

# 3Rs WG – Q2 Meeting

May 11<sup>th</sup>, 2021





# 1. Welcome to New Members

- Appreciate the engagement of new DCVMN members in the 3Rs Working Group
- Now, WG has representatives from 9 countries!
- Welcome to:
  - Jie Song, Head Quality Control, IMBCAMS, China
  - Lingyun Zhou, Department of Quality Research, Shanghai Zerun Biotechnology Co.,Ltd., China
  - Patricia Carneiro, QC Manager, Butantan Institute, Brazil

## 2. Sharing case studies on successful 3Rs implementation



- DCVMN encourage members to share successful case studies in implementing 3Rs. How?
  - During the 3Rs WG meetings
  - Present the process implemented (selection of the opportunity, team of people engaged, time needed, dialogue with regulators, impact (number of animals, costs saved, others))
  - Difficulties encountered and lessons learnt



## 2. Sharing case studies on successful 3Rs implementation

- Examples for Safety Tests
  - Abnormal Toxicity Test,
  - deletion of Specific Toxicity Test for Tetanus,
  - deletion of the pertussis irreversibility test and replacement of HIST with CHO-cell assays
  - Next Generation Sequencing (adventitious viruses/agents)
- Examples for Potency Tests
  - Serological assays
  - Single dilution
  - SRID, RIA, etc.
  - Antigen quantification
  - In vitro relative potency test

## 2. Sharing case studies on successful 3Rs implementation

- Volunteers to share case studies in the next call?
- Shall we plan to engage the DCVMN Regulatory Working Group?
- How?



