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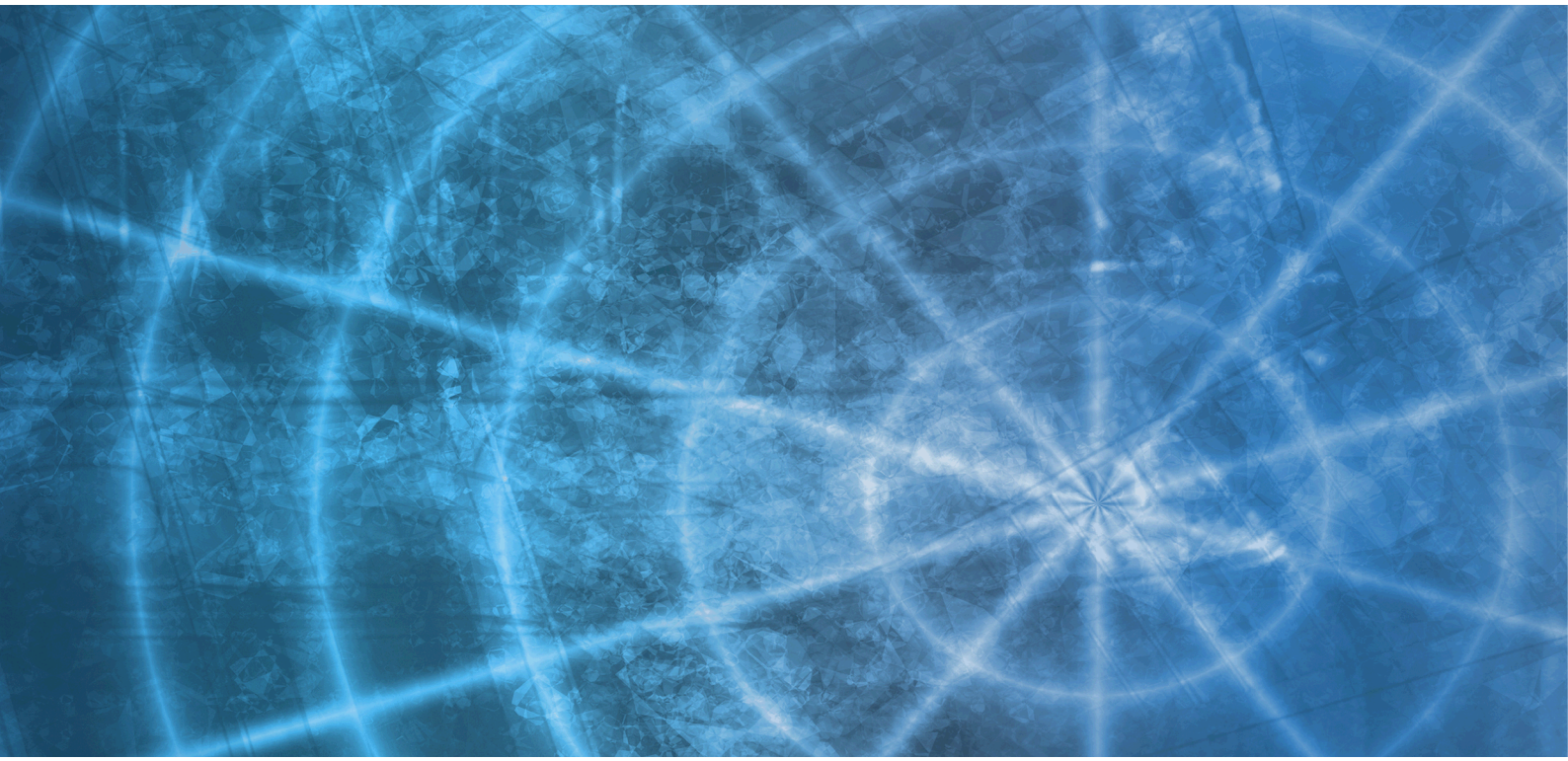

International workshop

Meeting Report

Draft reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing-authorisation applications to the EMA

6-7 September 2010
European Medicines Agency, London, UK

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Executive summary

On 6-7 September 2010 the European Medicines Agency (EMA) held an international workshop with a broad cross-section of stakeholders from around the world to discuss the global framework of clinical trials that has at its heart the protection of the rights, safety and wellbeing of patients participating in clinical trials anywhere in the world.

The workshop was part of the consultation process on the Agency's draft 'Reflection Paper on ethical and Good Clinical Practice (GCP) aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA'.

This report provides an overview of key discussion points raised during the meeting, the agenda, information on presenters and copies of their slides.

Some 140 participants from around 43 countries from the Americas, Asia, Africa and Europe participated in the workshop. They represented patient organisations, health care professionals, health-related non-governmental organisations, clinical trial sponsors, pharmaceutical industry, ethics committees, and regulatory authorities from all continents and intergovernmental organisations.

