The Association for Human Pharmacology in the Pharmaceutical industry Response to the HRA consultation

The Association for Human Pharmacology in the Pharmaceutical Industry (AHPPI) is an informal cross-industry group made from nearly 100 members representing the pharmaceutical industry and a significant number of Clinical Research Organisations. Our main function is to address issues facing those involved in early phase drug development and to educate members through focused symposia. For these reasons, we are pleased to make a response to the MHRA consultation request to help shape an effective role for the Health Research Agency (HRA).

As a collective, we believe we have relevant and valuable expertise into how the Health Research Authority (HRA) can facilitate the calibre of high quality research that can sustain the UK's position as a primary hub for clinical research. To this end we have been impressed by the world-class service the MHRA provides and are heartened that MHRA staff will be actively involved in the newly-formed Health Research Authority (HRA) project team.

We trust that this level of joint-working ensures that the new HRA embraces the efficient and transparent culture that is evident in the MHRA.

The criteria you use (or that should be used) when assessing the quality or risk of research in the NHS

The AHPPI believes that the process of research assessment and registration should be underpinned by an ethos that is flexible, transparent and efficient. Robust quality assessments do not need to be too onerous or duplicative. They must be timely, cost-effective and predictable. A clear example of this is the MHRA response to Phase 1 study applications, always available within 14 days of a valid submission, with a final response in the case of an initial non-acceptance usually given within 21

days of the valid first submission. This is good practice that is of an international standard and should be adopted practice within the new Health Research Authority.

Your views on what constitutes good quality ethical research

Good quality research is ethical, innovative and adaptive in its approach in providing a positive outcome for patients and the NHS as a whole. It is important that the regulatory process is sufficiently flexible to allow for this. Strictures such as template study designs can be a barrier to the end goal of providing a novel solution for clinicians and their patients. Good quality ethical research must proceed in an environment of excellence that extends to all parties involved, from the CRO staff, to Regulatory bodies and including the relevant Research Ethics Committees and their Coordinators. Success in this regard would see the UK recognised as a global centre of excellence for clinical research with a corresponding increase in the number of high quality clinical research projects performed here.

In the very short-term, our members' priority is to ensure that clinical research remains in the UK. To this end, it is important to demonstrate a level of efficiency and effectiveness to global sponsors. Current NRES timelines pose a very real threat to this as they are far and away divergent from the ones used by the MHRA. The AHPPI therefore suggest that the MHRA's excellent standard should be considered the gold standard in allowing our members to provide an efficient service to their sponsors. A more rapid turnaround of Ethics Committee decisions, as occurs in several other countries, is a priority if the UK is not to be commercially disadvantaged.

HRA's key priority

AHPPI members believe that HRA's key priority is to work to establish the UK as a global centre for high quality clinical research. To achieve this aim, the new organisation must ensure that regulation and its administration do not stifle innovation. To this end, we reiterate our encouraged use of the MHRA's role in the shaping of this new organisation and we urge the project team to look to the MHRA's model as a blueprint for timelines, quality and excellence in regulating clinical research.

The Industry as Partner

The AHPPI welcomes the government's initiative to streamline public health research for the benefit of patients by re-shaping the HRA. In particular, we are heartened by the Health Minister, Earl Howe's statement that:

"The HRA will protect the interests of patients and the public taking part in research and will benefit both the research community and the life sciences sector by simplifying and streamlining the regulatory processes associated with health care research."[i]

Together we should endeavour to find as many practical means as possible to realise this goal.

[i] http://www.dh.gov.uk/health/2011/12/creation-hra/