

Marseille Declaration on the worldwide implementation of high standards for animals housed and used internally and externally by the industry for scientific purposes

The company-signatories of this declaration share common values and believe that the welfare of animals used in the research and production of medicines and vaccines requires the greatest consideration. This work demands application of high and most consistent standards of animal welfare and laboratory animal science regardless of where it is performed.

In this document, the company-signatories state their expectations related to animal welfare practices to be used at their own sites in whatever country and by external partners worldwide when using living animals to conduct studies on their behalf. The company-signatories request that their external partners meet the following criteria or agree on a plan for implementation when using and caring for animals in connection with an existing business relationship.

- **Culture of Care:** The company commitment and dedication to and engagement of individual employees towards animal welfare is promoted via support of a strong and clearly defined and documented Culture of Care program. Such program is a key asset for a continuously evolving high quality animal care and use program.
- **Oversight Bodies:** Institutional independent multidisciplinary expert governance or oversight bodies¹ approve all animal use by ensuring the scientific merit and regulatory requirements of in vivo protocols are met. The considerations of the 6 Principles of Animal Research Ethics² are applied to ensure that the value and quality of life is considered for each individual animal and the 3Rs and that the quality of the animal care and use program is assessed.
- **Continuous Education & Training:** A holistic program of professional education and continuous professional development exists for all staff working with animals and conducting animal studies. The training program should be adjusted to the relevant needs of each employee and performed in respect with current best practices. This training program shall define training requirements for all roles that use animals directly or are responsible for animals via management of work or staff.
- **Veterinary Care:** Appropriate veterinary care to manage animals both at an individual and a colony-wide level. Presence of a competent veterinarian with sufficient authority for rapid intervention and veterinary advice. Institutional commitment to veterinary care is clearly in place and consistent with current best practice in veterinary medicine.
- **Housing & Husbandry:** Housing and husbandry conditions shall ensure that the basic needs of animals are fulfilled unless required by the objective of an experiment that is unavoidable and can technically and scientifically not be achieved in any other way. The basic needs of animals are species specific and entail at least: species adapted temperature, humidity, and noise; nutritious food and clean water; safe shelter; adequate and species specific stimulation; species specific environmental conditions that allow setting-up functional units (meals, sleep, play/explore, defecation, urination); social species socialization in groups according to species specific needs; provision of veterinary care; sufficient rest to maintain physical and mental health; freedom from harm, pain and fear; freedom from disease, injury and disability; freedom of movement with adequate space to execute physiological movement sequences and behavioral patterns.

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- Environmental Conditions: Controlled species-specific environmental conditions ensuring at a minimum that animal discomfort is prevented and that provisions for animal behavioral and physiologic needs are in place.
- Caging and enrichment program: Caging systems must be designed to meet the fundamental behavioral characteristics of each species, and the environmental enrichment program should be designed around the specific social, behavioral, and nutritional needs of every animal.
- Species: With special attention to the specific needs of dogs, pigs and non-human primates, all signatories are committed to applying and promoting the care and accommodation standards that are consistent with those required by the European Union and United Kingdom. If external partners do not meet these welfare and care expectations, they should provide a specific plan indicating how they will implement their intent to meet this goal. These species should be purpose-bred and NHPs should have a pedigree with individual animal history data provided and should preferably be from self-sustaining colonies.
- Post Approval Monitoring: A formal Post Approval Monitoring program of the site-specific animal care program, including regular program review and vivarium walkthroughs is in place and documented to ensure compliance and appropriate animal use. Relevant performance standards are used to advise the staff about the function of the animal care and use program. A qualified person is appointed who regularly oversees performance of animal activities.
- Risk Management: A program of disaster planning and risk management that covers all risks that may impact the welfare of animals or quality of results is implemented and regularly reviewed.
- Incident Reporting: A formal incident reporting process with a clear program for the development and implementation of corrective and preventative actions and parties responsible for implementation of actions is implemented and successes are documented. All incidents with the potential to impact animal welfare, quality of results, or company reputation must immediately be reported to the relevant sponsor.

¹Depending on the local regulation, this may be an Institutional Animal Care and Use Committee, an Animal Ethics Committee, an Animal Welfare (and Ethical Review) Body or other comparable body.

²Beyond the 3 Rs to a More Comprehensive Framework of Principles for Animal Research Ethics. David DeGrazia and Tom L. Beauchamp. ILAR Journal, 2019, Vol. 00, No. 00, 1–10

Principles of Social Benefit

- (1) The Principle of No Alternative Method
- (2) The Principle of Expected Net Benefit
- (3) The Principle of Sufficient Value to Justify Harm

Principles of Animal Welfare

- (1) The Principle of No Unnecessary Harm
- (2) The Principle of Basic Needs
- (3) The Principle of Upper Limits to Harm

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Signatory Pharmaceutical Companies

	Merck KGaA, Darmstadt, Germany, 2022 September 9th
	Novo Nordisk, Bagsvaerd, Denmark, 2022 September 9th
	Sanofi, Paris, France, 2022 September 9th
	Novartis AG, Basel, Switzerland, 2022 September 9th
	Lundbeck, Copenhagen, Denmark, 2023 March 27 th
	Leo Pharma, Ballerup, Denmark, 2023 March 27 th
	Ascendis Pharma A/S, Hellerup, Denmark 2024 June 17th

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Signatory Contract Research Organizations

	<p>BioReliance, a Brand of Merck KGaA Darmstadt, Germany, 2022 September 9th</p>
	<p>EyeCRO, Oklahoma City, Oklahoma, USA 2023 August 11th</p>
	<p>Preclinics GmbH, Potsdam, Germany 2023 October 17th</p>
	<p>Nuvisan GmbH & Nuvisan ICB GmbH, Berlin & Neu Ulm, Germany 2024 March 25th</p>