The System of RECs in Slovakia

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RECs in Slovakia: types

• Ethics Committee of the Ministry of Health („national“): 1
  – reviews research projects/CTs only exceptionally

• Ethics Committees („regional“) at the regional state authorities: 8 (Slovakia – 8 regions)
  – review research projects regularly
  – + the role of the „clinical (bio)ethics“ committee (primary)

• Ethics Committees („local“) at the health care facilities or inpatient research institutes: 60
  – review research projects regularly
  – + the role of the „clinical (bio)ethics“ committee (primary)
RECs in Slovakia: legislation (1)

- law No. 576/2004 Coll. on health care, part Biomedical Research
  - definition of an Ethics Committee (EC), its basic composition, tasks: „clinical (bio)ethics“ + review of biomedical research projects incl. CTs
  - system of authorization/approval of biomedical research
    - **inpatient** research health care facilities & research institutes
      - director of the health care facility/research institute
        after favourable opinion of the local EC
    - **outpatient** research
      - „state physician“ at the regional state authority Ecs
        after favourable opinion of the regional EC
  - **mono-centric** research – local EC (inpatient) or regional EC (outpatient)
  - **multicentric** research – „leading“/“multicentric“ EC (local or regional) – „single opinion“ (valid for all country) + all local ECs (opinion valid for the local health care facility/research institution – could prevent/stop research)
RECs in Slovakia: legislation (2)

- law No. 362/2011 Coll. on medicinal drugs and devices (former law No. 140/1998 Coll.)
  - CTs authorization
    - **phase I – III**: Ministry of Health (State Institute for Drug Control)
    - **phase IV**:
      - inpatient - monocentric: director of the health care facility/research institute + Ministry/SIDC is notified
      - outpatient: „state physician“ at the regional state authority
    - „non-interventional“ CTs – „state physician“ at the regional state authority
  - **mono-centric** research – local EC (inpatient) or regional EC (outpatient)
  - **multicentric** research – „leading“/“multicentric“ EC (local or regional) – „single opinion“ (valid for all country) + all local ECs (opinion valid for the local health care facility/research institution – could prevent/stop research)

- details on tasks & responsibilities of a sponsor, investigator, state (competent) authority, EC; inspections, adverse events. etc..

→ compliance with EU legislation + now some new, unfortunate requirements (health insurance companies, notifications...)

RECs in Slovakia: activities

• national ECs’ meetings (since 2002, with some time gaps, so far 18x)
  – IMEB n.f. (+ EC at the Ministry of Health + Slovak Society of Clinical Pharmacology of the Slovak Medical Association)

• other bioethics conferences, symposia (since 1990)
  – IMEB n.f. or other organizers: international – CoE, EC, UNESCO national: universities, scientific societies, industry, churches

• materials published in the journal Medical Ethics & Bioethics
  – IMEB n.f., since 1994, bilingual: papers, materials in Slovak or English, some international materials translated, „continuous course“ for Ecs or „materials for practice“ (since 2004)

• materials published at IMEB webpages (since 2004)
  www.bioetika.sk, www.bioethics.sk

• special courses for ECs members: basic and advanced (from 2012/13)
  – Institute of Health Care Ethics at the Slovak Medical University in Bratislava
RECs in Slovakia: „networking“

- no national association yet
  - lack of resources, not a strong interest in that model
  - seen as an extra work, not that much necessary

- informal networking
  - national (annual or even more frequent: 1-2x a year) meetings
  - other meetings, conferences, symposia
  - annual national workshop (since 2008): „Actual issues in clinical research and GCP“ (IMEB n.f. + Slovak Society of Clinical Pharmacology + Institute of Clinical Pharmacology of the Slovak Medical University) – at the premises of the Ministry of Health
  - informal telephone or e-mail consultations: IMEB n.f. + among ECs members

- plans for the closer future:
  - devoted web page for (R)ECs: „www.eurecnet.sk“
  - formal courses for ECs members at the Slovak Medical University in Bratislava („basic“, „advanced“, „refreshing“) – certificate (certification study)
  - publishing of the „cookbook“ for (R)ECs (CoE RECs Guide translated and printed)
Thanks for your attention!