The reflection paper responds to the challenges, for the EU marketing authorisation process, arising from the increasing globalisation of clinical research. In marketing authorisation applications submitted to the Agency between 2005 and 2009, only 38.8% of patients enrolled in pivotal clinical trials received their treatments at clinical trial sites within the European Union (EU) and the European Economic Area (EEA). These trials involved more than 44,000 clinical trial sites in 89 countries. The data generated were used to support 347 marketing authorisation applications as well as some applications for a variation or a line extension to an existing marketing authorisation.

"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", said Fergus Sweeney, Head of Inspections at the European Medicines Agency.

A number of practical proposals and recommendations are set out in the draft reflection paper. It was considered that EU regulators should only expect or require studies in support of an EU marketing authorisation application that would also be ethically acceptable in the EU. There should not be a different standard applied to trials conducted in the EU compared to those conducted elsewhere.

The discussions over the course of the two-day conference highlighted a number of points including:

- 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 was a 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.

"What is needed is a robust framework for the oversight and conduct of clinical trials, no matter where in the world the clinical investigator sites are located and patients recruited…" said the EMA's Executive Director, Thomas Lönngren, concluding the meeting, "… The Agency is committed to build and extend its relationship with regulators in all parts of the world and with international organisations to work to standards agreed and recognised by all."

1. Introduction

Clinical trials and clinical development programmes for medicinal products are increasingly globalised undertakings. This increasing globalisation of clinical research presents many challenges for the EU marketing authorisation process. In marketing authorisation applications submitted to the European Medicines Agency between 2005 and 2009, only 38.8% of subjects enrolled in pivotal clinical trials received their treatments at clinical trial sites within the EU and EEA. The remaining subjects were recruited in other parts of the world - (35.2%) in North America, 9.2% in Central and South America, 7.8% in the Middle East, Asia and Pacific regions. Smaller numbers were recruited in the Community of Independent States (CIS) region (3.8%), in Africa (3.0%), in Australia and New Zealand (1.5%) and in the non-EU part of Eastern Europe (0.7%).

Altogether these trials involved more than 44,000 clinical trial sites in 89 countries. The data generated were used to support 347 marketing authorisation applications as well as some applications for a variation or a line extension to an existing marketing authorisation.

Wherever in the world a marketing authorisation application is made, the majority of clinical trials will have been conducted elsewhere, under a different regulatory framework and in different cultural settings. However, all countries and regions 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.

The revisions to the EU pharmaceutical legislation which were put in place in 2004 increased the emphasis on the ethical standards required of clinical trials conducted outside the EEA that are included in marketing authorisation applications submitted in the EEA for medicinal products for human use.

In December 2008 the EMA published a strategy paper "Acceptance of clinical trials conducted in third countries for evaluation in marketing authorisation applications" outlining four areas for action. These are:

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.*

In 2009 the EMA established a Working Group on third-country clinical trials on medicinal products for human use. This Working Group drafted a reflection paper addressing these four actions. The actions encompass EMA processes having an impact on clinical trials, starting with activities prior to the early-phase clinical development including the preparation of Guidelines, provision of Scientific Advice, Orphan Product Designation and development of Paediatric Investigation Plans and continuing through to the finalisation of the CHMP opinion on the application (assessment and inspection) and post-authorisation activities.

A robust framework needs to exist for the oversight and conduct of clinical trials, no matter where in the world the clinical investigators' sites are located and patients recruited. An international network of regulators from all countries involved, working together to share best practices, experiences and information and working to standards agreed and recognised by all, can provide an effective platform

for such a robust framework. The EMA is seeking to build and extend its relationship with regulators in all parts of the world and with international organisations in order to work to achieve this.

The Working Group has prepared a draft reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing-authorisation applications to the EMA).

The reflection paper highlights and emphasizes the need for cooperation between Regulatory Authorities involved in the supervision of clinical trials and the need to extend and link networks to support these activities**.** This includes contributions, by EMA or EU National Competent Authority experts, to capacity building initiatives led by the EU, World health Organization (WHO), International Conference on Harmonisation (ICH), or other groups.

The specific scope of the reflection paper extends to clinical trials conducted in third countries and submitted in marketing authorisation applications to the EMA in respect of medicinal products for human use. The general principles and processes set out are nonetheless applicable in the context of any marketing authorisation procedure in the EU.

The document was released for a public consultation which remained open until 30 September 2010, and the EMA organised this international workshop, on 6-7 September 2010, as part of the consultation as a forum to discuss and provide feedback on the paper.

A wide range of EU and third-country regulators and stakeholders attended the workshop. The participation of some third-country regulatory authority representatives was sponsored by the WHO.

A key element of the workshop was to build on the concept of a network of regulators involved in clinical trial supervision as the basis for future activities such as capacity building, joint training and information exchange.

