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.

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. The dashboard shows metrics measuring compliance with our obligations to disclose key documents including protocol and results summaries, statistical analysis plans and plain language summaries. Our principle is to disclose publicly information about Haleon-sponsored clinical research that evaluates our products, in accordance with legal and regulatory obligations. Likewise, we encourage 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 on credible and publicly accessible databases, e.g., ClinicalTrials.gov, depending upon the study site and any additional country or regional study registration requirements, and 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.

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

Publication 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 those studies that are on public databases 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 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, 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.

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

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[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.

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, raw data from Haleon clinical trials (phase I-IV).

Anonymised participant level, raw 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**.*