APPLIED CLINICAL RESEARCH FOR THE SKIN
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Your Experienced and Innovative Partner in Applied Dermatological Research

CONTACT

SIT SKIN INVESTIGATION AND TECHNOLOGY HAMBURG GMBH

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01 / SIT – YOUR PARTNER FOR COSMETIC AND CLINICAL RESEARCH

SIT (SIT Skin Investigation and Technology Hamburg GmbH), an independent private dermatological contract research organization (CRO), is specialized in performing dermatological, cosmetic, clinical and pharmaceutical studies and research for the cosmetic, chemical, pharmaceutical and food industries.

Besides dermatological in vivo and in vivo -> ex vivo -> in vitro studies on human subjects, SIT also offers a wide range of innovative in vitro biological tests as well as alternative methods.

SIT is dedicated to providing its clients a flexible and prompt implementation of their study design, a quick study execution in line with European and international legislation and guidelines, and study results of high quality.

Our ideal location in the center of Hamburg allows us an easy and quick recruitment of volunteer subjects.

SIT is functionally and geographically associated to the DERMATOLOGIKUM Hamburg, a private dermatological clinic (www.dermatologikum.de), which supports SIT with its dermatological knowhow and a network of specialists in medical and natural science.
02 / STANDARD TEST TERRITORIES AND PRODUCT FIELDS

STANDARD TEST TERRITORIES

- Cosmetology
- Dermatology
- Ophthalmology
- Photobiology
- Clinical research
- In vitro cellular biology

PRODUCT FIELDS

- Cosmetic products
- Active ingredients
- Raw materials
- Hair care products
- Pharmaceutical products
- Toiletries
- Food supplements
- Medical / cosmetic devices
- Textiles
03 / GENERAL SERVICES

- Advice on the best study design for individual claim support
- Performance of standard trials and development of sponsor-specific study designs
- Full services in clinical research (phase I-III) including definition of the study protocol and the approval by an Ethics Committee
- Mono- or multicenter studies
- Recruitment of specific subjects out of a pool of more than 8,000 volunteers
- Highly specialized analytical and biophysical equipment
- Efficient and fast study execution
- Computerized network-associated data handling and direct automated data transfer
- Data processing, graphical presentations and statistical analyses (STATISTICA®)
- Detailed scientific study reports and publications
- Literature research
- Dermatological research
04 / GENERAL ASPECTS ON ETHICS AND QUALITY MANAGEMENT

- Certified quality management according to DIN EN ISO 9001
- Compliance with European and international legislation and guidelines (GCP, GLP)
- General approval by an independent Ethics Committee for dermatological cosmetic-orientated studies
- Recruitment and handling of subjects according to the current revision of the Declaration of Helsinki
- Computerized panelist database with every subject being dermatologically characterized
- Study performance in agreement with standard operation procedures (SOP)
- Study audit by Quality Assurance Unit
- Regular staff training
- Indoor and outdoor climate data under continuous supervision
05 / SKIN TOLERANCE TESTS

GENERAL ASPECTS

■ Standard trials or development of sponsor-specific study designs to meet your needs
■ Tests on subjects with special skin features (e.g. sensitive skin, atopic skin, etc.) if requested
■ Tests on scarified or tape-stripped skin if requested
■ Supervision by dermatologists, ophthalmologists or pediatricians if requested
■ Visual assessments by trained experts
■ Regularly performed training of experts by means of color vision tests (Farnsworth-Munsell 100-hue test)

PATCH TESTS

■ Epicutaneous patch test
■ Repetitive epicutaneous patch test
■ Repeated insult patch test

FURTHER SKIN TOLERANCE TESTS

■ Home in-use test / observed use test (dermatologist / ophthalmologist)
■ Repeated Open Application Test (ROAT)
■ Barrier integrity (TEWL)
■ Arm flex wash test
■ Forearm wash test
■ Acute irritation test
■ Stinging effects
■ Razure / depilation / epilation studies
■ Phototoxicity test / photosensitization test
06 / PROOF OF EFFICACY

STANDARD BIOPHYSICS

- Skin moisture
  (Corneometer®, SkiCon®, DermaLab®)

