GALDERMA

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R&D at Galderma

Galderma is committed to advancing dermatology for every skin story. This is grounded in our over 40-year heritage of investing in science-based innovation. We have a global team of over 600 R&D professionals who have executed more than 770 clinical trials with approximately 40,000 patients across 30 countries since 2019, and who have driven the achievement of more than 250 major health authority approvals since 2020.

Ethical Framework for R&D Activities

In accordance with the "*do the right thing the right way*" concept, all activities carried out or sponsored by Galderma, which are dedicated to product design and development, must follow a set of ethical guiding principles. These ensure that all R&D initiatives prioritize patient safety, scientific integrity, reinforce trust in Galderma and:

- Comply with international and/or local laws and regulations, adhere to the company culture, values and principles as expressed in the Galderma Code of Ethics, and follow relevant company policies, standard operating procedures or guidance manuals,
- Are conducted in accordance with the Ethical Principles defined by the World Medical Association originating from the Declaration of Helsinki; the rights, safety and well-being of all human subjects, including the most vulnerable, are the most important considerations and should prevail over the interest of science and society,
- When in-vivo/ex-vivo research activities are required, strictly adhere to animal welfare laws and guidelines. Furthermore, the use of animals must comply with the principles of the 3Rs framework (i.e., Replace, Reduce, Refine),
- Include carefully reviewed and validated expected outputs, ultimately triggering decisions to move initiatives forward considering pre-defined criteria – such decisions must involve all relevant stakeholders and consider, as appropriate, scientific, medical, safety, ethical and quality criteria,
- Use technologies (e.g., IT systems, digital health) in a fit-for-purpose way and adapt to the scientific and operational design of the development activities. Validation of such technologies, across their entire lifecycle (incl. planning, implementation, maintenance, retirement), should be based on a risk assessment that considers their intended use,
- Handle collection, storing and usage of identifiable data and biological materials in Health Databases and Biobanks as per considerations outlined in the WMA Declaration of Taipei – the privacy of research subjects and the confidentiality of their personal information should always be guaranteed.

Beyond strictly adhering to these ethical guiding principles, Galderma ensures it has the right systems and processes in place to uphold those ethical principles during all product design and development activities. This includes:

- Deploying a dedicated Quality System to uphold efficient design and development processes, reliable, accurate data generation and associated analysis and the overall compliance with effective guidance, standards and regulations,
- Complying with the effective external system of references (e.g., GxP, ISO),
- Conducting regular risk assessments related to topics such as patient/consumer safety, environmental impact of ingredients/products or investigators' qualifications,
- Documenting, in dedicated protocols/programs, the rationale, scope, goal(s) and objective(s) of each product design and development initiative. All initiatives should be subject to a controlled project management approach ensuring the successful achievement of the initiative while honoring the project constraints (i.e., time, budget, quality),
- Ensuring that all employees, contractors, suppliers and consultants (if any) have the appropriate qualifications and receive relevant training to perform the assigned tasks.

When product design and development activities conclude with a product being placed on the market, Galderma must have received formal approval and/or certification from the relevant Health Authority or Notified Body based on the product classification and applicable regulatory requirements of the concerned country(ies) and/or region(s). Finally, Galderma ensures that appropriate instructions related to product use are always available and provided.