Recruitment rescue
Case study

Study overview

An international, phase II, multicenter, randomized, double-masked, 4 parallel arms study to evaluate the ocular tolerance and safety of ophthalmic dispersion in patients with dry eye disease. Pharmnet was originally responsible for regulatory and monitoring services in the Czech Republic and Slovakia (the study was conducted in 10 countries).

Starting point

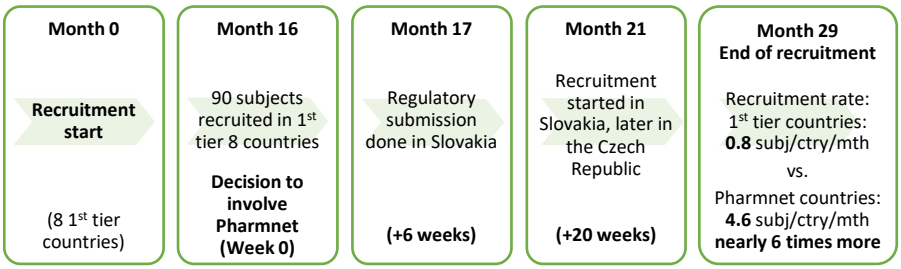
A global CRO approached Pharmnet on behalf of a sponsor about an ophthalmology study ongoing in eight Western European countries. The study had been running for one and a half years when the initial approach was made, with a slow recruiting issue. In order to quickly boost recruitment, Pharmnet advised the sponsor to open sites in Slovakia and the Czech Republic. The sponsor agreed to proceed with the feasibility in Slovakia. Within one month, Pharmnet identified suitable sites and conducted eight pre-evaluation visits (PSEV). Due to knowledge of local milieu, Pharmnet was able to identify suitable sites such as local hospitals and private ambulances, to ensure the patients' pool was sufficient.

Obtaining approval

All sites were approved by the sponsor, and preparation for regulatory submission and contract negotiations began immediately. Submissions to the RA and all relevant ECs were made only two weeks after the last PSEV. Approvals were granted within two months, and site initiation visits were performed. Because of Pharmnet's strong relationships with regulatory authorities, ethics committees, hospital management, and other stakeholders, the first patient was screened only 14 weeks after the regulatory submission.

Boosting recruitment

Due to the ongoing slow recruitment at some sites in other countries and knowing the size of the potentially eligible population, Pharmnet proactively prepared an executive summary on the additional recruitment options and the sponsor agreed to open sites in the Czech Republic too. Furthermore, Pharmnet identified and opened new sites in Slovakia.



Conclusion

Only ten months after initiating the study at the first site in Slovakia, the recruitment goal was met with Pharmnet's delivering 74 subjects, comprising 28% of global recruitment. The needs of the sponsor were addressed successfully, as worldwide recruiting recovered thanks to strong contributions from Slovakian and Czech sites. Furthermore, the Slovakian Regulatory Authority inspected a site in Slovakia, with only two non-substantial findings and two minor comments.

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