We've got Skin in the Game!

Dedicated to Global Skin Health.
Specialized Dermatology CRO.

Case Study for two Post Marketing Clinical Follow-Up Studies with two Medical Devices for Treatment of Facial Lipoatrophy, Morphological Asymmetry of the Face or Debilitating Scars

Skin health

Individual skin types have individual needs. As our biggest organ our skin requires special protection and care. Dermatology trials are essential to create new medicines to heal or improve skin disorders. They are multifaceted and bear a lot of responsibility. That is why your clinical project deserves a competent partner for whom integrity is an important value. In proinnovera you have found a solution – orientated full - service CRO that ensures your product a safe passage through all phases of dermatology drug development.

We know the nuances, challenges and solutions for dermatology research.

proinnovera CRO | Wienburgstraße 207 | 48159 Münster | Germany | www.proinnovera.com

Facial Lipoatrophy - Case Study

Extension of CE-Certification for 2 Medical Devices for Treatment of Facial Lipoatrophy, Morphological Asymmetry of the Face or Debilitating Scars achieved 2 months ahead of schedule.

Results

- CE-Certification extended 2 months ahead of schedule
- 53 randomized patients versus 40 projected randomizations in study for product 1
- 2 instead of 3 planned sites closed enrollment in study for product 2 within only 10 working days vs. 12 projected weeks

Sponsor's Feedback

"Thank you so much for your efforts over the last few weeks and for sending this through even before the deadline! I have already passed on the reports to our RA department for submission to GMED."

Sponsor Facts

Type of company: private
Headquarters: Austria
Repeat Customer: no
Company's focus: aesthetic dermatology

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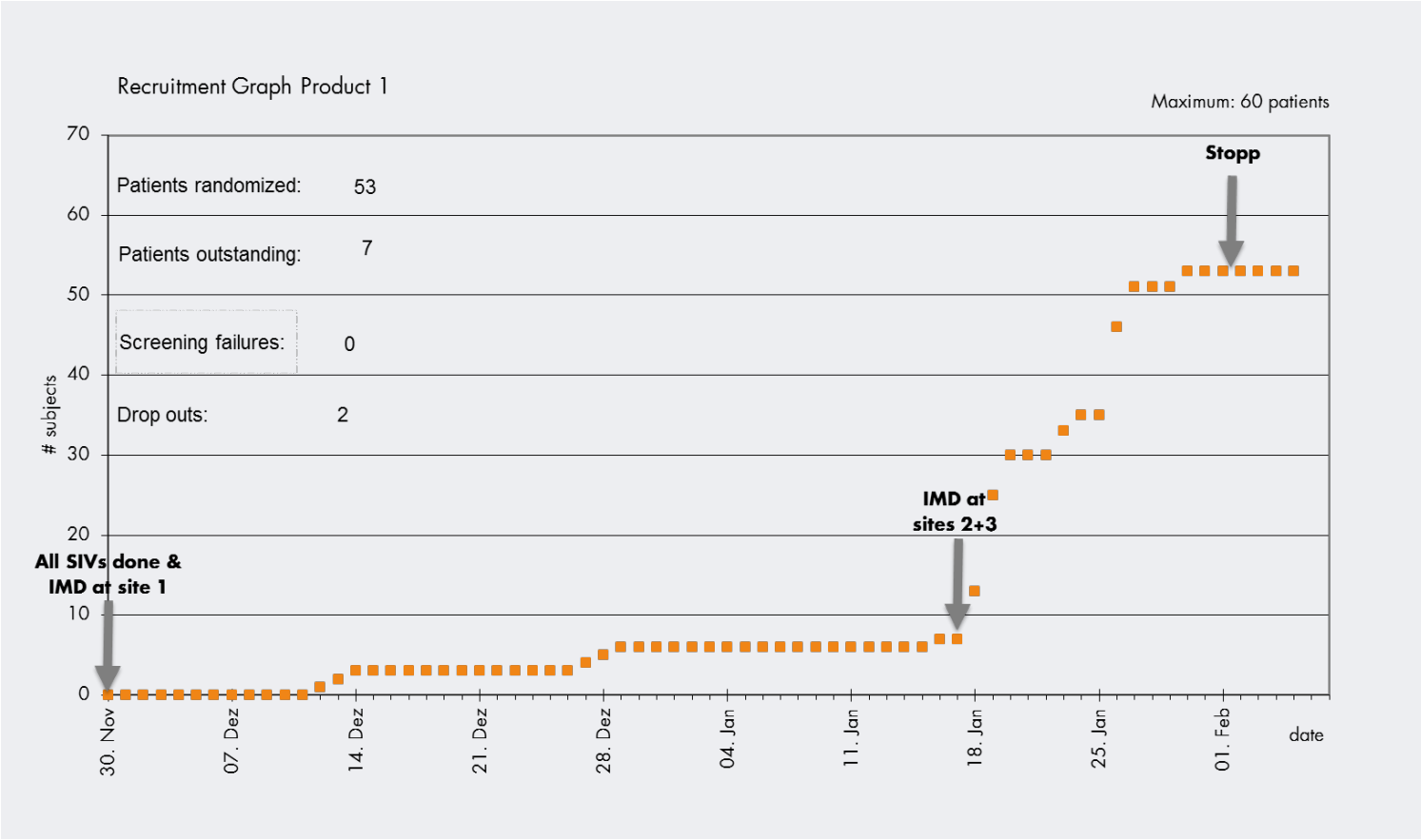

