Substantiate Your Product Claims...

An Indian CRO dedicated to Clinical Research For Skin, Hair & Food
How you Benefit

**Efficacy Testing**
- 3 Dimensional approach (clinical, instrumental & self assessment)
- Innovative approaches to prove efficacy and claims
- Rapid screening of promising new product concepts through ‘Proof of Concept’ studies
- Help understand requirements for product launch in India

**Safety Testing**
- Safety evaluation of new products, ingredients or delivery systems
- Customized to meet the regulatory requirements of different countries globally

**Sensory Evaluation**
- Demonstrate & make claims on the unique sensorial characteristics of products
- Help to understand the sensory attributes desirable to the Indian Consumer
- Identify unique sensorial characteristics of your product vis-à-vis competition

**Clinical Nutritional Research**
- Efficacy testing and Claim substantiation
- Post-marketing surveillance trials
- Managing Multi-centric trials

**Consumer Insighting**
- Identify right product attributes and what it means technically
- Uncover unique benefits of your product through consumer perception that are not apparent in clinical or instrumental evaluation

CLAIMS is the sole distributor of Delfin Technologies Ltd, Finland, in India.
Delfin Technologies Ltd is the world leader in portable & non invasive skin research instruments.
Consumer Insghting

We at CLAIMS believe that synergies ensure success. We have thus developed a process which bridges the gap between converting articulated and unarticulated consumer needs into product attributes.

We can help our sponsors to connect consumer needs with technically measurable parameters in the early stages of product development, thus making the entire product development process more objective and meaningful.

What does this mean for the sponsor?
We will help in:
- Applying the insights from market research to product design at the concept generation stage
- This is done by:
  - Consumer mining
  - Identifying “Product attributes” and what they mean technically
  - Techniques to quantify and measure these attributes
  - Structured approach to product development

This process of connecting consumer needs with technically measurable parameters can also be used to advantage in advertising and marketing.

Product Testing

We offer services to our Indian sponsors for SPF testing (In-Vitro & In-Vivo). The testing is carried out at Australian Photobiology Testing Facilities Pvt. Ltd. (APTF), Sydney, Australia.

The samples for SPF testing can be submitted to CLAIMS in India.
Since clinical trials require the use of human test subjects and can impact their well-being, and involves large investments; proper management is crucial.

At CLAIMS, our team of well experienced and trained professionals give utmost attention to all details for meticulous execution of the trials, whether for cosmetic products or other topical products, starting from:

- Understanding the sponsor’s objective as well as the specific requirement of the project concerned
- Study design in consultation with sponsor
  - Synopsis
  - Protocol
  - Case Report Forms
  - Informed Consent Documents
  - Miscellaneous (s.a. insurance coverage)
  - Selection of Principal Investigator / Co-investigator
- Project planning
  - Date
  - Budgetary plan
  - Quality plan
  - Project specific deliverables
- Selection of site (for multi-centric trial)

- Ethics committee approval (IRB approval)
- Project execution
- Quality assurance
  - Site audits
  - Vendor audits
  - Data audit
- Data management and analysis
- Executive summary report
- Final report
- Archives

We at CLAIMS offer end-to-end clinical trial management services.
At the same time, we are open to customize modular offerings depending on sponsor’s need.

Flexible enough to meet your needs, stringent enough to ensure accuracy & safety...

We commit.
Consumer awareness is growing in the areas of Nutrition, Nutraceuticals & the health benefits they offer. But consumers need to develop confidence in the claims made, before buying them.

CLAIMS undertakes high quality scientifically designed Human Nutrition Trials as per ICMR guidelines in the following areas:

- Nutraceuticals
- Dietary Supplements
- Functional Foods
- Nutri-cosmetics
- Food Ingredients
- Beverages
- Herbal Natural Products

Areas of investigation for nutritional and functional food product claims include:

