

Attendees: Pradip Kumar Das (Biological E) co-chair, Deepak Mahajan (Panacea Biotech), Zebun Nahar (Incepta Vaccine), Irma Riyanti Hidayat (BioFarma), Sureshbabu Rajan (Zydus Cadila), Rajanathan Chozhavel (Zydus Cadila), S. Sivakumar (Pasteur Institute of India), Gopal Singh and G. Brunda (Bharat), Laura Viviani (DCVMN), Sivashen Cunden (DCVMN), Sonia Pagliusi (DCVMN), Rajinder Suri (DCVMN). Excused: Sunil Gairola (Serum Institute of India) chair, Mahesh D (Indian Immunologicals), Indrajeet Poredi (Bionet Asia), Li Yi (IMBCAMS), Vu Tien Dung (Vabiotech), Hassan Ahmed (Amson), Taehyun Kim (LG-CHEM), Lingyun Zhou (Shanghai Zerun Biotechnology), Patricia Carneiro (Butantan)

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### **Brief introduction of participants and agenda**

Pradip Das (PD) welcomed all participants and introduced the agenda on behalf of 3Rs Chair Sunil Gairola who was unable to attend Q4 session.

1. Internal and External 3Rs initiatives and opportunities
  - Agree on DCVMN members further engagement
2. Share 3Rs-related cost savings data
  - Agree on what can be publicly reported
3. Nomination of new chair and co-chair for 2022
  - Introduce the process
4. ABO and wrap-up

### **1. Internal and External 3Rs initiatives and opportunities**

Laura Viviani (LV) reminded and informed 3Rs WG members of the internal and external DCVMN 3R Project status and other initiatives:

#### **Internal 3Rs initiatives and opportunities**

- **DCVMN/NIIMBL Pertussis Serological Potency Test (PSPT) Project**
  - Laboratories' testing phase almost complete
  - Statistical Analysis by independent consultant to be initiated
  - DCVMN's request to NIIMBL for project extension to be submitted
    - o Complete statistical analysis
    - o Workshop(s) on results review and support full validation studies' planning
    - o Documentation review; peer-reviewed publication; communication materials to promote project's outcomes
    - o Final meeting to be determined and will most likely be a hybrid meeting
- **DCVMN Workshop - Implementation of the single dilution assay for *Diphtheria* and *Tetanus* containing products – January 27<sup>th</sup>, 2022.**
  - The objective of the workshop is to share laboratories' experience in implementing the assay from quality control and regulatory perspective additionally to *discuss* opportunities for DCVMN members to implement the assay.
  - The presentation will expand on the presentation provided by PD to the 3Rs WG Q3 meeting.
  - Only DCVMN participants will be able to join and the workshop will be facilitated by 3Rs and Regulatory WG Chairs and co-chairs, in collaboration with the Italian Institute of Health/ISS.
  - Please see the agenda and register here: <https://dcvmn.org/DCVMN-3Rs-Workshop-Implementing-the-Diphtheria-Tetanus-Single-Dilution-Assay>
- **DCVMN Monocyte activation test VR**
  - Introductory course is available on the Moodle developed by the ISS
  - VR experience will be published quite soon on the DCVMN platform
  - VR will use Oculus Quest 2 (hardware)

- DCVMN will be working on future training opportunities in VR therefore feedback would be appreciated if members participate in the training.

- DCVMN 3Rs Planning for 2022



	Quarter											
	Q1			Q2			Q3			Q4		
	1	2	3	4	5	6	7	8	9	10	11	12
Increase WG membership and encourage quiet members to contribute (change Chair and co-chair in Q1)	█	█	█	█	█	█						
Positioning DCVMN is all key ongoing 3Rs projects, collaborations, partnership	█	█	█	█	█	█	█	█	█	█	█	█
3R WG Calls		█			█			█			█	
Project to support implementation of single dilution assay for potency test (DT)	█	█	█	█	█	█	█	█	█			
2 workshops (members only) on other 3Rs opportunities				█	█					█	█	

- LV described the planning for 2022 and expanding the number of committed members joining the 3Rs activities and those who will implement 3Rs actions.
- Additionally, LV would like to engage in as many ongoing 3Rs activities and projects that are relevant to the members.
- DCVMN would also like to propose a 9-month project wherein DCVMN will support the implementation of the single dilution assay for potency test. LV invites all members to join the dedicated workshop on January 27<sup>th</sup>, 2022 (link on page 1).

