

## COMPANY PROFILE



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## History and Mission

**Eurofins bioskin** is a leading full-service CRO with unique understanding and capabilities for dermatological clinical trials. Recognized by global companies as a valuable partner in trials for drugs, medical devices, food supplements and aesthetics since 1992, Eurofins bioskin provides early phase safety and Proof-of-Concept studies; global Phase II-IV trials for NCEs; new formulations with known actives and generics.

## Highlights

Eurofins bioskin has performed 600+ clinical trials in 20+ dermatological indications including 30,000+ patients and healthy volunteers with 140+ sites in 15 countries. For global early and late phase studies Eurofins bioskin partners with selected, reliable vendors throughout Europe, US, Latin America, Central Eastern Europe and South Africa. Eurofins bioskin manages clinical trials in all dermatological indications with a special expertise in psoriasis, alopecia, aesthetics and wound healing. Our in-house dermatologists consult on study design and interpretation of results.



www.bvma.de

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BVMA member since 2011  
Audits passed in 2011, 2014, 2017,  
2020 and 2023



bioskin



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## 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 evaluate efficacy in early clinical development
- Integration of biophysical measurement methods into study designs

### Phase II – IV Multinational Trials

- Conduct of multinational dermatology trials across Europe
- Selected SMO/CRO partners for international studies
- Global project leaders and central coordination at Eurofins bioskin

### Clinical Trial Management

- Leading of international crossfunctional teams for late phase as well as for early phase studies
- Submission of clinical trials to ECs and Competent Authorities
- Centralized electronic Trial Master File (eTMF)

### Medical Monitoring

- Review of clinical trial protocol and report with dermatological expertise
- Continuous medical oversight ensuring subject safety and trial integrity

### Monitoring

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

### Data Operations

- Design and development of eCRFs and clinical database
- Electronic data transfer in SDTM format (CDISC compliant)
- Statistical consultation on study design
- ADaM datasets (CDISC compliant)

### Medical Writing

- Clinical trial protocols, clinical investigation plan and reports, informed consents
- Scientific publications
- Lay language summaries



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