



CASE STUDY

# Demonstrating Clinical Efficacy and Tolerability of MedSpray®

Translating improved delivery performance into real-world clinical outcomes

# The Challenge

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New topical and transdermal delivery systems must demonstrate not only improved in vitro performance but also clinical efficacy, safety, and patient tolerability.

Sponsors needed to confirm that enhanced delivery achieved with MedSpray® would translate into meaningful clinical outcomes compared to established therapies.

## Approach

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MedPharm advanced a MedSpray® formulation into clinical evaluation following successful preclinical performance:

- Selected an optimized formulation based on in vitro permeation and delivery data
- Conducted a non-inferiority clinical study versus a marketed comparator (Lamisil Once 1%)
- Evaluated antifungal efficacy, safety, and tolerability following a single application
- Assessed adverse events (AEs) to compare tolerability profiles
- Monitored recurrence and relapse rates following treatment

## Outcome

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- Demonstrated statistically equivalent antifungal efficacy compared to the marketed product
- Achieved improved tolerability, with fewer adverse events reported
- Delivered comparable recurrence and relapse rates
- Confirmed alignment between preclinical optimization and clinical performance
- Validated MedSpray® as a clinically effective delivery platform

## Why This Matters

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Demonstrating clinical efficacy is critical for any new drug delivery platform. MedSpray® shows that improved in vitro performance can translate into real-world patient benefit, supporting both regulatory success and commercial differentiation.