- Skin roughness
  (silicon imprints, Primos® in vivo)

- Skin scaliness (D-Squames®)

- Skin elasticity (Cutometer®, Torquemeter®)

- Eye wrinkles and fine lines (Primos®)

- Structure of the dermis
  (Ultrasound DermaScan® C)

- Skin whitening / effects on melanogenesis
  (Siascope®, Mexamer®, Spectrophotometer®)

EVAPORATIVE WATERLOSS (DermaLab®)

- Skin barrier integrity
  (trans epidermal water loss, TEWL)

- Trans onychaeal water loss on fingernails
  (TOWL)

- Water holding capacity:
  Plastic Occlusion Stress Test (POST),
  Skin Surface Water Loss (SSWL)

- Skin resilience (following tape stripping)

PHOTODOCUMENTATION

- FotoFinder® System, ViSIA CR®
**IMPURE FACIAL SKIN**

- Sebum production (Sebumeter®, Sebupatch®)
- Skin surface shine, complexion (Glossymeter®)
- Acne reduction: lesion count, lesion size and redness (visual assessment, Colorimetry / Spectrophotometer®, Mexameter®, FotoFinder® System, VISIA CR®)
- Deep-pore cleansing effect of cosmetic products and/or devices (high-resolution photography and expert assessment)

**SCALP, HAIR AND NAILS**

- Skin moisture at the scalp (DermaLab®)
- Hair growth (trichogram, length and thickness)
- Keratolytic properties (anti-dandruff)
- Nail growth and quality (brittleness, histology, leukonychia etc.)
- Transonycheale water loss on fingernails (TOWL, DermaLab®)
- Photo documentation
ADDITIONAL SPECIAL PARAMETERS

- Subjective evaluation of product performance
- Anti-inflammatory effects (UV erythema model)
- Axillary studies (shaving, visual assessment)
  Deodorant effects (sniff test)
- Peeling (exfoliating) effect
- Shaving / depilation / epilation procedures
- Cleansing efficacy of cosmetics / cosmetic devices
- Diaper studies (newborn and babies)
- Oral food supplement studies
- Rinse off studies (short- and long-term kinetics)
- Leave-on studies with kinetics and regression phases
- Regenerative effect / cell renewal (DHA method)
- Natural moisturizing factor (e.g. urea analytics)
- Biochemical / molecular biological analysis

DERMATOLOGICAL MODE OF ACTION
(IN VIVO -> EX VIVO -> IN VITRO)

- Non-invasive via suction blister biopsies
  (e.g. collagen, interleukines, oxidative stress, cell proliferation, stell cell analytic, histology etc.)
- Invasive via punch biopsies
  (e.g. histology, molecular biology etc.)
07 / CLINICAL STUDIES

DERMATOLOGY

- On subjects with skin, hair or nail problems such as: atopic skin, impure skin, acne vulgaris, psoriasis, inflammatory dermatoses, nail dermatoses, diabetics, infants / babies etc.

- Visual expert grading at hands and feet (chapped hands, cracked heels) and fingernails (leukonychia, brittleness)

- Wound healing (e.g. medical devices)

- Anti-inflammatory efficacy (UV-induced erythema)

- Integrity of the skin immune system (UV-induced immunosuppression)

- Vasoconstriction test / blanching (glucocorticoids)

OPHTHALMOLOGY

- In-use applications (tolerance and efficacy assessment, slit lamp examination)

PEDIATRICS

- In-use applications (visual tolerance and efficacy assessments)
08 / PHOTOBIOLOGY

SUN PROTECTION FACTORS

- *In vivo* sun protection factor (SPF) determination according to Cosmetics Europe (formerly COLIPA), FDA or ISO guidelines
- Water resistant properties (*whirl pool, water curtain*)
- UVA protection factors:
  - *In vivo*: immediate and/or persistent pigment darkening (IPD and / or PPD)
  - *In vitro*: COLIPA Ratio, Boots Star Rating, Australian Standard, Diffey

