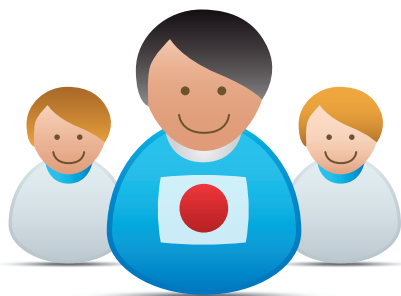


The Richmond Japanese Team commits to a challenging study.....and they deliver.

Richmond Pharmacology is Europe's largest provider of Japanese Bridging Studies and has been conducting studies involving Japanese subjects outside Japan for almost a decade. Such is their success that Richmond Pharmacology has been chosen by several pharmaceutical companies as their Preferred Provider for the conduct of Japanese studies.

The Challenge



A sponsor who had selected Richmond Pharmacology as a Preferred Provider was co-developing a compound with a partner company. Based on experience, Richmond Pharmacology was recommended for the conduct of a Japanese study with a twist.

The challenge of recruiting Japanese subjects is familiar. Richmond Pharmacology has been recruiting from within the UK's Japanese student population for many years and has a dedicated in-house Japanese recruitment department, supported by a targeted marketing strategy and their bespoke brand trials4japanese. Through their innovative approach to marketing and recruitment of this specialist population, they receive approximately 150-200 enquiries per month from potential Japanese volunteers.

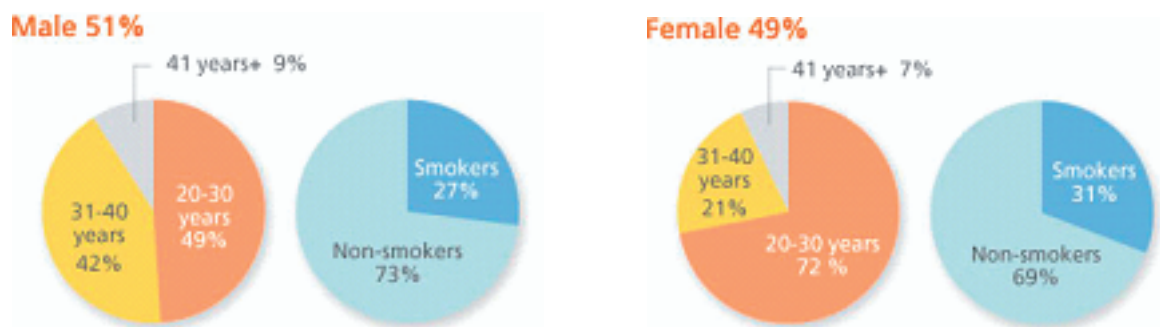
Comment:

"To generate awareness and interest in our trials amongst the Japanese community, we deliver sustained and targeted marketing campaigns. Our approach has been very successful to date as the marketing messages and advertising designs are constantly monitored to ensure they are tailored to the tastes of our Japanese student target population."

Subject Selection

The study involved a challenging subject selection process. The study required the inclusion of 18 Caucasian and 18 Japanese subjects. The inclusion of Caucasian subjects is nothing new to Richmond Pharmacology nor is this a challenge to Richmond's dedicated Volunteer Recruitment Team. Whilst Richmond Pharmacology has successfully recruited Japanese volunteers into a number trials since 2001 the pool of subjects we were able to access for this trial was limited due to the inclusion/exclusion criteria.

Breakdown of Richmond Pharmacology's Japanese Volunteer Panel



The Twist?

These are common criteria for a Japanese Bridging study in the UK, however two additional procedures were required before a subject could be included into this study. The protocol required the subjects to have a magnetic resonance imaging (MRI) scan within a 21 day screening window, following a screening visit at Richmond Pharmacology's Trial Centre at Mayday University Hospital. Upon the completion of the MRI and a pass for this stage of screening, the subjects had to undergo a baseline Positron Emission Tomography (PET) scan before the subject could be included into the study.

In addition, during the dosing phase, and therefore while the subjects were housed at Richmond Pharmacology's Trial Centre, a 'treatment' PET scan was required on Day 14.

Comment:

"Our biggest challenge was the coordination of our Phase I Unit schedule with the similarly strict schedule provided by the Scan Centre. They had a very fixed schedule and limited availability of scan slots due to commitments to other clients, including the NHS. Trying to match the scan centre's fixed schedule, possibly only 2-3 scans per week, to the availability of the Japanese subjects was a challenge. Due to potential language barriers, we arranged for a member of our Japanese volunteer department team to meet the subjects at the scan centre. However, not all subjects were able to locate the scan centre and not all subjects actually turned up for their appointments, resulting in a lost scan slot and a significant impact on our study schedule". This issue was quickly overcome through the quick thinking of the project team. Rather than meet the subjects at the scan centre, a former Japanese volunteer was employed by Richmond Pharmacology to chaperone all volunteers, (both Japanese and Caucasian), to the scan centre. Once this was implemented all MRI appointments where a volunteer was available were met on time.

Creating a very effective working partnership

Without a doubt the study would have faltered if it had not been for the dedication put in by the Richmond Pharmacology study management team, their Japanese colleagues in the Volunteer Recruitment department and importantly the commitment from the team at the scan centre, coupled with the good communication between all parties.



Comment:

“We kept in very close contact with the Director of Clinical Operations at the scan centre. On occasion, despite the meticulous planning, the PET scan could not be performed as scheduled, as the production of the radioligand failed. This created a very difficult situation for the volunteer who was already on site at the scan centre. Thankfully, our Recruitment Team were able to appease the volunteers and re-book them in for the next scheduled scan. The sponsor told us that they did not know of any other CRO who would have been able to manage this study as successfully as we did.”

How the study team made it happen!

Communication was the key to the success of this study. On occasion, when a volunteer did not attend the booked scan appointment or the scan failed, the scan centre telephoned the Richmond Team immediately. The schedule for the study changed on many occasions and due to the flexibility of the study team at Richmond Pharmacology they were able to accommodate these changes and coordinate appointments for all 36 subjects from the initial screening MRI to the baseline PET scan and lastly the treatment PET scan.

The end!

Through the excellent day to day management of the logistics of this project Richmond Pharmacology successfully completed the study, recruiting all the Japanese and Caucasian subjects required. A clear sign of their success in the completion of this study, and a result of the working partnership built up with the scan centre, the sponsor invited Richmond Pharmacology to perform a second similar study, including the same populations, once again with another twist, (poor and intermediate metabolisers would be excluded, thus reducing the suitable populations pools even further). The sponsor understood the efforts that had been made throughout the first study and were aware of the measures that had been taken to make the next study happen.

Are you concerned that your study may be too challenging for your current provider? The can do attitude and ability of the Richmond Pharmacology Study Teams ensures we can rise to the challenge, so go ahead

Challenge us!