HALEON

Our approach to clinical trials

Our Haleon position

Background

Clinical trials are conducted on development and marketed products. Regulators will only approve a new medicine if these trials, together with other research data, demonstrate it has a favourable risk/benefit profile.

This position describes Haleon's approach to conducting clinical trials. It sets out the philosophy underpinning our approach and covers topics including where we conduct our studies, the standard of care we apply, and access to medicines post-trial. It also sets out how we may put in place additional measures in countries with less developed research infrastructure, to help ensure that the rights, safety, and wellbeing of trial subjects are protected, no matter where in the world the trial is being conducted.

Haleon's position

All Haleon clinical trials are conducted according to the same fundamental ethical principles. Our trials follow the standards of the International Conference on Harmonisation (ICH) Good Clinical Practice guidelines, and the principles contained in the World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects. They also abide by other relevant international codes, principles and local regulatory requirements.

Our standards apply to all Haleon clinical trials in all locations, irrespective of whether they are conducted by us or on our behalf by external contract research organisations (CROs, onshore or offshore).

The type of reimbursement or other compensation offered by Haleon to trial participants for their time and/or for any discomfort experienced is appropriate to the local economy and approved by Independent Ethics Committees. Payments to investigators or their institutions reflect fair market value and are in line with local practices.

International standards

Haleon conducts clinical trials in accordance with the principles of the Declaration of Helsinki to safeguard the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. This includes addressing risks (including appropriate use of placebo), burdens and benefits, scientific requirements, informed consent, and transparency.

All clinical trials at Haleon, and those carried out by CROs on our behalf, are conducted according to the ICH's Good Clinical Practice Guidelines and this includes a commitment to regular monitoring of our trials. The Guidelines provide an internationally accepted ethical and scientific quality standard for designing, conducting, recording, and reporting trials. They cover topics such as having a clear, scientifically sound protocol, signed by relevant investigators and approved by an Independent Ethics Committee/Institutional Review Board (IEC/IRB); the selection and training of trial investigators; gaining voluntarily given informed consent from every trial participant; demonstrating that the anticipated benefits justify the risks; and ensuring that the rights, safety and wellbeing of subjects are the most important considerations. Managerial responsibility for ethical conduct in clinical trials is set out in two Standard Operating Procedures and all staff involved in trials undergo

training and awareness programs before performing any trial tasks. Staff undertake retraining on the relevant SOPs annually. A risk/impact assessment is performed before and throughout the execution of trials. Haleon has written standards specifying expectations of public reporting on monitoring outcomes, violations in clinical trials and corrective action.

In view of Haleon's focus on consumer products available without prescription, post-trial access to alternative medicines is not an issue in our trials.

Collection, storage and use of human biological samples

Research using human biological samples (HBS) is conducted to gain knowledge that contributes to human health and quality of life. Such samples are important for studies which aim to elucidate the mechanisms of human disease and discover new treatments. Haleon is committed to collecting, storing and using HBS consistent with high ethical standards which protect the dignity and identity of human donors. Biomedical research using HBS must always be carried out with respect for human rights. Informed consent must be freely-given. The HBS must be collected without inducement. The collection and use of HBS and/or associated data for research should never adversely affect consumer care. Haleon will seek to ensure that in collecting a sample, the physical risks to the donor are minimized. We also protect the privacy and confidentiality of any data derived from the sample. In addition, the risks related to privacy and confidentiality of donors' families, and/or identifiable populations or groups will be minimized to the greatest extent possible. As with all aspects of our research, Haleon will take into account any actions needed to avoid discrimination against, or stigmatization of, a person, family or group when collecting, using and storing biological samples.

Location of our clinical research programmes

We are committed to delivering better everyday health globally and, as such, we conduct clinical trials all over the world. The main criteria we use for determining location is consumer need and intent to register as we conduct trials only where the investigational product will be marketed. We also use operational criteria such as research infrastructure and the location's regulatory systems. There are also scientific and regulatory reasons why clinical trials are conducted in specific countries. For example, some countries, such as China, Japan, and South Korea, require the provision of clinical trial data from local populations as a prerequisite for product registration.

Ethical review

Haleon will always seek formal approval for clinical trials of medicines from Independent Ethics Committees and local regulatory authorities.

Informed consent

Informed consent is the practice of ensuring that every trial participant enrolled in a clinical trial voluntarily confirms his or her willingness to participate in the trial, having been informed of all aspects of the trial that are relevant to their decision to participate. The purpose is to ensure the patient is aware of the risks involved and has made an informed decision to participate. Every consent form presented to a potential research subject includes an explanation of what would happen if that person were to get injured while taking part in the study, and of the procedure to follow in the event of such injury.

Haleon recognises that informed consent in clinical trials is critical. In some circumstances, additional local cultural factors may be considered to ensure the informed consent is well understood. In this scenario, Haleon may work with local healthcare professionals to facilitate the consent process according to local custom and culture.

Where formal written informed consent from the participant is not possible in a Haleon sponsored trial (due, for example, to illiteracy), investigators will work with independent witnesses to document a verbal consent process. This is as per the standards set out in the ICH Good Clinical Practice Guidelines.

Payments and other recompense

The type of reimbursement, or other compensation provided to participants in a Haleon-sponsored clinical trial, must be appropriate to the local economy and submitted to Independent Ethics Committees for approval.

Disclosure of payment plans is an obligatory part of the Independent Ethics Committee's approval process. This ensures that any payments are appropriate to the local setting. The standard continues to be that participation in clinical trials is voluntary. Care must therefore be taken to avoid undue financial influence on participants' decisions.

Payments to investigators for their professional expertise, time and involvement are in line with local practices. These payments embody the concept of "fair market value" so that investigators / institutions are fairly compensated according to their local markets for their efforts in conducting good quality clinical trials.

Haleon discloses payments made to healthcare professionals and healthcare organisations involved in Haleon-sponsored clinical trials, in accordance with local requirements.

For more information on this, as well as our approach to transparency in publishing clinical trial data, please see our position on ***clinical research transparency****.*

Standard of care

Haleon designs and conducts clinical trials so that the care and treatment of participants during the trial is at least consistent with, and may be higher than, the standard of care available if they were not taking part. This includes the types and frequency of medical evaluations that are part of the trial. In addition, any comparative treatments used in a trial will have at least equal benefit with those that patients would have received outside the clinical trial, i.e., the local standard of care.

Use of placebo

A placebo is an inactive substance that looks like the treatment being tested. It is used in clinical trials to test the effectiveness of treatments. Placebo-controlled studies are conducted only when there are compelling and scientifically sound methodological reasons (including when there is no effective standard of care to use as a comparator), and when the risks to the study subjects who receive the placebo are minimised and are not an additional risk of serious or irreversible harm. As

for all studies, Haleon will ensure that subjects in placebo-controlled studies give their informed consent without coercion or inducement, that precautions are in place to minimise risks, and that there is appropriate oversight by the Independent Ethics Committees and approval by regulatory agencies.