

# Anatomy of the Clinical Trial application process

Daval International Limited, a private British pharmaceutical company, has now completed the challenging process of preparation for a Phase IIB clinical trial of its investigational hyperimmune caprine serum product

First, the trial medication and placebo need to be produced to Good Manufacturing Practice by a company with an Investigational Medicinal Product (IMP) manufacturing authorisation, and there are very few of these. For biological products such as our own, intricate attention needs to be paid to matters as diverse as immunogen and serum sourcing, batch to batch equivalence and stability, vialing, labelling and distribution. Patient safety is the overall master. Key documents include an IMP Dossier and an Investigator's Brochure, each with their prescribed formats. Both are huge!

Next, an investigator with expertise in what is, in the case of our own trial, a rather specialised area of medicine (bladder dysfunction in multiple sclerosis) needs to be identified. A detailed protocol is then jointly prepared and the Clinical Trial Authorisation application is lodged with the relevant Competent Authority (in the case of the UK this is the MHRA). This is a highly efficient but impressively detailed process. Meanwhile an Ethical Committee assesses ethical and scientific aspects of the study and the hospital itself looks at the practicality of the trial proposal with respect to

financing, facilities and staffing. A suitably qualified trial monitor and auditor are also engaged to ensure, inter alia, that Good Clinical Practice is maintained.

When positive responses are obtained from all parties and once Clinical Trial Insurance has been secured, recruitment can commence. The monthly expenditure, modest till this stage, now seems to mount exponentially. We are currently going through a similar application process in the United States, where the FDA oversees the awarding of the all-important Investigational New Drug (IND) number. Comparison of the systems should prove interesting. In recent months, veterinary studies have commenced in collaboration with three Australian Universities.

It is now a matter of waiting quietly in the hope that one's primary and secondary outcome measures show statistically significant responses to treatment and that in the end, such responses prove to be clinically meaningful to the patient. ●

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