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**“A Novel Exploratory Approach of Validation and Standardization for Test Methods and Evaluators to Conduct Safety and Efficacy Clinical Testing of Hair Growth Products”**

**Published Article  
in**

**PIJR**  
Paripex Indian Journal of Research



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TRIALS  
STARTUPS**

## Industry Outlook

CLINICAL TRIALS STARTUPS

THEINDUSTRYOUTLOOK.COM



## NOVOBLISS RESEARCH

AN INDEPENDENT CRO CARRYING-OUT HIGH PERFORMANCE GLOBAL STANDARD CLINICAL RESEARCH & CLINICAL ACTIVITIES



Maheshvari Patel, Founder

One of the world's foremost economically advantageous locations for clinical trials now is India. The primary driving force has been the WTO's altered intellectual property laws, and the key ideological basis for the expansion of India's clinical trial business is profit maximization over any kind of altruistic goal. Additionally, due to stringent regulatory standards, clinical trials for FMCG industry have increased. These products are released based on scientifically evidence-based claim substantiation safety efficacy studies. A distinctive CRO, NOVOBLISS Research provides clinical trial support for some of the major FMCG products that are used on a daily basis with the goal of providing high-quality, scientifically supported data.

### Inception Objective

Located in Ahmedabad and operating out of an 8000 square foot facility, NOVOBLISS Research offers science-based, global product development planning and strategy by recognizing the direction to the industry and applicable regulatory requirements, specifying the optimum solutions and regulatory strategy for a successful global market entry, and taking into

account potential distinct regulatory obligations contingent on focused local markets. "We started with a vision to be one of the cost-effective, scientifically data driven, qualitative CRO globally. Having a dedicated, efficient, experienced & passionate team, we are 'Committed to advancing innovation & science for Healthy life'. We back our clinical evaluations with AI tools, Biomarkers, Microbiomes, and Accurate Bioinstrumentation for skin, hair, ayurvedic, herbal, personal care, food, nutraceuticals, and pharmaceuticals market segments", shares Maheshvari Patel, Founder.

NOVOBLISS offers a series of services while focusing on result-oriented qualitative training by experts, validating the test methods & procedures, validation of bio-instrument operators, using electronic data capture tools, 100 percent quality control of clinical data, results, quality assurance, and research publication in high-impact journals. "For overall project management, we have a team of Project Directors, Leaders, Managers, Clinical Research Coordinators, Clinical Research Associates, Quality Assurance Auditors, QC Coordinators, Biostatisticians & Programmers, Pharmacovigilance, and PAN India site availability. We also have tie-ups with well known universities with whom we collaborate for Pre-Clinical studies, Academic clinical studies placements to nurture the talent", speaks Nayan Patel, Co-Founder.

Government regulatory organizations, including AYUSH, FSSAI, and self-regulatory group ASCI have enhanced regulations for labeling standards for herbal and food goods. Understanding the requirements for both domestic and international clinical trials,

NOVOBLISS has developed each component of the clinical trial services, starting with pre-sales business development, legal, finance, scientific marketing, scientific writers, including Ph.D. scholars, clinical trials patients' database, database of investigators and KOLs, and database on clinical trial sites, hospitals, and laboratories.

NOVOBLISS' focus is on the FMCG sector where skin, hair, and personal hygiene are of the utmost importance. Testing topical cosmetics and pharmaceutical products with high standards and globally accepted trial designs, specialized knowledge of highly experienced workers, and identity as one of the few high-quality CROs in the cosmetic industry, are just a few of the ways NOVOBLISS stands out from the competition.

NOVOBLISS Research provides clinical trial support for some of the major FMCG products that are used on a daily basis with the goal of providing high-quality, scientifically supported data

### Future Roadmap

The path of NOVOBLISS has been a roller-coaster, starting with just two team members at the inception of the company and growing to a strength of 20 full-time employees and 20 part-time contractual staff. The firm has completed more than 60 clinical trials on consumer goods, including oral care, eye care, cosmetics, food, nutraceuticals, skin care, hair care, and baby care. Moving forward, NOVOBLISS wants to launch subsidiary company activities in the US, EU region and Canada by December 2023. NOVOBLISS is expanding rapidly and is now looking to expand internationally as it anticipates forming a joint venture with well-known brands.

