

# Acute Lower Back Pain – Case Study

Recruitment of a Phase III study in acute lower back pain closed 24 weeks ahead of schedule.

## Results

- ✓ Patient recruitment closed 24 weeks ahead of projected milestone.
- ✓ 807 randomized patients versus 800 projected randomizations.

## Market Approval

Market approval has been granted approximately 18 months upon final study report. Today, the IMP is available in all pharmacies as an OTC.

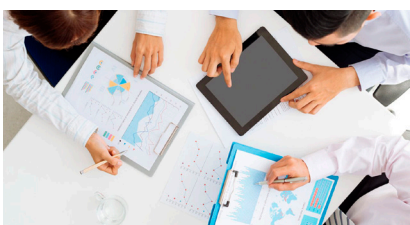
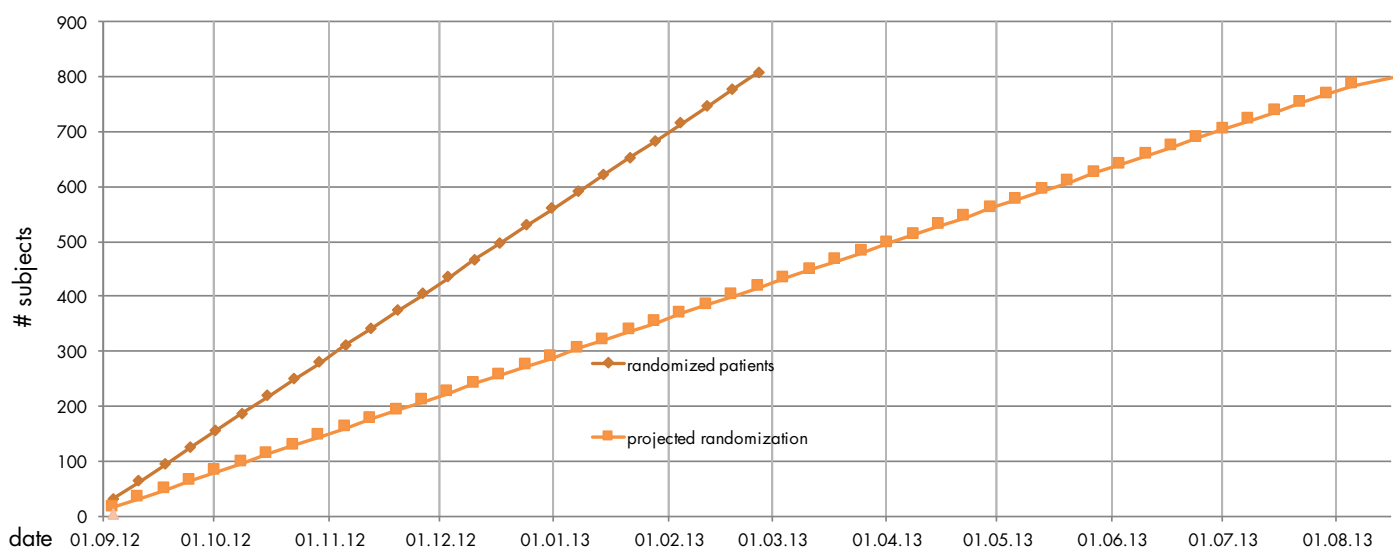
## Sponsor Facts

Type of company: private

Headquarters: Germany

Repeat Customer: no

Company's focus: Cardiology, Pulmonology, CNS, Oncology, Immunology



We've got Skin in the Game

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## Challenges

- 1** Reduction of external influences with impact on the subjectively felt pain at participating sites.
  
- 2** Ensure protocol compliance and patient adherence in spite of complex requirements.

## Proinnovera's Measures

- Strategic selection of eligible proinnovera sites considering specific logistic requirements:
  - Sites need a separate and air-conditioned room for each patient visit.
  - Patients have to spend each visit under standardized conditions and along with standardized entertainment.
- Composition of different types of sites: general practitioners, specialists for pain, centers for clinical studies, and university clinics.
- Intensive training of investigators and study nurses ensured protocol compliance.
- Special contracts allowed additional payment of study nurses for assuring continuous patient recruitment measures as well as high motivation for complying with protocol requirements.

### Indication

Acute lower back pain

### Phase

III

### Type

randomized, blinded, parallel-group

### Coverage

37 sites in Germany

### Services

Project Management,  
Clinical Monitoring, Medical Writing



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## Key to Success for your Study

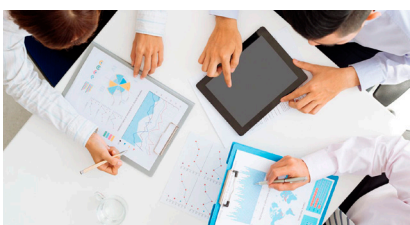
- ✓ Proinnovera’s long-lasting network of specialized sites allows for targeted site selection according to indication and study specific requirements. You will benefit from the enhanced enrollment in your study.
- ✓ Specialized dermatology CRO with a unique background in inflammatory diseases.: Our operational excellence from more than 140 successfully conducted dermatology and inflammatory studies guarantees reliable planning, conduct and control of your inflammatory 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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