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И СОЦИАЛЬНОГО РАЗВИТИЯ
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«Ethics Review of Clinical Research in Pharmaceuticals"

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SPEAKER'S CVs and SHORT PRESENTATION SUMMARIES

Presented in order in which they appear in the Programme

Opening Session: Mr Alexander Vladychenko, Director General of the Directorate General for Social Cohesion, Council of Europe

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

Dr Laurence LWOFF holds a MSc. in reproductive physiology from the University of Paris VI – Jussieu (France). She then obtained her degree in agronomy from the Institut National Agronomique Paris-Grignon (France) in 1986 and received her PhD in molecular biology in 1989.

She joined the Council of Europe in 1991, where she was entrusted with the responsibilities of the Secretariat of the Conventions concerning the use of animals in agriculture and science, in the Directorate of Legal Affairs. In 1999, her responsibilities were extended to biotechnology. She was the Secretary of the International Conference of the Council of Europe on Ethical Issues Arising from the Applications of Biotechnology (Oviedo, Spain, May 1999). In July 2002, she joined the Bioethics Department where she has been responsible in particular for the activities on human genetics and on the protection of the human embryo and the foetus.

She is currently Head of the Bioethics Division, and Secretary of the Steering Committee on Bioethics (CDBI).

Presentation Summary

Relevant Council of Europe legal instruments in the field of biomedical research

« Research on a person may only be undertaken if…the research project has been approved by the competent body after independent examination of its scientific merit including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability. » (Article 16, Convention on Human Rights and Biomedicine, ETS N°164, 1997)

Independent ethical review of research project is a fundamental element to safeguard the dignity, rights, safety and well being of the research participants as acknowledged by Article 16 of the Convention on Human Rights and Biomedicine elaborated by the Council of Europe – first international legally binding instrument in this field. This Convention laid down fundamental principles for the protection of participants in biomedical research. These principles have been further developed in an Additional Protocol to the Convention concerning Biomedical Research which addresses in more details the examination process of ethical acceptability of research project as well as the committees in charge of this evaluation. Independent prior assessment of research project, free and informed consent, proportionality of risks and benefit, transparency as well as responsibility are among the main principles on which the provisions of these instruments are based. If this unique normative corpus reflects a European consensus it has gained reference value at international level.

Efforts are now focusing on the implementation of these principles with a view to ensure appropriate protection of research participants contributing also thereby to a high quality research.

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

Curriculum Vitae

Dr. Lino Paula studied biomedical sciences and chemistry (M.Sc.) at Leiden University, and later obtained a M.A. in Biotechnology Law and Ethics from Sheffield University and a Ph.D. in Science and Technology Studies at the Vrije Universiteit Amsterdam.

He has held positions as researcher at the Faculty of Veterinary Medicine, Department of Animals & Society of Utrecht University, as assistant professor Biology and Society at the Athena institute of the Vrije Universiteit Amsterdam and as senior lecturer Biology and Society at the Institute of Biology of Leiden University. He furthermore worked as senior project officer at the Dutch Rathenau institute for technology assessment, for which he also was seconded to the Dutch Parliament. Dr. Paula has worked on several international projects and studies pertaining to the governance and ethics of the life sciences, in particular focusing on the use and impact of national ethics committees and public engagement in public policy.

In 2006 he became policy officer at the Governance and Ethics Unit of DG Research, European Commission, in which position he has been involved in the activities of the Science in Society programme (e.g. coordinating a European network of national ethics committees - NEC Forum) and the Socio-economic Sciences and Humanities programme. He currently is policy officer at the Ethics and Gender Unit of DG Research and Innovation.

Presentation Summary

Activities of the European Commission on ethics in biomedical research

The European Union is founded on values: respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights. These values also underpin EU legislation and policies in the area of research, and imply high ethics standards for research and innovation in the EU.

High ethics standards are important also because they add to the quality of research and innovation and increase its likely social impact. They promote research integrity and a better alignment of research with social needs and expectations. They also support the uptake of the new products, processes and services that are the result of scientific research, because high ethical standards generally merit public trust.

