

Brussels, 13 May 2011

To Whom It May Concern:

Concerning: Revision of the "clinical trials directive" 2001/20/EC. Request for a pan European approach for the registration of healthy volunteers participating in Clinical Trials in the European Community.

Dear,

The European associations active in early clinical drug development¹ from the United Kingdom (AHPPI), Germany (AGAH), France (Club Phase I) and Belgium (BAPU), would like to express their concerns about a safety issue regarding healthy volunteers participating in clinical trials.

An increasing number of healthy volunteers is crossing national borders to participate in clinical phase I studies in Europe. Phase I studies are research studies in which new drugs in development are being tested, often for the first time in humans. As volunteers taking part in these studies are mainly healthy individuals they are being paid to compensate them for their expenses and time spent in the trial. This financial compensation is a potential incentive for excessive participation. As there is currently no European system in place to check the participation in clinical trials, there is a real concern for "over-volunteering". By participating too frequently in clinical trials, not respecting wash-out periods between trials or taking part in several trials at the same time there is a serious risk for these people to put themselves at harm and they may compromise the research.

Although several national initiatives have been taken to overcome the problem² of over-volunteering, the existing databases are not used systematically by all European institutions performing clinical trials. Some of the reasons being: (1) there is no obligation to use them and there is consequently incomplete coverage, (2) the process results in extra work and costs and (3) none of the systems is sufficiently performant. More importantly, taking into account that healthy volunteers are crossing national borders, neither individual nor national databases can solve the problem of over-volunteering.

¹ AHPPI: Association for Human Pharmacology in Pharmaceutical Industry; AGAH: Association for Applied Human Pharmacology; Club Phase I and BAPU: Belgian Association of Phase I Units.

² France has a national database (Volontaires pour la recherche Biomédicale) which is obliged by law; in the United Kingdom units use either one or both of the two available registers, The Overvolunteering Prevention System (TOPS) and/or National Volunteer Register (NVR); in Belgium, Germany, The Netherlands and Switzerland a limited number of research sites make use of the Volunteer Inclusion Period Check system (VIP check) which is under the control of a private institution based in Freiburg, Germany.

It is obvious that there is a need for a pan European approach obliging all research sites to check for a safe availability of healthy volunteers willing to participate in non-therapeutic early stage development clinical trials prior to inclusion. Ideally this obligation should also apply to patient studies and to late stage development studies.

Given the current revision of the "clinical trials directive" 2001/20/EC, we request your attention to consider the incorporation of a European obligation on the registration of participation in clinical trials in the revised version of the directive.

An obligatory centralized European system for the registration and control of participants in clinical trials will increase the participant's safety, improve the quality of the data and may prevent human disasters. There is no doubt that such a pan European approach is in the interest of all parties involved and would raise the ethical standards of clinical research in Europe to a higher level in agreement with the Declaration of Helsinki. This view was unanimously shared by the participants of a recent international conference on early clinical drug development organised by the signing associations in Berlin on 31 March – 1 April 2011.

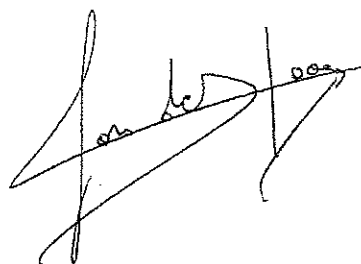
We would like to offer our knowledge, experience and critical considerations in the development of such an initiative.

If you could reciprocate by giving this your attention we would be grateful.

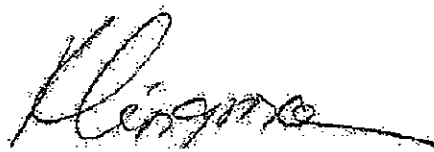
Yours faithfully,



Dr. Ulrike Lorch
Executive Committee AHPPI, United Kingdom



Prof. Dr. Jan de Hoon
Chairman BAPU, Belgium



Dr. Yves Donazzolo
President Club Phase I, France

Dr. Ingrid Klingmann
President AGAH e.V., Germany

