

Advice to CTPA Members – November 2018

Statistics Principles for Efficacy Testing for Cosmetics

CTPA is the trade association for the UK cosmetic, toiletry and perfumery industry. The Association's role is to advise member manufacturers, distributors and suppliers about the strict legal framework for cosmetics, to represent industry views to UK Government and external stakeholders and to help promote information to the media on issues relating to the safety, efficacy and quality of cosmetic products.

The science behind innovative cosmetics is carried out by highly qualified scientists from many different specialist fields. To put just one new product on the shelves can take up to five years or more, with a dozen senior scientists working on it, each supported by their own team of scientists. The laws surrounding cosmetic products are very stringent and cover the manufacture, labelling, claims and safety assessment of all cosmetic products supplied to the EU market. It is a legal requirement that all claims made on-pack must be substantiated. This information is open to review by the regulating authorities; in the UK, this is Trading Standards.

When compiling a body of evidence to substantiate claims, companies will assess which studies should be relevant to the claims being made. Companies will base their studies upon reliable and scientifically valid methodologies. The studies should be well-designed, well-executed and accurately reported so that the results are robust and reproducible. The validity of a well-designed study is therefore not limited in time. Studies are usually conducted prior to launch of a product and where a formulation, claims and target population remain unchanged there is no necessity to repeat studies over time.

The supporting information is kept by the Responsible Person as an obligation under the Cosmetic Products Regulation 1223/2009. The Responsible Person is required to ensure that each cosmetic product placed on the Community Market has a complete Product Information File (PIF). The PIF contains all of the mandatory information on the product, including proof of effect. The Responsible Person is easily identifiable as its name and address should be labelled on the cosmetics packaging. The PIF is the property of the Responsible Person.

Studies conducted on volunteers should respect ethical rules. Such studies should be carried out on a **justifiable number of volunteers** that are representative of the population at which the product is targeted. For example, evidence in support of a product that claims a cumulative moisturising effect on dry skin should include studies on subjects with dry skin. **Justifiable** in this context means sufficient to ensure the results obtained are unlikely to be the result of chance alone but reflect the anticipated result in the target population. Common statistical parameters enable the necessary number of volunteers to be estimated and should be used to explain the selection of the group sizes.

Appropriate inclusion and exclusion criteria should be used to screen volunteers for obvious mismatches and for levels of key characteristics e.g. wrinkles and age spots. In comparative studies, good experimental design allocates subjects in such a way that groups are essentially similar at the start of a study in terms of the parameters being studied.

What is the right number for a study?

- There is no single 'right number'.
- The required group size depends on the nature of the claim, the nature of the test method, the magnitude of the likely effect and the degree to which a chance result is to be excluded.
- Parity claims require larger panels than difference claims
- Controlled studies, especially where a subject can serve as their own control, often require smaller group sizes than consumer opinion panels.

Therefore, the right number of participants needs to be assessed on a case-by-case basis. When determining the panel size, the following key factors must be considered:

- variability;
- confidence interval;
- significance level;
- power calculations.

A good working knowledge of the science of statistics is necessary to be able to apply these factors correctly.

Studies can be performed on a remarkably small number of subjects (e.g. 3) under certain specific conditions; studies can also be performed on a relevant age group or on a certain skin type of subject where the benefit is targeted.

Depending on the claim, the number of volunteers required can be very high (e.g. above 1000).

Selection of relevant statistical tests are based on a knowledge of the scale of measurement, the variability of the data and the normality of the observations or data. It is important to use a statistical method that is appropriate to the purpose of the analysis, to the data type and to the data independency. Using a template or standardised number of volunteers (e.g. 50) for all studies is therefore incorrect as the right number of participants needs to be assessed on a case-by-case basis.