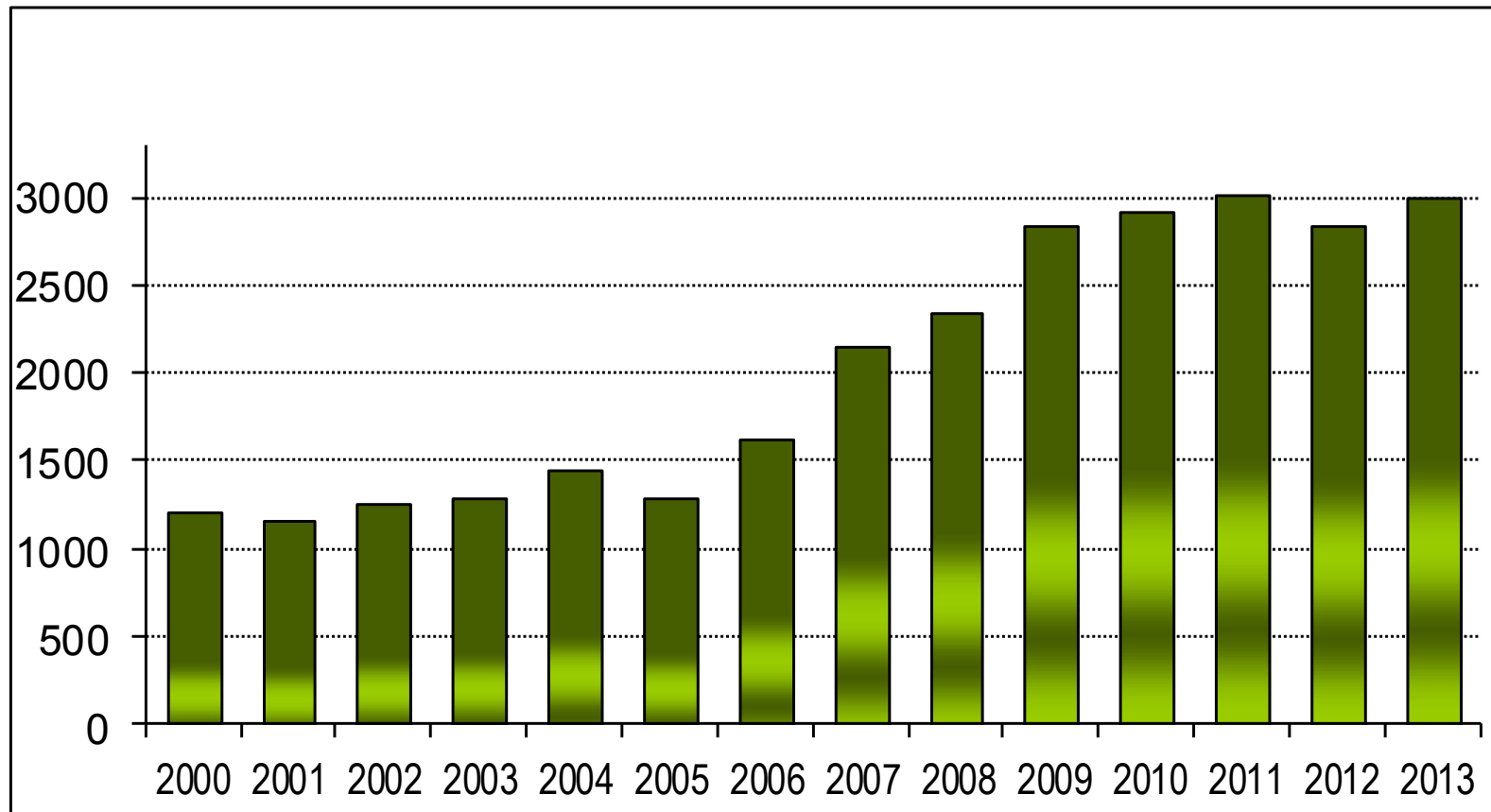


Assessment of the multicentric clinical study ethics in Austria – assessment process