The workshop was attended by 140 delegates from 43 countries. Most importantly a wide cross-section of patient representatives from Africa, Asia, North and South America and Europe attended. Ethics committee views were presented from Asia and Africa. Clinical trial sponsors, representatives from clinical research organisations (CROs) and pharmaceutical industry associations, academic researchers participated as did non-governmental organisations (NGOs) from the EU, Latin America and Asia. Reflecting the support for international cooperation in the supervision of clinical trials, regulators from Russia, China, Chinese Taipei, Japan, USA, Canada, Brazil, Thailand, Indonesia, Ghana, Tanzania, Croatia, Serbia, Turkey and representatives of international organisations (WHO, Council for International Organizations of Medical Sciences [CIOMS], World medical Association [WMA], Council of Europe), joined regulators from the EU, from national competent authorities of many EU member states (including assessors, inspectors, Clinical Trial Facilitation Group, heads of agency), the EMA secretariat and representatives of the Committee for Human Medicinal Products (CHMP), the Committee of Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and the GCP Inspectors Working Group, and the European Commission.

This report collects the issues and views shared during the meeting under the four key chapter headings from the draft reflection paper. The report does not set out to draw final conclusions on the issues raised in the context of the reflection paper. It has also not been possible to reflect all individual views but rather, the report provides an overview of the main themes of the meeting. The views expressed during the workshop form part of the feedback to the consultation which is being reviewed for the finalisation of the reflection paper. The written submissions to the consultation are also published alongside this report.

2. Practical application of ethical standards in EMA activities

The practical application of ethical standard for clinical trials in the context of the EMA activities is the topic of the first section of the reflection paper, which sets out EMA perspectives on basic elements of the protection of clinical trial participants. These principles form the basis for the practical activities to be undertaken and which are set out in the other sections.

The section seeks to clarify and provide a consensus position on key aspects of ethical standards for clinical trials required in marketing authorisation applications submitted in the EU. It is important to reach a common understanding of what is necessary and acceptable and what can be achieved in practice. The draft paper provided a detailed summary of EU and international guidance and legislation in this area. Many of these requirements are established in EU legislation and practice whilst others reflect international guidance. A number of these requirements extend beyond the scope of the pharmaceutical legislation itself into other areas such as the governance of research in humans as a whole, and most critically, policy areas relating to the consequences of poverty on access to medical care.

All participants recognised the importance of establishing a framework and process for international discussion of fundamental ethical constraints as a basis for greater cooperation in applying these standards during clinical research.

Key points discussed included:

- Ethical principles are universal and should not be negotiable. Participants emphasised that it is not acceptable to create double standards for EU countries and non EU countries. The same ethical and scientific standards should be applied everywhere in the world regardless of the current strengths or weaknesses of regulatory or other systems.
  While the ethical principles are universal, the translation of the ethical principles in procedure may depend on cultural differences, and this needs to taken into consideration.
- All countries play a role in the advancement of clinical research, drug development and human health, but there are wide variations in the extent to which the regulation of clinical trials has developed or been implemented in practice. These differences reflect the stages of development of regulatory frameworks and the degree to which adequate resource, capacity or expertise are available for the ethics review mechanism and regulatory framework for the supervision of clinical trials.
- The standards expected for the conduct of clinical trials conducted in non-EU countries should not be more stringent than those required within the EU and the guidance should not restrict the conduct of good trials or use of data from well conducted trials, wherever that takes place. Suppressing or withholding research in poorer countries is not an answer. Participation in clinical research is crucial for the development of the frameworks for clinical research and more generally health care systems. Recognition by leading agencies provides a stimulus and support for the development of local regulatory frameworks. The local research infrastructure, patients and professionals, benefit from the impact of properly conducted research.
- Ethics Committees play a key role in the verification that ethical standards are applied at the time that the trials are conducted.
  Participants recognised that the quality of Ethics Committees can vary widely between and within countries. Ethics Committees may need greater regulatory support to ensure that the ethical issues are addressed and need to develop greater expertise. The capacity buildings of Ethics Committees and the quality assurance systems for Ethics Committees should be points

for development.
Workshop participants identified the need for support for the following:

- capacity building of Ethic Committees;
- quality standards for the independence, operation, accreditation and audit of Ethics Committees;
- mechanisms in place to ensure that these quality standards are adhered to, such as a national accreditation or audit system;
- development of expertise to support Ethics Committees addressing difficult ethical issues such as the use of placebo/choice of active comparator, access to treatment post trial, clinical trials in vulnerable populations, and to develop consistency in addressing these issues.

- Patient representatives highlighted the need to take into consideration the patient's voice and the patient's views, and the need to protect the patient's interests. Patient representatives should be more involved in the process of review and approval of the clinical trials. Patient organisations and NGOs requested that a mechanism be established for appeal on issues of ethical concern.

