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Careful selection of physicians is required to allay public fears in clinical trials

I read the recent editorial by Kathleen Drennan in *Drug Discovery Today*[1] with great interest. One of the problems with clinical trials is that Phase I studies, by their nature, can be rigorously controlled and audited. This is because smaller numbers of volunteers are used, and the studies are normally performed 'in-house' by pharmaceutical companies or outsourced to specialist clinical research organizations. However, most of the notable catastrophes in clinical trials have occurred in the much larger Phase II and III studies. These are much harder to control as they are usually done in hospital settings and are usually multicentre, or even multinational, studies. The physicians responsible for these studies often complete them in combination with their main clinical workload and, therefore, the study is not their sole, or even primary, focus.

Study monitors and auditors often find it difficult to actually meet the physician who is the principal investigator responsible for the study (often because of their clinical workload) and even when they do, it quickly becomes apparent that they have often delegated the running of the study to subordinates, and that they have limited understanding of the logistics of the study. Furthermore, auditors do not audit to the same level in Phase II and III studies as they do in Phase I studies. Instead, the audit emphasis in Phase II and III studies has often been switched to data rescue. This is partly a result of the larger number of volunteer patients used in these studies and because these studies are spread over several sites.

However, the selection of physicians to run studies should, in my opinion, be performed with greater care. Just because a physician is a world leader in their particular field does not imply that they have either the necessary skills or the inclination to run, what are often, highly complex clinical studies. Another worry is that some physicians who run Phase II and III studies do not appear to have a grasp of the International Conference of Harmonization of Good Clinical Practice (ICH GCP), the international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of volunteer human subjects.

I am probably doing a disservice to the large majority of physicians who do take care in the running of clinical studies but, unfortunately, all too often a blind eye is turned to the inadequate minority, particularly as they often hold positions of power and influence. Another factor in the adverse reporting of clinical trials is that, in the eyes of the media the large numbers of trials that are done well and pass off without incident, are not newsworthy items.

For all clinical studies it is extremely important that none of us lose sight of our prime directive that the volunteers' safety is paramount. The easiest way to allay public fears surrounding clinical trials is simply to ensure that studies are run to the guidelines and laws that are currently in place.

Reference

1 Drennan, K.B. (2001) Have the ultimate benefits of clinical trials been maligned beyond repair? *Drug Discov. Today* 6, 597–599

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Virogenomics: the future looks bright

The article by Früh *et al.* in a recent issue of *Drug Discovery Today*[1] assesses an emerging trend in the field of antiviral drug discovery. The authors outline the preliminary evidence that human genomics is providing an under-appreciated benefit to antiviral researchers. Most antiviral drug research has centered on the relatively small number of non-structural protein targets in the viral genome; for instance, there are less than ten such targets in HIV, and the hepatitis C (HCV) and human papilloma (HPV) viruses. By contrast, viruses use the host-cell systems throughout their life cycle to infect, replicate and re-infect. If the host proteins that are intimately involved in the viral life-cycle could be inhibited without impairing the host, a broader array of targets for combating viral infections would become available. In addition, the inhibition of host proteins will avoid the hypermutability of

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