

Actinic Keratosis - Case Study

Recruitment of a Phase 3 rescue study in mild to moderate actinic keratosis closed 5 weeks ahead of schedule.

Results

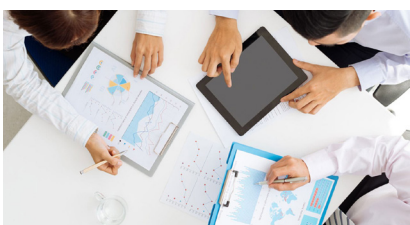
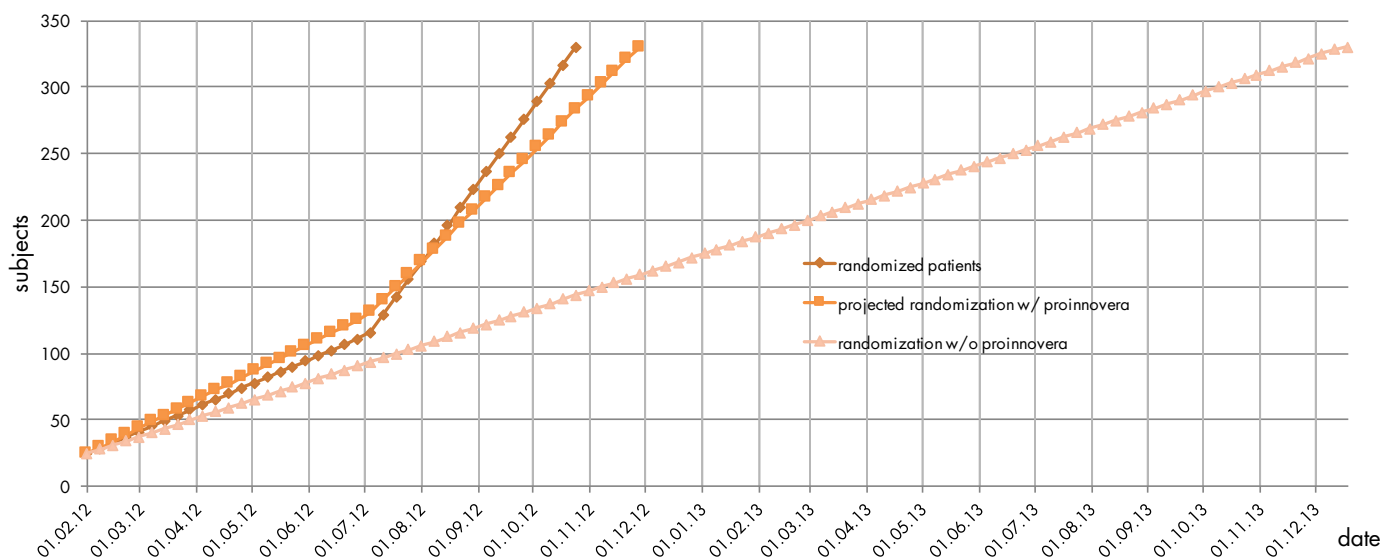
- ✓ PIV's patient recruitment closed 5 weeks ahead of projected milestone
- ✓ 149 randomized patients versus 100 required randomizations
- ✓ Actually 1,55 patients per site per week randomized versus projected enrollment

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



We've got Skin in the Game

Actinic Keratosis - Case Study

Recruitment of a Phase 3 rescue study in mild to moderate actinic keratosis closed 5 weeks ahead of schedule.

Challenges

Enrollment was well below plan prior proinnovera’s contribution.

Proinnovera’s Measures

- ✓ Confirmed availability for super-fast conducted, detailed site feasibility within only 2 working days.
- ✓ All six additionally selected sites have already participated in previous or current dermatology studies rely on only true numbers provided by feasibility responses managed by proinnovera. Thereby, our study team could rely on only true numbers provided by feasibility responses and 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 six sites are well known for prior excellent recruitment results in actinic keratosis and regularly see the eligible patients. Both facts exemplify their capability to enroll the eligible patients with moderate.

Indication

Actinic keratosis, mild to moderate, grade I to II, according to Olsen et al., 1991

Phase

III

Type

Double-blind, randomized, vehicle-controlled

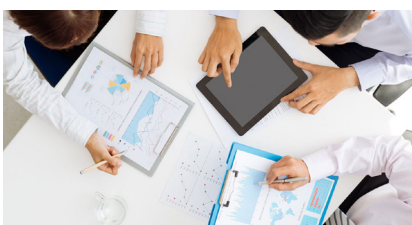
Coverage

6 sponsor sites + 6 proinnovera rescue sites in Germany

Services

Project Management Support, Clinical Monitoring

Indicators	Projection	Actual
Randomized patients	100	148
Recruitment period in weeks	21	16
Patient enrollment rate per site per week	0,79	1,55



We’ve got Skin in the Game

Actinic Keratosis Case Study

Recruitment of a Phase 3 rescue study in mild to moderate actinic keratosis closed 5 weeks ahead of schedule.

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.

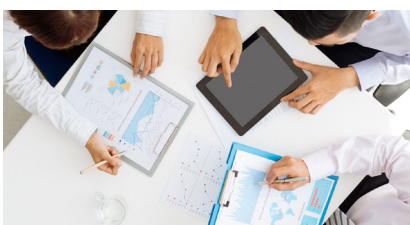
Our primary goal is to deliver fast and efficient solutions for clinical research. We strongly believe that this is the best way to make you successful and to make your product ready for the market.

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!



We’ve got Skin in the Game