



EUROPEAN COMMISSION
DIRECTORATE- GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 02/10/2017

MEETING OF THE EXPERT GROUP ON CLINICAL TRIALS

7 November 2017,
Centre de Conference Albert Borschette CCAB, rue Froissart 36,
1040 Brussels

DRAFT AGENDA

(from 10.00 till 17.00)

1. Welcome
2. Adoption of the draft agenda
3. Adoption of the minutes of the meeting held on 28 September 2017
4. Update by EMA on the development of the EU CT Portal and Database (*for information*)
5. The principles for the transitory period (*presentation and discussion*);
6. Draft text of the revised Q&A document on the CT Regulation (*discussion*)
 - Q&A on emergency clinical trials;
 - Discussion on selected questions;
7. Requirements of the application dossier Part II (for discussion)
8. Member states preparedness for the implementation of the Clinical Trials Regulation – initial discussion on the Member states cooperation in the assessment of Safety Reporting information (*discussion*).
9. AOB