This importance of ethics in research has long been recognised by the European Commission, which has stimulated bioethics research and ethics review since the early 1990s, via funding numerous international bioethics research projects, networks, conferences and capacity building actions. In doing so, the Commission has been instrumental in establishing a robust bioethics research community, as well as furthering a comprehensive infrastructure for ethics review in Europe. DG Research and Innovation itself has implemented a comprehensive ethics review procedure that is an integral component of the research proposal evaluation procedure for research funded via the EU's 'Framework Programme for Research'.

The ethics activities of DG Research and Innovation form part of a broader framework of activities that aim to ensure 'Responsible Research and Innovation'. This is all the more important as research and innovation is a key pillar in the EU's growth strategy "Europe 2020".

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

Curriculum Vitae

Isabel de la Mata was born in Bilbao (Spain). She graduated in Medicine at the University of Basque Country in 1983 and holds post-graduate degrees from the University of Leuven and Paris VI. She is specialist in Preventive Medicine and Public Health.

She worked at the Ministry of Health of Spain and at the Regional Departments of Health in the Basque Country and in Madrid. She has an experience working with International Organisations, such as the WHO, Pan American Health Organisation and Inter-American Development Bank.

From 2004 until February 2008 she worked at the Permanent Representation of Spain to the EU.

Since 1 March 2008 she works as Principal Adviser for Public Health at Directorate SANCO – Health & Consumers.

Speaker: Dr Fergus Sweeney, Head of Sector, Compliance and Inspection, European Medicines Agency

Curriculum Vitae

Current Responsibilities
Fergus Sweeney is Head of the Compliance and Inspection Sector at the European Medicines Agency. The Compliance and Inspection sector coordinates GCP, GLP, GMP/GDP and Pharmacovigilance Inspections in support of the centralised procedure, and provides the secretariat and chairs for the European Inspectors Working Groups. The sector provides the secretariat of the Quality Working Party, coordinates sampling and testing of centrally authorised products, issues Certificates of Medicinal Products for the Agency and manges Notifications of Parallel Distribution. The sector coordinates the GMP annexes of Mutual Recognition Agreements and inspection activities with its counterparts in third countries and international organisations.
The sector manages the EudraCT and EudraGMP database systems.

Brief Employment History
In 1999 Fergus joined the Agency Inspections Sector to coordinate GCP and more recently Pharmacovigilance inspections. He was appointed Head of Sector in May 2009.
Fergus has a Degree in Physiology (Trinity College Dublin, Ireland, 1979), a Doctorat de Troisiéme Cycle in cancer biology (Université de Paris, 1982), and a PhD in Pharmacology (UCD, Ireland, 1986). Prior to joining the Agency he worked in industry from 1982 to 1999, covering phase I-IV clinical research, pharmacovigilance and laboratory activities, primarily in the field of quality assurance.

Presentation Summary

Activities of the European Medicines Agency on ethics in biomedical research

The European Medicines Agency (EMA) is responsible for the evaluation of applications for European marketing authorisation for medicinal products, through the centralised procedure. EU legislation requires that clinical trials submitted in support of marketing authorisation applications (MAAs) meet standards equivalent to those set for the conduct of clinical trials in the EU, and reflecting those in the Declaration of Helsinki, international standards for Good Clinical Practice and local regulatory requirements in the country where the trial is conducted, and that these requirements are verified at the time of Marketing Authorisation Application.
In 400 MAAs submitted to the Agency between 2005 and 2010, 39.4% of patients were enrolled in pivotal clinical trials in the EU / EEA, 3.9% CIS, 8.6% Latin America, 8.7% Middle/East/Asia Pacific, 34.5% North America and 2.1% other. These trials involved more than 57,363 clinical trial sites in 90 countries. Russia contributed the highest number of patients (21,601) and was involved in the second highest number of trials (171) outside of EU and North America. Wherever in the world we stand, the majority of clinical trials are being conducted somewhere else in the world, under a different regulatory framework and in different cultural settings. However, we all rely on the same trials to make decisions: as regulators, to allow or disallow marketing authorisations, and, as patients and healthcare providers, to use or not to use a medicine.
In 2009 the EMA established a Working Group to develop practical proposals for tasks and procedures or guidance to address four action areas:
1. Clarify the practical application of ethical standards for clinical trials, in the context of European Medicines Agency activities.
2. Determine the practical steps undertaken during the provision of guidance and advice in the drug development phase.
3. Determine the practical steps to be undertaken during the Marketing Authorisation phase
4. International cooperation in the regulation of clinical trials, their review and inspection and capacity building in this area.