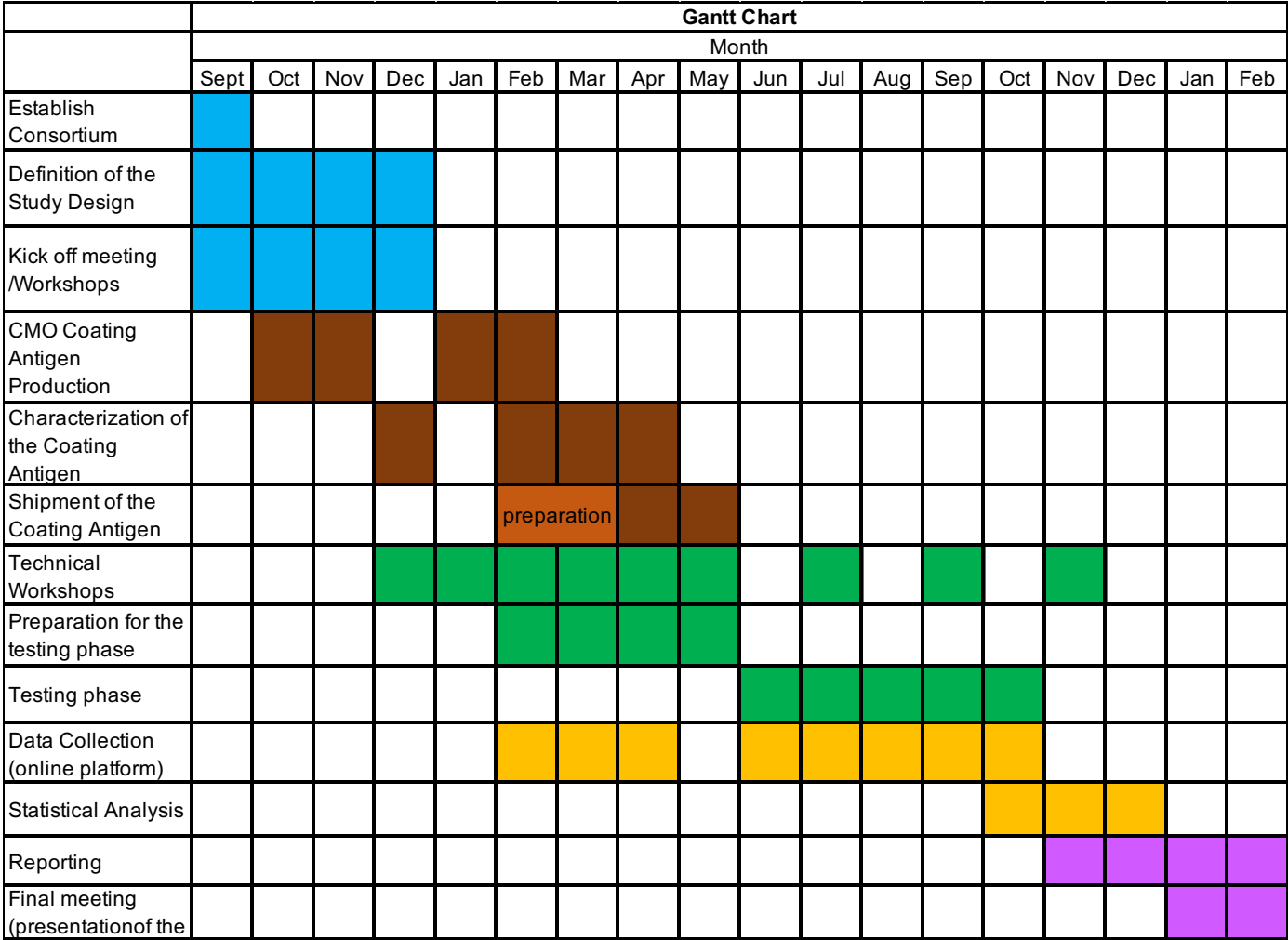


### 3. Single dilution assay for DT vaccines

- Could it be a next project for DCVMN members?
- Experience to share?
- ISS/Italy available to support

## 4. DCVMN updates

# PSPT wP Project



What is happening now



Labs Get Ready!





# DCVMN 3Rs Paper

Work ongoing

- Integrate findings from the DCVMN Survey on animal use and 3Rs implementation
- Authors and contributions from the 3Rs WG
  - 3Rs WG members are welcome to work with DCVMN on the draft
  - **Volunteers?**

# Updates on 3Rs initiatives & opportunities

- Abnormal Toxicity Test



- Animal Free Safety Assessment Collaboration + EFPIA plans half a day discussion (first half of October) with industry and regulatory stakeholders to speed up deletion of the test
- Invitation to DCVMN and all its members will come in the next weeks

- Rabies – replacement of NIH with ELISA



- EDQM/EPAA BSP148 phase 2 started – protocol distributed, vaccines samples distribution



# Updates on 3Rs initiatives & opportunities

- Polio Vaccines – NGS to replace MAPRECT+Monkey NVT
  - PATH is looking for interested manufacturers to join FDA/NIBSC phase 2 international collaborative study. If interested contact Kutub Mahmood - kmahmood@path.org



- HSI Working Group “Accelerating 3Rs methods in vaccine testing in China”



- Promotion of the WG activities at Symposium on Regulatory Science Issues Related to Vaccine R&D and Registration" (疫苗研发注册有关的监管科学问题座谈会), May 15<sup>th</sup>, 2021.

# Updates on 3Rs initiatives & opportunities

- NC3Rs: Reviewing animal use requirements in WHO biologics guidelines – opportunities for the 3Rs – <https://nc3rs.org.uk/review-animal-use-requirements-who-biologics-guidelines>
  - Review work ongoing.
  - Survey to manufacturers and regulators will be shared



National Centre  
for the Replacement  
Refinement & Reduction  
of Animals in Research

# DCVMN 3Rs Training opportunities

- MAT
  - E-learning module (DCVMN moodle) (end of Q2)
- DT
  - E-learning module (DCVMN moodle) (Q3)
- Statistical analysis of the stability testing
  - E-learning module available in June

# Key 3Rs publications

- Characterisation of tetanus monoclonal antibodies as a first step towards the development of an *in vitro* vaccine potency immunoassay. <https://doi.org/10.1016/j.biologicals.2021.04.002>
- Characterisation of diphtheria monoclonal antibodies as a first step towards the development of an *in vitro* vaccine potency immunoassay. <https://doi.org/10.1016/j.biologicals.2020.12.002>
- Variability of *in vivo* potency tests of Diphtheria, Tetanus and acellular Pertussis (DTaP) vaccines. <https://doi.org/10.1016/j.vaccine.2021.03.078>

Next Meeting: Q3 doodle poll will follow