65 subjects vaccinated in 1 day? - No problem for Richmond Pharmacology's Study Team

Recruitment can sometimes be a challenge, however the tighter the timelines and the larger the group required, the more Richmond Pharmacology rises to the challenge.

Vaccinations for perennial problems such as influenza, need to be tested within very tight timelines. The WHO stipulates which strains of influenza should be included in the vaccination, the manufacturer produces the trial supplies, the trial takes place and test results are analysed; all within a very short timeframe of approximately 3 months. Mass manufacture then takes place in order to ensure that supplies are available globally for the vaccination period commencing in September.

Tight Timelines

We were approached by the sponsor to participate in this study in January 2008, with a commitment to vaccinate 65 subjects in just 1 day. There had to be an approximate 50:50 split between volunteers aged 18 to 60 and 61 plus. All subjects were then due to return exactly 21 days later for a follow-up visit to determine if the vaccine had worked and that they were now immunised against the ever evolving strains of the influenza virus.
Richmond Pharmacology was one of only two sites tasked with undertaking this study. It was the first time Richmond had been asked to take part in this study whilst the other site had conducted this study for several years on behalf of the sponsor

The first challenge was preparing all the necessary documentation for the Ethics Submission. Following selection by the sponsor, we had just 3 weeks in which to make the deadline for submission. This deadline was met and approval followed the meeting very quickly.

Comment
"Richmond Pharmacology's dedicated Project Managers understand the tight timelines that are very common for early phase trials. Our vast experience of dealing with regulatory agencies and ethics committees ensured we know the dates of all upcoming ethics committee meetings and typically we have 3-4 submissions in any given month. As such we were quickly able to identify a suitable committee and produce the application and associated documents in time and to a standard that would allow for approval at the first time of submission".

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RICHMOND Pharmacology

Recruitment

Richmond Pharmacology is well known within the pharmaceutical industry for being able to recruit a large number of volunteers in very short time periods. The recruitment team at Richmond Pharmacology has grown since the company was formed to include tele-recruiters, volunteer recruitment project managers, a dedicated recruitment doctor, marketing professionals and a recruitment management team that ensures Richmond Pharmacology can deliver on most volunteer panels.

The recruitment team were tasked with recruiting 32 volunteers aged 18-60 and 35 volunteers aged 61 or older. This was no challenge at all as the team had Richmond's vast volunteer database to use, (more than 80,000 registered potential volunteers), incorporating a large population for each age demographic. The challenge for this trial was to ensure all volunteers were dosed in one day and that the age and sex split was achieved. As such the team booked in approximately one and half times the number of volunteers needed per demographic to ensure that most appointment slots was covered by more than one potential volunteer to account for cancellations, no shows, (on the day), and screening failures.

Comment

"Screening and enrolling 65 subjects in one day takes a lot of work. A good result is dependant on good planning. We understood that processing such a high volume of screening and subsequent enrolment appointments in one day required very strict co-ordination between several of our teams, including the research physicians, nursing staff, pharmacists, clinical trial assistants and the recruitment team. Running this trial required a well organised and strong leader and that is exactly what we had in the form of our Project Manager for this study.

All appointments were staggered over the day starting from 7:30 am and continuing on till 6.30pm. We anticipated that we would not need these last appointments, however to be sure of completing the task we ensured we had a safety net in case we were unable to enrol enough volunteers earlier on in the day. Volunteers were booked in in groups of 15 per age demographic and this was staggered to ensure we were enrolling both age groups throughout the day rather than one demographic followed by another."

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The wait for the “go” signal

Whilst Richmond Pharmacology already had ethics approval, the regulatory approval came through only one day before screening and enrolment of the subjects was due to start. The moment clearance was received to start the study, it was all hands on deck to ensure every volunteer booked in previously was called and reminded of their appointment. The site for this challenging task was prepared by the project team and all went to bed early for what would be a long day ahead.

Comment
“Being able to mobilise a team at a moments notice is something we are used to at Richmond Pharmacology. Our ability to adapt to a situation and the can do attitude of staff ensures that in most situations we are able to achieve the targets we are set, no matter how challenging they may be”

Dealing with the volunteers

The day started out extremely well. The first appointment arrived on time and Richmond was under way. The good news to follow was that the volunteers just kept coming and coming. By 10:30 am 45 volunteers were already on site with 97% of appointments attended. Whilst all at Richmond Pharmacology were pleased with the number of volunteers attending, the issue arose of where to put all of the subjects waiting to be screened and subsequently enrolled. Quickly the recruitment team converted the one office space into a secondary waiting room and all volunteers now had somewhere to sit. Newspapers and magazines were provided to ease the waiting time and the Richmond Pharmacology in house kitchen team went into overdrive making sandwiches to keep the volunteers hunger at bay

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Comment
“Once again the can do attitude and the understanding that this goal had to be achieved ensured that the team did actually work as a team. Every member of staff involved in the study had a sense of ownership of the study; due to their involvement in this study form the early planning stages. This sense of ownership coupled with the can do attitude and flexibility of our staff is vital for our continued success”

Recipe for a successful day - teamwork

The first subject was vaccinated at 8.30am, with the 65th and final subject leaving the unit at approximately 5.30pm – earlier than originally anticipated. As such Richmond pharmacology was able to cancel all appointments booked from 3:00 pm onwards as by

this stage there were already 85 volunteers at Richmond's trial centre at St George's Hospital. Whilst some volunteers were disappointed not to be able to take part, the recruitment team were able to offer these volunteers the ability to take part in one of several ongoing or upcoming trials Richmond Pharmacology was involved in at the time.

The smooth running of the day was facilitated by the teamwork and organisation of the clinical and volunteer recruitment team running the study. Although some subjects had to wait quite some time to be seen by the Research Physicians and Clinical Staff, there was a good atmosphere amongst the staff and volunteers.

Comment
"It was a full-on day, but with everyone pulling together it ran very smoothly, to the satisfaction of all involved, but especially to the onsite Independent Monitors working on behalf of the sponsor company."

Not Over Yet

Whilst the study was over for some at Richmond Pharmacology, this was not the case for the study's Project Manager and the recruitment team involved in this study.

The volunteer recruitment team's next challenge was to ensure contact was maintained with the subjects to ensure that they returned for their follow-up appointment 21 days later. This was crucial to ensure that the sponsor was able to gather the correct quantity of data required for the study. On the follow-up day, all 65 subjects returned. The sponsor was therefore able to obtain the necessary quantity of data required and some months later the latest influenza vaccine was available to the general population.

Comment
"One of the key parts of our role is to ensure follow-up visit appointments are adhered to. Payments are only made after a volunteer has completed all appointments in a study and this helps to ensure the majority of subjects do not withdraw from a study for no good reason. Nevertheless it is often the personal touch created by regular communication that ensures that volunteers return as scheduled and return again in the future to participate in other studies.
We had the chance to be part of something we had not done before and this coupled with the fact that we were able to very quickly see the effect of our work on the general population made this a very satisfying challenge for all concerned".

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