

# Bacterial Infected Eczema – Case Study

Recruitment of a Phase 3 rescue study in bacterial infected eczema closed 4 months ahead of schedule.

## Results

- ✓ Patient recruitment closed 4 months ahead of projected milestone
- ✓ 416 randomized patients versus 400 projected randomizations
- ✓ 43 patients per month enrolled versus planned 11,5 patients per month

## Sponsor's Feedback

I can confirm that we are very satisfied with proinnovera's work (...). Thanks for achieving such fast recruitment these past few weeks, the dates for final CSR of our two parallel studies are so close to each other we are able to apply for market authorization in one step as planned. I am convinced that we have a good chance of authorization, not least because of the good work by the proinnovera team.

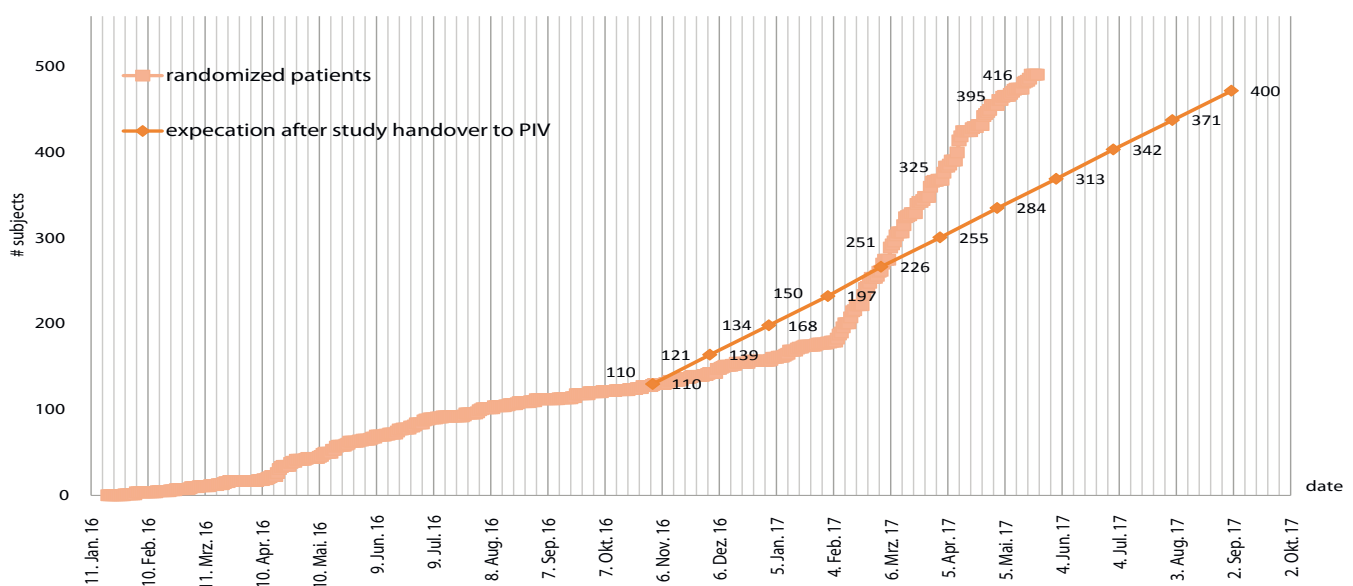
## Sponsor Facts

Type of company: private, mid-size

Headquarters: Germany

Repeat Customer: yes

Company's focus: Dermatology



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## Challenges

Enrollment was well below plan at takeover.

## Proinnovera’s Measures

Strategic selection of four eligible proinnovera rescue sites:

- ✔ All four additionally selected sites have already participated in previous or current dermatology studies managed by proinnovera. Thereby our study team could accelerate the negotiation process without the need to focus on legal language but only on study specific aspects.
- ✔ Our Clinical Monitors could tie in with prior collaboration, providing the benefit of a quick site initiation and effective site training as well as a clearly structured ongoing site communication.
- ✔ All four sites are well known for prior excellent recruitment results exemplifying their capability to enroll eligible patients with bacterial infected eczema.

## Indication

Bacterial infected eczema

## Phase

III

## Type

Double-blind, randomized, vehicle-controlled

## Coverage

11 sites+ 4 piv rescue sites in Germany

## Services

Project Management Support, Clinical Monitoring

Indicators	Projection	Deliverables
Enrollment Period	10 months, aiming for September 2017 for LPFV according to the current enrollment speed at takeover	Enrollment closed 4 months ahead only after 6 months in May 2017
Enrollment Rate	11,5 patients per month	43 patients per month
Randomized Patients	400	416
Enrollment Rate	11	15 including 4 proinnovera sites



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## Key to Success for your Study

- ✓ Proinnovera’s worldwide network of dermatology sites allows for targeted site selection according to indication and study specific requirements. You will benefit from the enhanced enrollment in your study.
- ✓ Specialized dermatology CRO: Our operational excellence from more than 100 successfully conducted dermatology studies guarantees reliable planning, conduct and control of your dermatology study. For you, this means a performance within budget and time.
- ✓ Proinnovera’s value-based company culture continuously shapes our daily work. We believe in a clear and transparent communication structure between all internal and external study team members. A dedicated study team will take true ownership of your study. You will have time to breathe and to focus on other important things in your daily business.

Our primary goal is to deliver fast and efficient solutions for clinical research. We strongly believe that this is the best way to make you successful and to make your product ready for the market.

Our corporate philosophy is based on value-oriented thinking and performance.

At proinnovera, commitment, sustainability and success are the pillars of any cooperation. Giving and keeping our word is our guiding belief and creativity is our contribution!



**We are globally dedicated to skin health!**



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