These proposals are presented in the 'Reflection Paper on ethical and Good Clinical Practice (GCP) aspects of clinical trials of medicinal products for human use conducted outside of the EU and submitted in marketing authorisation applications to the EU' which has been published for consultation and it is anticipated a final version will be published in early 2012. The best approach for achieving these objectives is to ensure that a robust framework exists for the oversight and conduct of clinical trials wherever they take place. An international network of Regulators and Ethics Committees, working together to share best practices, experiences and information and working to standards agreed and recognized by all, can provide an effective platform for such a framework:

- Ethical principles are universal and not negotiable. Equivalent ethical and scientific standards should be applied everywhere in the world regardless of the current strengths or weaknesses of regulatory or other systems.
- There is substantial consensus on the important role to be played by greater practical cooperation and networking between regulatory authorities and ethics committees involved in the supervision of clinical trials, including capacity building activities.
- Increased transparency of information on clinical trials is essential to establishing public confidence in the clinical trial process and the assessment of trial information at the time of marketing authorisation. This includes prospective clinical trial registers used at the time studied are initiated and the provision of information about ethical and GCP aspects of the Marketing Authorisation application and assessment in the European Public Assessment Report (EPAR).
- The greatest impact is achieved by building the ethical and scientific standards into the conduct and supervision of clinical trials from their outset, assessment at the time of marketing authorisation can only reinforce that process but not replace it. Patients' views should be included from early on in this process to ensure the adequate protection of clinical trial subjects.

Ethics Committees play the key role in the verification that ethical standards are applied at the time that the trials are conducted.

More information can be found at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000072.jsp&mid=WC0b01ac05800268ad

Speaker: Dr Marat Sakaev, Head of Department of state regulations of pharmaceuticals circulation, Ministry of Health and Social Development of the Russian Federation

Curriculum Vitae

Marat Rustamovich Sakayev, Director of the Department of state regulation of circulation of pharmaceuticals of the Russian Ministry of Health and Social Protection, Ph.D in biological sciences. He graduated from the Saint Petersburg State Chemicals and Pharmaceuticals Academy in 1996. From 2001 to 2004 he was chief specialist and Deputy head of a section of the Department of state control of pharmaceuticals, medical products and medical equipment of the Russian Ministry of Health.

From 2004 to 2008 he was Deputy director of the Department of pharmaceutical activities, regional and information policy on matters of health protection and social development of the Russian Ministry of Health and Social Protection. During the period 2008-2010 Marat Sakayev was Deputy director of the Department of pharmaceutical market and medical equipment market development of the Russian Ministry of Health and Social Protection. On 25 August 2010 he was appointed to the post of Director of the Department of state regulation of circulation of pharmaceuticals.

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

Curriculum Vitae

Boris Grigorevich Yudin, associate member of the Russian Academy of Sciences, Ph.D, Professor.
Head of the Department of complex problems of studying the human being, Institute of Philosophy of the Russian Academy of Sciences.
Editor-in-chief of the Russian Academy of Sciences popular science journal *"Человек"* ["Human being"].
Director of the Bioethics centre of the Institute of fundamental and applied problems at Moscow University for the Humanities.
Russian representative on the Council of Europe's Steering Committee on Bioethics.
Vice-Chair of the Russian Committee on Bioethics under the Russian Federation Committee on UNESCO affairs.
Member of the Board of directors of the International Bioethics Association from 1999 to 2007.
Leader of and participant in a number of Russian and international UNESCO projects on bioethics.
Member of the International working group on the analysis of ethical problems relating to international biomedical trials organised within the framework of the US Presidential Committee for the examination of bioethics questions – 2011.
He has published over 450 academic works.

