Clinical Research in General Practice - a significant income enhancer -

Globally the Pharmaceutical Industry spent about $72 billion on research and development (R & D) in 2004. Of this, $22 billion was spent on phase II and III studies in clinical practice. In South Africa, it is estimated that approximately R600 million was spent on clinical development in 2004. This includes costs for laboratory tests and special investigations like X-rays and MRI's. R200 million of the total was paid out to investigators, all clinicians who participated in clinical trials.

There is an increasing tendency and willingness of multi-national pharmaceutical companies to engage in more clinical development outside the USA & Europe. C. Garnier, CEO of GSK, recently said in a press release that GSK plans to conduct 20-30% of their clinical development in the so-called "rest of the world". South Africa has been involved in clinical research for more than 30 years, and our clinicians and clinical development work are highly regarded internationally. SA is also one of the few countries outside the USA and Europe that has completed total clinical drug development, from first time in man to FDA registration, in at least two drugs that I know of.

The question is: How much of this money found its way into your practice? If the answer is nothing, it may be worth your while considering clinical research as a supplement to your profession fees. Unfortunately this does not happen automatically – firstly there must be a serious interest in doing clinical trial work and secondly, your practice must be organised and managed in a way that facilitates clinical trials. The right infrastructure must be in place and this does not necessarily require a capital out lay.

Medpharm Publications (Pty) Ltd, publisher of *SA Family Practice* , in collaboration with the pharmaceutical industry in SA, has taken the initiative to publish a series of articles which inform and facilitate the family/general practitioner in order to participate in clinical drug development. There is some fluctuation in the availability of trials that can be done in general practice. It is thus important to render high quality work at a competitive price in order to increase the flow of studies to SA. Due to the vast numbers of patients that we see, of which some are treatment naïve, SA practitioners normally enrol patients faster than their counterparts in the developed world. The average number of enrolments per site of investigator is 1.2 per month in the USA or Europe. In SA we normally enrol 3-5 patients per site per month. This shortens the development time and gives us a tremendous competitive advantage.

How much should I expect to be paid for a clinical trial?

Investigators are normally paid on a "per completed patient" basis, and the investigator fee is obviously protocol dependent. Some studies have a few patient visits, others have many over an extended period of time. It also depends on what has to happen at each visit, how much time the practitioner must spend with each visit and how much can be delegated to the sister or study site co-ordinator (SSC). SAMA rates are used as a basis for a visit. For example, if it is an 18 month study with 10 visits in total, the reasonable per completed patient fee will be R300 x 10 visits = R3000. Companies normally add 50% to this for time spent on investigator meetings and with the Clinical Research Associate (CRA) of the company, as well as for resolution of queries and side effect reporting. A reasonable fee per completed patient would thus be R4500. Some fees are also paid for screening patients. The number of patients screened vs. the number enrolled is an indication of the quality and judgement of the investigator. Thus, his or her understanding of the inclusion or exclusion criteria for enrolment into the study. Don't try to earn more by screening excessively – you may not be asked to participate in the next study.

SA investigators often argue that they do the same work as the American investigators, so they should get the same fee. This is simply not rational. In reality, American GP's earn three times as much as SA GP's and cannot, with that income, maintain the same quality of life as we do. We should, in reality, earn a third of their fee. Another request is to be paid in US Dollars. This is also not a reasonable request. In January 2001 there were R12 to the US Dollar. Today, this is about R6. Investigators would get half the value in Rands if they insisted on being paid in US Dollars. Special investigators in SA like labs and radiology charge for services at their specialist bodies' recommended fees. These fees are often high compared to that charged in many overseas countries and it makes development in SA expensive and not competitive enough. (In some countries these investigations are seen as part of normal patient care, and are paid for by the Health Authorities.) It is therefore important that we do not price ourselves out of the international market if we want to be involved in more clinical studies.

Remember, most drugs were developed without participation by SA – so they don't really need us!

The next article will be on the obligations of investigators – towards the sponsor and the regulatory authorities.

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