

## Dermatological clinical research in India

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For many decades in India, topical products have been considered the least complicated, for various reasons. Research therefore was limited. Even new and innovative ingredients for dermatological and cosmetic formulations have emerged fairly recently. It must be noted however, that skin is the most amazing, largest and most complex organ of the human body. Every pharmacist knows that a damaged skin can be vulnerable to many diseases.

With seemingly simple and basic functions of protection and temperature regulation, the skin vies for the greatest attention of the consumer who is becoming increasingly aware, and seeks better products for skin and hair. They are no more satisfied with sticky ointments or lotions, may it be a cosmetic or pharmaceutical preparation.

All this has led to a quest for research and development to make better products that meet the new-age consumer expectations. Formulators are now taking into account the Indian skin type and its characteristics. Marketers are also going head-over-heels to make some additional claim that can attract the demanding consumers. These changes have now thrown newer challenges for the evaluation of such formulations.

While clinical research for various pharmaceutical drugs, mainly ingestible and parenteral has evolved over a period of time in terms of standardisation of clinical parameters as well as analytical methodologies to ascertain bioavailability and bioequivalence, the same cannot be said for topical products. Such products now encompass topical drugs, OTC formulations or cosmeceuticals which border between cosmetics and drugs in terms of what they have to offer. The evaluation becomes much more challenging for OTC and cosmeceuticals since one has to critically consider not only clinical improvement and manifestation of the treatment often described as 'Do good' criteria but also sensorial attributes of the products referred to as 'Feel good' factors which can significantly impact purchasing decision in this competitive market place.

The designing of clinical trials for topical products thus needs a multi-

dimensional approach. With the emergence of specialised techniques like bioengineering and imaging though, one can only be constrained by one's imagination and not by technical limitation.

Such holistic trials for the topical product, either drug, OTC or Cosmeceutical can reveal significant findings provided they capture various dimensions such as clinical improvement, quantifiable data using non-invasive bioengineering instruments, product sensorials using standardized methodologies and if required 'Consumer insights' though in classical sense it may not be termed as a clinical trial.

The supervision of an expert cannot however be understated. Designing of the trial for a topical formulation, whether for safety or efficacy evaluation, needs careful consideration of inclusion/ exclusion criteria such as specific skin type, skin site and abnormal skin conditions. These could vary with age, sex and lifestyle, apart from genetic predisposition. These are over and above the normal considerations such as concomitant treatment and others which are routinely considered in well designed clinical trials.

Of the above conditions, skin type and skin condition plays very significant part since these can impact the outcome of the trial. Also, in case of cosmeceuticals, which are targeted for specific end users, knowing them well makes the trial more focused and meaningful. This can be done only by experts who have experience and exposure not only in the clinical evaluation but much broader in terms of lifestyle conditions.

Another upcoming area is that of using bioengineering instrumentation to generate more quantifiable and repeatable data. For example, in skin blanching studies for ascertaining bioequivalence of topical corticosteroids, USFDA guidelines too recommend use of 'chromameter' which can give more reliable and reproducible data compared to visual grading.

Skin hydration or moisturisation and aging is another area that is becoming more complex.

'Drying of skin' results from more than just water loss. There could be nutritional deficiencies, exposure to sun, prolonged

exposure to air-conditioning, pollution, age etc. Specific products and ingredients that deliver moisturisation to deeper layers of the skin are now available, resulting in differing efficacies. These need to be evaluated accordingly too. There are numerous instruments now, which can be reliably used for measuring skin hydration, either superficially or in deeper layers. Same is the case for measuring skin colour, skin pigmentation in dermal and epidermal layer, skin wrinkle, skin gloss etc.

The holistic approach in the skin trial however can not be ignored at any stage. Professor Albert Kligman, 'Guru' in the field of dermatological research who has authored several books and published innumerable technical papers, says in his provocative statement 'A fool with a tool is still a fool'. The complete tool in a study is much more than the instrument used in the measurement or scanning. It is also the study design, including the purpose and the clearly identified end points, the sample size, the statistical method, the legalities and ethical practices involved and finally the competence of the researchers that make the outcome of research more meaningful.

Safety of topical formulations also needs special mention here. It involves thorough knowledge of ingredients and their possible interaction with each other and skin. It may result in skin irritation and allergic reactions which can be ascertained through simple tests like open or occluded patch test to more evolved tests like Repeat Insult Patch test, photo patch test and Repeat Insult Photo Patch test. Which test to be deployed can be judged considering product application and use, skin site, skin conditions etc.

Another important consideration while designing the trial would be legal compliance with statutory norms which are country specific. While these are relatively well defined for pharma products, cosmetics too have certain guidelines led down under BIS standards in India. While exporting the product one has to certainly consider other norms as led down by COLIPA for EU, USFDA, ASEAN directives and others.

All in all, dermatological and cosmeceutical products are getting more and more complex and this requires expert evaluation to prove the benefits scientifically.

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