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History and Mission

bioskin is a leading CRO with unique understanding and capabilities for both early and late phase dermatological clinical trials.

Recognized by global companies as a valuable partner in trials for drugs, medical devices, food supplements and aesthetics, bioskin provides early phase safety and Proof-of-Concept studies; vasoconstrictor assays according to FDA guideline; global Phase II-IV trials for NCEs; new formulations with known actives and generics.

Highlights

Our core expertise is the development of innovative test designs, interpretation of study results, integrating biophysical measurement methods to deliver objective data about skin function and structure to support traditional clinical endpoints. For global early and late phase studies bioskin partners with selected, reliable partners throughout Europe, US, Latin America, Central & Eastern Europe and South Africa.

bioskin manages clinical trials in all dermatological indications with a special expertise in psoriasis, alopecia and aesthetics. Our in-house dermatologists consult on study design and interpretation of results.

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BVMA member since 2011
Audits passed in 2011, 2014, 2017 and 2020

bioskin

unique in dermatology research

www.bioskinCRO.com

Services

Phase I and Proof-of-Concept studies at our Research Center
- Risk mitigation by early recognition of cutaneous safety issues
- Unique innovative designs to maximize information about efficacy gained in early clinical development
- Integration of biophysical measurement methods into study designs

Phase II – IV multinational trials
- Conduct of multinational dermatology trials across Europe
- Extensive network of investigators and dermatology KOLs
- Selected SMO/CRO partners for international studies
- Global project leaders and central coordination at bioskin

Clinical Project Management
- Leading of international cross-functional teams for late phase as well as for early phase studies
- Feasibility analysis, site identification and selection
- Submission of clinical trials to ECs and Competent Authorities
- Investigator contracts/payment supervision

Monitoring
- In-house CRAs and an established team of freelance CRAs
- Risk based monitoring/remote monitoring

Data Operations
- Design and development of eCRFs and clinical databases
- EDC training; Data Management Plan (DMP)
- Electronic data transfer in SDTM format (CDISC compliant)
- Statistical consultation on study design
- Randomization; Statistical Analysis Plan (SAP) development
- ADaM datasets (CDISC compliant)

Medical Writing
- Clinical study protocols, subject information/informed consents, study reports
- eCTD format, linking and bookmarking
- Scientific publications (manuscripts, abstracts, posters)