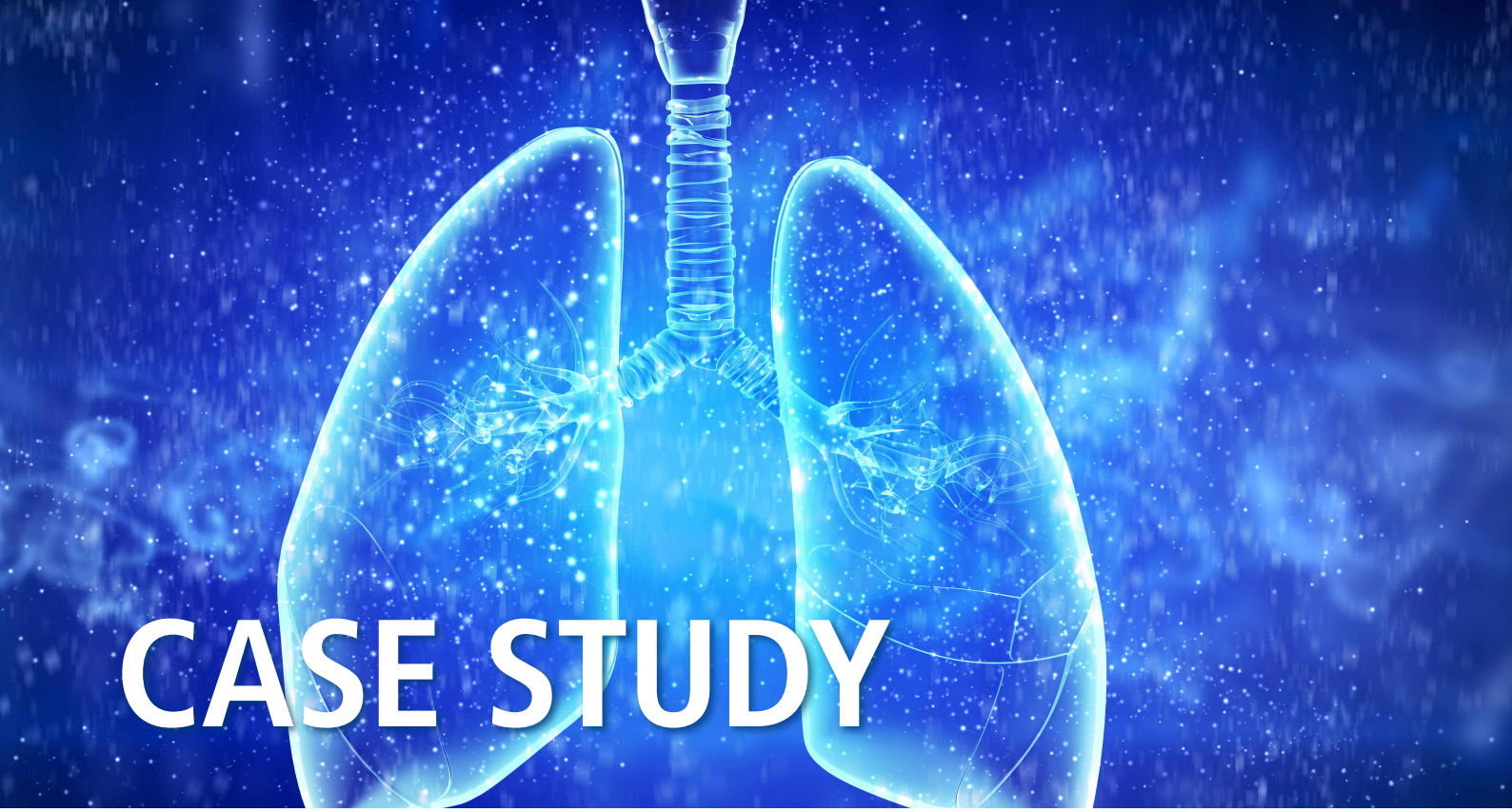


CASE STUDY

RESPIRATORY POST-AUTHORISATION SAFETY STUDY: TURNING COMPLEX INTO SMOOTH

Initially it looked like a routine situation, but preconditions required careful consideration by our experienced team for this obligatory, non-interventional post-authorisation safety study on a respiratory drug, especially as it was to be carried out in eleven European Union countries. With a tailor-made strategy and customised tools, Scope International delivered excellent data, thereby staying within the timeframe and undercutting the planned budget.

The non-interventional post-authorisation safety study (PASS) on a respiratory drug was to be performed with 2,500 subjects in 250 sites in continental Europe. As often is the case, there had been pre-conditions and distinct requirements, which provided for the unique features and individual challenges of the study all of which required their individual attention via process design and experience.

