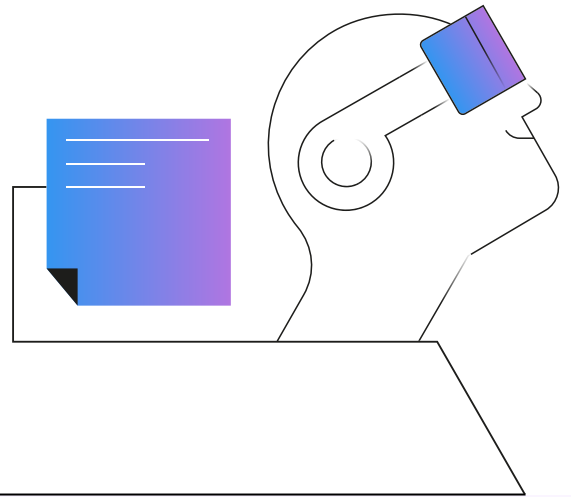


Developing Clinical Outcomes Assessment Measures Suitable for Regulatory Label Claims

Case Study | Regulatory Label Claims

Development of novel, fit-for-purpose Clinical Outcomes Assessment (COA) measures for inclusion in pivotal trials in alopecia



Background

No fit-for-purpose patient reported outcome (PRO) measures to assess signs/symptoms specific to alopecia areata (AA) existed.

The need for clinician reported outcome (ClinRO) measures specific to certain aspects of the disease were also lacking.

The Challenge

The sponsor wanted to develop novel COA measures for use in their planned Phase III clinical trial evaluating treatment in patients with AA.

The sponsor required measures to be developed that met global regulatory requirements including understanding the responder definitions. In addition, considerations for HTA requirements were needed.

The Solution

Clarivate Commercial Consulting

Our COA experts designed and executed a suite of bespoke projects to develop and conceptually validate novel measures, including:

- Expert dermatologist interviews
- Combined concept elicitation and cognitive debriefing patient interviews with qualitative exploration of meaningful change
- Novel PRO and ClinRO measures developed to assess key clinical trial endpoints (associated with scalp, eyebrow and eyelash hair loss, nail changes, and revisions to an existing PRO [Skindex])
- Within-patient clinically meaningful change thresholds identified to inform responder definitions
- The COA team worked closely with their design team to develop a photo guide to support the novel measures.
- Supporting studies in Japan to test conceptual relevance and meaningful change thresholds
- Usability testing for ePRO devices

The Results

The product was approved with novel measures included in the label



Sponsor's product was approved by FDA, EMA and PMDA, with data from the novel COA measures included in the labels/product information



Published in several journals including Journal of Patient Reported Outcomes, British Journal of Dermatology, and American Journal of Clinical Dermatology

[Click here to learn more](#)

Discover solutions at:

clarivate.com