Product 1

Indication
Facial lipoatrophy, Morphological asymmetry of the face or Debilitating scars

Phase
Post Marketing Clinical Follow-Up

Type
open-label, uncontrolled

Coverage
Product 1: 3 sites in Austria

Services
Project Management, Clinical Monitoring, Regulatory Affairs Management, Data Management, Bio-Statistics, Medical Monitoring

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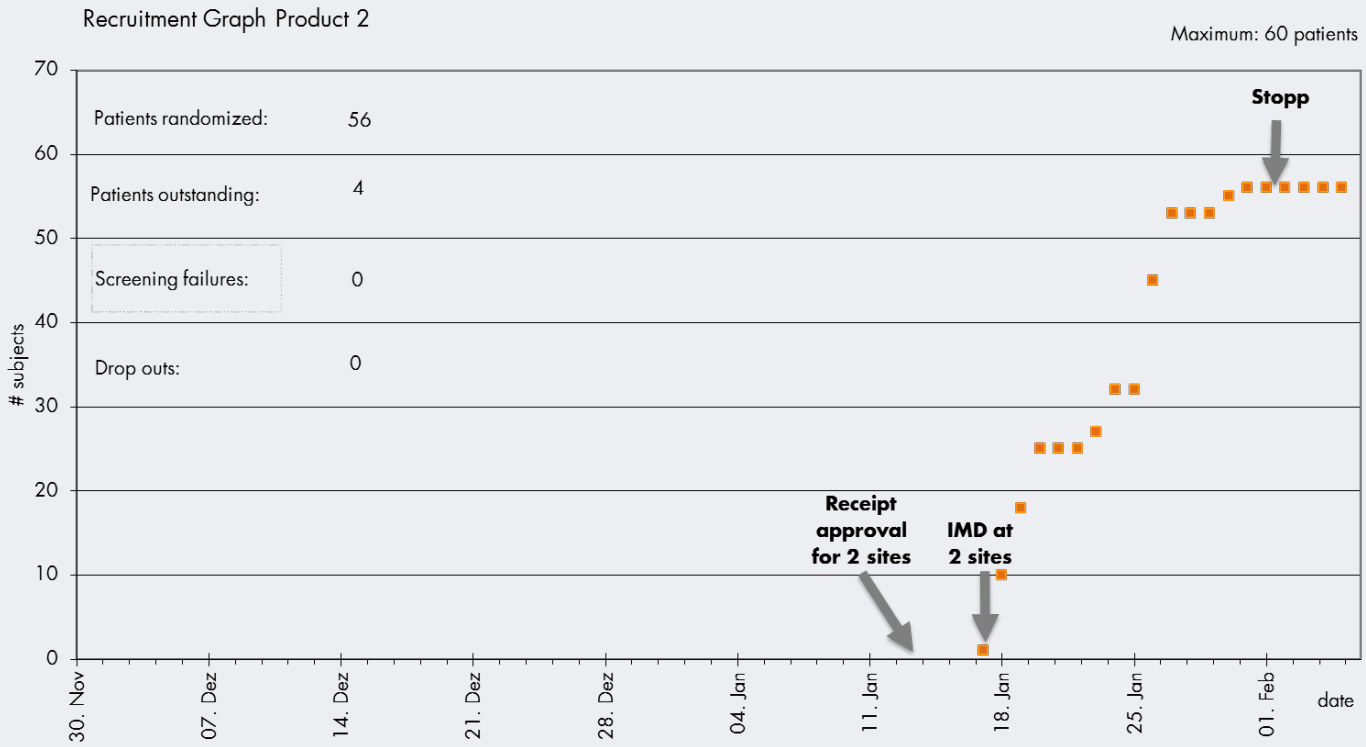

