

SUPPORTING YOUR CLINICAL
& DEVELOPMENT NEEDS

SKIN CARE RESEARCH SERVICES





Skin Care Research Services

Ensuring the safety and efficacy of your skin care products is critical to success. In an era where financial prudence is a necessity, getting your clinical strategy right first time is more important than ever.

At Intertek, we understand the need to have a responsive, flexible testing resource, with experienced project management to meet your critical milestones and deliver robust data every time.

Supporting your R&D, Regulatory and Claim Support needs:

- Clinical Studies
- Instrumental Measures
- Auditing and Assurance
- Regulatory Support

Intertek's Clinical Research Services group has been a trusted partner for those manufacturing skin care products. Intertek offers considerable experience with the recruitment and management of clinical trials. Intertek's clinical capabilities support the full clinical trial life-cycle,

including protocol development, ethical review, participant recruitment, full study management, data management, statistical analysis and reporting. We provide robust data to support the efficacy and safety of skin care products and can generate claim support and marketing data to meet tight product launch deadlines.

One of Intertek's fundamental values is quality. By applying a risk based approach to our services we can deliver a bespoke package fitting your requirements allowing a cost effective approach without any loss in quality and ensuring compliance with applicable legislation.

Our Capabilities

Intertek's systems and procedures have the flexibility to provide a tailored service for both regulated and cosmetic products. Our operations have undergone a statutory GCP inspection by UK regulatory authorities.

Subject Recruitment	Intertek's clinical research group maintains one of the largest databases of pre-qualified participants. This cloud based application allows the efficient management and monitoring of participants. Key data such as skin conditions (e.g. eczema), cosmetic concerns (e.g. cellulite), demographics and skin type is captured to allow effective searches to be conducted, therefore reducing recruitment time and cost, as well as improving qualification rates.
Examiners	<p>Intertek understands the critical need for trained and experienced examiners to perform clinical assessments on studies. To this end, Intertek maintains a pool of skin examiners assessing dryness, inflammation, erythema, skin tone, fine lines etc.</p> <p>Our Dermatologists and network of medics provide medical oversight and support in areas such as atopic dermatitis, psoriasis and seborrheic dermatitis. Our medical staff can perform point of care tests and conduct dermatological investigations using standard clinical assessments, e.g. SCORAD.</p> <p>Intertek undertakes structured and regular training and calibration programs, giving examiners and medics the opportunity to meet regularly and share skills. Through calibration exercises we ensure consistency amongst examiners and greater flexibility in resourcing studies.</p>
Instrumentation	<p>In addition to our team of examiners our technical experts can support your efficacy requirements by generating robust data using a variety of instrumental techniques. With access to a network of suppliers Intertek can source innovative techniques to develop bespoke protocol designs.</p> <p>To achieve the most reliable and reproducible results all instrumentation is maintained and calibrated. Validation packages are available as required and for studies involving regulated products such as medical devices and medicines.</p>
Clinical Facilities	<p>Each Intertek clinical research site offers the optimal blend of practicality and flexibility. As such all sites offer the capability to accommodate studies in different indications, with a balance of clinical rooms made up of climate control rooms, private examination rooms, interview areas and sample preparation areas.</p> <p>Additional general facilities at sites include:</p> <ul style="list-style-type: none"> • Secure, temperature monitored test product storage • Emergency resuscitation equipment • Fire-proof storage for trial documents <p>Intertek's systems and procedures have the flexibility to provide a tailored service for both regulated and cosmetic products and our operations have undergone a statutory GCP inspection by UK regulatory authorities.</p>
Standards of Service	<p>Whether your product falls within cosmetics, medicines or medical device regulations you can be assured that Intertek will comply with all legal and ethical guidelines for clinical testing.</p> <p>Intertek complies with Good Clinical Practice (GCP), UK medicines regulations, ISO 14155 and COLIPA guidelines.</p> <p>For cosmetics a tailored service can be provided based on trial complexity and risk. Key aspects of GCP can be applied; however the safety and wellbeing of the participants will never be compromised.</p>
Auditing and Assurance Services	<p>Intertek provides a systemic approach to supporting our customers' Quality Assurance efforts in each of the areas of their operations including R&D, raw materials sourcing, components suppliers, manufacturing, transportation, distribution and retail channels, and consumer management. Our global network of auditors and technical experts are dedicated to helping you meet any auditing or certification challenge you may face. Services include:</p> <ul style="list-style-type: none"> • Good Clinical Practice compliance audits • Clinical Investigator site qualification audits • Global supply chain • Accreditations: <ul style="list-style-type: none"> ◦ ISO 13485:2003 Medical Management System ◦ ISO 22716 Good Manufacturing Practices ◦ ISO 13485:2016 Quality Management Systems for Medical Devices ◦ ISO 9001 Quality Management