SUN PROTECTION AT THE CELLULAR LEVEL

- Photo-aging (*elastic fibers and collagen destruction in vivo*)
- UV-induced immunosuppression (*Langerhans cells and functionality of the skin immune system*)
- UV-induced immunomodulation (*expression of inflammatory and immunoregulatory cytokines, in vivo and in vitro*)
- Sunburn cell formation (*in vivo and in vitro*)
- Immunohistological analyses of UV-induced DNA-damage *in vivo and in vitro* (*thymine dimers, 8-oxo-guanine*)
- Repair kinetics of UV-light induced DNA-damage (*host-cell-reactivation assay*)
- Expression of metallo-proteinases (*MMPs*)
- Oxidative stress (*lipid peroxidation and protein oxidation*)
- Pigmentation and whitening (*effect on melano-genesis*)
09 / IN VITRO TESTING

CELLULAR AND MOLECULAR ANALYSES WITH HUMAN SKIN CELL CULTURES, ORGANOTYPIC SKIN MODELS AND IN VIVO -> EX VIVO -> IN VITRO SAMPLES (SKIN BIOPSIES AND SUCTION BLISTER BIOPSIES)

- Cytotoxicity testing
  (NR-test, MTT-test, WST1-test)

- Phototoxicity testing
  (NR-test, MTT-test, WST1-test)

- Cellular toxicity and apoptosis

- Cell proliferation and differentiation

- Cell metabolism (e.g. ATP content)

- Irritation testing (RBC-test)

- Differential gene expression via Real Time PCR

- ELISA tests (e.g. collagen, fibrillin, hyaluronic acid, 8-isoprostan, carbonyl proteins, metallo-proteinases, cytokines)

- Protein synthesis

- Anti-oxidant testing

- Immunohistological analyses of UV-induced DNA-damage in vitro
  (thymine dimers, 8-oxo-guanine)

- Repair kinetics of UV-light induced DNA-damage
  (host-cell-reactivation assay)

- Histological and immunohistological analyses

- Pigmentation and whitening
  (effect on melanogenesis)

- Anti-inflammatory effects
  (e.g. secretion of inflammatory cytokines)

- Sun protection
10 / DERMATOLOGICAL RESEARCH

- Cooperation with universities and dermatological clinics
- Activities in different scientific dermatological societies
- Participation in international evaluation and validation studies
- Research on a products' mechanism of action
- Establishment of innovative study designs

11 / STAFF – THE MULTIDISCIPLINARY TEAM OF SIT

SIT’s continuing success stems from its qualified and highly motivated employees. Over the years, SIT has filled the key positions on its staff with a broad range of highly qualified experts:

Dermatologist | Biologist | Biochemist | Immunologist | Dermatohistologist | Instrument Engineer | Biostatistician Technician | Cosmetician | Cosmetic Scientist
12 / ROOMS AND EQUIPMENT

With about 1000 square meters, you will find our spacious facilities optimized for the performance of dermatological studies and clinical trials.

Our eight laboratories and comfortable waiting rooms are climate rooms under continuous temperature and humidity control, which ensures testing under standardized conditions and provides reliable test results. In addition, you will find functional laboratories for special *in vivo* studies and for *in vitro* tolerance, toxicity and efficacy tests.

Diverse state-of-the-art bioengineering and cell culture instruments and equipment provide the platform for an efficient and objective data evaluation for your safety assessment and your product claim substantiation.
SIT was founded in 1997 as an independent international dermatological Contract Research Organization by:

**Joachim Degwert, Ph.D.**
Scientific and Managing Director

Immunologist and cell biologist with 25 years experience in applied dermatological research (10 years of these with topics such as efficacy testing, clinical tolerance testing, sensitisation testing and claim substantiation in the headquarter of a large international cosmetic / pharmaceutical company).

**Volker Steinkraus, M.D., Prof.**
Scientific Consultant

Dermatologist and dermatohistologist with 25 years experience in clinical and applied dermatological research of the human skin. Formerly Acting Chairman and Managing Director of the Department of Dermatology, University of Hamburg. Prof. Dr. Steinkraus provides SIT with his expert knowhow and a network of private practice specialists in medical and clinical science.
DIRECTIONS

- underground to Stephansplatz
- local trains to Dammtor
- main-line trains to Dammtor
- bus routes 4, 5, 102, 109, 112
- express buses 34, 36

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