- **Glycemic Index Testing**
- **CHD Management: Evaluation Parameters include-**
  - Serum Cholesterol
  - Lipoprotein Fractions
  - Total Body Weight
  - Total Body Fat %
  - Abdominal Fat
- **Weight Management: Evaluation Parameters include-**
  - Physiological
    - Reduction in Total Body weight
    - Reduction in Body fat%
    - Increase in Lean Body Mass
    - Increase in Basal Metabolic Rate
    - Satiety
    - Changes in Body Composition
  - Psychometric
    - Stress Management
    - Improved Self Assessment
      (Positive Self Image, Self Confidence)
- **General Well Being: Evaluation Parameters include-**
  - Physical well being
  - Improved physical performance
  - Improvement in all fitness parameters like stamina, strength etc
  - Improvement in Cognitive skills
  - Improved Psychometric Scores
  - Increase in Height and Weight
  - Improved Appetite
  - Reduced frequency and severity of infections and illness
  - Psychological development in Children
- **Skin Benefits-**
  - Skin glow
  - Skin lightening
  - Reduction in skin aging signs or Skin rejuvenation
CLAIMS has extended its services in the area of safety and efficacy testing of Household / Homecare products in addition to the Clinical Research and Sensory Evaluation for Skin, Hair and Body care products.

**Efficacy Testing**
- Anti bacterial efficacy as per EU guidelines or ASTM guidelines (Time Kill Method)
- Anti viral efficacy using Haemagglutination assay
- Cleansing

**Safety Testing**
- Mildness testing using Hand immersion test
- Patch Test
- Exaggerated use test
  - Flex test
  - Arm wash test
  - Hand wash test
- Normal use test

Products that can be tested:
- Anti-microbial products
- Mosquito repellents
- Disinfectants
- Hand Sanitizers
- Hand wash
- Cleansers
- Floor Cleaners
**SKIN CARE & BODY CARE**

CLAIMS has the expertise of conducting Clinical Research and Sensory Evaluation for Skin and Body Care products such as Cosmetics, Dermaceuticals and Topical drugs.

Whether it is the alleviation of skin aging signs, improvement of the barrier function or skin hydration, de-pigmentation or skin lightening, reduction in acne, or measurement of body firming action; our state-of-the-art technology allows non-invasive examination of various skin-specific parameters and enables us to develop individual study-designs for your claims.

**Indicative studies for skin and body care products:**

**Efficacy Testing**
- Skin Lightening
- Hyper pigmentation
- Acne
- Skin Wrinkles
- Skin firming and elasticity
- Under eye puffiness
- Under eye dark circles
- Skin cleansing
- Skin Hydration

**Sensory Evaluation**
- Spreadability
- Tackiness / greasiness / stickiness
- After-feel
- Fragrance acceptance

Sensory evaluation is done as per ASTM (American Society for testing and Materials) by our qualified panel.

**Safety Testing**

**Skin Irritation**
- Patch Testing
- Repeat Insult Patch Test
- 21 day cumulative irritancy test

**Skin Sensitization**
- 48 hrs Patch test
- RIPT with challenge phase

**Photosensitization**
- Phototoxicity with 48 hr patch followed by UVA exposure
- Repeat Insult Photo Patch Test

**Ocular Irritancy**
- Cosmetics with unintended ocular contact such as eye care and make-up products

**Others**
- Mildness Testing
- Comedogenicity
- Cosmetic Intolerance Test
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<td>Measures L*, a*, b* values</td>
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<td>VapoMeter</td>
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<td>MoistureMeter SC</td>
<td>Surface moisture measurement</td>
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<td>MoistureMeter D</td>
<td>Fluid changes at different depths in the skin</td>
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<td>Skin Gloss Meter</td>
<td>Measures skin shine</td>
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<td>Sebumeter</td>
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<tr>
<td>Cutometer</td>
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<td>3-D Fringe Projection</td>
<td>3D analysis of skin surface, Silicon Imprint Analysis</td>
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<tr>
<td>Spectrophotometric Intracutaneous Analysis</td>
<td>Skin Chromophore mapping of Melanin, Hemoglobin, Collagen</td>
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Products You can Test (illustrative examples):

- Fairness
- Anti aging products
- Anti wrinkle products
- Cleansers/Toners
- Moisturizers
- Anti-pigmentation products
- Skin firming products
- Anti-acne products
- Under-eye dark circles products
- Under-eye puffiness products
- Scar treatment
- Wound Healing
- Topical Drugs
- Soaps and Bathing products
- Body shaping products
- Chin and neck firming
- Deodorants etc.
Our team of experts has extensive experience in performing efficacy, safety and sensorial evaluations, thus helping in claim substantiation for hair and scalp care products. Right from having a dedicated Hair studio, appropriate instrumentation for objective assessment, dermatologist/trichologist for clinical evaluation, to a trained panel for sensory evaluation, CLAIMS has a very professional approach towards managing of such trails.

