**AHPPI response to MHRA Phase 1 Accreditation proposed changes**

1. The change to a single level of accreditation is cosmetic and risks being more confusing rather than less.  The ‘single’ level of accreditation can have exclusions specified on the certificate, and Appendix 1 continues to divide the requirements into ‘Standard’ and ‘Additional’.  So instead of having the 2 defined levels, it appears that it might be possible to have multiple levels according to which additional requirements the site complies with and what exclusions are stated on the certificate.  This perhaps gives more flexibility, but at the expense of less clarity.
2. The requirement for QC of data for dose escalation needs more specific detail of what is expected and appears to demand even higher standards than those that currently exist.
3. The concept of a PI “Mentor” seems unclear with regards to the specific role of the mentor and who takes responsibility. Surely, if the PI needs a mentor then the mentor has to take responsibility for, at least some, of the decisions made by PI. To say that a (Inexperienced by inference) PI takes overall responsibility does not seem right.
4. There is a need for sponsor and PI to approve dose escalations. Should we be more specific and say this should be a Physician, experienced in this area, acting on behalf of the sponsor?
5. The concept of a “Committee” overseeing procedures still bothers us as, despite the Committee, the PI retains overall responsibility for the trial. Should the Committee, which may contain more experienced Clinical Pharmacologists not take that responsibility? This would be fine in the medium term whilst PI could still be responsible for local and acute decisions. We feel that this concept is, as yet, not clear enough to work efficiently in practice and could be a minefield if something were to go wrong and most parties denied responsibility.
6. There are still references to supplementary accreditation in the final draft of the document, e.g. page 9

Peter Dewland, Chair, on behalf of AHPPI