
Ethics Committee perspective

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What is important?

**Protect the rights, welfare and safety of
research subjects**

Levels of ethical review in Russian Federation

- The Federal Ethics Committee of Russia
- Local Ethics Committees (medical centers, medical university etc.)

Basic Legal Documents

- ❑ Constitution of Russia
- ❑ The Federal Law on Medicines (N86; 22.06.1998)
- ❑ The Federal Law “Bases of the legislation on health protection of citizens” (N 5487-1; 22.07.1993)
- ❑ The National Standard on Good Clinical Practice GOST-R 52379-2005 (2005)
- ❑ Declaration of Helsinki (1964)
- ❑ Recommendations of WHO “Operational Guidelines for Ethics Committees That Review Biomedical Research” (2000)
- ❑ Regulation about Ethics Committee

Features of ethical review in Russia

- Two-level system (Federal and local committees)
- Necessity to submit documents and get an approval twice
- No division of responsibilities between Federal and local Ethics Committees

Clinical trials prohibited by Federal Law on Medicines (N86; 22.06.1998)

Vulnerable populations:

- Underage patients, who haven't parents
- People in the military
- Convicts
- Pregnant women

Federal Ethics Committee of Russia.

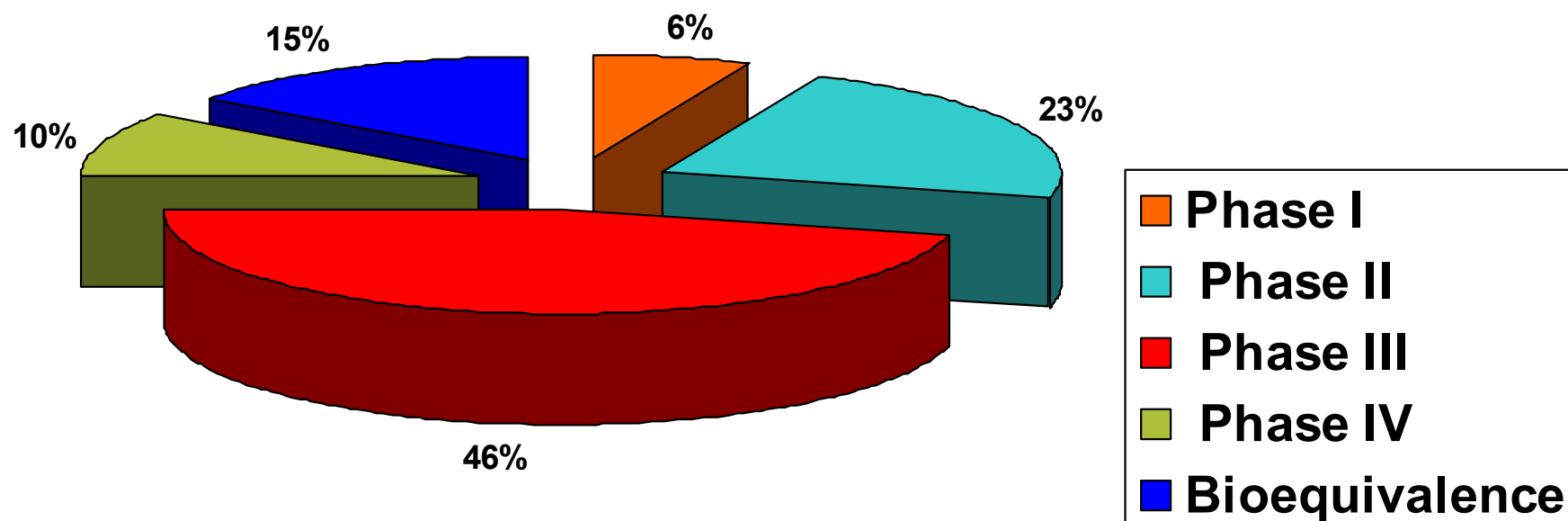
Basic facts

- The Federal Ethics Committee of Russia was founded for the supervision of clinical trials in Russia
- The list of members of Federal Ethics Committee of Russia was changed in 2007
- It currently has 37 members
- It works under the SOP's that were created according to the GCP and the National Standard

