HALEON

Clinical research transparency

Our Haleon position

Background

The healthcare industry communicates the results of its clinical research by publishing in scientific journals; by presenting results at scientific congresses; and, in line with established industry commitments and evolving legal requirements, by posting information and results on internet-based public registers. This disclosure is in addition to submission of information to national or regional regulatory authorities as part of the product development or approval process.

Despite this, however, concerns have been raised by some stakeholders about:

– whether study results which may be viewed as "negative" for companies' medicines are published in scientific literature;
– whether published studies accurately reflect the conduct of the study;
– whether some journal articles are "ghost-written" (where doctors put their name to articles written by healthcare companies); and
– the lack of access to the underlying participant level data that is collected during the study.

Our position

Haleon understands the importance of transparency in conducting clinical trials. We are committed to public disclosure and this position sets out our approach, which meets all applicable legal and regulatory requirements. We reinforce these commitments by continually assessing our performance. A monthly dashboard of metrics on our transparency activities is maintained as part of our internal business monitoring. Our principle is to disclose publicly information about Haleon-sponsored clinical research that evaluates our products, irrespective of whether the results are likely to be perceived as positive or negative. Likewise, we require investigator-sponsored studies, supported by Haleon, to be conducted and publicly disclosed on registers, with the results submitted for publication in a peer-reviewed journal. As well as supporting transparency in clinical research, publicly available internet-based registration of ongoing clinical research can help to increase participation. It also provides an important reference point so interested parties can track the subsequent public disclosure of the results.

We disclose our clinical research in the following ways:

- Before the first subject is enrolled in a study, we post protocol summaries of all Haleon sponsored studies on the Haleon Clinical Studies Register.
- Haleon Sponsored Interventional studies are also posted on ClinicalTrials.gov

Irrespective of the outcome of the study, we post result summaries within 12 months of primary completion date for interventional studies. At the time of results' registration, we also post the full protocol and the statistical analysis plan.

Our commitment includes posting results from studies of terminated interventions, in order to help inform the scientific community about non-productive areas of research and to reduce unnecessary exposure of study participants to similar interventions in other clinical trials.

To inform investigators of the outcome of a Haleon-sponsored trial, we provide them with a summary of the study results, along with a lay summary to share with study participants (in Phase II – IV trials).

Haleon also discloses payments made to healthcare professionals (HCPs) and healthcare organisations (HCOs) involved in Haleon-sponsored clinical trials.

Publication and internet-based posting of clinical research results

The posting of information about Haleon-sponsored clinical research in the ways described above does not replace the need to publish studies in peer reviewed journals. Our approach is to submit studies as more comprehensive manuscripts for publication in peer reviewed journals, with an increasing focus on open access journals that are indexed by online search engines such as Medline and Embase. The manuscripts are submitted within 18 months of study completion, regardless of market authorisation or termination.

We aim to publish all interventional and non-interventional studies that evaluate the efficacy, safety, or effectiveness of our products in humans. We also aim to publish other human subject research when the results provide important scientific knowledge or are relevant for patient and consumer care.[1]

However, there are well-recognised constraints associated with this approach. With limited journal capacity, some studies or analyses may not be considered a priority by some journals and therefore may not be accepted for publication. At times,

1 Haleon generally does not support publication of data from an individual centre in a multi-centre trial. It is Haleon's position that the results from the entire trial should be published before information from individual centres is published, and that individual centre data should always reference the primary publication of the entire study.

through a governance review process, we also recognise that a publication attempt would be futile for reasons such as early study termination with limited enrolment.

Posting result summaries on internet-based registers is part of the solution as it ensures that the results of clinical studies are available in the public domain, whether or not they are accepted for publication.

Authorship

Haleon's policy prohibits "ghost writing" of journal manuscripts and abstracts by requiring authorship and acknowledgements for scientific publications, consistent with the requirements of the International Committee of Medical Journal Editors (ICMJE). Haleon and external medical writers are either named as authors or included in the acknowledgement section of manuscripts. We determine this based on the level of intellectual contribution to study design; data acquisition; analysis and interpretation; and writing or revising the manuscript. Some journals, however, have a narrower definition of authorship and this convention is followed for such journals.

Access to participant level data

Publication of clinical studies in the scientific literature and result summaries on registers typically only contain aggregated data. These publications therefore have limitations for those who wish to examine the data more closely or to combine it with other studies in meta-analyses. To address these limitations, there needs to be greater access to underlying participant level data.

Haleon has an online system to enable researchers, once the study has been published, to request access to anonymised participant level data from Haleon clinical trials (phase I-IV).

Anonymised participant level data from Haleon studies is only made available provided that an Haleon Internal Review Panel approves an associated research proposal, and the investigator signs a Data Sharing Agreement. The Review Panel accepts or rejects proposals based on the scientific rationale and relevance to medical science or participant care. The Panel also considers the qualifications of the investigators, the management of potential conflicts of interest, and publication plans. Access to the data is provided in a secure manner to help ensure participant privacy is protected and the data is used only for the intended purpose.

*For further information on this topic, please see our **position on our approach to clinical trials**.*