



Brussels, 23/09/2011  
SANCO/D/3/SF/jr D(2011)  
11/SANCO/CT/14

**MEETING OF THE *AD HOC* GROUP FOR THE DEVELOPMENT OF IMPLEMENTING  
GUIDELINES FOR THE “CLINICAL TRIALS DIRECTIVE” 2001/20/EC  
ON 6 OCTOBER 2011, AT 10H  
IN THE “CENTRE DE CONFERENCE ‘ALBERT BORSCHETTE’”(CCAB)  
RUE FROISSART 36, B-1040 BRUSSELS<sup>1</sup>  
DRAFT AGENDA**

1. Welcome
2. Adoption of the draft agenda (Working document 11/SANCO/CT/14)
3. Adoption of the minutes of the previous meeting of 13 July 2011<sup>2</sup> (Working document 11/SANCO/CT/13draft)
4. Revision of the Clinical Trials Directive (Working documents 11/SANCO/CT/12<sup>3</sup>, 11/SANCO/CT/15, 11/SANCO/CT/16) (*for discussion*)
5. Results-related information in EudraCT (Working document 11/SANCO/CT/17) (*for discussion prior to publication by Commission*)
6. Follow-up to revised Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use (‘CT-3’)<sup>4</sup> (working document is the guidance document CT-3, *for discussion*)
7. Update on other related initiatives
  - European Network of Research Ethics Committees<sup>5</sup>
8. Any other business
9. Closing of session (scheduled for 18:00h at the latest)

**NB:** Next tentative meeting date<sup>6</sup> for the *ad hoc* group for the development of implementing guidelines for the “clinical trials directive” 2001/20/EC: **07/02/2012**

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<sup>1</sup> For 'newcomers': Access plan is here [http://ec.europa.eu/oib/pdf/building-map\\_en.pdf](http://ec.europa.eu/oib/pdf/building-map_en.pdf)

<sup>2</sup> Sent to participants on 19 July 2011.

<sup>3</sup> Sent to participants on 7 July 2011.

<sup>4</sup> [http://ec.europa.eu/health/files/eudralex/vol-10/2011\\_c172\\_01/2011\\_c172\\_01\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-10/2011_c172_01/2011_c172_01_en.pdf)

<sup>5</sup> <http://www.eurecnet.org/contact>

<sup>6</sup> Subject to change (availability of meeting rooms).