As a first requirement, the sponsor chose to select almost all sites themselves, which is often the case for non-interventional studies and a routine and well-known situation for Scope International's experienced team. In the case of the respiratory study, this provided several unknown factors: The experience and the recruitment potential of the sites involved were untested as well as their performance and motivation. In fact, 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. Last, but most importantly, the tight budget with low investigator fees also had to be considered.

To stay within the tight timeline, more than ten subjects needed to be recruited on each workday. However, in three countries the start of the study was impeded by delays in regulatory authorisations, which meant that pressure on recruitment figures increased dramatically.

CUSTOMISED SOLUTIONS

For Scope International, the task consisted in tackling all these challenges by designing a highly cost-efficient monitoring scheme and communication platform. Scope International therefore developed a comprehensive strategy: It tailored an efficient and adaptive monitoring approach, which combined on-site as well as remote monitoring. More precisely, Scope International created bespoke processes for this study, which evaluated the data collected by the EDC system generating actionable data. The study-customised 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 supported powerful and efficient time management of the project.

With this custom-built approach, Scope International 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 optimising CRAs'

travel routes, leading to a reduction of travel costs of around 50 per cent of the originally scheduled travel budget. Similarly, in the light of low investigator fees, Scope International's monitoring method also maximised useful contact time with the study sites.

One of the biggest risks for the study was the relative paucity of clinical research experience amongst many participating sites. In order to overcome this hurdle, Scope International developed a transparent and structured communication plan to bring all involved parties together and to ensure appropriate, intensive training and support for all team and sites staff members.

To ensure the high recruitment rates (>10 subjects per workday), Scope International developed a risk mitigation plan which involved several back-up countries on stand-by that could have joined the study in case of a potential slowdown in the recruitment process.

Scope International also mastered the poorly defined legal situation that had arisen in some countries due to the study being performed during migration from local regulations and establishment of the Pharmacovigilance Risk Assessment Committee (PRAC): Scope's expertise with, and direct access to the 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 intense from both the administrational as well as the regulatory point of view, Scope International had reached the recruitment target ahead of the timelines in the end while ensuring regulatory compliance.

PLENTY OF BENEFITS

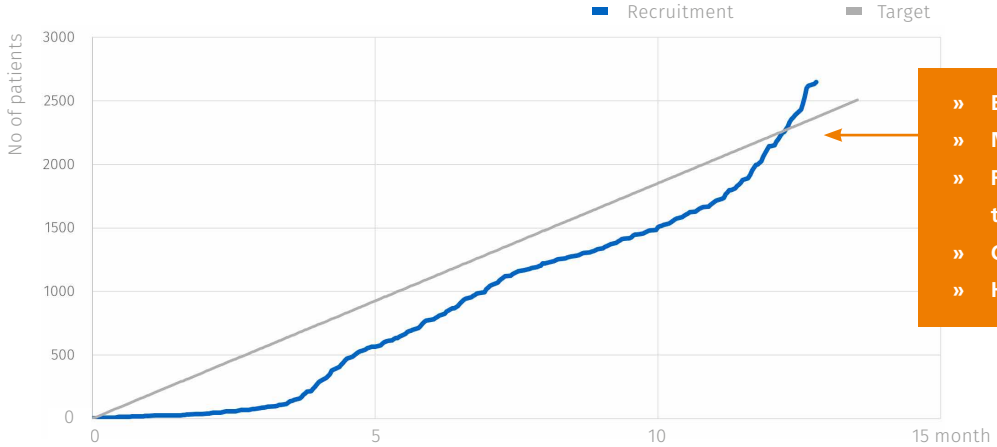
Scope International's comprehensive approach made the post-authorisation study extremely efficient. Due to the structured communication plan, the study could be achieved within the tight timeframe because it allowed rapid decision-making. This in turn motivated the team members who enjoyed a highly efficient training. Set-up time of the study was also kept short.

The customised, anticipatory reporting tools contributed significantly to the efficiency of the process: Not only did the tools reveal opportunities and allowed to the team to exploit them, they also predicted issues and potential setbacks and were able to prevent them – a much smoother way than the time-consuming experience of having to fix a problem that has already occurred.

The study sites profited in particular from the efficient time management, which contributed to motivation of the site team members despite the comparatively low investigator fees.

As a result of the overall good organisation of the study, the recruitment process was finalised ahead of the agreed timelines. Cost savings were remarkable, since total incurred monitoring costs were below the already very favourable budget. Last but not least, the elaborate, tailor-made approach and tools resulted in the delivery of highest quality data within the defined, tight timelines. Despite the initially complex situation, the post-authorisation study became a thoroughly positive experience for the both SCOPE International and our sponsor.

RECRUITMENT RATE



- **Efficient time management**
- **Motivation of the site team members**
- **Recruitment target finalised before the timelines**
- **Cost savings**
- **Highest quality data**

Konrad-Zuse-Ring 18 I D-68163 Mannheim I Phone +49 621 42939-0 I Fax +49 621 42939-40 I contact@scope-international.com I www.scope-international.com