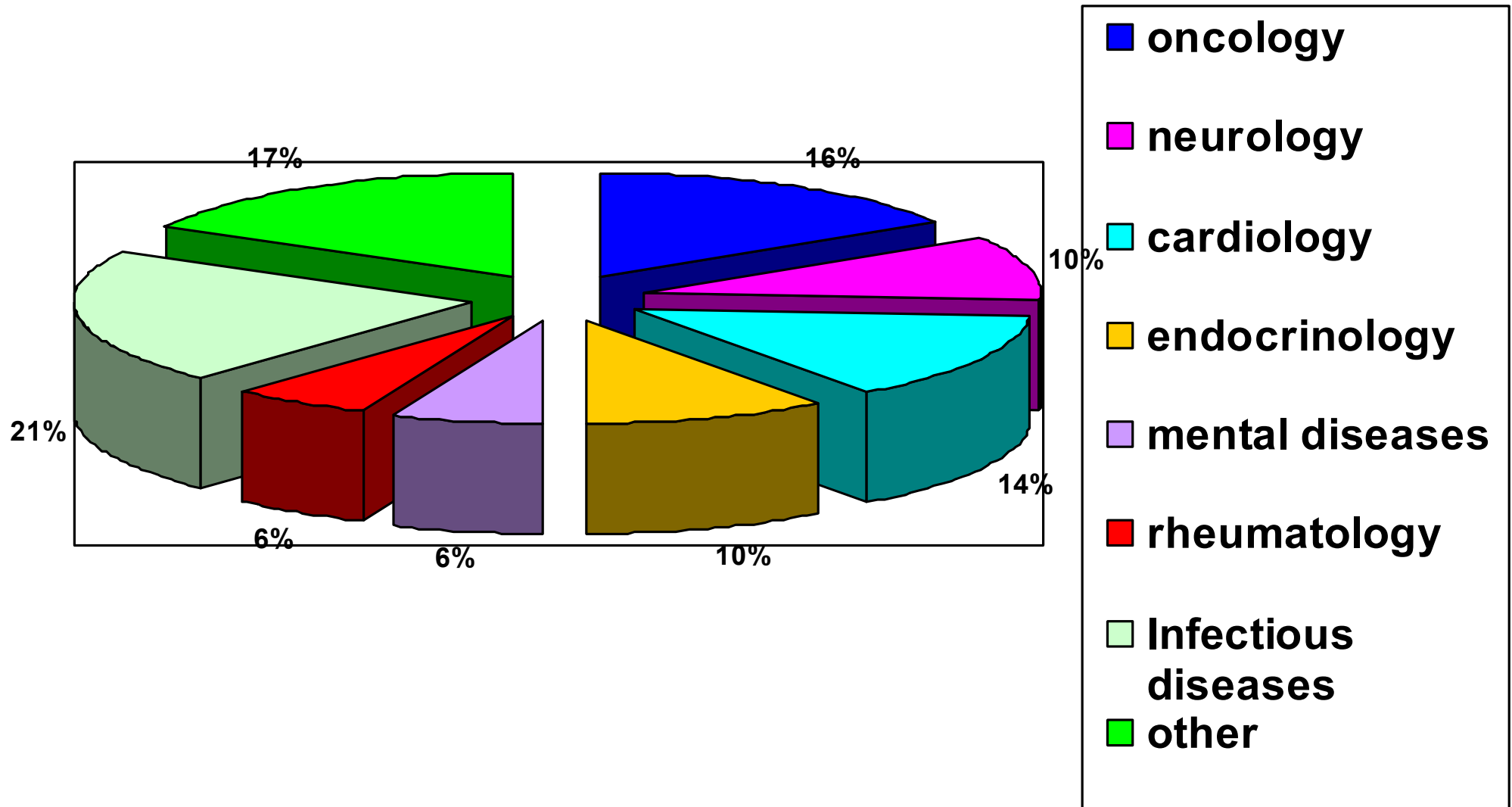
Special attention for:

- Minorities and Seniors
- Unconscious patients
- Patients with incurable diseases
- People living with HIV/AIDS
- Patients with mental diseases
- Women in reproductive age
- Placebo-control studies
- Non-therapeutic studies

Phase breakdown (2009)



Breakdown of medical areas (2008)



Submission to expert bodies

- Clinical trial protocol **signed by PI's**
- Investigator's brochure **with the results of previous studies**
- Consent form **with EC contacts**
- Case report form
- List of research sites
- Insurance (**life/health insurance and liability insurance**)
- Principal investigators' CVs (**two-year experience**)
- Patients' documents

The usual issues that prolong initial ethical review:

- Not enough information about previous studies of the product's safety profile
- Information about PI's qualification or experience in trials (two years) is absent or insufficient
- PI consent for study is not included
- Risk-benefit ratio for subjects (especially for placebo-control studies) is unacceptable
- Defects of ICF
- Discrepancy between the English and the Russian version in paperwork

Committee decisions

- Approval
- Tentative approval
- Not approval
- Withdrawal of previously given approval

Approval rate (2008)

- 91% - Approval
- 7% - Tentative approval
- 2% - Rejection

Progress:

- Definite SOPs
- EC operation is absolutely transparent (SOPs, new information, reports, schedule are published on the Roszdravnadzor web-site www.roszdravnadzor.ru)
- EC schedule provide meeting on the 2-week basis
- EC recommendations from EC office reach sponsors immediately
- Possibility for an immediate dialogue with sponsors

Review process (2008)

- Usual review process for initial approval – 20 days
 - For additional information (protocol's amendments, new version of ICF, new information, etc.) - 10 days
 - Estimated waiting time from applicant – 21 days
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Perspective:

- Determine responsibilities for Federal and Local Ethics Committees
 - Create a training program in research ethics for EC members and staff
 - Create a regular training program in research ethics
 - Develop a system of SOPs
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Questions/Comments