Product 2

Indication
Facial lipoatrophy, Morphological asymmetry of the face or Debilitating scars

Phase
Post Marketing-Clinical Follow Up

Type
open-label, uncontrolled

Coverage
2 of 3 sites from product 1-study in Austria

Services
Project Management, Clinical Monitoring, Regulatory Affairs Management, Data Management, Bio-Statistics, Medical Monitoring

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Challenges

1 The CE-certification of two similar Medical Products will expire in September 2017. As per sponsor specs, reports of 6 months data of 10 patients per 3 indications for each protocol had to be ready on 15-Sep-2017 for delivery to Notifying Body. According to the projected study milestones, recruitment was capped by

- 3 weeks recruitment for product 1 to meet 11-Dec-2016 for LPLV, requiring an enrollment rate of 4,44 patients/ site/Week
- 12 weeks recruitment for product 2 to meet 12-Feb-2017 for LPLV, requiring an enrollment rate of 1,87 patients/site week

Proinnovera's Measures

Upon conduct of feasibility and Site Qualification Visits, 3 eligible sites have been selected:

- Recruitment challenges are compensated by a balanced mix of different types of site: 1 university hospital and 2 private practices have been selected with different recruitment potentials
- All sites confirmed higher enrollment potential than initially projected

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Challenges

2 1 local Ethic Committee had a massive delay in approval and postponed projected milestones significantly.

- Due to internal delays at this Austrian EC via law having no timelines for certified MPs within clinical routine, first deficiency was issued on 24-Oct-2016
- In spite of identical responses to EC deficiencies, only one EC gave approval, whereas the second EC provided further restrictions

Proinnovera's Measures

- It was closely communicated with both ECs for accelerating the process wherever possible
- In parallel, the local protocol amendment and the applicable amended local ICF have been developed. Furthermore, an argumentation to address further EC questions has been developed proactively
- Sites were informed about delay and possible scenarios for recruitment were developed together with the investigators

3 Much faster recruitment than projected within much shorter recruitment period in study for product 2 and higher enrollment numbers than projected in study for product 1

- Planned monitoring visits were handled flexible: prompt monitoring with increased monitoring resources to handle high workload
- Sites were advised to only recruit max. 3 patients until first SMV, which was immediately performed after first enrolment or even on day of first enrolment
- Monitoring was performed in parallel for both studies. For compensation of high workload, often 2 CRAs visited the sites for 2 days. For product 1, one IMV was added

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Challenges

4 Because of postponed date for receipt of approval in both studies, targeted date for delivery of final CSR for study 1 and Interim Report for study 2 to Notifying Body could not be met

Proinnovera's Measures

Sponsor's correspondence with NB resulted in acceptance of alternative sponsor proposal to present primary endpoint results (week 4 effectiveness) until 03-Jun-2017

To full-fil the requirements by Notifying Body although initial planned study timelines were significantly postponed, study planning has been revised from Interim Analysis and Interim Report to Snapshot Analysis on short notice. Thereby, 2 months prior target, Notifying Body confirmed that CE certificates are extended for both products!

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Key to Success for your Study

- Proinnovera's worldwide partnerships allow for flexible country selection according to indication and study specific requirements. 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.
- 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. 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!
- Specialized dermatology CRO: Expertise from more than 100 successfully conducted studies guarantee reliable planning, conduct and control of your international dermatology study.

We are globally dedicated to skin health!

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