You can plan a study meticulously but when you start a First-Time into Human study……prepare to be flexible!

The first CRO to receive Supplementary Accreditation for two hospital based Units:

Richmond Pharmacology, Europe's leading Early Phase CRO for the conduct of First Time into Human studies is the first and only UK CRO to receive MHRA Standard and Supplementary Accreditation for two hospital based Trial Centres. Receiving both Standard and Supplementary Accreditation is a clear sign of the high quality of their clinical trial facilities, the training of their dedicated and committed staff and their experience in conducting Early Phase studies.

Having specialised in conducting First Time into Human studies for over 10 years, the team at Richmond Pharmacology are very proud to have been awarded the highest level of Accreditation. It confirms that their approach to running intricate First Time into Human studies (including those that require submission to the Expert Advisory Group (EAG)) is of the highest standard; the highest standard in fact achievable in Europe.

Relevance to the task at hand

Last year Richmond Pharmacology was asked by a US sponsor to conduct a First Time into Human study. More specifically, it was a Double-Blind, Single-Dose Safety, Tolerability and Pharmacokinetic Study of a new achiral chemical entity in 72 young healthy male subjects.

Comment:
"I was delighted when I was contacted about this First Time into Human study. We had worked with this US client on a previous occasion on a large young and elderly healthy volunteer study and that study had gone very well, completing on time and meeting all recruitment targets on schedule. It was great to welcome them back. This is not uncommon as we have a very good repeat business rate of approximately 70%. With 2 Trial Centres and a total of 100 beds we can accommodate various studies, whether it be a First Time into Human study run in perhaps just one volunteer at a time or a large QTc study with multiple groups of up to 20 subjects each."

St George's University of London,
Cranmer Terrace, Tooting, London SW17 ORE
T:+44 (0)20 8664 5200 F: +44 (0)20 8664 5201
E: info@richmondpharmacology.com

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Study Set-Up commences!

Following initial discussions about the study, and prior to the Ethics and the Regulatory submission, it was time for the sponsor to progress with the development of the protocol. Richmond Pharmacology was sent a robust draft protocol and distributed this amongst the Study Team for review and comments.

Richmond Pharmacology is able to offer advice from a scientific perspective, including therefore analysis of the risk assessment and the risk management required during the conduct of a study. This is combined with the need to ensure that protocols follow all applicable UK clinical trial guidelines and regulations, particularly in reference to the requirements of both the Research Ethics Committees aswell as the MHRA Phase I Accreditation Scheme. Richmond Pharmacology are experienced in not only taking studies through the Ethics approval process but also in the submission of Clinical Trial Applications to the MHRA. The benefit of the advice offered is that the studies receive timely approvals from both parties and all relevant approvals are in place to start the study as per the timelines agreed with the sponsor.

The sponsor had outsourced the preparation and management of the Regulatory submission to Richmond Pharmacology, a request that over the past 3 years has become increasingly common. Richmond Pharmacology's Regulatory Consultant was involved at every step in the preparation of the regulatory submission package. The submission was made to the MHRA and following receipt of the CTA approval, and the Ethics approval, the study started on schedule, as planned.

> Comment:
> "We yet again saw an impressive turnaround from the MHRA. The regulatory submission package was validated by the MHRA on the 20th January 2009 and the initial response received on the 30th January; within just 10 days! Our response to the one question received was acknowledged by the MHRA on the 4th February and full regulatory approval received 1 day later on the 5th February! This meant we received full written approval to conduct this FIM study in just 16 days.

Time for change!

During the clinical phase of the Single Dose Study it became apparent that absorption of the compound was not as effective as first thought and it was decided to re-formulate the product. This happened at dose level 4 and dose levels 5 and 6 were still to be conducted. To avoid continuing with the current formulation into yet higher dose levels where similar results were anticipated the decision was taken to continue with cohort 5 but thereafter put cohort 6 on hold, until the product formulation was changed. 2 additional cohorts were also added to the study to evaluate the new formulation.

Comment:
"We work in Early Phase research and so are fully aware that we have to plan for this type of event. We need to be very flexible with our Unit schedules and adapt very quickly to changes. Our in-house data management team had provided the data for interim analysis and dose escalation conferences. During discussions regarding this data we quickly became aware that the study schedule would need to be adapted. Working together with the sponsor a protocol amendment was prepared to ensure that the regulatory and Research Ethics Committee submissions could be made at the earliest opportunity and that the study was back on track as soon as possible. In parallel with the preparation of the amendment our Project and Resource Management Departments successfully completed the planning of the adapted schedules.

When discussing the set-up and conduct of the First-Time into Human Single Dose Study, the sponsor also asked Richmond Pharmacology to conduct the Multiple Dose Study. Their plan was for the Multiple Dose Study to start as the Single Dose Study was coming to an end.

Comment:
"We are seeing this approach more often, with a particular emphasis on saving both time and money during the drug development process. We now see that sponsors are planning both the Single Dose and the Multiple Dose within one combined flexible protocol. This allows our sponsors to progress through First Time into Human, Single Ascending Dose, and Multiple Ascending Dose, and perhaps even add a Food Effect cohort, all within the same protocol. If applicable during the compound's early development there is also the option that that sponsors can add in comparative cohorts in other populations such as Japanese or a cohort of patients in the target population. This saves our sponsors a great deal of time and money when they progress from First Time into Human through to Proof of Concept and Proof of Principle"

Watch this space!

And so the study continues…..to learn how the study developed return to our next update to be published shortly on our website www.richmondpharmacology.com.

"Richmond Pharmacology has extensive experience of conducting First Time into Human studies, including studies involving biologics, and we have a very experienced team on hand to help you…….you can be sure we will rise to the occasion."

Challenge Us!

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