EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – quality, safety and efficacy

Brussels, 30/01/2012
SANCO/D/6/SF/FDA D(2012)
12/SANCO/CT/01

MEETING OF THE *AD HOC* GROUP FOR THE DEVELOPMENT OF IMPLEMENTING GUIDELINES FOR THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC ON 7 FEBRUARY 2012, AT 10H IN THE "CENTRE DE CONFERENCE 'ALBERT BORSCHETTE'"(CCAB), RUE FROISSART 36, B-1040 BRUSSELS[1]
DRAFT AGENDA

1. Welcome

2. Adoption of the draft agenda (Working document 12/SANCO/CT/01)

3. Adoption of the minutes of the previous meeting of 6 October 2011[2] (Working document 11/SANCO/CT/18draft)

4. 'Questions and Answers' Document in EudraLex Volume 10: New and revised Q&A in the draft version 10.0 (Working document 12/SANCO/CT/02) (*for discussion prior to publication by Commission*)

5. Draft Guideline on the Requirements for Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials (Working document 12/SANCO/CT/06) (*for discussion prior to publication by Commission*)

6. Revision of the Clinical Trials Directive
   - 6.1. Update on state of play
   - 6.2. Definitions (Working document 12/SANCO/CT/03) (*for discussion*)
   - 6.3. Conduct of a clinical trial (Working document 12/SANCO/CT/04) (*for discussion*)
   - 6.4. Data submitted to Commission by Heads of Medicines Agencies (Working documents 12/SANCO/CT/05) (*for discussion*)

7. Update on other initiatives
   - Publication of results-related data in the 'ClinicalTrialsRegister.eu'

8. Any other business

9. Closing of session (scheduled for 18:00h at the latest)

NB: Next tentative meeting dates:[3] 20 June 2012, 13 November 2012

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1 For 'newcomers': Access plan is here http://ec.europa.eu/oib/pdf/building-map_en.pdf
2 Sent to participants on 11 October 2011.
3 Subject to change (availability of meeting rooms).