RECs system in Latvia

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REC system in Latvia

- 4 Clinical Drug Trial committees
- 5 committees dealing with other kinds of research (IRB's)
- National body: Central Medical Ethics Committee

Clinical drug trials (CDTs)

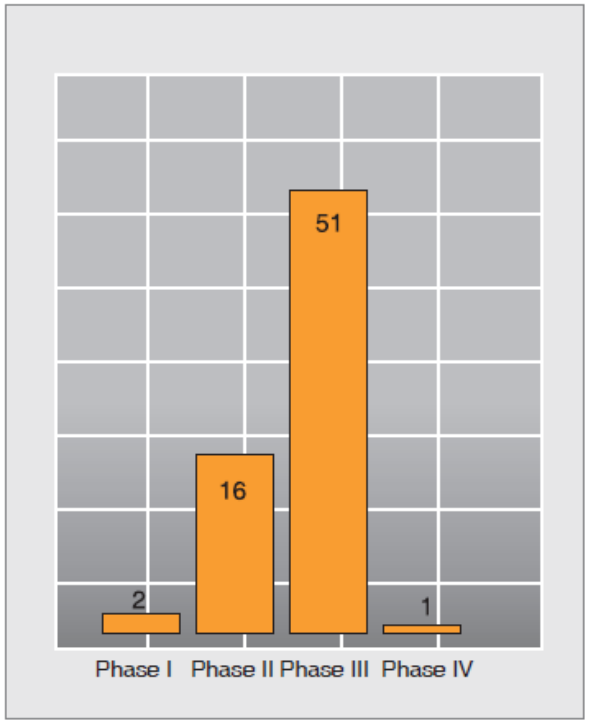
- Review clinical trials of drugs and pharmaceutical products.
  - consist of at least 9 members.
  - regulated by *Law on Pharmacy* (1997),
  - *Cabinet Regulation No. 289* (2010) on good clinical practice.
- CDT protocols are reviewed by RECs and authorised by State Agency of Medicines (SAM).

State Agency of Medicines “Annual Report 2010”

- Received **77 trial applications**.
  - Authorised 70 trials and 2 post-trial registers.
- Altogether **241** clinical trials were conducted.
  - 19 clinical trials included biological medicinal products obtained with **DNA technology** (monoclonal antibodies, interferons, growth factor inhibitors).
  - 10 of the clinical trials involved **children**.

Clinical drug trials (CDTs)

Number of clinical trials authorised in 2010 (distribution according to phase)



Distribution of clinical trials authorised in 2010 according to the field of medicine

Field of medicine	Number or trials
Pulmonology	11
Oncology	11
Endocrinology	11
Neurology	10
Rheumatology	8
Nephrology	4
Psychiatry	4
Cardiology	4
Ophthalmology	2
Dermatology	2
Surgery	2
Gynecology	1

Clinical trial centres that participated in the clinical trials authorised in 2010

Clinical trial center	Number of trials
P. Stradins Clinical University Hospital	40
Riga Eastern Clinical University Hospital	30
Clinical hospital „Gailezers"	18
Latvian Oncology Center	5
Clinic "Linezers"	7
Daugavpils Regional Hospital	22
Vidzeme Hospital	12
Children Clinical University Hospital	10
D. Teterovskas Doctors Endocrinology Practice	7
"Health Center 4"	7
Liepaja Regional Hospital	7
S. Salenieces Doctors Rheumatology Practice	6
State Limited Responsibility Company "Maritime Hospital"	6
Limited Liability Company „Olvi"	5
Medical Company "Center for Examination and Treatment of Allergic diseases"	5
Dr. Viktorijas Vēveres Doctors Pulmonoly and Allergology Practice	5
D. Saulītes – Kandevicas Cardiology and Rheumatology Private Practice	5
Other clinical trial centers (71 in total)	1 – 4 trials at each center

IRBs and other RECs

- RSeview all other kinds of research
  - consist of 7 – 13 members.
  - regulated by *Cabinet Model Regulation No.1* (1998) issued according to the *Law on Medical Treatment.*

IRBs and other RECs

- *Law on Medical Treatment:*
  - not defined as RECs, but as “medical ethics committees... that... shall examine ethical matters related to the activities of medical practitioners and new medical technologies” (Section 14).
  - These RECs are functioning within medical treatment institutions as “advisory bodies established for resolving problems of medical ethics” (Section 13).
- Other regulations are their own statutes and international guidelines.

IRBs and other RECs

- “Information on statutes, *de facto composition, basic statistics* on the number of reviewed research protocols (not including the list of approved and rejected research projects), in many cases, is not publicly available.” (Dranseika V. *et al.*, 2011)

CMEC

- Central Medical Ethics Committee.
  - Established in 1998 by Cabinet Regulation No. 9. “Statutes of Central Medical Ethics Committee”.
  - consists of a chairperson and 11 members.
  - an annual budget is paid from the budget of Ministry of Health is Ls 5000 (€ 7114).
  - CMEC is the most important element of the whole system.

CMEC

- CMEC is seen as the central and the most important element of the whole system.
- A newly amended version of statutes has added another very important function: (Art 4.9) "**to coordinate and methodically supervise the operation of ethics committees reviewing biomedical research…**".

(Silis V., 2010).

Other functions of CMEC

(1) to **consult and advise** the interested institutions about the ethical issues of biomedical progress;

(2) to consult governmental, municipal, medical and other institutions about the compliance of regulations issued by those institutions to the **norms of medical ethics**;

(3) to facilitate the inclusion of medical ethics in the **study programs** of social medicine, psychology and communication;

(4) to **review any application** from either physical or legal person and to **issue resolutions** on the ethics of biomedical pogress requested by ethics committees of professional organizations of medical specialists;

Other functions of CMEC

(5) to **evaluate** the compliance of new medical technologies, biomedical research involving human subjects (biomedical research) with the norms of medical ethics;

(6) to **initiate** the revocation of medical certificates in case of breach of ethical norms;

(7) to **take part** in developing draft laws and other regulations regarding the ethics of biomedical progress;

(8) to **cooperate** with institutions interested in the ethics of biomedical progress (both Latvian and foreign);

Other functions of CMEC

(9) ... to educate the population, advise on the ethical issues of biomedical progress, and consult ethics committees reviewing biomedical research.

(10) to **issue resolutions** regarding research and biotechnologies of both national importance and international scale;

(11) to evaluate the compliance with principles of **ethics in genetic research**, creation of genome data base and the activities of the chief processor.

Existing or planned networking activities

1. CMEC plans to organize a **seminar meeting** of Latvian RECs to discuss currtent situation and plan for future.
2. Facilitation of **public communication** by means of modern technologies.
3. Revision of normative documents and establishment of a register of acting RECs.

Thank you!