Presentation Summary

Bioethics training for researchers and ethics committee members

A feature of present-day practice in biomedical trials is the compulsory ethical supervision carried out on the basis of (a) ethical expert appraisal of each research project carried out by a person authorised by the ethics committee and (b) information provided to every potential participant in the research (or their legal representative) and the obtaining of that person's consent to participate. Accordingly, both the conducting of trials and participation in the work of the ethics committee presupposes familiarity with the principles and standards of research ethics. In many countries, and particularly those which are especially active in the field of biomedical research, there are systems for the training and further training of researchers and members of ethics committees in questions of research ethics. Furthermore, certification attesting to the completion of the corresponding courses, often on-line, is a mandatory requirement for authorisation to conduct trials or work on an ethics committee.

Ethics training for researchers and members of ethics committees is particularly important in a context where biomedical trials are more often than not multi-centred, making it necessary to take account of the ethics standards of both the sponsor countries and the countries taking part. Many Russian specialists taking part in such trials have undergone the corresponding training and obtained certificates. Now we must go a step further and make bioethics training and certification compulsory for all our researchers and ethics committee members.

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

Curriculum Vitae

Yelena Nikolayevna Baybarina, born in 1953, married with two children, has been working at the Scientific Centre since 1982, beginning as a junior scientific officer and then becoming a senior scientific officer in 1986 and chief scientific officer in 1998.
In 1999 she presented a paediatric doctorate thesis on "Renal dysfunction in critically ill new-born children".
She produces a large volume of academic work, having published over 250 academic papers. She holds 5 copyrights for patents and one copyright for a computer programme. She is a qualified neonatologist.
Yelena Baybarina has devised scientific bases for the parenteral feeding of new-born children, made a major contribution to improving the treatment of pneumonia, sepsis and acute renal insufficiency in new-born children and developed many theoretical and practical aspects of nursing premature babies and preventing disabilities from childhood.
Yelena Baybarina has 34 years' academic experience. 10 master's theses have been prepared and presented under her guidance, and she was awarded a professorship in 2006. She is trained in GCP.
She carries out public work at the Russian Federation Ministry of Health and Social Development, where she is chief neonatology specialist and a member of the Ministry's Coordination council tasked with increasing the effectiveness of medical assistance for mothers and children in their first year of life, frequently travelling to the different regions of the Russian Federation to carry out inspections and provide assistance.
She is a member of the Centre's Academic council and a member of the editorial boards of the *"Российский Вестник Перинатологии и Педиатрии"* [Russian Bulletin of Perinatology and Paediatrics] and *"Акушерство и гинекология"* [Obstetrics and gynaecology] journals.
She constantly strives to develop her professional skills, speaks fluent English and masters the latest computer technologies. Yelena Baybarina recently underwent training on WHO courses in "Methodology for organising scientific research" in Romania and "Methodology for the critical appraisal of scientific research" in Hungary. In 2001 she was elected consultant for reproductive health matters of the European office of WHO.
She has chaired the Board of ethics since 2010.

Presentation Summary

Ethics Review of Clinical Research in the Russian Federation

Ye.N. Baybarina - Chair of the Board of Ethics, MD, Professor, Deputy director of scientific affairs of the V.I. Kulakov Scientific Centre for obstetrics, gynaecology and perinatology federal state institution of the Russian Ministry of Health and Social Development

The Board of Ethics was created by Ministry of Health and Social Development decree no. 774 of 31 August 2010. The Board has 18 members - doctors, academics, law specialists, sociologists, education specialists and public figures. The Board operates in accordance with Russian legal and regulatory acts in the sphere of biomedical ethics and the Declaration of Helsinki of the World Medical Association.
The documents on which the activities of the Board of Ethics are based are to be found in Federal Law no. 61-FZ of 12 April 2010, Decree no. 774 of 31 August 2010, appendix 2 (paragraph 3) and Standard operating procedure no. 1 ratified by the Board of Ethics on 24 November 2010 (Protocol no. 6).
In its first year of work the Board of Ethics examined 1,559 applications. To date it has approved 78% of applications and rejected 22%.