The issue of vulnerability was discussed, and participants expressed a concern that the cumulative citation of different guidelines in the reflection paper results in the perception that a very large proportion of trial subjects would be considered vulnerable. Whilst this is the case to some degree, since illness creates a vulnerability in itself which is then compounded by other issues such as age, understanding of clinical trials, or lack of access to care, the participants still asked that the paper be more concise and focussed on the key concerns in the present context, and in the overall discussion of the vulnerability resulting from the consequences of poverty and of insufficiently developed ethical or regulatory frameworks and infrastructure. A request was also made to address the particular concerns that arise in the context of healthy volunteer studies, both phase I trials of novel products and bio-equivalence studies, and in the context of non-therapeutic trials.

The participants also suggested that the section on care in the case of trial related injury also be reviewed.

3. Guidance and advice during the drug development phase

This chapter relates to determining the practical steps that can be undertaken during the provision of guidance and advice in the drug development phase, and therefore can influence the proper and ethical conduct of clinical trials before they take place.

All participants highlighted the need to improve transparency to clarify which ethical standards the Agency considers acceptable – the development of the reflection paper plays a key role in that process.

Representatives from sponsor organisations highlighted the need to recognise that there can be a conflict between some regulatory requirements, or perceptions of these, and ethical standards, for example regarding some uses of placebo or choices of active comparator. Judgment needs to be applied so that a proportionate approach is achieved in balancing the need for new treatments or therapeutic strategies with requirements about the design or conduct of research.

There is a need to promote transparency by:

- ensuring that the basic principles are taken into account in the development of any new guidance or revision of existing guidance, provision of scientific advice or decisions on paediatric investigation plans;
- including ethical considerations, justifications and provisions in protocols;
- ensuring that all trials are required to be prospectively entered in public clinical trial registries, and in particular, in the present context, any trial that might be used in a marketing authorisation application submitted to the EU;
- publishing assessment reports, informed consent information and clinical trial study reports and providing access to this information.

More attention should be paid to explaining clearly and carefully the rationale for trial designs and requirements so that there is a better understanding of the circumstances in which designs involving placebo or certain comparator choices are both necessary and ethically acceptable.

4. Steps during the marketing authorisation phase

The practical steps that can be undertaken during the marketing authorisation review phase and in the post-authorisation period were discussed.

Participants agreed that every application for marketing authorisation should contain information on the adherence to ethical standards.

Key elements raised included:

- When assessing an application, regulators should consider both scientific and ethical aspects. The Agency should develop processes for evaluating applications for marketing authorisation that take into consideration the ethical aspects, including check lists to be used during the assessment process.
- There was discussion of the proposal for the establishment of a pool of experts supporting the EMA/CHMP in relation to the assessment of marketing applications, the interpretation of requirements and actions to be taken in particular difficult cases.
- The pool of experts should include the perspectives low income countries and patient's representatives.
- The review at the time of marketing authorisation is not intended to be a rerun of the original ethics review of each and every trial in an application dossier. It cannot substitute for proper ethics committee review at the time of conduct of the trial, and for proper reporting of the conduct of each trial, including justification of the choice of design and study population and description of significant problems encountered and how they have been addressed.
- The resource available is clearly finite and the processes established need to enable regulators to identify particular studies that may need additional attention, to ensure that ethical aspects are properly addressed in study reports and assessment reports, and to ensure transparency once the application review is complete. Standardisation of the information to be provided by applicants for use in evaluating the trials and that included in EPARs will be a key aspect.
- The CIOMS offered to give support and to help in clarification of CIOMS guidance.
- GCP inspections may be used to verify the contents of the application. The GCP inspections should be done at an earlier stage than in the marketing authorisation phase and the number of inspections in third countries should be increased. Cooperation between regulators and

inspectors in all regions is key to achieving this. The steps taken during product development and at the time of assessment of the application, to ensure GCP and ethical standards, should be included in the EPAR.

- EU Competent Authorities who have serious concerns about the design or conduct of a clinical trial should in certain cases refuse to consider data from studies where serious violations of ethical standards have occurred, and should communicate their concerns to the national regulatory authorities where the trials have been carried out. Serious non-compliance with ethical guidelines should have serious consequences. This should be made clear and a range of regulatory options established to enable proportionate action to be taken.
- The rejection of any particular trial is a very serious step and should only take place after careful consideration of the nature of the violations and the consequences of not using the trial data. These include the possible need to rerun a study, with consequent exposure of more subjects to trial risks, as well as the loss of research progress and consequent delays that might arise. However if ethical standards have been seriously violated, other standards of scientific and technical integrity may also have been undermined.

5. International cooperation on review and inspections

The final chapter of the draft Reflection paper addresses international cooperation in the regulation and oversight of clinical trials, their review and inspection and capacity building in this area.

