EUROPEAN COMMISSION
DIRECTORATE- GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 26 February 2015
SANTE/CA/hp

MEETING OF THE AD HOC GROUP ON CLINICAL TRIALS

'Centre de Conference Albert Borschette' CCAB,
Room AB-2A, rue Froissart 36,
1040 Brussels.[1]
9 March 2015, from 10.00 h.

DRAFT AGENDA

1. Welcome

2. Adoption of the draft agenda

3. Adoption of the minutes of the meeting held on 1 December 2014.

4. Update by EMA on the development of the EU CT Portal and Database (*for information*)

5. Issues raised during the discussions of the EMA expert group on CT Portal and Database (*for discussion*)

6. 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)

7. Union controls (Art 79 of Clinical Trial Regulation) (*for discussion with Commission Food and Veterinary Office (FVO)*)

8. Any other business

   - Update on the state of play of the preparation of the Implementing Regulation on GCP inspections and Delegated Regulation on GMP for IMP

   - Update on stay of play on labelling issues related to Art 66&67 and Annex VI of the Clinical Trial Regulation, raised by stakeholders

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

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