

# DCVMN 3Rs WG

## Key Learnings

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## DCVMN Commitment to 3Rs

- DCVMN promotes the implementation of the 3Rs Principle (Refinement, Reduction, Replacement of animal testing) and the removal of obsolete tests (4th R) in vaccines' batch release process.
- The implementation of 4Rs can bring significant impact in terms of cost saving (from few dollars per test up to thousands) and reduction of products' release time to the population, down to few days instead of weeks.

## DCVMN 3Rs Working Group

- Share members' successful case studies from both the technical and business perspective (workshops and working group calls).
- Provide access to external expertise (webinars, workshops, trainings)
- Actively participating in the international projects and global dialogue.
- Create ad hoc projects

16 companies from Brazil,  
India, Pakistan,  
Bangladesh, Thailand,  
Vietnam, China, Indonesia,  
South Korea

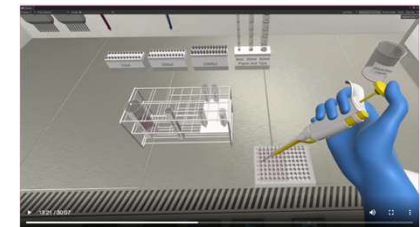
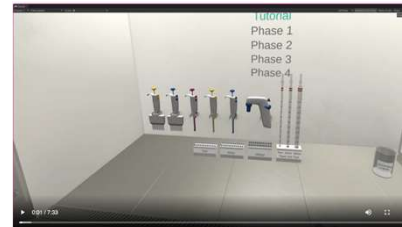
# 3Rs - Focus Areas

- Deletion of Abnormal Toxicity Test
- Replacement of Rabbit Pyrogenicity Test with Monocyte Activation Test
- Collaboration with NC3Rs/WHO Project
- DTP containing vaccines 3Rs opportunities (serology, single dilution, *in-vitro* potency assays)
- *In-vitro* opportunities for Rabies, Hepatitis B
- Next Generation Sequencing



# Type of Activities

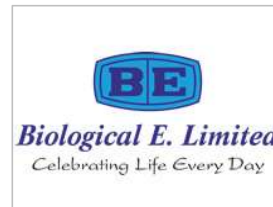
- Quarterly Calls
- Internal Surveys and data collection
- 3Rs E-learning  
(<https://moodle.dcvmn.net/>)
- Webinars and Workshops  
(<https://www.dcvmn.org/-Webinar-materials-13->)
- Virtual Reality Training on specific new methods  
(<https://www.dcvmn.org/Vaccine-testing-using-Monocyte-Activation-Test>)
- Dedicated projects (funded externally)



Completed!

# Pertussis Serological Potency Test

- International assessment of the PSPT in mice to replace the intracerebral-challenge Mouse Protection Test (MPT) for whole-cell Pertussis (wP)
- Funds from the National Institute for Innovation in Manufacturing Biopharmaceuticals



Completed!

# Pertussis Serological Potency Test

- 15 technical workshops and a hybrid meeting to discuss the project outcomes with international stakeholders which took place in New Delhi, India.
- PSPT results from all the 10 participating laboratories demonstrating that the PSPT is fit for purpose;
  - 8/10 laboratories are willing to carry out full validation studies (not in scope with this project)
- Updated Standard Operating Procedures;
- Produced in collaboration with BioLyo (Belgium) 2000 vials of *Bordetella Pertussis* coating antigen materials:
  - Independently characterized by Intravacc and reviewed by Steering Group
  - 1000 vials already donated to all participating laboratories under Material Transfer Agreements.
- 2 peer reviewed publications – in preparation

*Starting soon!*

## Single Dilution for Tetanus and Diphtheria Potency Test

- Goal: Support companies to plan the implementation of the Single Dilution Assay for the Tetanus and/or Diphtheria components of their own products.
- Funded by PATH Grant.
- 6 participating companies.
- Members will receive dedicated support from external experts which will provide theoretical knowledge and common form to support the creation of the own implementation plans.
- External experts from ISS/Italy, Sciensano/Belgium and PEI/Germany.
- DCVMN members that has successfully implemented the assay are welcome to join the external experts and share their feedback, but they won't be able to access the other members implementation plans.



## 3Rs WG Key Learnings

- Open dialogue within companies is key to understand interest, experience and priorities in implementing 3Rs (+4th R)
- Internal collaboration and shared experience facilitate engagement and planning
- External collaboration and shared experience promote understanding of opportunities and engagement in dialogue with other organizations and stakeholders, in particularly the regulatory authorities
- Trainings, hands-on experience, participation in projects provide with direct access to expertise and experience that can promote 4Rs implementation!