**CMT**  
**CosmohomeTech** Expo  
Where Formulation Meets Technology

Mumbai, 07<sup>th</sup>-8<sup>th</sup> Feb 2023



**hpci**  
INDIA

Mumbai, 16<sup>th</sup>-17<sup>th</sup> Feb 2023

Dr Nayan Patel  
and  
Maheshvari Patel  
attended

## Study 1 :

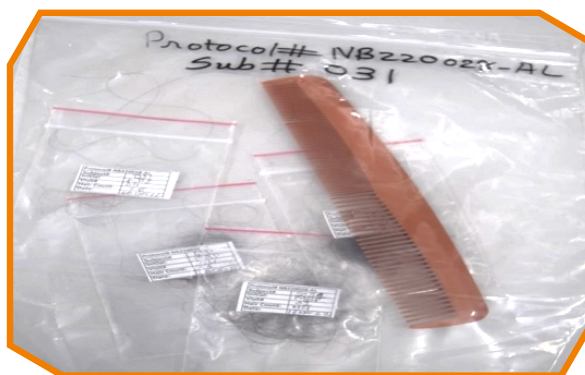
### **A Proof-of-Concept, Safety, and Efficacy Study of Hair Growth Promoting Product in Healthy Adult Human Subjects with Hair Fall Complaints**

A total of 32 subjects ages 23 to 45 years were enrolled, and 29 subjects completed the study. This clinical trial has been registered at CTRI. Subjects were screened on the basis of 60-Seconds Hair Combing Test where in females with 40-50 counts and males with 25-30 counts of hair fall were considered. Subjects were provided with a Hair Growth Promoting Product and instructed to use for consecutive 60 Days. Subjects were instructed to apply a generous amount using the dropper directly to the scalp in the area of hair loss and massage into the scalp using their fingertips. Subjects were instructed to use the test product every night before going to bed as that gave the serum enough time to work while sleeping. Subjects were provided with supplemental shampoo and were instructed to use it throughout the study period. Subjects were asked to use the shampoo thrice a week as their regular shampoo to wash their hair.

Assessment of efficacy parameters was done before test product usage on Day1 and test product usage on Day 30 and Day 60. The test product was evaluated for the improvement in hair growth rate, hair thickness, hair density, and scalp condition using CASLite Nova, pluck test to measure anagen-telogen ratio of hair to check improvement in the hair growth phase reduction in hair fall, change in the general appearance of hair i.e. hair volume, hair reflection, hair plasticity, hair density, hair smoothness, hair oiliness, hair shininess, Scalp appearance i.e. itchiness, redness, roughness, and scaliness of scalp and improvement in hair strength. The effect of the test product in terms of product perception was assessed by Subjective Product Perception Assessment. There were 06 visits during the conduct of the study. There were no adverse events reported by the subjects/parents, nor by the Investigator throughout the study period.



**60-second hair count technique**



**Separate comb was used for individual subject & hairs collected in zip log bag after the testing.**



**Before Test Product Usage**

**Sub#01 - Day 01**

**Scalp Condition - Dry Scalp with much Keratin**



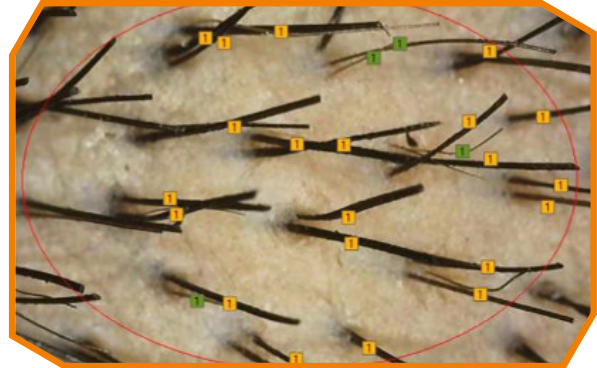
**After Test Product Usage**

**Sub#01 - Day 60**

**Scalp Condition - Normal Scalp- good Condition**



**Before Test Product Usage**  
**Hair Density – 236sqcm**  
**Sub#023, Visit-02**



**After Test Product Usage**  
**Hair Density – 245sqcm**  
**Sub#023, Visit-06**



**Before Test Product Usage**  
**Hair Thickness - 17µm**  
**Sub#01, Day 01**



**After Test Product Usage**  
**Hair Thickness - 20µm**  
**Sub#01, Day 60**



**Before Test Product Usage**  
**Sub#01, Day 01**  
**Growth Rate: - 395µm/day**



**After Test Product Usage**  
**Sub#01, Day 60**  
**Growth Rate: - 430µm/day**



**Before Test Product Usage**  
**Sub#25, Day 01**  
**Hair Fall Count: 102**



**After Test Product Usage**  
**Sub#25, Day 60**  
**Hair Fall Count: 28**

## Study 2 :

**Evaluation of Dermatological Safety of Test Products by  
24 Hours Patch Test under Complete Occlusion | Semi Occlusion |  
Open Patch on Adult Healthy Human Subjects**



### Patch Application

**All the test products were found 'Dermatologically Safe',  
'Dermatologically tested, 'Skin Compatible' for use & 'Non-Irritant' in the study population.**