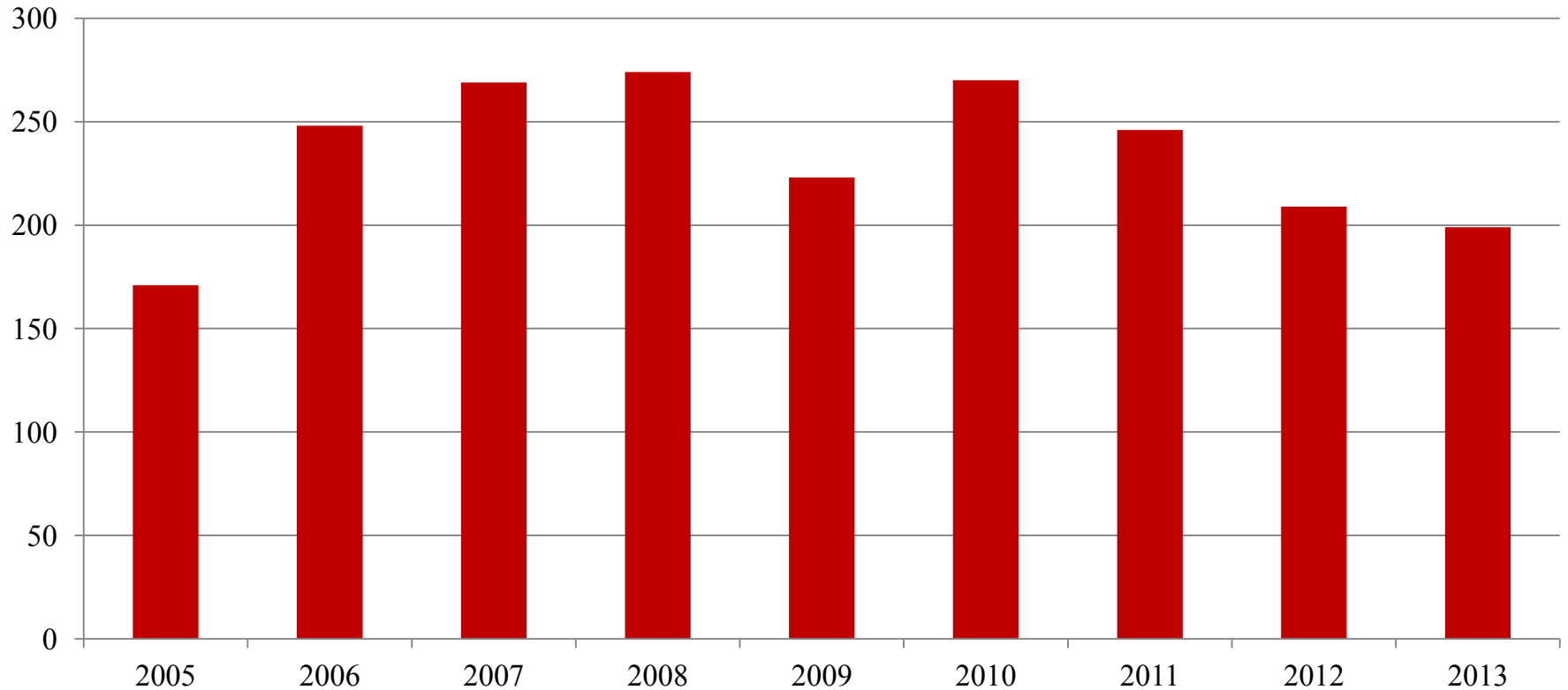
Ernst A Singer

Ethics Committee Medical University of Vienna
Bratislava July 3 2014

ECs Austria – Votes on all types of studies



Austria - Multicentre Drug Studies



Independent Ethics Committees (IECs) in Austria

- Regulations under four different laws (Medical Act, Medical Device Act, Hospital Act, University Organisation Act)
- IECs for each hospital plus one IEC for out-of-hospital research in each of the 9 federal states
- Somewhat different regulations apply for hospital vs non-hospital IECs.



- 26 ECs in Austria (formerly 42),
- 7 of them „Leading ECs“
- „Leading ECs“ are entitled to vote on multicentre drug studies

- Leading ECs are accredited by the Ministry of Health. The accreditation applies only to this function of the EC and not to the EC itself.
- There are defined criteria an EC has to fulfill to be a Leading EC.

Interaction EC - CA

- Applicant may file project with EC and CA
 - at the same time, or
 - first with EC and then with CA,
 - but not first to CA and then to EC
- ECs usually do not handle issues regarding the IMP (manufacturing and quality issues)
Direct interactions occasionally, but regular
- Yearly meeting of CA and all ECs

The Austrian Forum of Ethics Committees (1997)

Aims

- standardise application procedure, e.g. common application form, common form for amendments to protocols and SAEs.
- establish a mutual recognition procedure (studies other than medicinal products)
- discuss financial issues, e.g. common agreement on review fee or honorarium for expert reviewers.

The Austrian Forum of Ethics Committees (1997)

Aims

- discuss legal questions, patient protection, liability
- establish public relations and education for members of IECs.
- **serve as contact for CA**

The Austrian Forum of Ethics Committees (1997) Positive Outcomes

- common website
- harmonised forms for application, amendments, SAEs
- sample text for patient information, insurance, patient information for research involving genetic testing
- general information (links to WMA, EMEA, important Austrian legislation)

The Austrian Forum of Ethics Committees (1997) Problems

- The Forum does not have legal authority, therefore
- decisions not binding, adherence different (e.g. mutual recognition of votes, use of common documents)
- issues are unresolvable if an unanimous vote is not reached (e.g. text on patient information for studies involving children)

Ethics Committee of the Medical University of Vienna

- Online-training for members
 - one introductory course for new members (before they are allowed to participate in the sessions)
 - one additional course each year (obligatory for medical members)
- Use of a global software solution (ECS) for submission via Web-Interface and practically paperless administration of all studies.

ECS „Ethics Committe System“

- open-source, externally validated, meets the necessary regulatory standards (Good Automated Manufacturing Practice, GAMP).
- Covers the entire workflow of EC-related issues of a clinical research project from submission to vote, including session agenda and all post-vote issues (amendments, safety reports, notifications)
- safe long-term data storage in encrypted form.
- ECS allows targeted access of individual persons to selected projects. (Has proven extremely useful in exchange of information with authorities).

Questions?

