GCP accreditation – a worthwhile investment?

To the Editor: The exponential increase in the clinical trial industry, especially in developing countries, has been well publicised.[1-3] Subjects in these countries are particularly vulnerable, most notably because of limited economic development, inadequate human rights, an insufficient understanding of scientific research and limited health care treatment.[3,4] Recent reports estimate that clinical trials in South Africa generate in excess of one billion rand annually.[5] It is therefore not surprising that clinical trials are susceptible to unethical practices and even to the occasional instance of scientific fraud. The growth in the clinical trial industry has resulted in the development of a new medical subspecialty, commonly referred to as research medicine. However, this is the only specialty where formalised specialised training or proven expertise is not required.[1]

When investigators sign the FDA 1572 form (Statement of the Investigator), they are certifying that they are qualified to conduct all aspects of the clinical trial. With no standard method of assessing whether the investigator is actually qualified, a certification process may be of value. The idea of investigator certification programmes is not new and there are now four organisations in the USA offering such certification.[1]

The Medicines Control Council (MCC) has recently made training in Good Clinical Practice (GCP) mandatory for all investigators. GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. The guidelines represent the ethical principles embodied in the World Medical Association Declaration of Helsinki (formulated June 1965, updated October 2000). Ethics committees are likewise demanding similar training.

There are, however, currently no accreditation and/or standardisation guidelines for such training. This has resulted in a plethora of training courses, often at substantial costs, being offered by various institutions. They typically run over 2 - 3 days, with shorter refresher courses offered as updates. Time constraints of investigators have resulted in these courses being shortened considerably at the expense of course content. In some cases, the qualifications and/or the expertise of providers is also questionable. Faced with a similar predicament, the European Union (EU) has issued a directive (Clinical Trials Directive 2001/20/EC) and a syllabus for training clinical investigators.[6]

To ensure continued investment and growth in this profitable area, South Africa (like the EU) needs to implement structures that will ensure a certain level of professionalism in the local clinical trial industry. Insisting on GCP accreditation is a sure

way to guarantee research integrity and offer investors a worthwhile return on their money.

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NOAH rescues AIDS orphans

To the Editor: Wim Delva *et al*.[1] are to be thanked for raising the issue of the orphan epidemic that is the eventual (perhaps inevitable) consequence of the AIDS pandemic.

It is quite possible that our attempts to reduce the numbers of orphans by treating their parents will fail. In fact it is probable that we will not reduce the numbers of children being orphaned, at least not in a socially meaningful way. Even if there were no further deaths from AIDS, we already have over a million orphans in South Africa alone. Currently around 19 children are orphaned because of AIDS deaths each hour.

It was for exactly the reasons set out in that article[1] that we began an NGO with the aim of addressing this challenge on a scale that might be meaningful to the country. That was in 2000/2001.

We are called NOAH (Nurturing Orphans of AIDS for Humanity). Our view is that it is simply wrong to begin any strategy that is so expensive (in terms of money or manpower) that it cannot be rolled out on a large scale. The pool of resources is small and any expensive plan for children in one place simply robs resources from children elsewhere.

We try to build networks that care for orphans within their own communities. These consist of three fundamental elements: (*i*) a committee of community leaders to control the programme and motivate the community; (*ii*) a volunteer group trained in counselling to visit orphans at home and to check on their wellbeing (home circumstances, school attendance, etc.), reporting back to the social worker; and (*iii*) a resource centre that acts as a day care and aftercare centre to unburden caregivers at home by having orphans occupied (in a positive and safe place) all day and fed when they arrive home.

We believe that these elements constitute a core of support that is sustainable and that can be extended throughout South Africa. We are currently working in 68 communities with the support of corporate South Africa, our government and the US PEPFAR programme. The support of everyone approached has been typically South African. From the top businessmen we asked to give of their time to serve on our board to unemployed rural volunteers, South Africans are standing up to meet this challenge.

We know of other excellent NGOs such as Heartbeat and Hands at Work that are providing support using similar models.

Given the high levels of unemployment and the lack of skilled people in South Africa it is essential that all of us 'do our bit' if we are to raise these children to be whole adults. The consequences of inaction or apathy are too horrible to contemplate.

I encourage all of my colleagues to find orphan initiatives near their homes (local is sustainable and orphans are everywhere, in every community) and see what they can do to help. Whether your skills lie in working with the children or helping with the bookkeeping is not important, there is something everyone can do.

You can find out more about NOAH at **Noahorphans.org.za**

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