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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – quality, safety and efficacy
Head of Unit

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MEETING OF THE AD HOC GROUP ON CLINICAL TRIALS

'Centre de Conference Albert Borschette' CCAB,
Room AB-4B, rue Froissart 36,
1040 Brussels.[1]
1 December 2014, from 10.00 h.

DRAFT AGENDA

1. Welcome
2. Adoption of the draft agenda
3. Adoption of the minutes of the meeting held on 6 June 2014.
4. Update by EMA on the development of the EU CT Portal and Database (*for information*)
5. Working document on the detailed arrangements for the inspection procedures including qualification and training requirements of inspector, in preparation for a Implementing Regulation by the Commission (*for discussion*)
6. Working document on Good Manufacturing Practices for Investigational Medicinal Products, in preparation for a Delegated Regulation by the Commission (*for discussion*)
7. Draft text of the revised Q&A document on the CT Regulation (*for discussion*)
8. Union controls (Art 79 of Clinical Trial Regulation) (*presentation by Commission Food and Veterinary Office (FVO) followed by discussion*)
9. Discussion on the involvement of the *ad hoc* group in the preparation of new and revised guidelines on clinical trials (including setting priorities, tentative schedule and responsibilities)
10. Any other business

    Labelling issues related to Art 66&67 and Annex VI of the Clinical Trial Regulation, raised by stakeholders *(for discussion)*

[1] Access plan: http://ec.europa.eu/oib/pdf/building-map_en.pdf.