For insignificant failings affecting the safety and emotional comfort of patients, applications are not rejected but observations are made, recommending that the working procedure be corrected.

If a patient information sheet is found to be incorrectly completed in a manner that may affect the safety of a research participant, the go-ahead for the clinical trial is not given and the case is reconsidered after the shortcomings observed have been remedied. No fewer than half the applications turned down are rejected because of a discrepancy between the information in the protocol and the information provided to the patient.

Applications also failed to gain approval as a result of unethical wording in the patient information sheet prompting unpleasant and negative feelings of incomprehension in the patient.

One of the grounds for refusing applications is the presence of gross errors in the compiling of the file, such as illegible text, missing pages and compliance failures regarding the title of the preparation in the clinical research protocol and the patient information sheet. These infringements prevent the Board from fully familiarising itself with the application and arriving at well-founded conclusions as to the ethical conducting of clinical research.

In some cases there have been faults in the design of the research, carrying obvious risks for the patients or volunteers. Needless to say, applications containing faults of this kind are not approved.

Clinical trials involving children are a subject of particular interest and concern in society. The Board of Ethics proceeds on the understanding that children need, and their lives may depend on, up-to-date, effective pharmaceutical preparations authorised for use on their age-group. Without clinical trials on children it will not be possible to provide them with good-quality treatment.

The safety of clinical trials involving children is guaranteed by numerous provisions of Federal Law no. 61-FZ, article 43, paragraphs 5 and 6.

Children may participate in clinical research only if it is necessary to improve their health or prevent child illnesses. The purpose of such clinical research is to obtain data on the optimum dosage of a pharmaceutical intended to treat children.

Any clinical trials involving children must be preceded by a study of the pharmaceutical preparation in medical use on adults.

When clinical trials are conducted on children, written consent must be obtained from their parents/adoptive parents. Clinical trials involving orphans and children without parental care are banned in Russia.

With all due regard for confidentiality requirements, the Board of Ethics publicises the results of its work and the classic errors made in devising clinical research in order to raise awareness of the ethical aspects of clinical research.

Speaker: Professor Eugenijus Gefenas (Lithuania), Chair of the Steering Committee on Bioethics of the Council of Europe

Curriculum Vitae

Dr. Eugenijus Gefenas is a director of the Lithuanian Bioethics Committee as well as an associate professor and director of the Department of Medical History and Ethics at the Medical Faculty of Vilnius University. Eugenijus Gefenas graduated from the Medical Faculty of Vilnius University in 1983 and practiced as a medical doctor at Vilnius University Hospital until 1989. He obtained his Ph.D from the Institute of Philosophy, Sociology and Law in 1993.

E. Gefenas has been teaching medical ethics at the Medical Faculty of Vilnius University since 1993. Together with the colleagues from the Center for Bioethics and Clinical leadership of the Graduate College of Union University (USA) he also co-directs the Advanced Certificate Program in Research Ethics in Central and Eastern Europe. E. Gefenas was a member of the UNESCO International Bioethics Committee from International Bioethics Committee from 2002 to 2009. In 2007 he was elected to the Board of Directors of the International Association of Bioethics. His international activities also include the membership in the European Society for Philosophy of Medicine and Health Care. E. Gefenas has been the member of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) and in 2011 he was elected as a chair of the Council of Europe Steering Committee on Bioethics (CDBI).

The areas of his academic interest in bioethics include among others the ethical, philosophical and policy making issues related to human research, psychiatry and health care resource allocation.

