

DCVMN 3Rs Experts Working Group Meeting Minutes – 1st Teleconference February 5th, 2020

Attendees:

Adhir Chaubal (Indian Immunologicals),
Rajanathan Chozhavel (Zydus Cadila),
Pradip Kumar Das (Biological E),
Sunil Gairola (Serum Institute of India),
Sunil Goel (Serum Institute of India),
Yojana Shinde (Serum Institute of India),
Manish Gautam (Serum Institute of India),
Lavit Jambu (Panacea Biotec),
Taehyun Kim (LG Chem),
Deepak Mahajan (Panacea Biotec),
D. Mahesh (Indian Immunologicals),
Anand Kumar Manesh (Indian Immunologicals),
Zebun Nahar (Incepta Vaccine),

Sonia Pagliusi (DCVMN),
Irma Riyanti Hidayat (BioFarma),
Dr. Maya Ramdas (Panacea Biotec),
Shri T. Sekar (Pasteur Institute of India),
Gopal Singh (Bharat),
Laura Viviani (DCVMN).

Excused:

Indrajeet Kumar (Bio-Net Asia),
Tien Dung Vu (Vabiotech),

Agenda of the first 2020 teleconference 3Rs WG meeting:

1. Introduction of all the members of the WG (15 minutes) – All
2. Nomination of a chair and co-chair of the WG (5 minutes) – Laura
3. Update on the status of the PSPT grant submission (10 mins) – Laura
4. Education and training opportunities and needs of the WG (15 mins) – All
5. Key updates and events about current/future projects on 3Rs for Vaccines. What is happening in your country/region? International? (15 mins) - All

1. All the attendees introduced themselves and their role to the group.
2. The attendees agreed to nominate Sunil Gairola from the Serum Institute of India as chair of the 3Rs WG and Pradip Kumar Das from Biological E as co-chair. The role of the chair and co-chair would be of assistance in defining the WG activities; developing meeting's agenda and chairing meetings or teleconferences; approving the minutes of the meetings; supporting the facilitator and the Secretariat to seek for fundraising opportunities for future working group activities.
3. Laura Viviani updated the attendees on the status of the submission of the PSPT project to NIIMBL for an eighteen months grant. Submission date: February 13th, 2020.
DCVMN took the role of project coordinator, while the interested laboratories that filled in the DCVMN online form are: Biological E Limited (India), Pasteur Institute of India (India), Bio Farma (Indonesia), Panacea Biotec Limited (India), Bharat Biotech International limited (BBIL) (India), Serum Institute of India PVT LTD, INCQS (Brazil). Update after the teleconference: NCL Thailand and NCL Indonesia are interested in participating to the study. DCVMN wrote also to CDSCO in India (no answer) and NCL in South Korea (negative answer), and NCL in Bulgaria.

Eurofin (Belgium) has sent its quote to produce the coating antigen material.

QUESTION: Adhir Chaubal (Indian Immunologicals) asked about the type of documentation requested for the additional test - the PSPT - to be performed in the QC Lab/Facilities, since it is a non-compendial method. Both Sunil Gairola (Serum Institute of India) and Pradip Kumar Das (Biological E) confirmed that the PSPT can be considered an R&D activity within the framework of 3Rs and animal ethics and can be managed as a Change Control approved by the QA department.

ACTION: follow up about the possibility to include the capture antibody, or a reference serum (positive control) among the reagent materials provided within the study, as requested by some of the participants. That request was not foreseen within the study materials, so DCVMN is going to follow up with Intravacc and ISS about that and inform the interested laboratories.

4. Laura Viviani informed the attendees of the possibility to have an e-learning module to be prepared by Prof. Coenraad Hendriksen.

ACTION: share with the WG, Prof. Hendriksen contents' proposal.

The attendees were informed about the next 3Rs Workshop (Hyderabad, end of April) following the Changes/variations management workshop. They were informed about the possibility to engage with EVI/Vac2Vac for the agenda items. However, because of the current COVID-19 emergency, the meeting is not confirmed.

The attendees were also informed about the possible collaboration with ISS (Italy) on MAT. A webinar and a video training are under consideration together with a WG F2F Meeting (H2, 2020), hosted by ISS in Italy.

5. Laura Viviani informed the attendees about the IABS Conference, that took place in Bangkok on 3-4 December 2019. A report will be published in Biologicals.


Another important event that is going to take place in 2020 is the World Congress on Alternative Methods – Maastricht, The Netherland, 23-27 August, 2020: <http://wc11maastricht.org/>

Laura Viviani asked the attendees whether there were any key updates about 3Rs acceptance from the 3Rs WG members' countries. Gopal Singh, Adhir Chubal, Sunil Gairola and Pradip Kumar Das confirmed the Indian Pharmacopoeia Committee and the National Regulatory Authority are actively collaborating with industry in implementing 3Rs opportunities, such as the waiver of the Abnormal Toxicity Test which has been obtained by many of the companies represented in this call. Same openness and support have been provided with the introduction and acceptance of the Bacterial Endotoxin Test as alternative to the Rabbit Pyrogenicity Test.

The meeting was adjourned.

Note

The WG will have a call every quarter, and at least a face to face meeting once per year. The next face to face meeting is not yet defined due to the COVID-19 emergency.


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