All participants agreed that international cooperation is necessary to regulate international clinical trials effectively and efficiently. Participants highlighted the importance of establishing a framework for the sharing of information, knowledge and expertise, including for example the identification of contact points in each national regulatory authority. This international cooperation should include the implementation of systems for the control of clinical trials and the improvement of capacity building for Ethics Committees and Regulatory Authorities according to their local needs.

The discussion also highlighted that in fact there are existing areas of cooperation between some regulatory authorities, but that these have limitations such as the absence of formal process or agreement for sharing of information, limited resources, or purely local regional effect. Any initiatives already underway should be encouraged, and these initiatives should be linked to each other in order to reduce duplication of effort and improve the scope of oversight.

Participants suggested that the Agency take a leading role in coordinating international cooperation and synergy, and that it participate actively in training, in partnership with regulators from EU and other regions. Regulators should take a pro-active role in creating opportunities for joint reviews and inspections with national regulatory authorities from other countries, using these occasions as part of capacity development. It was proposed that a service be established at EMA to support these processes and link with initiatives of other regulators, regional associations and international organisations.

The coordinating role of the Agency could also include the establishment of an inter-institutional committee to link the Agency via its secretariat with regulatory networks.

Other possible actions include:

a) to further progress bilateral arrangements with the national regulatory authorities of third countries where clinical trials are commonly conducted;

b) to establish an interaction between the EMA and various existing regulatory networks. This could include a group of representatives of organisations such as the Developing Countries'

Vaccine Regulators Network (DCVRN), the African Vaccine Regulatory Forum (AVAREF), the European and Developing Countries Clinical Trials Partnership (EDCTP), the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) and the Pan-African Clinical Trial Alliance (PACTA), Asia Pacific Economic Cooperation (APEC), Pan American Organization (PAHO) etc.. The WHO offered to help with this and is ready to discuss further the establishment of the proposed "centre" to support such activities.

c) to develop guidelines (code of practice) for member regulatory authorities and local Ethics Committees to enable appropriate interactions with trial sponsors, investigators and other regulators, and for the assessment of local strengths and weaknesses and the development of mechanisms for requesting assistance from each other.

6. Conclusions and next steps

The workshop demonstrated the overall support for the continuation of the EMA initiatives on third-countries clinical trials, for the finalisation of the reflection paper and to progress with the practical steps. Greater international cooperation, mutual support and assistance between regulators, more involvement of patients in the process of drug development and greater overall transparency throughout the process were key themes. All of these should be with the focus of ensuring proper protection of trials subjects so that research and medical progress are founded on principles of ethical and scientific integrity, agreed and implemented by all.

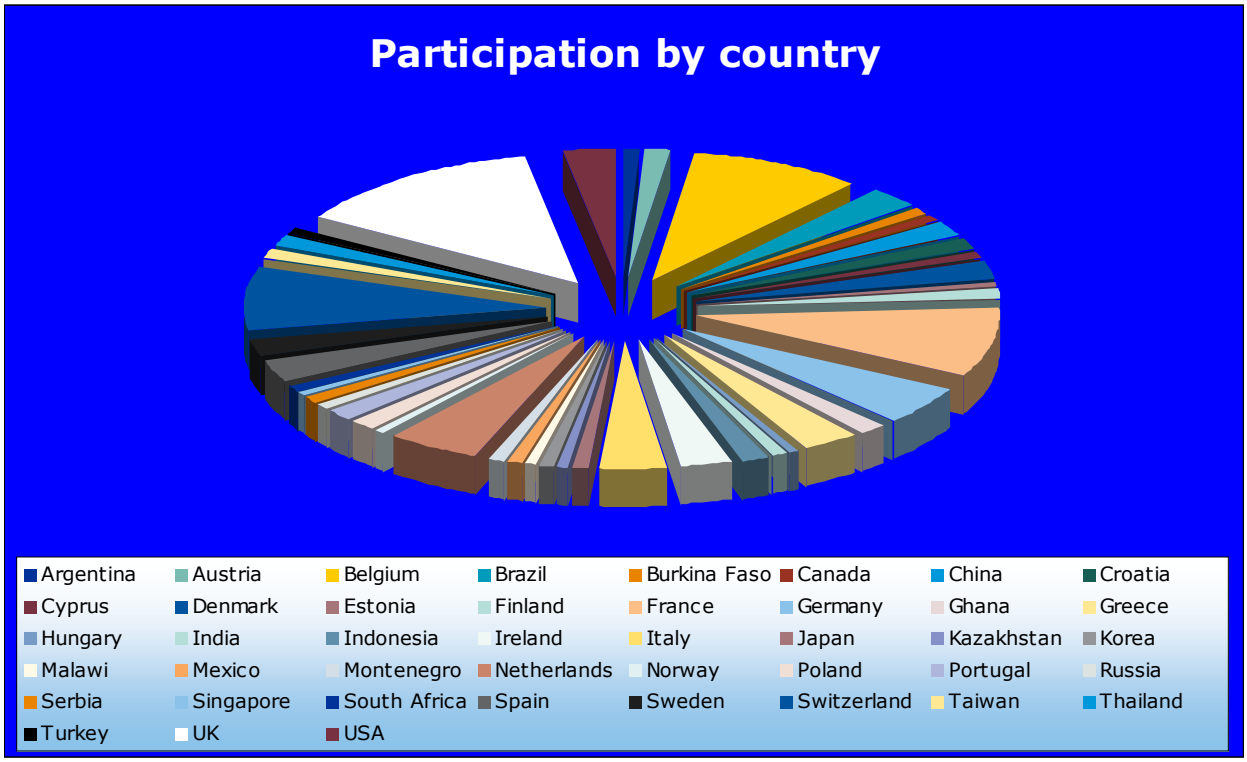
This report is published along with the slides shown during the workshop and the written submissions to the consultation on the draft reflection paper. The paper is now being revised in the light of all these discussions and is expected to be finalised in 2011.

