GALDERMA

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Clinical Trials at Galderma

Galderma seeks to continuously demonstrate its ethical, clinical and scientific endeavors to the public and, in turn, believes that patients, healthcare professionals and other members of the public should have access to medically important information from Galderma's clinical research.

Trial Data Transparency

In compliance with legal and regulatory requirements, as well as guidance from the Declaration of Helsinki and the International Committee of Medical Journal Editors ("**ICMJE**"), Galderma registers its Phase IIb, III and IV clinical interventional trials involving drugs, biologics, medical devices and combination products in publicly accessible databases prior to enrollment of the first participant for any clinical trial.

Galderma's internal policies and procedures provide specific instruction to all clinical trial management teams defining what details are to be registered, in which registries and by what deadlines, ensuring accurate and updated registries. Clinical trial participants are informed that a description of the clinical trial and a subsequent summary of the results will be made available on clinical trial registries in a manner that does not reveal their personal information or identify them in any way.

Galderma is committed to publishing the results in a timely, objective, accurate and balanced manner, regardless of trial outcomes. Making clinical trial details available in such public forums supports Galderma's commitment to guiding decisions about patient care regardless of the study outcomes. Galderma is committed to publishing trial results in credible peer review journals whenever possible.

Galderma's Position on Ethical Conduct of Clinical Trials

Governance and Clinical Trial Oversight

The ethical conduct of clinical trials is of the utmost importance to Galderma. Our Pipeline Committee, chaired by the Global Head of Research & Development, governs matters relating to product pipeline, quality and safety and is responsible for decisions associated with our development programs.

All parties involved in a Galderma study, including Galderma, third-party vendors contracted to perform clinical trial activities and investigational site personnel, are required to conduct the study in accordance with ethical principles based on the Declaration of Helsinki, Good Clinical Practice ("**GCP**"), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("**ICH**") guidelines and the applicable national and local laws and regulatory requirements.

In cases where Galderma contracts with a Contract Research Organization ("**CRO**") or other third-party vendors to perform clinical trial activities on behalf of Galderma, each of these vendors goes through a thorough qualification assessment by our Quality Assurance team. Additionally, the training and experience of critical vendor staff is assessed to ensure appropriateness for the nature of the study. Only those vendors and their staff who meet our quality standards are selected to perform activities on behalf of Galderma.

In accordance with ICH/GCP guidelines, Galderma, as the sponsor of a clinical trial, ensures oversight of all trial-related duties and functions carried out on its behalf, including clinical trial-related duties and functions that are sub-contracted to another party by the sponsor's CRO or other contracted vendor. Key elements for oversight in a clinical trial, including vendor/CRO oversight, include, but are not limited to:

- Risk management
- Budget, milestones and payments
- Vendor selection, audit planning and contracts
- Project management plan and issue management
- Resources training and delegation
- Study documents
- Study product management
- Study start-up and site activation
- Monitoring and on-site quality visits
- Safety handling and data review
- Study completion and site close-out visits
- Archiving

Independent Ethics Committee/Institutional Review Board

To further secure Galderma's commitment to the ethical conduct of clinical trials, an Independent Ethics Committee ("**IEC**") or Institutional Review Board ("**IRB**") is contracted to review and approve all clinical trial protocols, informed consent documentation and other relevant trial materials to ensure ethical requirements are met prior to the study commencing at each study center or the study product being released to the investigator. Any necessary extensions or renewals of IEC/IRB-approved documents are submitted for review and approval prior to implementation and the IEC/IRB is notified when the study has been completed.

The IEC/IRB will be informed promptly of any new information that may adversely affect the safety of the trial participants or the conduct of the study and all required follow-ups will be promptly communicated.

Trial Participant's Voluntary, Prior and Informed Consent

Galderma understands that joining a clinical trial is an important decision for potential clinical trial participants. We are therefore committed to obtaining voluntary, informed consent from all clinical trial participants prior to any clinical trial procedures being performed. The process of obtaining informed consent must be in accordance with applicable regulatory requirements and must adhere to Good Clinical Practices ("**GCP**"). No trial participant will undergo any study-related examination or activity before receiving information about the clinical trial and being given the opportunity to ask questions they may have and having given their written informed consent to participate in the study.

Informed consent documentation for all Galderma trials provides critical details necessary for a participant to make an informed decision regarding their participation, including, but not limited to:

- The reason why the clinical trial is being performed
- What will be expected of the participant should they decide to participate
- The potential risks and benefits of participating in the trial
- Alternative treatments, if any, should the participant decide not to participate in the clinical trial
- Timely communication of new findings that could affect the participant's safety or willingness to continue participating in the clinical trial
- The costs and payments associated with their participation
- Important study contact information

Participation in any Galderma clinical trial is voluntary and participants can stop participating in the study at any time for any reason. There will not be any penalty or loss of benefits to which the participant is otherwise entitled if they decide not to take part or if they decide to stop participating in the study. A participant's consent to participate in a Galderma study does not deprive them of any legal rights in the case of negligence (carelessness) or other legal fault of anyone involved with the study.

Clinical trial participants are encouraged to communicate any questions, concerns or complaints throughout their study participation. The informed consent documentation sets out the grievance mechanisms and advises trial participants to contact the investigator should they experience any medical problems, suffer a study-related injury or have questions, concerns or complaints about the study. Contact information for the IEC/IRB overseeing the research is also provided in case a participant has questions about their rights as a research subject.

Regular Monitoring of Clinical Trial Activities by Qualified Personnel

Galderma understands that ensuring the ongoing ethical conduct of a clinical trial requires regular monitoring of the trial activities and data. Galderma ensures that routine monitoring of ongoing clinical trials by qualified personnel occurs throughout the duration of the trial (as specified in the trial-specific Clinical Monitoring Plan).

All study team members and investigational site personnel will be trained prior to study initiation on the condition to be treated, the standard operating procedures to be used in the clinical trial, the protocol and all trial-specific procedures. Team organization, communication and operational issues will also be discussed and agreed upon. Regular ICH/GCP training (at least annually) is also required.

Clinical trial monitors will carry out source-document verification procedures to ensure the data collected in the case report form is accurate and reliable. Any identified deviations from the protocol will be documented and communicated accordingly to Galderma and the IEC/IRB for further evaluation as per defined procedures and classification prior to database lock.