



International Scientific Conference «Ethics Review of Clinical Research in Pharmaceuticals»

**Organised by the Council of Europe and the Ministry of Health and Social Development
of the Russian Federation**

Moscow, 28-29 November 2011

PROGRAMME

Day 1: Monday, 28 November 2011

08:30 - 10:00 **Registration of participants**

10:00 - 10:30 **Opening Session**

**Mrs Veronika Skvortsova, Deputy of Minister, Ministry of Health and
Social Development of the Russian Federation**

**Mr Alexander Vladychenko, Director General of the Directorate General for
Social Cohesion, Council of Europe**

SESSION I LEGAL ASPECTS

10:30 - 10:50 **Relevant Council of Europe legal instruments in the field of biomedical
research**

**Speaker: Dr Laurence Lwoff, Head of Bioethics Division, Council of
Europe**

10:50 - 11:05 **Activities of the European Commission on ethics in biomedical research**

**Speaker: Dr Lino Paula, European Research Area – Ethics and Gender Unit,
Directorate-General for Research and Innovation, European Commission**

11:05 - 11:20 **Clinical Trials for Medicines and Ethics: the European Union Approach**

**Speaker: Ms Isabel de la Mata, Principal Advisor with Special interest
in Public Health, Directorate-General for Health and Consumers,
European Commission**

- 11:20 - 11:40 **Activities of the European Medicines Agency on ethics in biomedical research**
- Speaker: Dr Fergus Sweeney, Head of Sector, Compliance and Inspection, European Medicines Agency**
- 11:40 - 12:00 **Questions and Answers**
- 12:00 - 12:30 ***Break***
- 12:30 - 13:00 **Legal framework for the conduct of biomedical research in the Russian Federation**
- Speaker: Dr Marat Sakaev, Head of Department of state regulations of pharmaceuticals circulation, Ministry of Health and Social Development of the Russian Federation**
- 13:00 - 13:20 **Bioethics training for researchers and ethics committee members**
- Speaker: Professor Boris Yudin, Head of the Department of Complex problems of human studies of the Institute of Philosophy of the Russian Academy of Sciences**
- 13:20 - 14:00 **Questions and answers**
- 14:00 - 15:30 ***Lunch***
- SESSION II ETHICS REVIEW BODIES**
- 15:30 - 15:50 **Ethics review in the Russian Federation**
- Speaker: Professor Yelena Baybarina, Chair of the Ethics Board, deputy director of V. I. Kulakov “Scientific Centre for Obstetrics, Gynecology and Perinatology”, Federal State Institution of the Ministry of Health and Social Development of the Russian Federation**
- 15:50 - 16:10 **Ethics reviews in Council of Europe member states:**
- Baltic States**
- Speaker: Professor Eugenijus Gefenas (Lithuania), Chair of the Steering Committee on Bioethics of the Council of Europe**
- 16:10 - 16:30 **France**
- Speaker: Professor François Lemaire, Department of Clinical Research and Development, Assistance Publique-Hôpitaux de Paris (APHP)**
- 16:30 - 17:30 **Questions and answers**

End of Day 1

Day 2: Tuesday, 29 November 2011

SESSION III	ETHICS REVIEW PROCESS
09:00 - 09:30	Guide for Research Ethics Committee Members Speaker: Professor Elmar Doppelfeld, Chair of the Group of Specialists on Biomedical Research, Member of the Bureau of the Steering Committee on Bioethics, Council of Europe
09:30 - 10:00	Questions and answers
10:00 - 10:30	<i>Break</i>
10:30 - 10:50	The role of patients' organisations in protecting the rights of participants in clinical trials Speaker: Mr. Yuri Zhulev, co-chair of the All-Russian union of the public patients' organisations, Deputy Chair of the Board of public patients' rights organizations under the Ministry of Health and Social Development of the Russian Federation
10:50 - 11:10	Clinical research ethics in oncology in the Russian Federation Speaker: Professor Sergey Tyulyandin, Deputy Director for Science Research in the Research Institute of Clinical Oncology, N. N. Blokhin Russian Cancer Research Center of the Russian Academy of Medical Sciences, Head of the Clinical Pharmacology and Chemotherapy Department
11:10 - 11:30	Clinical research ethics in paediatrics Speaker: Professor Vladimir Bulatov, Head of the Hospital Paediatrics Department, Kazan State Medical University
11:30 - 11:50	Current clinical research ethics with HIV patients Speaker: Professor Alexei Yakovlev, Head of the Infectious Diseases Department, Epidemiology and Hygiene, St. Petersburg State Medical University, Chief Medical Officer of the S.P. Botkin Clinical Infectious Diseases Hospital
11:50 - 13:00	Questions and answers
13:00 - 14:30	<i>Lunch</i>
14:30 - 14:50	Practice of compulsory insurance of clinical trials in Russia - ethical aspects Speaker: Mr. Dmitriy Shishkin, Head of Department, insurance company "InGosStrakh"
14:50 - 15:50	Panel discussion on achievements and difficulties of ethics review processes
15:50 - 16:00	Closing remarks Dr Marat Sakaev, Director of the Department of state regulations of pharmaceuticals circulation, Ministry of Health and Social Development of the Russian Federation