veeda edge

Competent team for clinical end-point studies of your Topical Products to prove Therapeutic Equivalence

Most topical generic drugs require Bioequivalence assessment using clinical end-points with 3-arms for treatment of an approved indication in patient population. These studies are necessary to prove therapeutic equivalence with the reference product and superiority with the placebo. With a **competent team of 250 experienced scientists** and a **stern focus on providing quality solutions**, **Veeda is well equipped to meet the special clinical trial execution** requirements of clinical end-point studies for topical products.

Main challenges for clinical end-point studies for topical products

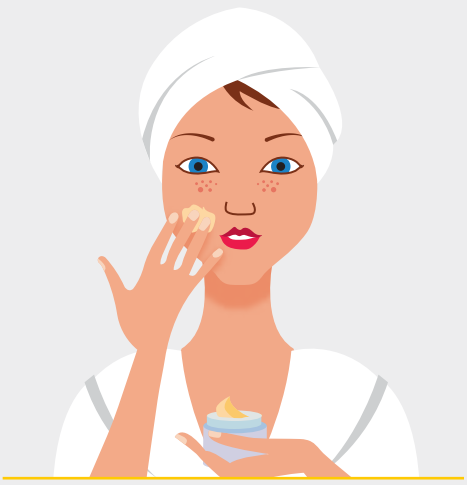
1. **Defined methodologies are not available** unless specified by individual regulatory guidance recommendation.
2. Requires **large patient population** due to unknown inter-subject variability within reference product.
3. Long study duration, seasonal variation and patient compliance.
4. **Justification of placebo arm** with ethical consideration for favorable regulatory opinion.
5. Maintaining the **blinding** through specific procedures of **randomization** across the sites.

Few therapeutic indications for topical products which require clinical end-point studies

- **Acne Vulgaris** • **Actinic Keratoses** • **Atopic Dermatitis**
- **Psoriasis** • **Tinea Pedis** • **Vaginal Atrophy**
- **Vulvovaginal Candidiasis**

Our Capabilities to ensure successful trials

- **Team having experience in resolving the study design challenges** to achieve the study objective and regulatory requirements.
- **Biostatistician with expertise in selecting appropriate statistical tools** for designing statistical attributes and calculating sample size requirements.
- **Consultant Dermatologist on board** to oversee the study design and execution.
- **Database** with good number of **experienced Investigators' sites** for faster recruitment of patients.
- Experience in **randomization techniques** to ensure blinding across the sites.
- **Excellent regulatory liaison** with proven track record.



Veeda Advantage

Fast recruitment rate for healthy volunteers and patient population

Road Map for **more than 25 molecules for Patient based Pharmacokinetic Studies** and **more than 15 molecules for Clinical End Point Studies**

CLICK HERE TO KNOW MORE

Proven regulatory track record with **8 USFDA, 4 European, 4 WHO & 7 ANVISA** audits

State of the art Bio-analytical Unit with **more than 340 validated assays** in its library of compounds, **35 NCE methods** and **20 more Under development.**

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For more information email: info@veedacr.com