**In-Vivo Trials**
for determining product efficacy

- Anti Dandruff
- Hair Growth / Hairfall
- Androgenetic alopecia
- Depilatory
- Hair color retention

Also in-vivo studies can be undertaken to evaluate sensorial attributes.

**In-Vitro Trials**
(on hair swatches)

- Hair sensorial for evaluation of:
  - Wet combability
  - Dry combability
  - Detangling
  - Gloss / Shine
- Hair Breakage & Protein Loss
- Evaluation for hair colors and hair dyes for:
  - Coverage
  - Spread
  - Smoothness
  - Bounce
  - Static
  - Color imparted
  - Retention of colour

**Safety Testing**

- Patch test for primary skin irritation
- In use test for assessment of the tolerability
- Clinical Assessment of scalp can be made for:
  - Erythema
  - Dryness
  - Papules, excoriations, etc.
- Ocular irritancy for shampoo formulations
## Hair Care

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<tr>
<td>Trichoscan</td>
<td>Measures A/T ratio, Hair density, hair growth rate, vellus and terminal hair</td>
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<tr>
<td>Spectrophotometer</td>
<td>Measures L* value (for Hair color)</td>
</tr>
<tr>
<td>GlossMeter</td>
<td>Measures hair shine</td>
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### Products You can Test (illustrative examples):

- Shampoos
- Conditioners
- Serums
- Hair Dyes
- Hair colors
- Anti Dandruff products
- Anti Hair fall products
- Hair vitalizers
- Hair styling products
- Oils
- Hair sprays
- Hair gels etc..
We Envision

To create a ‘Center of Excellence’ for Skin, Hair & Nutraceutical Clinical trials which will,

- Surpass global standards with respect to quality of service, proactiveness in adapting & innovating newer tools & techniques; and providing value for money
- Conduct pioneering clinical research for products based on traditional Indian knowledge
- Dissipate knowledge and services to community at large

We Believe in

- Assurance of quality, timeliness & confidentiality for doing proprietary clinical research work
- Consumer safety and their rights
- Adherence to all ethical guidelines set time-to-time by regulatory authorities for doing such work
- Being sensitive to the needs of our sponsors
- Integrity, Compassion, Excellence and Team work amongst our team members and associates
- Providing challenging, apolitical environment to all members of our community, purely based on their abilities and skills

Corporate Profile

CLAIMS was formed by experts in the field of cosmetics, clinical research, medico-marketing and dermatology with many years of experience behind them. Their collective exposure to various aspects of evaluating product efficacy and safety, including consumer insights, ability to help articulate claims & to effectively manage trials, makes the organization Unique, Comprehensive & Reliable.

Salient Features

- Have the expertise and holistic approach to designing studies
- Complete understanding of the regulatory environment, product formulation & claim substantiation
- Have conducted over 150 trials in diversified areas of Cosmeceuticals, Dermatologicals, Dietary Supplements, etc.
- Our Independent Ethics Committee (IRB) meets once every month
- We have an In-house Volunteer database
- We have handled sample size from 20-600 and studies running upto 6 months
- We manage multi-centric trials
- We manage 24 hrs trials with in-house facilities for housing volunteers

Business Associates

In our endeavor to bring the best of international practices & services to our clients, we have associations with

Delfin Technologies Ltd.: CLAIMS represents Delfin Technologies Ltd., Finland; for their range of high end, precise skin measurement instruments in India.

MediaMedic Communications: They provide value added services in Health & Nutrition science support, Advertising, Brand Development, Public Relations & Creative services.

Australian Photobiology Testing Facilities Pvt. Ltd. (APTF): CLAIMS has associated with APTF for advanced In-vitro and In-vivo SPF testing.