Presentation Summary

Ethics Review in the Baltic States

The paper aims at presenting the main features of building research ethics infrastructure in the Baltic States. The analysis of the developments and functioning of the ethical review systems for biomedical research in the Baltic States can also provide some insights into the ethical review and protection of research participants in other European countries, especially those facing difficulties of the transitional period. The paper will show how the international European guidelines and legal standards are being applied in the societies where tradition of institutionalized ethical review is rather recent. It will also emphasize the areas of concern in the emerging framework of ethical review of human research. In particular, the problems related to public availability of information about RECs activities, management of conflicts of interest, composition of RECs as well as differing levels of stringency of ethical review for different types of studies will be identified. We will conclude by emphasizing the importance of developing networking activities between European RECs to develop efficient national systems of ethical review

Speaker: Professor François Lemaire, Department of Clinical Research and Development, Assistance Publique-Hôpitaux de Paris (APHP)

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

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

Curriculum Vitae

Yuriy Aleksandrovich Zhulev was born in Odessa on 8 August 1967.
He is a Haemophilia A-sufferer (severe form). Married, with an 11 year-old son.
He graduated as a law specialist from the Moscow Law Institute.
From 1989 to 1992 – Vice-President of the Association of Haemophilia Sufferers,
From 1992 to present-day – President of the Society of Haemophilia Sufferers,
From 2000 to present-day – President of the All-Russian Haemophilia Society.
From 2002 to 2004 – member of the executive committee of the World Federation of Haemophilia and the Steering Committee of the European Haemophilia Consortium. He has assisted the conducting of World Federation of Haemophilia programmes in CIS countries as a volunteer.
In 2006 he was awarded the Frank Schnabel prize for volunteers by the World Federation of Haemophilia.
He is currently co-chair of the All-Russian Union of the public patients' organisations and Vice-Chair of the Council of public organisations for the protection of patients' rights attached to the Russian Federation Ministry of Health and Social Development.

Presentation Summary

The role of patients' organisations in protecting the rights of participants in clinical trials

In Russian Federation a process of forming the public associations setting for itself task of protection the patients' rights on the whole or specific groups of patients with separate diseases runs actively.
In connection with it a necessity arises to coordinate efforts of such organizations and set up a place for exchange of experts' views between public associations and authorities.
An interesting and important initiation in our country is creation of Russian Union of Patients' Public Societies and Council of Public Organization under Ministry of Health and Public Development of Russia.
There is no doubt that close collaboration between Ministry of Health and patients' societies will allow to do expertise of legal texts preparing and reveal problems to amend at operational procedures in health protection system.
In our opinion, collaboration with patients' societies in area of protection of clinical trials participants' rights.
The collaboration may be developed in following directions:
- Amend the operational laws regulating the clinical trials;
- Involving the patients' societies of specific severe chronic or rare disorders to discussing design of protocols of specific clinical trials;
- Informing patients' community on both general rules of clinical trials and specific clinical trials and rights its participants have.

At the same time involving the patients' societies to preparing the clinical trials should not substitute direct contact among researchers, doctors and patients.
The dialog with representatives of patients' community will allow the most fully take account of the participants in clinical trials and protect their legal rights.

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

Curriculum Vitae

Dr. S. Tjulandin is Professor of Medical Oncology, Head of Clinical Pharmacology and Chemotherapy Department, and Director of Clinical Research of Institute of Clinical Oncology at the Russian Cancer Research Center of the Russian Academy of Medical Sciences. He is a founder and Chairmen of the Russian Society of Medical Oncology.

Dr. Tjulandin earned his degree from the First Moscow Medical Institute in 1979. He then worked as clinical research fellow and the Assistant Professor in the Department of Clinical Pharmacology and Chemotherapy of the Russian Cancer Research Center. In the following years he served as a research fellow in the Department of Medical Oncology at the Royal Melbourne Hospital, Australia (1988-1989) and as visiting researcher at the UCLA's Jonsson Comprehensive Cancer Center, Los Angeles, USA (1991). In 1993 he earned a degree of Doctor of Science (Medicine) and in 2001 Professor of Medical Oncology from the Russian Cancer Research Center.

Dr. Tjulandin is an expert in the treatment of germ cell tumors, breast and ovarian cancer. He is actively participating in numerous clinical trials with special focus on phase I-II trials in oncology. He is a recipient the Russian National Award in Science Achievement (2002), member of editorial boards of many national and international journals, the Editor of the Russian Edition of Journal of Clinical Oncology.

