Accelerate non-animal batch release testing for human vaccines

Year 2 Report

The work performed during the second year has produced significant results along numerous lines of activity through the implementation of global and local strategies.

1. *Engagement of international Experts*

The project's proceeded to widen its outreach, establishing opportunities and conditions for expanded collaborations with key experts:

The number of engaged experts has grown significantly. Through the International Steering Committee (ISC) a number of experts where reached, including representatives of: EDQM, Health Canada, Indian Pharmacopoeia Commission; National Control Laboratories from Germany, Austria Thailand; industry associations (EFPIA, IFPMA, DCMVN, KoBIA-South Korea, RDPAC -China); IABS; PATH; and NC3Rs.

Further engagement came through direct participation to meetings, and organization of workshops within the following key international events:

- EMA 3Rs Working Party Stakeholders Meeting, March 20th, 2024.
- IABS/DCVMN Workshop on NGS, June 18th-20th, 2024. On June 18th, half a day workshop for DCVMN attendees presenting the implementation plan tools developed and used within the project.

- WHO Pre-ICDRA 2024, New Delhi. Workshop nr.8 "Replacing, Reducing and Refining dependence on animal studies", held on October 15th, was organized in collaboration with the WHO Laboratory Network and Services. The workshop's final recommendations have been endorsed by ICDRA.
- 6th General Meeting of WHO Network of National Control Laboratories for Biologicals (WHO-NNB), 26-27 November 2024. Led the organization of the workshop "Transitioning DTP containing vaccines to animal free batch release testing strategy. Strategies for implementation. The NCLs perspective." in collaboration with WHO NNB team. Information on testing performed by NCLs was captured through a pre-workshop survey.

2. Local face-to-face meetings:

Meetings have been organized and run to sample local conditions, needs and reactions to the opportunities available for replacement of animal use in batch release testing, to ensure biases are emerged and realistic expectations produced, and most importantly, so that realistic planning can be put in place cooperatively.
They have produced remarkable insights which will help shape future activities in the countries involved and in general activities in all the target countries, and beyond.

- Indonesia: Meeting with stakeholders took place on 15th May 2024 in Bandung. Attended by about 50 representatives from BioFarma (Quality Control and R&D), Bandan POM, Institut Teknologi Bandung, and Universitas Padjadjaran.
- South Korea: one day workshop organized in collaboration with the Ministry of Food and Drug Safety (MFDS) and the Korean Biomedicine Industry Association (KoBIA) within the Global Bio Conference on September 6th. About 200 attendees from big and small pharma companies, the ministry, universities attended the workshop.

3. Implementation Plans

Success has been met in the definition of local priorities and outlining of local implementation plans through direct liaising with companies from India, Indonesia and Brazil.
In particular:

- The internally developed tool to support local stakeholders in the definition of priorities, animal reduction targets, timelines, and potential investments and savings, has proven its usefulness with industrial stakeholders.
- 1:1 calls have been held to support companies in the definition of their own potential replacement plans.
- Actionable priorities have been identified, including: DT in vitro potency; aP and wP in vitro potency, implementation of the serology for wP as refinement approach, combined in vitro potency assay for DTaP or DTwP, single dilution for DT, Rabies in vitro potency, MAT, rFC, NGS (adventitious viruses), ATT deletion.

4. Webinars

A number of technical webinars have been executed in 2024. They play a pivotal role in enacting expert-to-expert information transfer and facilitate objective and credible evaluation of alternatives by the various stakeholders.
All the webinars were met with significant participation and received high praise from participants.

- March 27th: Transition to non-animal based vaccine batch release testing. Policy and regulations theoretical aspects and case studies, with 263 attendees and participants from: Europe, UK, Switzerland, Tunisia, South Africa, Ghana, Nigeria, Russia, India, Pakistan, China, Thailand, Japan, South Korea, Indonesia, Australia, USA, Canada, Brazil, Argentina
- July 2nd: Global availability of critical reagents for biologicals testing: Current status, challenges and possible solutions. This was a HSI sponsored webinar organized by the International Alliance for Biological Standardization, which saw 153 attendees (58% from Industry, 39% from government and academia, the remaining were graduate students), with a report submitted to Biologicals
- August 22nd: Introduction to recombinant Factor C and its future in India, with 186 attendees and stakeholders representing human biopharmaceutical companies (including CROs) based in India, the Indian Pharmacopoeia Commission, CDSCO, NCLs, local universities, recombinant technology suppliers, and biopharmaceutical companies from France, Italy, Argentina, Maroc, Germany, USA, Brazil, Tunisia, WHO
- September 25th: Status of global implementation of MAT for biologicals. Product Specific Approaches and Regulatory Alignment, with 143 attendees from Europe, UK, Switzerland, South Africa, Ghana, Nigeria, Russia, India, Pakistan, China, Thailand, Japan, South Korea, Indonesia, Australia, USA, Canada, Brazil, Argentina. A workshop report is in preparation

Planned Activities for 2025

Events:

- a final conference on the theme "Animal testing replacement for vaccines. A One Health View: global outlook and future strategy" to be held in December 2-4, 2025, in Bangkok, Thailand, is being organized in collaboration with IABS.
- a session proposal has been submitted for the project to be represented at the 13th World Congress on Alternatives and Animal Use in the Life Science that will take place in Rio de Janeiro on August 31st to September 4th, 2025.

Participation to key meetings:

- EFPIA workshop "3 BASKET APPROACH: RECOMMENDATIONS TOWARDS THE COMMISSION ROADMAP TO PHASE OUT ANIMAL SAFETY TESTING IN CHEMICALS", Brussels, 16 January 2025.

- WHO Stakeholder meeting to discuss the Guideline "Guidelines on the phasing out of animal tests for the quality 6 control of biological products", Geneva, Switzerland, February 27th and 28th 2025
- World Congress on Alternative Methods to Animal Testing (WC13), Rio de Janeiro, Brazil from August 30th to September 4th, 2025
- Conference "Animal testing replacement for vaccines. A One Health View: global outlook and future strategy" to be held in Bangkok, Thailand, from December 2nd to December 4th 2025. Organization of the conference is done in collaboration with the International Alliance for Biologicals Standardization (IABS).

Webinars and workshops planned:

- *DT-containing vaccines replacement opportunities: Status of methods development and possible next steps*. Online workshop. 29-30 January 2025.
- *The future of Pyrogenicity in Brazil. How MAT and recombinant methods will shape the future Pyrogenicity testing strategy?* – Online workshop in Portuguese – February 2025
- *Replacing the monkey neurovirulence test: challenges and opportunities for the future* – Webinar Q1 2025
- *Webinars series in China* – February 2025 (3 dates)
- *Local webinar on recombinant technologies for Bacteria Endotoxin Test in South Korea* (Q1)