**“I was a Human Guinea Pig”**

**By Leon Horton**

**Volunteering for clinical trials, so the brochures would have us believe, can be a rewarding experience - not least financially. But under what safeguards are these studies conducted? What sort of people volunteer for them? And what would they say to anyone interested in getting involved? Leon Horton dons a lab coat and puts research under the microscope...**

“You don’t want to do that - you might grow a second head.” Thus opined my friend when I told him I’d signed up to test a new hygiene product. Quite how a mouthwash might result in an extra noggin is anyone’s guess; but with several high-profile cases of clinical malpractice levelled at drugs testing companies in recent years, I decided to conduct a little research of my own; namely: just who on earth would want to be a lab rat?

Nathaniel, 50, works as a support worker in social care. He started volunteering with Intertek (a testing and certification company for the chemicals and textile industries) after a friend, already a volunteer, recommended it. “I was waiting on a CRB check before starting a new job and needed extra cash. As a single parent, my reasons for signing up were mostly financial, but I was also curious about the work they were doing. I ended up testing a new deodorant.”

How did he find the experience? “It was fascinating. I met some nice people, and the money came in handy. I should say the deodorant gave me a rash, which worried some of my family, but that soon cleared up.”

Testing a new deodorant is classified as a ‘low-risk’ study, but under UK statutory law is every bit as subject to the stringent regulations laid down in the guidelines for Good Clinical Practice (GCP) as would be, say, a new anti-viral drug or painkiller. GCP is the international quality assurance on how clinical trials should be conducted, designed to protect the rights of human test subjects.

Subjects such as Sharon and Danny, a married couple in their 40s, who first started volunteering four years ago after a recruitment leaflet dropped through the letterbox. A private tutor and a sound engineer respectively, they’ve tested numerous skin, hair and dental products. “We’re both self-employed, so can fit the studies around the work we do,” says Danny. “The process is easy and the studies always interesting.”

Sharon agrees: “I like doing a variety of things to earn money, and like that it isn’t set hours. As a science teacher, I’m always fascinated by scientific research.”

Despite some initial reservations from friends, the couple are happy to recommend this type of clinical testing to anyone in reasonably good health. “I think some people mistake product testing for drug trials - which this certainly isn’t.”

Drug trials, perhaps, like the one that took place in 2006 at Northwick Park Hospital, London, where six male volunteers were contracted by US drug testing company Parexel to test a new anti-cancer drug known as TGN1412. Within minutes of being injected, the men began vomiting, their heads puffed up to twice their normal size, and some began slipping in and out of comas as they showed signs of multiple organ failure. By all accounts, it was a deeply disturbing story.

Thankfully, the volunteers all recovered, but the incident raised serious concerns about trial procedures and medical ethics. A subsequent interim report by the Medicines and Healthcare Products Regulatory Agency (MHRA) found that Parexel had conducted the study according to protocol, and concluded that ‘the serious adverse reactions experienced by the volunteers were the result of an unpredicted biological action.’ It was an unprecedented event, unlikely to occur again, but it’s fair to say that the drug testing companies - and clinical trials in general - took a critical drubbing.

But not everyone has a horror story to tell. Maggie was a barmaid in her early 20s when she took part in residential drug trials with Medeval, now Icon Development Solutions: “I had several friends who’d taken part, and all said it was easy money, nothing to it, perfectly safe, etc. I was living in Longsight, Manchester, at the time, had been broken into twice and was desperate to move. I just wanted to make some money to put a deposit on a flat.”

Was she concerned about possible side-effects? “No. I did two trials, both for drugs already in use, which I considered to be less scary. One involved being woken up every morning with a shot of vodka. So what’s not to like?” So she’d do it again? “I couldn’t even if I wanted. I have a history of depression, which would automatically exclude me from most studies. That and the fact my mum, who was a nurse at the time, was horrified when she heard what I was doing. Looking back, I think she was maybe right to be concerned. She was much more aware than I was that things can go wrong.”

As they have in India in recent years. Between 2008 and 2011 over two thousand deaths were reported during clinical trials in the country, forcing the government to tighten the regulations surrounding what was described as “a culture of impunity for drug research companies and the doctors who work for them.” The drug companies, many of them international pharmaceutical companies, were initially drawn to India (where the clinical trials industry is estimated to be worth 326 million pounds) for several reasons, including patient availability, low costs and a “friendly drug-control system.”

The companies concerned defended themselves by saying they were conducting trials on patients who had little or no hope of cure (and should therefore not be blamed for the deaths) and that the “standards applicable to all clinical trials in India are no different from the US or EU.” With the change in the law, however, many of these companies (led by America’s top research centre, the National Institute of Health) have subsequently pulled out from India; a move which has done little to assuage the concerns of the World Health Organisation.

No one in their right mind would deny the need, not to say necessity, for clinical trials. They are essential for the development of new medicines. And how else will we find the cure for cancer? But the regulations and codes of conduct under which these studies are carried out need to be of a universally accepted standard, and not dictated by the financial considerations of multinational pharmaceutical companies, health bodies or governments.

As for volunteering, it remains with the individual to decide what they are willing to participate in, and to fully verse themselves on the potential risks. “I’m not sure I’d recommend drugs testing,” says Maggie, “it would depend what it was for. I’d say use your common sense. If they want to make you taller or fill you full of hormones, just say ‘no’”.

**BOX OUT:**

**Trials and Tribulations**

**Clinical Studies at a Glance**

**The Nuremburg Code (1947)**

At the end of the Second World War, numerous Nazi doctors who had performedhuman experiments were tried at the war crimes tribunal in Nuremburg. During thetrials, the Nuremburg Code was drafted as a set ofstandards for judging physicians and scientists who had conducted biomedicalexperiments on concentration camp prisoners. This code became the prototype/foundation of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner.

**Thalidomide Scandal (1957 - 61)**

In the 1950s Thalidomide was developed as an anti-convulsant drug and introduced on the German market without any governmental review. Thalidomide was used by expectant mothers to control the symptoms of morning sickness, and tragically led to many babies being born with severe physical disabilities. The reported number of those harmed varies, but studies indicate that more than 10,000 people worldwide were affected.

**The Declaration of Helsinki (1964)**

The ethical principles set out in the Nuremburg Code are further elaborated on and clarified by the World Medical Association. The Declaration of Helsinki provides the ethical foundation for the European Clinical Trial Directive and national clinical research legislation.

**Good Clinical Practice (1996)**

The clinical trials ‘Bible’ is introduced, the contents of which have been implemented into the European clinical trial quality standards through the Clinical Trials Directive (2001) and the GCP Directive (2005). The content of these Directives has in turn been transposed into national law by each of the Member States e.g., The Medicines for Human Use (Clinical Trials) Regulations of 2004 in the UK.