Pulmonary inflammation home visit case study in Australia.

Abstract: While adoption/acceptance/use of Mobile Clinical Services (MCS) is growing/increasing in most regions around the world, a number of Asia-Pacific countries remain hesitant to commit to this new approach to clinical trials. This case study reviews Fortrea MCS support of a global pulmonary inflammation clinical trial that was active in Australia, highlighting the benefits on a global level and the specific challenges faced in the Pacific country.

Over the past few years, and particularly during the COVID-19 pandemic, MCS have become a keystone in the conduct of clinical trials, both conventional and decentralized alike. Having a professional group of Mobile Clinicians conducting scheduled visits, or ready to support trials as a safety net in case of unexpected issues, improves the safety and compliance of patients while reducing the workload difficulties that investigator sites may experience. MCS have been prevalent for years in North America and Europe, and have more recently been used in some regions of Latin America, Africa and the Middle East. However, due to the regulatory and cultural heterogeneity of the Asia-Pacific (APAC) region, its implementation has been gradual on a country-by-country basis. This is a case study about the use of MCS in Australia.

A Sponsor wanted to conduct a Phase II study on a pulmonary inflammation clinical trial for an adult population with around 230 patients. This clinical trial had simple assessments, with very few laboratory specimens. The primary objective was to evaluate the improvement of lung function, measured by daily self-administered spirometry. Therefore, the main risk for the Sponsor was to ensure patient compliance in this home setting, especially in countries with long travel times between the patient and the investigator site. In this context, the Sponsor decided to set up Fortrea MCS in all of the countries.

During the study, the MCS team supported scheduled visits mandated by the protocol to review the compliance of the patients with the study processes, as well as to retrain them in the use of the hand-held spirometer in case the quality of the measurements was low. This allowed the investigator site to have a professional in the field who was able to follow up with the patient directly and rapidly increase the quality of the measurements. It also provided a way to supply a spirometer replacement in a very short timeframe. Finally, this also benefitted the patient, who was able to avoid traveling to the investigator site for the compliance re-trainings.

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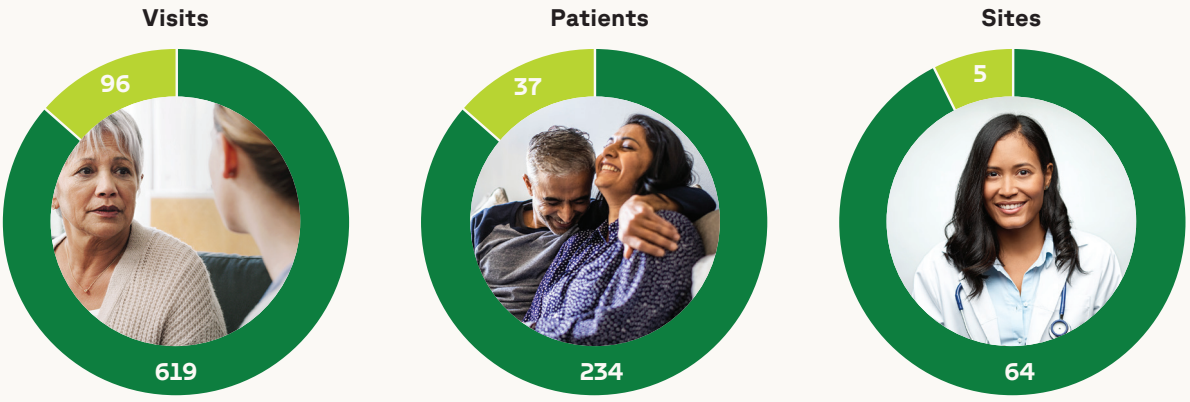
Australia was one of the two countries that adapted the fastest to this approach, conducting successful visits as early as the first month of the trial. During the conduct of the trial, 37 different patients from Australia had 96 visits conducted at their home or alternate location of their choice, which progressively increased the patient compliance and measurement quality in the spirometry, subsequently contributing to the success of the clinical trial.

In Australia, our team faced very different challenges compared to other countries. On one hand, the extension and demographic profile of the country meant that some patients could live far away from investigator sites and high population cities. This meant additional efforts and time were needed to identify suitable Mobile Clinicians, but ultimately the Fortrea team was successful in securing personnel who lived within 1 hour of the patient and were able to conduct unscheduled visits in a short timeframe.

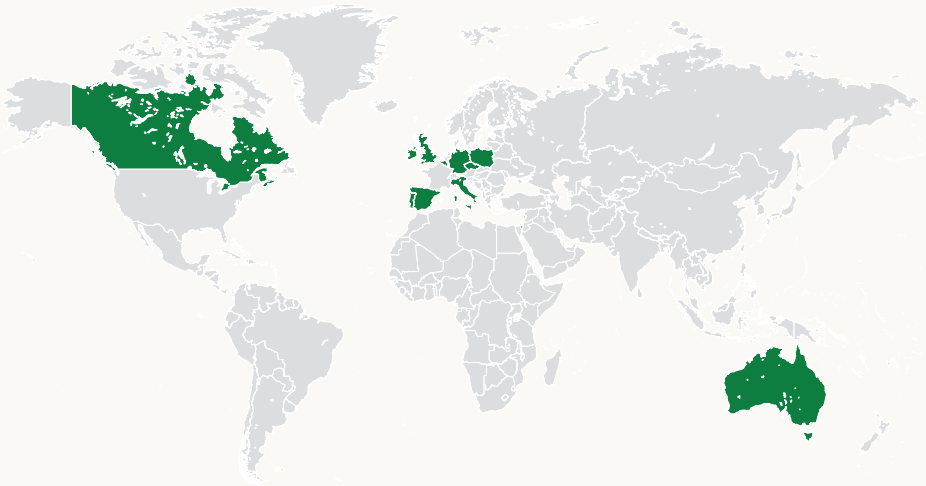
Another important challenge in each was the customs difficulties in returning the training material (dummy spirometers) to the vendor at the end of the clinical trial, as the CRO was not able to arrange a solution on their own. Fortrea MCS, closely collaborating with the spirometer vendor and the Sponsor, was able to trigger the appropriate shipments and return the material back to the vendor in compliance with all regulations for this process.

In summary, this clinical trial was a huge success for the Sponsor, sites and patients across 14 countries. The Sponsor got a higher retention rate for patients and higher data quality for the 234 patients visited globally, the 64 investigator sites involved in the study around the world could oversee the patient compliance with less impact on their workload and patients enjoyed the convenience of being visited at home and avoiding long travel times.

Impact of mobile clinical services on this study



Supported countries



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