EUROPEAN COMMISSION
DIRECTORATE- GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 26/07/2017

MEETING OF THE EXPERT GROUP ON CLINICAL TRIALS

18 September 2017,
Centre de Conference Albert Borschette CCAB, rue Froissart 36,
1040 Brussels

DRAFT AGENDA

18 September 2017

1. Welcome
2. Adoption of the draft agenda
3. Adoption of the minutes of the meeting held on 25 April 2017
4. Short update by EMA on the development of the EU CT Portal and Database (*for information*)
5. Draft text of the revised Q&A document on the CT Regulation (*discussion*)
   - Q&A on emergency clinical trials;
   - Revision of section 8 and 9.
6. Member states preparedness for the implementation of the Clinical Trials Regulation (*discussion*)
   - Implementation of national law: sharing of best practices and discussion of challenges regarding aspects related to national law which are the competence of Member States, including national organisation and responsibilities
     - 6..1. legal representative/contact person;
     - 6..2. damage compensation systems;
     - 6..3. cluster trials;
     - 6..4. national requirements for processes exempted from GMP (Article 61(5) and 65 of CTR)

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7. Interplay between the clinical trials authorisation requirements and GMO authorisation requirements (*presentation of the outcome of the mixed Pharma/GMO task group discussions*)

8. AOB