TOPS: an internet-based system to prevent healthy subjects from over-volunteering for clinical trials

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Dear Editor,

We thank Drs Berelowitz and Täubel for their comments. We welcome the opportunity to give some further details about the over-volunteering prevention system (TOPS) that we had to omit from our paper because of space limitations.

The explicit aim of our paper was to report and comment on our experience with TOPS, not to describe the range of other systems that might be available. In any case, TOPS is currently the only system used by almost all the clinical pharmacology research units in the UK, and no useful data have been published about the performance of other systems.

The efficacy of a system in the detection of over-volunteering is not something that can be assessed in a formal clinical trial: rather, we depend upon careful observation and the gathering of circumstantial evidence. Thus, although we cannot prove that healthy subjects do not travel from other EU countries to “over-volunteer” for trials at our unit, we do have evidence to support our view: in spite of our consistently searching our volunteers for signs of recent participation in a trial, we do not find such signs in volunteers from continental Europe. As mentioned in our paper, those signs include venepuncture or cannulation marks on the arms, resolving skin inflammation from ECG electrodes, and low blood haemoglobin concentrations or a microcytic blood film. If “volunteer tourism” were truly a problem, we should find such signs from time to time—but we do not.

Contrary to Berelowitz and Täubel’s assertion, our data are best explained by the fact that TOPS truly has reduced attempts to over-volunteer. We continue to check every volunteer for signs of recent participation in the trial, and

our detection rate by that method continues to be far below the level that we experienced before the introduction of TOPS. Personal communication with other commercial phase 1 contract research organisations (CROs) shows that they have noted the same phenomenon. Thus, there is strong substantial circumstantial evidence that TOPS deters over-volunteering.

Although TOPS is highly effective, we acknowledge in our paper that it could be improved, and we discuss possible ways of doing so. However, we can certainly reject Berelowitz and Täubel’s claim that TOPS is underutilised. Fifty-eight units, including academic, industry and CRO units, have registered to use TOPS. The total number of volunteers who have been registered in TOPS is entirely consistent with the system’s regular and comprehensive use: as Fig. 1 in our paper shows, the number of users of TOPS has been increasing progressively, and many of them have been registering subjects for only a fraction of the lifetime of TOPS. The only commercial phase 1 CRO that does not consistently register subjects in TOPS is Berelowitz and Täubel’s own unit: we hope that our paper, coupled with this further explanation of our data, will encourage them to use TOPS in future.

Although TOPS was originally developed and established by a CRO, it is now under the control of a charitable trust that administers the system for the benefit of both users and volunteer subjects. The high level of uptake by UK phase 1 units is the strongest possible evidence that users are not reluctant to submit the data to the system.

As regards continental Europe, we cannot share Berelowitz and Täubel’s enthusiasm for the French system: its sophistication notwithstanding, there is no published evidence of its efficacy. We agree that continental Europe needs a multinational system, and the need is probably greatest in the Schengen countries without borders, such as Germany, Belgium and Holland. However, we believe that the needs of the UK are best served by universal support of the TOPS system.

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