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Key Achievements on Animal Welfare and the 3Rs 2024 Summary

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EXECUTIVE SUMMARY

Our policies aimed at fostering an environment of responsible use and humane treatment of animals.

As such they support key principles so that a strong rationale is established before animal use, especially for primates or genetically modified animals, that animal ethics committees operate in an independent and impartial manner, that members of the personnel take full responsibility for animal use, both in-house and at external partners, that 3Rs principles are anchored in the research and testing strategy, and, last but not least, that full consideration is given to the intrinsic value of animal lives – under all circumstances, including crisis situations – and that rehoming of animals is the preferred option whenever possible, after they have been used for science.

When science or regulation necessitates the use of animals, *the 3Rs principles are at the core of every project so as to bring the best of science and innovation together with animal welfare considerations.*

1. Animal Use Reduction

Between fiscal years 2020 and 2024, Sanofi achieved a significant 48% reduction in animal use, nearly reaching its original 2030 target of a 50% reduction well ahead of schedule. This milestone was primarily driven by scientific advancements and innovations in quality control testing.

2. Replacement Achievements

2.1. Vaccine Testing Improvements

Sanofi made substantial progress in replacing animal-based tests with alternative methods. Notably, European authorities approved the removal of positive controls from dermonecrotic toxin tests on mice for whooping cough vaccines. Additionally, the rabbit pyrogen test was eliminated for the Verorab vaccine, and the abnormal toxicity test was removed for the Diphtheria/Tetanus vaccine. One production site fully ended in vivo quality control activities, saving approximately 1,000 mice annually by transitioning to a new vaccine that only requires in vitro inactivation studies. Furthermore, Sanofi submitted a new ELISA test for Fimbriae antigens to replace mouse testing for whooping cough vaccines (PPH Acel).

2.2. New Approach Methodologies (NAMs)

The Company launched the "NHPig project," a public-private consortium aimed at reducing the use of non-human primates in non-clinical safety assessments. Through the Inno4Vac project, Sanofi also developed lung cell models for flu and RSV infections, as well as in vitro skin and muscle models for reactogenicity testing. To support the implementation of these NAMs in vaccine R&D, a Novel Translational Models Lead was appointed.

3. Reduction Achievements

3.1. Hexaxim Single Immunogenicity Assay (SIA)

The SIA received 2nd prize in Sanofi Vaccines Awards 2024. This assay allows to merge 3 different potency tests with potential severe suffering in one single test with mild severity on guinea pigs. Additional benefits are:

- A 10-fold reduction in Diphtheria / Tetanus / Whooping Cough vaccines manufacturing write-off
- A drastic reduction in the number of guinea pigs used for potency testing
- Substantial cost savings and millions of additional vaccine doses available

3.2. Virtual Control Groups

Sanofi partnered to develop digital control groups using retrospective datasets, aiming to remove the need for live control groups in in vivo studies.

4. Refinement Achievements

4.1. Housing and Care Improvements

The company introduced a non-invasive genotyping method using fur samples instead of tail biopsies in mice. Female rabbits are now housed in groups during studies, and rodent monitoring has been enhanced through digital cages and live video systems.

4.2. Rehoming Program

Sanofi successfully rehomed several laboratory animals, including 51 rabbits, 3 minipigs, 7 rats, and 14 dogs, ensuring their continued care beyond research use.

5. Governance and Awareness

5.1. AAALAC International Accreditation

All of Sanofi's animal care and use programs either maintained or renewed their AAALAC International accreditation, reflecting a continued commitment to high standards in animal welfare.

5.2. Culture of Care

To promote awareness and best practices, Sanofi organized Biomedical Research Awareness Day (BRAD) events across multiple sites and launched the Sanofi Vet Network to facilitate knowledge sharing among veterinary professionals. A global working group was also established to embed a culture of care throughout the organization.