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Research Accelerated

Novum
PHARMACEUTICAL RESEARCH SERVICES

CASE-STUDY:

Accelerating Patient Recruitment: Topical Tacrolimus for Atopic Dermatitis

Successfully enrolled **783 patients** across India in Two Phase-III studies **in just 5 months**.

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Background

- **Atopic Dermatitis (AD)** is a prevalent chronic inflammatory skin condition characterized by itchy, eczematous lesions and small blisters.

- Treatment goals for AD include managing dry skin, reducing inflammation, controlling itching, promoting healing, preventing infections, and minimizing flares.

- Long-term use of topical glucocorticoids is the primary treatment for AD but is associated with adverse drug effects (ADRs) such as irreversible skin atrophy.

- **Tacrolimus**, an immunomodulator, is a safe and effective non-corticosteroid alternative for treating AD.

- The study sponsor approached Lambda to support site enrolment for Phase III study for Tacrolimus Ointment in atopic dermatitis.

Study Details

Lambda conducted two randomized, double-blind, vehicle-controlled, multi-center Phase-III studies to evaluate the efficacy and safety of topical Tacrolimus in patients with moderate-to-severe Atopic Dermatitis.

Study-1	Study-2
0.1% Tacrolimus Topical Ointment	**0.03% Tacrolimus Topical Ointment**

The studies involved the application of Tacrolimus topical ointment twice daily to a defined symptomatic area of 200 to 1000 cm^2 of skin for a duration of three weeks.

Challenges Overcame

- **Limited Awareness**: Atopic dermatitis may be underdiagnosed or misdiagnosed, requiring increased awareness to educate patients and healthcare providers about the condition.

- **Stringent Eligibility Criteria**: The recruitment process involved meticulous screening of participants who met specific criteria related to disease duration, affected area, and severity. These criteria included a minimum disease history of three months, a specified body surface area (BSA) for the affected area of atopic dermatitis, adherence to the severity range of moderate to severe according to the Hanifin and Rajka criteria, and a validated Investigator Global Assessment (vIGA) scoring system indicating at least moderate disease severity.

- **Patient Engagement**: Maintaining patient engagement throughout the study duration was crucial to minimize dropouts and ensure adherence to the treatment protocol.

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Our Approach

- Successfully tackled challenges related to stringent eligibility criteria, awareness, and patient engagement, employing effective strategies to ensure a diverse and representative study population.

- Effective engagement with sites from the beginning of the studies to identify and recruit eligible patients.

- Providing comprehensive training to sites on the necessary scales and scoring systems required for these studies.

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Outcome

783 Patients

from across India were successfully recruited in **just five months.**

Study-1	Study-2
0.1% Tacrolimus Topical Ointment	**0.03% Tacrolimus Topical Ointment**
429 Patients	**354 Patients**
19 Sites	**17 Sites**

The achievement of recruiting a substantial number of patients within a short timeframe demonstrates Lambda's effective patient outreach and engagement strategies.

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Dermatology Excellence:

A Proven Track Record

80	33195	1412
Dermatology Studies	Patients	Sites

Leverage Lambda & Novum's extensive experience & proven track record to accelerate your dermatology clinical trials.

Unlock seamless collaboration with Lambda's expert team. ✉ **BD@lambda-cro.com**

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