufacturer's country or in countries where the manufacturer exports the product) that do not accept variations in release testing that can reduce, replace, refine animal testing. It was also reported that the legal and mandatory characteristics of local regulations and pharmacopoeias that manufacturers are required to comply with, make the decision to invest in non-compendial methods even more challenging. The WG requested that members reflect on how the group and DCVMN could promote global harmonization. L. Viviani reminded the group about the ongoing projects and activities aimed at promoting such regulatory harmonization, one of which has DCVMN involved (see next agenda point).

ACTION: DCVMN to distribute 3Rs Survey report presented during this meeting to the 3Rs WG members to collect any additional feedback on the content.

ACTION: DCVMN to finalize the Survey report and share it within all DCVMN.

2. NC3Rs project: Reviewing animal use requirements in WHO biologics guidelines, opportunities for the 3Rs

Dr. Zebun Nahar (Incepta Vaccine) presented NC3Rs and its current project to review animal use in the WHO TRS guidelines. Various experts engaged in the project were divided into two main groups, one dedicated to viral vaccines and the other to bacterial vaccines. Within those two groups, sub-groups have been identified to work on specific TRS guidelines. She is the DCVMN representative working on reviewing specific guidelines, and will engage the WG and DCVMN if any further input is welcome. Sunil Goel is representing (Serum Institute of India) in NC3Rs project and is included in both the viral and bacterial groups.

3. DCVMN Training 3Rs Opportunities

L. Viviani reported briefly the upcoming training 3Rs opportunities organized by DCVMN.

MAT

- Webinar on Feb 18 - recording available DCVMN website
- E-learning module (DCVMN moodle) (Q2)
- Working on developing a VR experience (Q2/Q3)

DT

- E-learning module (DCVMN moodle) (Q3)

1-day e-workshop on **Statistical analysis of the stability testing** April 21st

- Speakers: Tim Schofield (CMC Science, US); Dr. Parikshit Tyagi, Serum Institute of India).
- Pre-readings – free access to the papers in the Biologicals special issue on Stability Evaluation of Vaccines: <https://www.sciencedirect.com/journal/biologicals/vol/37/issue/6>
- Registration: <https://dcvmn.org/E-workshop-on-Statistical-Analysis-of-Stability-Testing>

The meeting was adjourned.

DCVMN will send out the invitation to the next 3Rs WG meeting, taking place by TEAMS on May 5th, 2021, at 9 AM CET.



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Post-meeting notes.

Due to lack of time, the planned updates that were not provided during the meeting will be distributed separately.

A handwritten signature in blue ink, appearing to read 'Sunil Gairola', is written over the printed name.

Dr. Sunil Gairola
Serum Institute of India
Chair of the 3Rs WG