Draft advice to the European Medicines Agency from the clinical trial advisory group on legal aspects

Meeting 1 SUMMARY OVERVIEW

A lively discussion took place on the agenda points concerning the exceptions of commercial confidentiality, protection of intellectual property rights including copyright and legal remedies against decision to release data.

In general, all participants supported greater transparency however there seems to be a clear disagreement about the way to implement a public access to clinical trial data. The key dividing line is whether access should be provided to all or "restricted" to qualified actors, and under some exceptional conditions.

For example: access to data should be given only to *bona fide* research, after having assessed the nature and the context of the request and on an exceptional basis, with a selection of scope of the investigation. Other participants believe that the idea of a filter to information would replicate the shortcomings of the status quo and therefore the only real alternative is to provide full, unconditioned access to all clinical data held by the Agency.

There has been a contribution asking whether there is a need to protect from disclosure some clinical trial data in the interest of protection of public security (bio-terrorism). Some participants have highlighted the fact that the current form for "informed consent" of trial participants might be inadequate for further processing of data. All points about patient confidentiality are addressed by a different group and were not taken onboard.

Some participants raised the issue that data should be publicly available also to guarantee the public accountability of regulatory institutions taking decisions on medicines.

With a look at the future of medicines, a remark was also made that the legal framework should be able to accommodate different degrees of protection also in light of the specific qualities of data (genetic/proteomic), but the point was not further developed.

With regard to copyright and legal remedies, there was no extensive participation and in general the participants referred to possible legal obstacles only in very general terms.