Advice to the European Medicines Agency from the clinical trial advisory group on legal aspects - Discussion document

Scope of the Advice:

Are there any legal aspects other than personal data protection that need to be addressed when drafting the Agency's policy?

Are there exceptional circumstances under which data can be claimed to be commercially confidential?

Commercially confidential information

- Are there exceptional circumstances that would justify a different assessment of the confidentiality of the clinical trial data? If so, what could be a proportionate mechanism to provide access to a set of non-confidential information?

Copyright

Article 16 of Regulation (EC) 1049/2001 states that: "This Regulation shall be without prejudice to any existing rules on copyright which may limit a third part's right to reproduce or exploit released documents"

- What are the measures needed in order to implement in the most effective way the provision of Article 16 of Regulation (EC) 1049/2001 in granting pro-active access to clinical trial data on the EMA's website ?

- At the workshop, some participants have highlighted the importance of setting appropriate "licence conditions" that would enable a meaningful re-use of these data (for example, for new analysis etc.). Would a licence be needed/justified in order to grant access to clinical trial data ?

Legal Remedies

- How could the Agency ensure the availability of legal remedies against the disclosure of data ?