Case Study

Phase 1/2 Diabetic Foot Ulcer study achieves recruitment goal in record time

nRollmed contributes more than half of study's participants and cuts recruitment time down by 2+ years

nRollmed
Faster patient recruitment for your clinical trial

The Challenge

A pharmaceutical company developing an innovative stem cell treatment for diabetic foot ulcers (DFU) launched their first-in-human study. Working with only one site, the sponsor anticipated difficulty reaching the recruitment goal on schedule. nRollmed was brought on a few months in to widen the pool of patients and thereby speed up the study.

Several challenges to recruitment arose. Barriers to participation needed to be addressed such as reliable transportation for patients, many of whom were not fully mobile.

As the recruitment efforts proceeded, it became apparent that most patients with DFUs did not initially meet the stringent criteria, adding to the study's many challenges.

Finally, once a patient passed all the screening stages and signed consent, there was a 50% drop off in the two weeks leading up to the randomization visit for reasons such as developing an infection, or the ulcers shrinking more than the allowed amount.

The nRollmed Process Drives Recruitment Results

nRollmed provided 186 pre-screened leads

22 patients signed consent
12 patients enrolled

34 months of recruitment time saved

A Customized and Collaborative Approach

- Social media outreach brought in hundreds of interested patients. The site could not handle this volume, so nRollmed rigorously pre-screened all interested patients and referred only those who were well-qualified to the site.
- nRollmed employed other innovative strategies to bring in patients such as advertising in WhatsApp groups for audiences that traditionally do not use the internet, approaching nurses and community doctors, and collaborating with online influencers and the National Diabetes Association.
- To save the site and patients' time, nRollmed had patients securely send a photo of their ulcer to the site to assess if a screening visit was warranted.
- nRollmed recommended that the sponsor reconsider several stringent criteria. This led to a protocol amendment, allowing more potential patients to screen.
- nRollmed developed a deep understanding of the patient population and the study's criteria, which enabled ongoing optimization of the advertising and prescreening strategy.
- nRollmed developed a close relationship with the study coordinator, which enabled troubleshooting, increased commitment, and allowed nRollmed to step in without delay to help the site reach and follow up with patients.
- nRollmed periodically checked in with patients who didn't qualify but had the potential to in the future, such as someone with an active infection in the ulcer, or someone with an ulcer that was too "new" to meet the inclusion criteria.

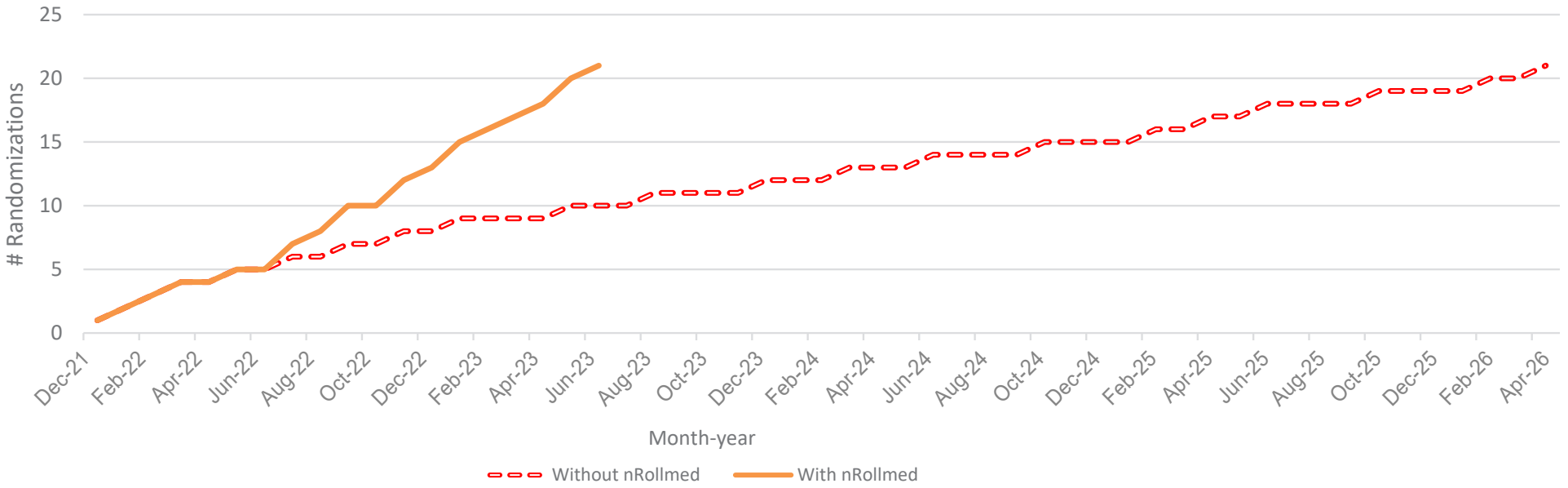
nRollmed's Method

Awareness campaign | Pre-screening | Site support | Sponsor insights | Optimization

Results

Over the 14 months that nRollmed worked on the study, 186 pre-screened patients were referred to the site, 21 consented, and 12 were randomized. The site on their own enrolled 5 patients during this time period. nRollmed's contribution to the patients recruited was 70% in the time active, and 57% for the study overall. Considering how long it would take the site to recruit the extra patients that nRollmed provided, 34 months of recruitment time were saved.

Comparison of recruitment time with and without nRollmed



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