Presentation Summary

The clinical research is an engine of progress. It is essential mechanism by which scientific advances are translated into new and effective cancer therapies. The globalization of conduct of clinical trials is already an established reality, with increasing number of investigators, sites and trial subjects in developing countries. The reasons for trials to be performed in third-word countries are multiple. Some types of cancer have the highest incidence in the developing word (as liver cancer in China). There are geographical and ethnical variability in the biological properties of tumour (like frequency of EGFR mutation in Asian and Caucasian ethnicity). They can be economical due to the reduced cost of investigators and facilities and greater availability of patients with shorter recruitment time. It allows to bring a new effective treatment in a shorter timeframe and to allocate a save money to new research projects. But features of many developing countries, particularly poverty and low level of investment in health care system, affect both the ease of performing trials and the selection of trials that can be benefit the populations of the country.

Russian Federation has become one of the most active players on the market of industry-sponsored clinical researches. Since the beginning of this century between 400-600 new clinical trials have been registered annually. The largest number of studies was initiated in Oncology (20-25% from the total number) and about 12000-15000 cancer patients annually received their treatment in the frame of clinical trials. The scientific and ethical issues concerning clinical trials in oncology in Russia will be discussed.

Speaker: Professor Vladimir Bulatov, Head of the Hospital Paediatrics Department, Kazan State Medical University

Curriculum Vitae

DOB: 27/12/1946
Since 1986 V. Bulatov is Head of the Hospital paediatrics department of Kazan State Medical University on the campus of the Republic Clinical Children's Hospital of the Ministry of Health of the Russian Federation

Participation in seminars, training sessions and courses on the conducting of clinical research (in reverse chronological order):

Name	Date (month/year)		Name of training establishment/organisation, address (city)
	from	to	
Research in monoclonal antibodies against RSV illnesses (GCP training)	10. 10. 2005	11.10. 2005	MedImmune, Inc. Barcelona, Spain
Research in monoclonal antibodies against RSV illnesses (GCP training)	08. 09. 2007	08. 09. 2007	MedImmune, Inc. Budapest, Hungary

Participation in clinical research (in reverse chronological order, including at present):

Code, number of research	*Field of research*	*Research phase*	*Role (chief researcher, co-researcher, coordinator, chemist etc)*	*Date (year)*	
				from	*to*
MI-CP 124	Paediatrics	III	Chief researcher	2007	2009
CMA-0631-PR-0010	Paediatrics	III	Chief researcher	2009	Present
2008085	Paediatrics	III	Chief researcher	2009	Present

Number of publications: 256
Academic works: author of 9 academic works

Presentation Summary

Ethical Aspects of Clinical Trials in Paediatrics

The present report focuses on the extremely important question of developing the ethical aspects of conducting drug trials on children. Is it sufficient to demonstrate the effectiveness of a new method of treatment or diagnosis in research on adults and then apply it in paediatric medicine? Or perhaps further trials on the given age group are necessary? For the ensuing discussion we raise the obvious problem - that of the methodological and ethical issues of trials on a particularly vulnerable population group, namely children. With the rare exception of strictly paediatric preparations, clinical drug trials on children have been carried out from time to time to complement analogous drug trials to test effectiveness and safety on adults. Pharmacokinetic trials of new drugs or generics on healthy children are not carried out owing to potential trauma and complications. With the arrival on the scene of more perfected non-invasive and safer methods of analysis, the possibility of carrying out pharmacokinetic trials can now be reconsidered. The pharmacokinetics of new drugs and generics must be studied only in children whose illness serves as an indicator for the use of the drug concerned. Devising safe and effective drug therapy in paediatrics requires the conducting of clinical trials involving a particular vulnerable group of subjects - children. During clinical trials the scientific value of the results obtained must be balanced with compliance with ethical standards aimed at protecting every subject participating in such trials.