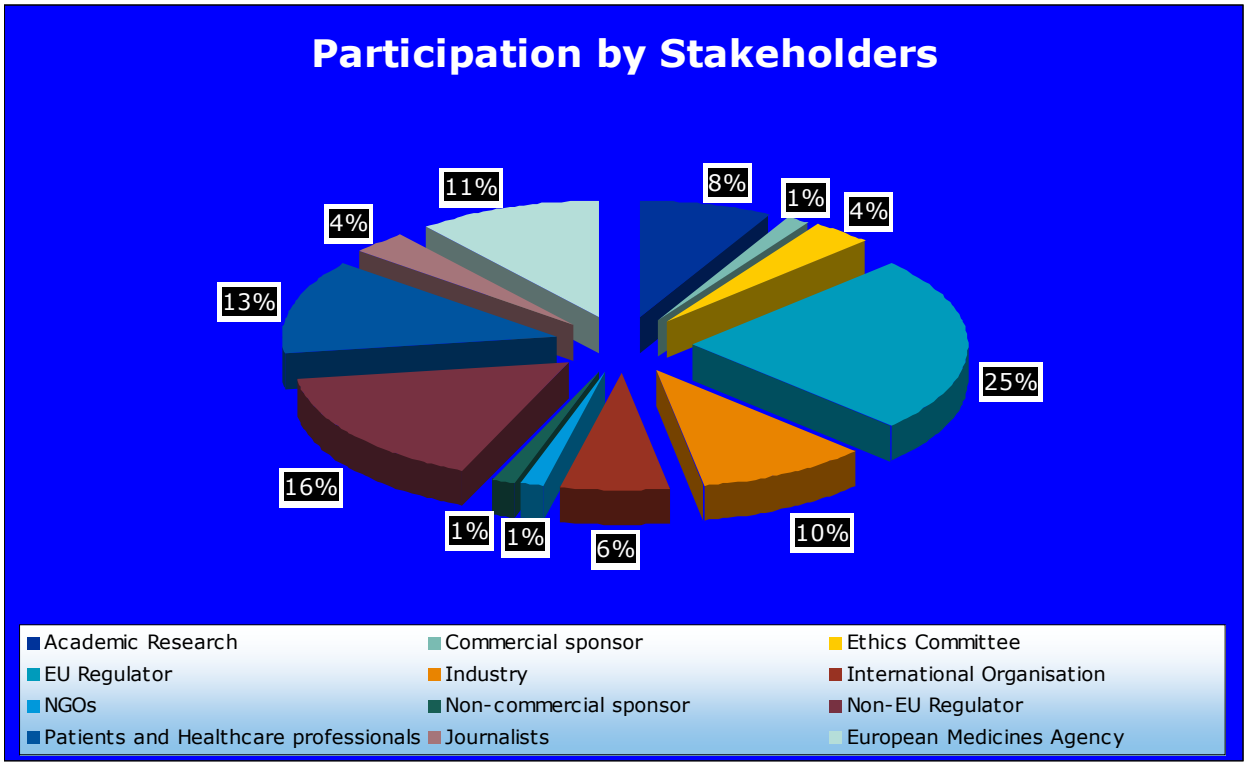
In the meantime many practical initiatives are already underway, and improvements in transparency, international cooperation and capacity building are being achieved progressively. For example, GCP inspectors from many countries in Africa, Asia and Latin America have already participated in two EU GCP inspectors training workshops (November 2010 and March 2011), and a joint workshop, immediately after this conference, allowed GCP inspectors to share experiences and initiatives.

"What is needed is a robust framework for the oversight and conduct of clinical trials, no matter where in the world the clinical investigator sites are located and patients recruited…" said the EMA's Executive Director, Thomas Lönngren, concluding the meeting, "… The Agency is committed to build and extend its relationship with regulators in all parts of the world and with international organisations to work to standards agreed and recognised by all."

