The Implementation of the CTR 536/2014 in Germany: How to coordinate a swift Assessment

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Structure

- **<u>Implementation Law</u>**
  - Registration requirements for RECs
  - Composition of RECs
  - Responsibilities NCAs / RECs
  - Decision - making

- **Training/Qualification of the members of RECs and their staff, role of AMEC in Germany**
- **Résumée**

THE IMPLEMENTATION LAW

- End of March 2016 the German Federal Cabinet passed the draft for the implementation law for the CTR 536/2014.
- The law shall enter into force 3rd quarter of 2016
- The law speficies the structure and composition of RECs, tasks and responsiblities of the NCAs and the RECs, and their cooperation.

Implementation Law : Registration of RECs

Requirements (§ 41 new)

- **State of the art expertise of the members**
- **Multidisciplinary composition: at least one lawyer, one person with expertise in medical ethics, three practising physicians, and one lay person → Biostatistician !**
- **Equal access for female and male members**
- **By-laws covering internal procedures, transparency, decision-making etc.**

Implementation Law : Registration of RECs

Requirements (§ 41 new)

- **Business office with duely qualified staff**
- **Adequate technical equipment and performance**
- **Proof of the independence of the members and external experts (= no CoI)**

Tasks and Responsibilities of RECs and NCAs

- **PART I will be assessed jointly by NCA and REC, NCA taking the lead → lead coordinator**

- **Part II will be assessed solely by competent REC**

- **The final decision (Art.8 CTR) by the MS Germany will be provided by the competent German NCA.**

Actions and Contributions of the Association of RECs in Germany

- ✓ **Since 2012 the CTR is regularly a main topic at the two annual national meetings of RECs in Germany**
- ✓ **The CTR is a regular topic in the continued education curriculum für members of RECs**
- ✓ **There is internal CE für local RECs and its staff too**
- ✓ **NCA and 27 RECs have already started a Pilot Project assessing CTAs according to the procedures and time lines of the CTR 536/2014**

Cooperation of AMEC Germany with relevant Committees and Working Parties

- ✓ Adhoc Group on Clinical Trials of Europ. Comm.
- ✓ EU-Portal Expert Group (application and assessment-template part I, and II, lead (II): Prof.Dr.K.Racké, subgroup H (safety reporting), etc.
- ✓ EU Working Parties, e.g., Ethical Considerations of pediatric Studies and re Informed Consent
- ✓ European Network of Research Ethics Committees (EUREC)
- ✓ Participation : UATs of the EU Portal of EMA

Résumée

- The implementation law structures the application of the CTR 536/2014 in Germany.
- There are clear provisions re the structure of RECs and the tasks and responsibilities of NCAs and RECs in Germany.
- As AREC was involved on EU level from the beginning in many discussions re the CTR , we feel well prepared to succesfully implement it in Germany.
- The Pilot Project of the RECs & NCAs will provide usefull experience even before CTR 536/2014 enters into force.