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

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Structure

- Implementation Law
  - 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 specifies the structure and composition of RECs, tasks and responsibilities 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 Col)
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

✓ 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 successfully implement it in Germany.
- The Pilot Project of the RECs & NCAs will provide useful experience even before CTR 536/2014 enters into force.