Clinical Research Services

Intertek offers safety, efficacy and claim support for skin care products. In addition our experienced team is able to design clinical testing methodologies for your specific needs or source innovative instrumentation and techniques.

Safety

Intertek offers a range of dermatological safety studies including:

- Dermal irritation: 24, 48, 72 or 96-hour patch tests to screen for irritation potential
- Contact sensitization: Repeat insult patch test 100 or 200 subject patch test to investigate sensitisation (allergy) potential following repeated exposures & a challenge at a naïve site
- Cumulative irritation: 14 or 21-day patch test to investigate potential irritation from chronic exposure
- Phototoxicity / Photosensitisation: Screening test for irritancy and/or allergy potential following exposures to UV light
- Sun Protection

Efficacy

Consumers are increasingly demanding effective high quality cosmetic and healthcare products. As a manufacturer it is important to instil confidence in your brands to ensure a loyal customer base and solid market share. Common efficacy endpoints and claims supported include:

- Moisturisation / skin hydration
- Improvements in skin barrier function
- Skin elasticity / firmness
- Skin pigmentation
- Reduction in cellulite
- Anti-ageing such as reduction in fine lines and wrinkles
- Skin smoothening
- Skin softening
- Skin healing

Additionally, our Dermatologists and medical experts can support the assessment of skin conditions such as atopic dermatitis, psoriasis and acne in both adults and children.

Instrumentation

To support efficacy investigations and substantiate claims, instrumental measures and imaging are both key to success. Intertek's technical team can utilize a number of instrumental measures including:

INSTRUMENT	TECHNIQUE	EFFICACY MEASURE / CLAIM
Biox Aquaflex		Water loss
Courage & Khazaka Tewameter		
Courage & Khazaka Corneometer		Hydration
Cortex Dermalab		
Courage & Khazaka Sebumeter		Sebum
Silflo replicas		Smoothness/fine lines/wrinkles
Canfield Primos		
Perimed PeriCam PSI system		Skin microcirculation/blood perfusion/inflammation
Vivascope 1500 and 3000		Delivery specifically hair follicles / sweat glands
Michelson Vivosight OCT		Stratum corneum thickness
Canfield Visia CR		Anti-aging
River Diagnostic's Raman Spectroscopy		Topical absorption
Diastron Ballistometer		Elasticity
Courage & Khazaka Cutometer		
Diastron Dermal Torque Meter		

Sampling

Skin samples can be collected and analysed for a range of attributes. These include:

- Buffer scrubs (washes)
- Tape stripping / D-squame sampling
- Punch biopsy
- Blister biopsy

Additionally, through a number of research partners, Intertek is also able to provide supporting bioanalytical and microbiological services.

Consumer Perception and Quality of Life

Feedback from consumers can be critical in the product development process. To this end, Intertek can offer self-perception questionnaires, focus groups, interviews and home-placement studies. For dermatological conditions our team is experienced in the use of quality of life questionnaires, disability indexes and patient reported outcome measures.





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Intertek Clinical Research Services
Elm House, Unit A4
Oaklands Office Park
Hooton Road
Hooton
Cheshire CH66 7NZ
UK

 +44 151 347 4810

 clinicalresearch@intertek.com

 intertek.com/crs
