CASE STUDY

YOUR CRO FOR

RESPIRATORY

SCOPE

For this non-interventional post-authorisation study (PASS) on a respiratory drug, what initially presented itself as a smooth trial for our experienced SCOPE International team proved to be far more complicated than originally anticipated. Implementation of a tailor-made strategy scaled to the site level, and the use of customized tracking tools were key to meet the ever-changing demands of this large-scale trial carried out in eleven European Union countries. Despite unforeseen setbacks, SCOPE International successfully delivered results within the projected timelines and under budget.

10/d

Recruitment Rate

250

Sites

2,500

Subjects

The trial was originally forecast to be performed with 2,500 subjects at 250 sites across continental Europe. As often is the case, pre-conditions and distinct requirements provided challenges for the study, all of which required individual attention via process design and experience. As a first requirement, the sponsor chose to independently select almost all sites for the trial, which is often the case for non-interventional studies, and is a routine and well-known situation for SCOPE's experienced team. In the case of this respiratory study, there were several unknown factors; the experience and the recruitment potential of the sites involved were untested. In addition, their performance and motivation were unknown. Most of the sites had never carried out a clinical study. As a consequence, the site's staff involved in the study required extensive training and support. A final challenge was a tight budget with low investigator fees. To stay within the timeline, recruitment forecasted ten subjects per day. However, the start of the study was impeded by delays in regulatory authorizations for three countries, which meant that pressure on recruitment figures increased dramatically.

CUSTOMIZED SOLUTIONS

For SCOPE, the task of tackling these challenges was accomplished by designing a highly cost-efficient monitoring scheme and communication platform. SCOPE therefore developed a comprehensive strategy: we tailored an efficient and adaptive monitoring approach, which combined on-site as well as remote monitoring. More precisely, SCOPE created bespoke processes for this study, which evaluated the data collected by the EDC system generating actionable data. The study-customized reporting tools enabled regular online oversight with reliable decision-making insights. In addition, the tools ensured that the focus remained on the most critical issues of the study. Taken together, these features enabled efficient time management of

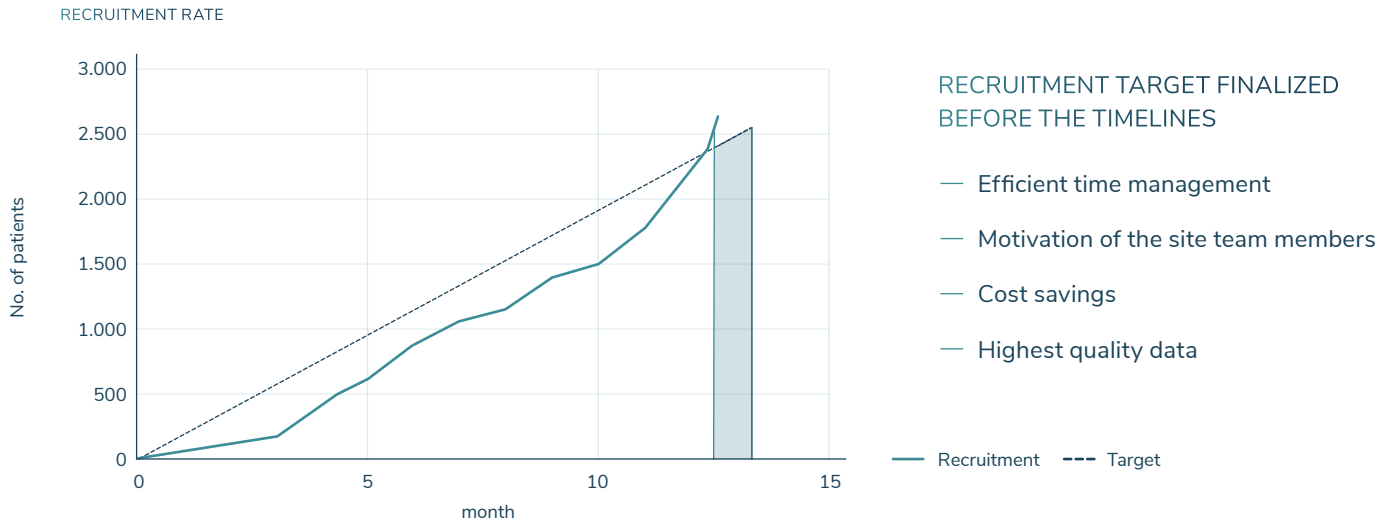
the project. With this custom-built approach, SCOPE could guarantee minimal monitoring costs, which were significantly below those of all other competitors, while at the same time maintaining the highest data quality. Considerable savings were achieved by carefully planning and optimizing CRAs' travel routes, which led to a reduction of travel costs by around 50% of the originally scheduled travel budget.

One of the biggest risks for the study was the lack of clinical research experience amongst many participating sites. In order to overcome this hurdle, SCOPE developed a transparent and structured communication plan to bring all involved parties together and to establish appropriate intensive training and support for all team and site staff members. To ensure the high recruitment rates (>10 subjects per work-day), SCOPE developed a risk mitigation plan which involved several back-up countries on stand-by that could join the study in case of a potential slowdown during the recruitment period.

SCOPE also navigated the poorly defined legal situation that had arisen in some countries due to the study being performed during a period of migration from local regulations and establishment of the Pharmacovigilance Risk Assessment Committee (PRAC). SCOPE's expertise with, and direct access to, regulatory authorities and ethics committees in the individual countries paved the way for a solution to this special situation. Submission procedures had to be executed under the old and new schemes and, while this process was more time intensive from both the administrative as well as the regulatory point of view, SCOPE reached the recruitment target ahead of timelines while ensuring regulatory compliance.

PLENTY OF BENEFITS

SCOPE's comprehensive approach made the post-authorization study extremely efficient. Due to the structured communication plan, the study was executed within the tight time frame because it allowed for rapid decision-making. This in turn motivated the team members who, enjoyed the highly efficient training. Set-up time of the study was also kept short. Customized, anticipatory reporting tools significantly contributed to the efficiency of the process: not only did the tools reveal opportunities and allow the team to exploit them, but they also predicted potential issues and possible setbacks. This allowed for proactive prevention – a much smoother process than the time-consuming experience of having to fix a problem that has already occurred. The study sites profited in particular from efficient time management, which contributed to motivation of the site team members despite the comparatively low investigator fees. As a result of the overall structured organization of the study, the recruitment process was finalized ahead of the agreed timelines. Cost savings were remarkable, since total incurred monitoring costs were below the already favorable budget. The elaborate, tailor-made approach and tools resulted in the delivery of highest quality data within the defined timelines. Despite the initially complex situation, the post-authorization study was a positive experience for both SCOPE and our sponsor.



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