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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!