3Rs WG – Q1 Meeting

February 23rd, 2022

dcvmn
Developing Countries Vaccine Manufacturers Network

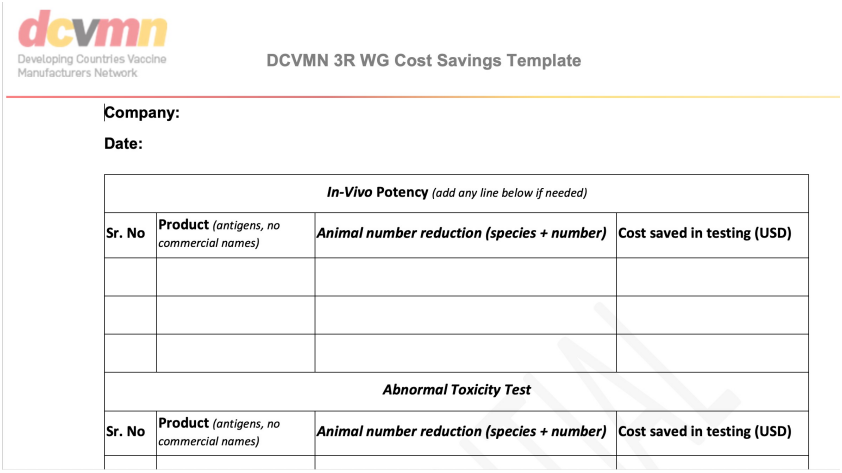
1. Agenda

Wednesday 23 February 2022		
Time	Topic	Speaker
12:00-12:05	Brief introduction of all participants & agenda	Chair & co-chair
12:05-12:20	**3Rs Cost Saving Data Collection** • *Feedback to the group*	Chair & co-chair
12:20-12:30	**Updates on the PSPT Project** • *Save the date for the final meeting*	Chair & DCVMN
12:30-12:45	**Deletion of the Abnormal Toxicity Test** • *Update and DCVMN ad-hoc data collection*	Chair & DCVMN
12:45-13:00	**Single Dilution Assay Workshop** • *Feedback and next steps*	DCVMN
13:00-13:15	**External Collaborations & Opportunities** • NC3Rs/WHO Project • VAC2VAC Project	Chair & co-chair
13:15-13:30	**AOP & Wrap up** Next call is planned on May 25th at 1 PM CET.	Chair & co-chair

2. Share 3Rs-related cost savings data

- Why?
  - Business aspect of the 3Rs implementation might provide with key information to companies and regulators and increase adoption
- What?
  - Number of not-used animals per batch
  - Reduction of batch production overall cost – in %?
  - Cost of the implementation – investment done vs cost reduction?
  - Other?
- When and Where?
  - 3Rs publications (in general and on specific projects)
  - DCVMN external presentations in conferences/workshops/webinars
  - Company internal presentations

2. Share 3Rs-related cost savings data



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DCVMN 3R WG Cost Savings Template

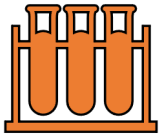
Company:

Date:

***In-Vivo* Potency** *(add any line below if needed)*			
Sr. No	**Product** *(antigens, no commercial names)*	***Animal number reduction (species + number)***	**Cost saved in testing (USD)**
Abnormal Toxicity Test			
Sr. No	**Product** *(antigens, no commercial names)*	***Animal number reduction (species + number)***	**Cost saved in testing (USD)**

- Received data from 6 companies
- 4 companies informed DCVMN that no 3Rs opportunity is in place, yet
- Need to further collaborate with companies to better define cost saving parameters
  - Saving on ATT per batch from 7 to 64 USD
  - Savings on Rabbit Pyrogenicity Test per batch around 100 USD
- Agree on collecting cost per batch
- Agree on how the saving is calculated (cost of animals; cost of the animal facility and test supplies; cost of personnel; etc.)

3. DCVMN/NIIMBL Pertussis Serological Potency Test (PSPT) Project



- Laboratories' testing phase completed
- Statistical Analysis by independent consultant ongoing
- 31 March 2022 – Workshop with preliminary data presentation, assay improvement recommendations (in view of validation plans)
- Documentation review; peer-reviewed publication; communication materials to promote project's outcomes
- Final meeting week of July 4th - SAVE the DATE
  - Face to Face in New Delhi – if minimum number of participants reached
  - Online event (over 2/3 days for 2/3 hours per day)
  - Meeting open to external stakeholders and all DCVMN interested members

4. Deletion of Abnormal Toxicity Test

- DCVMN collaborates with HSI/AFSA and EFPIA on follow up activities as agreed during the workshop **"Accelerating Global Deletion of the Abnormal Toxicity Test. Planning common next steps"** *on October 14th, 2021*

  All materials available here: https://www.afsacollaboration.org/biologicals/att-deletion-workshop/

- HSI/AFSA in collaboration with some IPFMA companies will create a map on the status of ATT deletion and waiver.
  - IPFMA data collection ongoing
  - DCVMN to contribute to the map. Agree on data collection.
- DCVMN invited to participate to EFPIA/IPFMA call to align on promotion of the topic at:
  - WHO/ICDRA – dialogue already initiate
  - ICRMA – engagement strategy to be agreed

5. DCVMN Workshop on DT Single Dilution Assay

- Held on January 27th, 2022
- Sciensano provided to DCVMN the presentation gave to WHO NCLs – DCVMN is working on a dedicated section with all SDA materials

- About 10 companies interested in participating to a dedicated project
- DCVMN submitted request for funding
- Project dedicated to support companies to plan the implementation of the Single Dilution Assay
  - Preliminary discussion with ISS/Italy and Sciensano/Belgium for technical support
  - Project to start second part of 2022

6. NC3Rs/WHO Project

- European workshop on March 2nd, 2022. Register here: https://www.nc3rs.org.uk/events/nc3rs-workshop-implementing-3rs-who-guidelines-understanding-impact-quality-control-and
- Asian region workshop on April 28th, 2022. Register here:
- https://www.nc3rs.org.uk/events/nc3rs-workshop-implementing-3rs-who-guidelines-understanding-impact-quality-control-and

7. VAC2VAC project - Vaccine batch to vaccine batch comparison by consistency testing

- Project final conference held on February 15th and 16th
- Important achievements on DTaP (antigens characterization, use of ELISA and Luminex as potency assay), TBE (MAT and ELISA as potency assay), clostridials (cell-based safety tests) and rabies (ELISA).
- Key publications available and more to come along 2022
- Industry and regulatory engagement to promote implementation and acceptance – series of local webinars (2022-2023)
- **DCVMN will be involved and engaged into the local webinars and into the final conference activities**

www.vac2vac.eu - www.iabs.org - www.afsacollaboration.org - www.euvaccine.eu

8. DCVMN 3Rs Workshops

- What is your interest in new analytical methods?

9. ABO and wrap up

Next Meeting: Q2

25 May 2022

T H A N K Y O U !