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

Presentation Summary

Current Clinical Research Ethics with HIV patients

There are six main types of studies in HIV/AIDS area: medical (clinical) therapeutic, medical (clinical) non-therapeutic, epidemiological, behavior preventive, behavior descriptive and "social network".
Each protocol of any biomedical study must be considered by Ethics Committee which operating within lows and rules of the Country and independent both from the researcher and sponsor in compliance with Declaration of Helsinki. It's necessary for researcher to submit the compliance of ethical principles.
At the same time some studies don't need the consideration of Ethics Committee, including analysis of spices or data collected earlier without research aims and personal data, observations made in public areas without personal registration when researcher didn't meddle in the actions took place at that moment, data collection and analysis for internal control and improvement of standard programs of organization.
All studies having human as it's object are have to provided in compliance with three basic ethical principles: respect for people, mercy and justice which are in base of the lead principles of all biomedical studies.

Lead principles of all biomedical studies

1. Human studies must be based on the adequate laboratory and pre-clinical studies, acknowledgment of modern scientific literature, accurate detection of risk degree and potential benefits of the research
2. Program and compliance of the study must be clearly formulated in Protocol of the study, which has to considered by Independent Committee for possible suggestions and remarks. Protocol must has the Section about the compliance with principles of research ethics
3. Researcher must has to take agreement in written form from every participant of the research based on full information — *informed agreement*
4. Every participant doesn't be in dependency from the researcher while making up the informed agreement (excessive influence or intimidation are highly inadmissible)
5. Indemnity for participants of any inconvenience and spent time must be acceptable
6. The researcher is responsible for participant's health. Personal free and immunity, including the defense of physical, mental and genetic integrity must be provided
7. Studies on the vulnerable groups (children, pregnants and breastfeeding women etc.) may be provide when there's no alternative or risk for health is no more than minimal
8. Justice in distribution of hardship and advantages of the study. Right of participants for compensation (financial or other help) in cases of any physical damage during the study.
9. Defense of privacy is the duty of the researcher. The abilities of the researcher for defense of privacy must be specified in Protocol of the research.

There're also some ethical problems with motivation of patients for study especially in its 2nd phase. Usually these studies have short observation period and connected with multiple collections of venous blood and by the start of HAART it can be appears that some patients aren't conform to its prescription criteria. The pecuinary compensation is needed for those patients connected with collection of material, covering their transport expenses and organization of meals. As the studies carry out in municipal structures their budget doesn't provide covering of this kind of expenses. It's important to keep HAART scheme unchanged in 3rd phase of study regardless of its finishing and to provide patients with other medicines by the registration of studied ones. This case can has positive influence for patients decision and motivate them to clear compliance of clinical protocol.

Speaker: Mr. Dmitriy Shishkin, Head of Department, insurance company "InGosStrakh"

Curriculum Vitae

Education:
2004 – Bachelor's degree at the Economics faculty of Lomonosov Moscow State University
2006 – Master's degree at the Economics faculty of Lomonosov Moscow State University

Professional experience:
From 2004 onwards employed at the "Ingosstrakh" joint stock insurance company, currently occupying the position of head of the Civil liability insurance department.

Since 2005 responsible for developing the clinical trials insurance sector.

During that period he has developed a number of insurance products covering clinical trials geared as far as possible to catering for market needs, protecting the interests of patients and fully complying with the requirements of legislation.

Presentation Summary
Practice of Compulsory Insurance for Clinical Trials in Russia - Ethical Aspects.

Law FZ-61 "On the circulation of pharmaceuticals" entered into force on 1 September 2010, laying down the fundamental principles governing compulsory life and health insurance for patients participating in clinical drug trials. Compared with similar western products this insurance provides substantial protection for the interests of patients participating in clinical trials. The insurance applicable in the Russian Federation is geared precisely to the social and ethical aspects. At the same time, there is a whole host of potentially dangerous factors that may adversely affect protection of patients' interests, such as an incomplete mechanism for determining amounts of insurance payouts.

Another important factor requiring further work is the issue of professional liability insurance for doctors carrying out clinical trials. Under existing legislation the patient receiving a payout under compulsory insurance may make a further claim on the medical establishment where the trial was carried out and demand further compensation. Accordingly, the interests of the medical establishment and its staff are not protected by the current law, which is at odds with worldwide practice.

To sum up, we may conclude that compulsory insurance helps maintain high ethical standards for conducting clinical trials in Russia while having potential for further improvement.