7. Overview of participation

Overview of participation





8. Speakers' biographies

Ms Annagrazia Altavilla, Paediatric Committee (PDCO - EMA),"Méditerranée-Hémoglobines" Association (MED-HEM) - France

- Lawyer at the Bar of Taranto (Italy)
- Associate Senior Lecturer - Espace Éthique méditerranéen (Bioethics Research Centre EA3783-Université de la Méditerranée –France)
- Member of Paediatric Committee (EMA) ;
- Member of Working Group for Third Countries Clinical Trials and Rapporteur ;
- Coordinator of the activities in the field of Ethics of Task-force in Europe for Drug Development for the Young (TEDDYNoE) ;
- Member of CPP Sud-Méditerranée I (Ethics Committee)- France ;
- Member of World Medical Association for Medical Law (WAML) ;
- Member of International Institute of Research in Ethics and Biomedicine (IIREB) –Canada ;
- Author of more than thirty articles in national and international journals;
- Speaker in more than forty conferences in ten countries;
- Lecturer in many universities across Europe.

Maria Antonietta Antonelli, European Medicines Agency

Maria Antonietta Antonelli qualified as a biologist at University of Rome La Sapienza in 1995 and holds a Specialisation in Toxicology, a Master Degree in Bioethics and a Master Degree in Clinical Trials.

She worked as Study Director/Toxicologist at a Contract Research Organization from 1999 to 2001.

In November 2001 she joined the Italian Ministry of Health and then in 2004 the Italian Medicine Agency (AIFA) where she has worked as a senior GCP senior inspector until September 2008

She has participated in approximately 85 GCP inspections mainly in Italy but also elsewhere in Europe and Africa.

Maria Antonietta joined the European Medicines Agency EMA in September 2008 as a Scientific Administrator in the Compliance and Inspection Sector. She is involved in the coordination of EMA GCP and PhV inspections.

She is a Member of the EMA Working Group on Third Country clinical trials, she supported the preparation of the "Draft Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA" and she is the coordinator of the International Workshop on Draft Reflection Paper on Ethical and GCP Aspects of Clinical Trials in 3rd Countries.

Dr Pierre Henri Bertoye, AFSSAPS

Pierre Henri Bertoye, M.D., M.Sc, is Deputy Director of the Inspection and Companies Directorate, at Afssaps, the French product agency. He is in charge of non clinical and clinical trials, pharmacovigilance and the international affairs in these fields.

Pierre Henri Bertoye came to the Afssaps in 94 as the Head of GLP and GCP inspection sector. He is Member of the GCP Inspector Working Group at EMA and is Member of the European Commission Ad Hoc group for the development of implementing guidelines for the "Clinical Trials Directive".

From 1987 to 1994, Pierre Henri Bertoye served in pharmaceutical industry in international clinical development, GCP and Methods.

Dr Laurent Brassart, European Medicines Agency

Laurent Brassart is responsible for information compliance and consistency in the Medical Information sector. Educated as medical doctor, specialised in clinical trial methodology, he has been clinical assessor at the French Agency before joining the EMA as project manager for marketing authorisation applications and responsible for the secretariat of the Efficacy Working Party.

Dr Liliana Chocarro, WHO

Dr. Chocarro has worked for the regulatory authority in Argentina for 15 years (quality control of vaccines), for a manufacturer of vaccines for 5 years in Canada, as a consultant to WHO, industry and educational institutions for 8 years before joining WHO headquarters in 2004 where she is responsible for Regulatory Pathways at the Vaccines Department.

Perry D Cohen, Parkinson Pipeline Project

Management consultant with expertise in systems planning, information/ communication technology, organizational development, outcome evaluation, and continuous quality management for health services, medical research and regulatory evaluation of science based medical innovation.

Leader for advocacy interests of US Parkinson's disease; spokesman for all seriously ill patients

Attended Carnegie Mellon University and completed graduate studies at MIT, Sloan School of Management.

Emer Cooke, European Medicines Agency

Emer Cooke has previously held positions in the Irish drug regulatory agency, EFPIA, and the pharmaceutical unit of the European Commission. In 2002 she joined the European Medicines Agency as Head of Sector for Inspections. She became the International Liaison Officer in 2008, responsible for the Agency's international strategy.

Mr Gunnar Danielsson, Medical Products Agency, Sweden

Gunnar Danielsson has more than 25 years experience from the field of clinical research within the pharmaceutical industry. He has held various positions covering monitoring, project leadership and auditing as well as process implementation. The work has been carried out both within local Market Companies as well as Corporate Headquarters in Sweden, UK and US. Since 2003 Gunnar holds the position as Pharmaceutical Inspector with emphasis of GCP inspection at the Swedish Medical Products Agency and has conducted a vast number of inspections in Sweden and internationally.

