Your innovation experts in natural health products

# WEIGHT MANAGEMENT

*A category for innovation & growth*

The prevalence of overweight and obesity is increasing dramatically. According to the WHO, obesity has nearly tripled since 1975. Being overweight or obese is associated with several noncommunicable diseases, such as **cardiovascular diseases, diabetes, or some cancers.** And even the risk of serious complications or death resulting from Covid-19 are clearly linked to increased body weight. As expected, first studies could show that consumers behaviour during Corona lockdown led to significant weight gain.

## HOW TO CONDUCT WEIGHT MANAGEMENT TRIALS

In the EU, the use of claims on food or food supplements is regulated by the **Nutrition and Health Claims Regulation** ((EC) No 1924). Basically, the scientific evidence backing a health claim is evaluated by the **European Food Safety Authority (EFSA)**, which publishes an opinion on the claim, either supporting or not supporting the claim under evaluation. The European Commission (EC) then usually adopts this opinion. Different EFSA guidance documents are available to assist applicants in drafting the dossier but also to give indications on how to conduct weight management trials properly.

## HIGHLY EXPERIENCED TEAM

Our clinical research team is highly experienced with clinical trials on weight management, especially in the fields of **weight loss** and **appetite control**. Indeed, weight management studies can be designed very differently, depending on the outcome parameters. Especially in studies with a long study duration, **recruitment can be challenging**, as can keeping the enrolled subjects compliant with study requirements. In these cases, a tight supervision by our own study center and experienced cooperating practices has been crucial.

In cooperation with our regulatory team, we can support you from many angles including **scientific and regulatory aspects**, but also with the practical implementation of a weight management study with all of the pitfalls that are not mentioned in the official EFSA guidance.

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## OUR SERVICES INCLUDE

As a full service CRO with our own associated study site, a&r can carry out studies from A-Z:

- Expert advice during the **conception and planning** of clinical studies including advice on the design, study population, outcome parameters, or study duration
- Submissions to and communication with **ethic committees**
- **Coordination and performance** of studies including patient recruitment and handling of investigational product (incl. randomization/labeling/blinding/logistics)
- **Subject database** with several thousand test subjects, enabling a quick and specific recruitment
- **Own study center** enabling the implementation of complex studies e.g. appetite studies where food preparation and intake can be controlled
- Writing of all relevant **study documents** including study plans, reports, and publications
- **Monitoring** including quality control, preparing and conducting study site visits, supervising the progress of the trial, and compliance with SOP and GCP guidelines
- **Data management and statistics** including sample size calculation, concept development of statistical analysis, statistical analysis of study data, and drafting of relevant documents
- Contract and financial management

## OUR EXPERIENCE WITH WEIGHT MANAGEMENT STUDIES

At a&r, we have conducted 18 weight loss and maintenance as well as appetite control studies at our study site in Berlin together with our experienced investigator network:

- Randomized, placebo-controlled; cross-over or parallel group designs
- Nearly 2000 overweight/obese (class I) subjects enrolled
- Intervention periods from 3-12 months
- Methods:
  - Body composition: BIA; MRT (determination of abdominal fat)
  - Laboratory: blood sample analysis, fat biopsy analysis
  - Test meals: controlled (ad-libitum) meals
  - Validated questionnaires: quality of life, appetite sensation
  - Dietary counselling (dietician-based)
  - Microbiome assessment

## LICENSING OPPORTUNITIES

Within our network we offer some very specific commercially ready products and value propositions for licensing.

# CONTACT US


**FELIX ALT**
Head of Clinical Operations
*falt@a-r.com*



**analyze & realize GmbH**
Waldseeweg 6
13467 Berlin – Germany
*www.a-r.com*