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 <u>local EC</u>
 - outpatient research
 - "state physician" at the regional state authority Ecs after favourable opinion of the <u>regional EC</u>
 - mono-centric research <u>local EC</u> (inpatient) or <u>regional EC</u> (outpatient)
 - multicentric research "leading"/"multicentric" EC (<u>local</u> or <u>regional</u>) "single opinion" (valid for all country) + <u>all local</u> ECs (opinion valid for the local health care facility/research institution could prevent/stop research)

RECs in Slovakia: legislation (2)

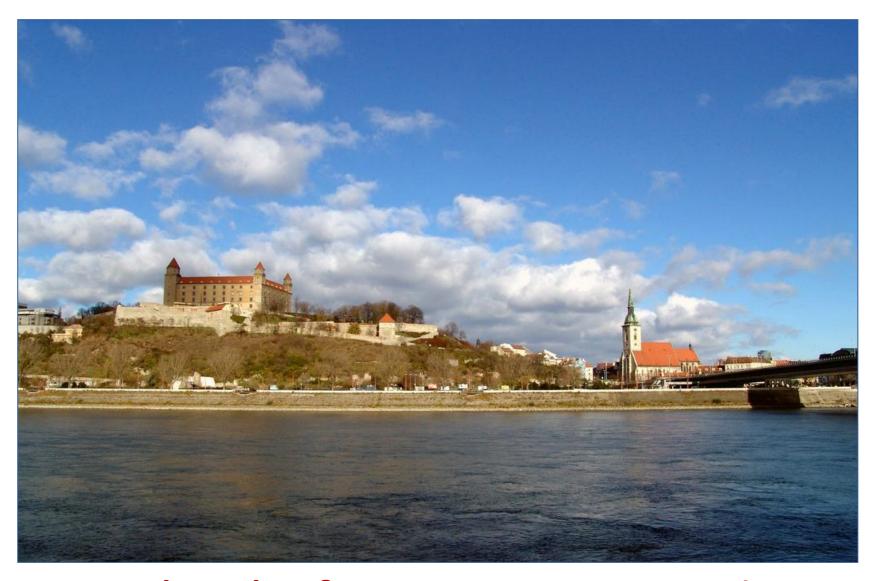
- law No. 362/2011 Coll. on medicinal drugs and devices (former law No. 140/1998 Coll.)
 - CTs authorization
 - phase I III: Ministry of Health (State Institute for Drug Control)
 - phase IV:
 - inpatient monocentric: director of the health care facility/research institute + Ministry/SIDC is notified
 - outpatient: "state physician" at the regional state authority
 - "non-interventional" CTs "state physician" at the regional state authority
 - mono-centric research <u>local EC</u> (inpatient) or <u>regional EC</u> (outpatient)
 - multicentric research "leading"/"multicentric" EC (<u>local</u> or <u>regional</u>) "single opinion" (valid for all country) + <u>all local</u> 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 Associaiton)
- other bioethics conferences, symposia (since 1990)
 - IMEB n.f. or other organizers: interntional 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!