### External 3Rs initiatives and opportunities

- IABS: Accelerating Global Deletion of the Abnormal Toxicity Test. Planning common next steps
- VAC2VAC project - Vaccine batch to vaccine batch comparison by consistency testing
- NC3R - Review of animal testing requirements in WHO guidelines and recommendations for biologics: a proposal to implement 3Rs principles
- WHO-National Control Laboratory Network for Biologicals
- Updates from the European Pharmacopoeia
  - Histamine sensitisation test in mice (acellular Pertussis vaccines)
  - Toxicity for tetanus vaccines
  - Toxicity for Diphtheria vaccines
  - Strategic plan to delete Rabbit Pyrogenicity Test from all monographs by 2026

For more details, please refer to the 3R presentation (attached to email)

### 2. Share 3R-related cost saving data

LV stated that the sharing of Business-related aspects of 3Rs implementation might provide with key information to companies and regulators and increase adoption and therefore she would like encourage within the working group the sharing of this data. DCMN is aware that not all data can be shared due to competitive reasons but would like to understand what can be shared. LV suggests the following ideas:

- Number of not-used animals per batch
  - Reduction of batch production overall cost – in %?
  - Cost of the implementation – investment done vs cost reduction?
- PD stated that regarding the number of animals used and saved was captured in the previous survey conducted a year ago. Sharing the cost saving figures may not be possible but the animal numbers should not be a problem from the companies as numbers are defined by pharmacopoeia.

- Brunda G (BG) provided a cost saving data based on assays performed by Bharat Biotech (could not be shared due to sensitive information).
- Rajinder Suri (RS) asked that in the future all currencies be reflected in USD so the information is easier to understand by all members.
- It was agreed to collect data based on the BG cost-saving template.

### **3. Nomination of new chair and co-chair for 2022**

- Please submit your nominations with your CVs by December 15th, 2021 to the DCVMN Secretariat (Mr.Suri, cc: Laura Viviani)
- The secretariat will share the names, qualification, experience, publications etc. of all group members as also the suggested names for Chair & Co-Chair who will be met by 2 Board members and CEO before finalizing their candidature.

#### **Profiles:**

- Expertise in implementing quality control related changes (from in-process control to final batch release with good understanding of the regulatory requirements and processes)
- Specific expertise in implementation of Reduction, Refinement and Replacement opportunities (recognized by local regulatory authorities and/or WHO or other authorities; not yet recognized methodologies);
- Experience in participating in international collaborative studies, projects, expert groups, committees or similar (country-specific or international or both) for the 3Rs implementation.

#### **Closing remarks**

- RS and LV thanked current chair and co-chair (Sunil Gairola and Pradip Das) for the excellent work in leading the most engaged working group of the DCVMN.
- RS suggested that while the rotation of members is suggested DCVMN still welcomes previous participants to join the WG when possible.
- RS also suggested that participation of other DCVMN members is encouraged and should be invited to the meetings in 2022 and members should try to participate in the calls vocally even if there is a language barrier so to become more comfortable working as a team.
- PD thanked all members for their participation and continued efforts in 2022.

#### **Actions**

- ❖ Nomination of new chair and co-chair for 2022 submit your nominations with your CVs by December 15th, 2021 to the DCVMN Secretariat (Mr.Suri, cc: Laura Viviani)
- ❖ Participants to assess what cost-saving data can be shared with the DCVMN in 2022

DCVMN will send out doodle for the next 3Rs WG meeting, taking place by TEAMS on in Q1 of 2022The meeting was adjourned 14:20 CET.

Signature



Pradip Das

Co-chair 3Rs WG