



The precious value of the clinical scores

The implementation of the efficacy studies refers to the regulation in each world zone and sometimes each country. In Europe, the reference is the European regulations for cosmetics (EC.N° 655/2013 Art.20 -Art.22) with principally the common **Product Information File (P.I.F)**.

To substantiate the product claims cosmeticians must respect the **6 common criteria**: Compliance with legislation, Truth, Adequate and verifiable evidence, Sincerity, Equity, and Choice with knowledge of causes. There are no specific norms for each test (excepted sensory analysis and sun protection index cf. ISO) and the testing managers can follow guidelines for human testing such as EEMCO, Good Clinical Practices...

These scientific objectivation processes protect the consumer from misleading claims and preserve the credibility of the cosmetic industry. The investigators can choose to validate clinically on human the performance of their active ingredients or finished products among **4 categories**:

1. **Consumer tests**: these studies are performed by a naïve panel under normal conditions of use of the product. The insights of the consumer are collected via an auto-evaluation of the treatment using a questionnaire design case by case.
2. **Sensory or emotional analysis**: this testing performed by trained experts or naïve panels, in real life conditions or online, to objectivate the product activities perceived by the subjects.
3. **Biometrological studies**: this objectivation is a direct measurement of the several mechanisms of the skin, the hair or the nails using instrumental devices to visualize or quantify the influence of a treatment.
4. **Clinical score tests**: This is a scientific approach of the evaluation of a product efficacy by experts using dedicated scales and descriptors.

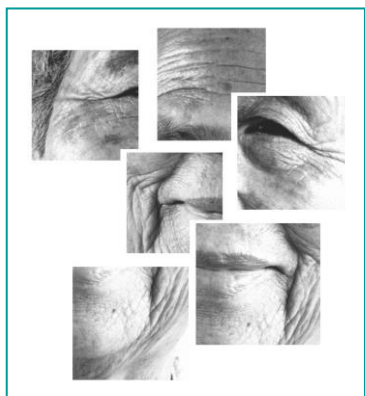
Cosmeticians can also design the protocol of the studies combining 2 or 3 of type of testing.

Why clinical scores are suitable for the performance evidence ?

The clinical evaluation methods by trained experts or dermatologists enables with photos and scales, the **objective visual and tactile quantification** of the several clinical signs present at the skin, scalp, hair or nail surface. In this case, **the “eye” and the fingers become the real instrumental devices**.

We can find numerous scales and atlas linked to various criteria. They have been developed to help to objectivate the several performances of cosmetics. But there are **no norms** and anyone, sponsor or investigator can **create its own scale** referencing pictures with the adequate grade related to the studied criteria. We notice that, because of the specificity of each assessor and the test conditions of each lab, the intercenter objectivation is more difficult to implement.

However, since more than 10 years, there are specific atlas published by L’Oréal R&D team such as the well known atlas currently named “**Bazin Atlas**” ones that everyone consults for the ageing evaluation and subject inclusion. They exist for several skin types: Caucasian, Afro-American, Indian and Asian. Other dermocosmetics brands like Pierre Fabre, Clarins, Chanel, Yves Rocher among other, have also developed their own atlas.



The clinical score is a **global approach** which can be doubled by photographs of the face, front or profile, which can be randomly scored 2 by 2 and classified by naïve or experts’ panel. The disadvantage of the picture score is its 2D format, the variation of the type support (screen..), the absence of a dynamic... But it is an interesting method because of the flexibility it offers (assessor type, timing) and especially for the data treatment with **AI algorithms and modelling**.

What scores for what claims ?

For some claims, there are scales which are generally used; this list is not comprehensive. We know that some parameters are more difficult to evaluate by the experts.

- **Moisturising effects:** Analogue visual scale; ODSS Overall Dry Skin Score; SRRC Specified symptom sum score. The dry skin/ichthyosis area and severity index (DASI)...
- **Skin ageing:** Lemperle classification, Carruthers scales, Kappes & Elsner scoring, the Bazin & co Atlas...
- **Complexion radiance:** one of the most difficult score to objectivate, CLBT (JC Pittet) scoring for colour, luminosity, brightness and transparency for Caucasian and Asian skin.
- **Colour:** Skintone (Pantone) scale
- **Body morphology:** 2 scales for body-images (Gardner and al.), Body shape Questionnaire (Rousseau and al.), Body-image assessment scale (Thompson and al.)
- **Cellulite:** mechanically accented microrelief of thigh skin (Perin and t al.), photo scale of Skin roughness using oblique light (Bielfeldt and al.), photo numeric cellulite severity scale (Hexsel and al.)
- **Other claims:** all the visual aspects of the skin such as erythema, black spots, lightening, whitening, greasy skin, redness, make-up lasting, prone to acne, sagging of the face, softness... can be evaluated using scale.

What are the considerable advantages of the score ?

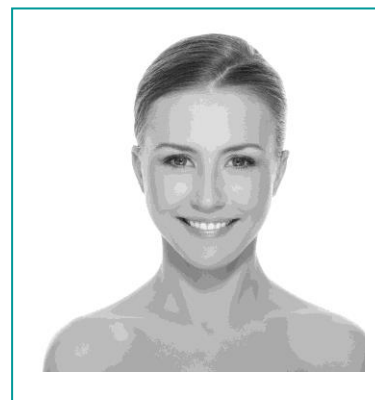
s.a.r.l HAPPYWAY-SKINOBS . Le Koala Technolac . 17 rue Lac Saint André . BP 20526 . 73375 LE BOURGET-DU-LAC . France T. 33.(0)6 30 08 90 98 . Email : contact@skinobs.com SIREN 818878381 . RCS Chambéry

- A global 3D **in life** visual and tactile including qualitative and quantitative aspects: surface, size, numbers, intensity,
- An **objectivation by seasoned professionals**
- Tests **easy and quick** to conduct,
- A **predictive and sensitive** tool.

The challenges of the clinical scores: beyond repeatability and reproducibility

- The precise **definition of the criteria** for each product claim with the characterisation of the entire process: zone, distance, scale type...
- **The training of the evaluators** to reduce the inter-assessor variability, implement yearly (minimum each year),
- The **conditions of the test**: lighting, positioning, distance of the subjects and the evaluator, colour of the clothes, the hair style . The Evalux bench (Orion concept) and other photo bench seem to be a reliable solution to standardize the subject’s positions.

When conditions are met, the clinical evaluation is a good **predictive tool** because of the **sensitivity and the precision** of the human analysis combining knowledge and experience. It gives elements to better understand the product effect which is not always demonstrable by the instrumental devices. This method seems to give **closer results to the consumer tests** and to be **generally coherent with other methodologies**, depending of the studied signs.



Good news! **AI is around the corner** and cosmetics labs, CROs and devices and software manufacturers are focused **in the learning process of neural networks**. The training of the AI systems with tens of thousands face pictures of multi-ethnic panels allow an **automatic grading made by the machine** (Newtone technologies). Then, the sophistication of the smart phone sensors and the **augmented and virtual reality systems** make any innovative tool in this field relevant, simple and accessible.

The demand for personalized diagnostic coincides with the smart technologies’ diffusion (IA, deep learning...). It will give the opportunity to the consumer to be more and more her “self-assessor”. To achieve this numerical evolution the expertise of the “clinical experts” is really needed. The clinical score never dies !

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