

A pan-European registration system for volunteer participation is within sight

Berelowitz K and Taubel J
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To the Editor: Boyce et al.¹ reflect on the use of one of several trial participant registers but they fail to give a balanced appraisal of the full spectrum of systems available².

The authors claim that "*We have no evidence that healthy subjects travel from other EU countries just to volunteer for a clinical trial in our unit.*" This is incongruous with our experience; they do. Possibly a small problem in Leeds or Erfurt, it is a considerable problem in locations such as Basel, Cologne or London where borders are nearby or transportation is good. The authors appear to oppose a wider EU initiative. To publish in the EJCP seems an odd choice when all they want is to promote an insular mentality where all is supposedly well for the UK.

TOPS is claimed to have achieved a success in preventing volunteers from over-volunteering yet the authors do not provide evidence that this has in fact been achieved. They show that their detection rate has declined over the years, yet do not discuss other possible explanations for this phenomenon; amongst other reasons such as the general decline in the number of trials in the UK, one very obvious explanation would be that volunteers have found ways to circumvent their detection. TOPS is an imperfect system: it allows multiple registrations by for example the use of a national insurance number in one unit and a passport in another. The data presented by the authors show that TOPS is underutilised: its UK competitor the National Volunteer Register (NVR) holds just under 130,000 records from one single site, so it is of an approximately equal size to TOPS. Assuming a 5-10% market share of that particular unit, TOPS should hold records for the remaining 90-95% of volunteers, i.e. well over one million records. Even assuming some overlap between the two systems it shows that TOPS is not as widely used as the authors wish to claim. The reason may well be that TOPS is run by a CRO and that there may be some degree of apprehension by other users to submit data to one of their competitors.

There are initiatives under way to create a European search system using a different approach to TOPS, VIP-Check, NVR and VRB. The latter systems are databases, whilst the former is a search engine only accessing data held by clinical trial sites where it remains under the control of the local data controllers. It is collectively controlled by its users and searches are based on robust personal identifiers yet provide better data protection to the users submitting their data and the subjects whose data is accessed. Trials are under way in Germany and the UK and are scheduled for Belgium and Holland later this year. The system is low cost, flexible, not labour intensive to users, resilient to unauthorized access by hackers and above all it is international.

No single database is likely to be established across Europe. Contrary to the authors' assertion, it is France that has the most sophisticated system in Europe preventing volunteers from over volunteering but can only do so in France. Like any national system it is incapable of tracking volunteers crossing borders. VIP-Check or TOPS effectively are privately owned local service providers and can only ever be an addition but not an alternative to a search engine based system which will be a major improvement over the current state of play.

Ref:

¹Boyce et al. *TOPS: an internet-based system to prevent healthy subjects from over-volunteering for clinical trials*; *Eur J Clin Pharmacol*; Online First DOI 10.1007/s00228-012-1231-8

²Peremans A (2011) Available at:

http://www.agah.info/uploads/media/Sessios5_Presentation_A_Peremans_pdf.pdf