

First 3Rs WG Meeting Teleconference

5 February, 2020

Developing Countries' Vaccine
Manufacturers' Network International

Agenda

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. Introduction of all the Members

- In less than one minute per person
- Introduce yourself

2. Nomination of the chair and co-chair

- Role of chair and co-chair in collaboration with the 3Rs WG Facilitator (Laura Viviani):
 - help in define 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 fundraise to ensure the sustainability of the working group activities.

3. Update on the status of the PSPT grant submission to NIIMBL

- DCVMN - Project Coordinator
 - Interested Labs: 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)
 - Contacted: Thailand NCL
 - Plan to contact: India NCL – *any help?*
 - Eurofin (Belgium) to produce the coating antigen

3. Update on the status of the PSPT grant submission (II)

- Intravacc (The Netherland) – Scientific/Technical Support + Antigen qualification
- ISS (Italy) – not officially part of the NIIMBL proposal – available for scientific/technical support

3. Update on the status of the PSPT grant submission (II)

- Laboratories responsibilities:
 - laboratory costs related to the in-house testing assays (e.g. materials/reagents/supplies and technicians required to carry out the routine batch release testing (Kendrick Test/MPT) and the QC laboratory work for the ELISA
 - minimum number of batches of wP-containing vaccines (pentavalent or other) within the timeframe of the project (12 months).
 - being able to perform the testing within a timeframe of 6 months
 - share all the relevant raw data with the biostatistician for the pooled statistical analysis of the results obtained in all laboratories

3. Update on the status of the PSPT grant submission (III)

- DCVMN is responsible for:
 - free the coating antigen, independent statistical analysis, scientific advice by independent expert laboratories, and the participation in person of a representative of each laboratory to max 3 meetings (lodging expenses are covered by DCVMN)

3. Update on the status of the PSPT grant submission (IV)

- Submission due February 13th
- Final feedback expected end of April
- If positive, first key steps:
 - Establish a Consortium
 - Set up the kick-start meeting in order to define the study design and review all the procedures and SOPs

4. Education and training opportunities and needs of the WG

- E-learning module
 - Preferred content?
- 3Rs Workshop (Hyderabad, end of April) following the changes/variations management workshop
 - Preferred content?
 - Possibility to work with EVI/Vac2Vac for the agenda
- Collaboration with ISS (Italy) on MAT
 - Video training and WG F2F Meeting (H2, 2020).

5. Key updates and events about 3Rs

IABS Conference, Bangkok, 3-4 December 2019
– report will be published in Biologicals (work ongoing)

World Congress on Alternative Methods –
Maastricht, The Netherlands, 23-27 August, 2020

<http://wc11maastricht.org/>

5. Key updates and events about 3Rs

Any updates from your countries?

Pharmacopoeias' update?

Industry/Regulators meetings?

Conferences?

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