Mrs Delese Darko, Food and Drugs Board, Ghana

Pharmacist by profession. Worked with the Pharmacy Council of Ghana for 6 years from 1991 to 1997, and has been working with the Food and Drugs Board from 1997 to date.

Was the Head of Drug Evaluation and Registration Department and is now the Head of the Safety Monitoring (Pharmacovigilance) and Clinical Trials Department.

Mr Nikos Dedes, EATG

Nikos Dedes has been involved in the HIV field since 1995. Currently WorldCAB coordinator at ITPC and co-chair of the PCWP at the EMA. Former chair of the EATG and co-chair of the EU HIV/AIDS Civil Society Forum of DGSanco. He is member of the EACS Treatment Guidelines and of the Steering Committee of the HIV European Clinical Trials Network.

Ms Annelies den Boer, WEMOS

Annelies den Boer is project coordinator at the Wemos foundation in the Netherlands. Wemos is a

Irene Schipper, Senior Researcher, working for SOMO since 1993. Corporate accountability, supply chain responsibility, promoting sustainable development and fighting negative consequences of globalisation are key words in her researches. In recent years she published about ethics for drug testing in low and middle income countries and how to protect clinical trial participants in developing countries against unethical practices.

Mrs Hawa Dramé, French Neuromuscular Association

Biochemist for AFM (French Neuromuscular Association), therapeutic development coordinator for the orphan drugs program of EURORDIS (European Organisation) and expert at the COMP.

Mrs Hawa Dramé founded FITIMA, dedicated to the rehabilitation and education of children with disabilities and rare diseases.

Consulting in the field of health strategy for International Organisation (UNICEF, WHO,...).

Dr Harald Enzmann, BfArM

Harald Enzmann has experience in academic, corporate and regulatory settings. A physician by training (graduation 1985), he received his MD "summa cum laude" from the Karl Ruprechts University, Heidelberg, Germany. Subsequently, he worked as a postdoctoral fellow at the German Cancer Research Center and at the Institute of Pharmacology and Toxicology at the University of Erlangen, Germany.

Harald joined Bayer AG research and development in 1989 and worked on in vivo and in vitro cancer models. The development of cancer models continued at the American Health Foundation in Valhalla, NY, USA in 1995 through 1996. From 2000 to 2002, Harald was head of the department of Rodent Studies and Genotoxicity with Bayer AG.

In 2002 he joined the German Federal Institute for Drugs and Medical Devices (BfArM) and is currently head of Licensing Division 2 and responsible for the areas of cancer, immunology, hematology, metabolism, gastrointestinal disorders, and endocrinology.

In 1987 Harald received the Award of the German Cancer Research Center for Outstanding Research and in 1995, the Animal Welfare Research Award of the German Ministry of Health.

He received the Master of Science Degree for Experimental Pathology from the New York Medical College in 1996, the title "Privatdozent" and the venia legendi in Experimental Pathology from the University of Heidelberg in 1999. At the University Duisburg-Essen, he is Associate Lecturer for Pharmaceutical Medicine and member of the Examination Board.

Harald is a fellow of the International Academy of Toxicologic Pathology, member of the European Society of Toxicological Pathology, of the Society of Toxicology and of the European Association for Cancer Research.

He is member of the Safety Working Party (SWP) of the European Agency for the Evaluation of Medicinal Products (EMA) and German Delegate to the Committee for Human Medicinal Products (CHMP).

Dr (Pharm) Pavel Farkas, EGA

Pavel Farkas, Pharm.Dr., graduated from J.A.Comenius University in Bratislava, Slovakia and completed a specialization degree in Clinical Pharmacy. He has joined a generic pharmaceutical industry following his career in the field of basic pharmacological and endocrinological research 18 years ago. He joined PLIVA in 2004 with responsibilities and experience covering pharmacokinetic, bioequivalence and therapeutic equivalence studies for generic products, conducted mostly for EU/CEE, US and Canadian regulatory submissions as well as respective GCP and regulatory aspects. Pavel Farkas is currently responsible for PLIVA/TEVA's European Biopharmaceutics operations and acting as a member of Bioequivalence Working Group of European Generic Association (EGA).

Dr Umberto Filibeck , AIFA, Italian Medicines Agency

MD (1972). Post-graduate education: Experimental Pharmacology, Bioethics and Protection of HR. Officer of the Italian Ministry of Health (1976-2004). Since 2004 head of the GCP Promotion and Inspection Unit (AIFA). International level: collaboration with UE, UN, WHO, EMA.

Currently, GCP senior inspector; responsible for the project Training courses on Ethics and GCP in CT in Developing Countries (AIFA-UNICRI).

Mr Torkil Fredborg, Eli Lilly and Company

Torkil trained as a pharmacist in Denmark. For 10 years, he held various positions within Eli Lilly and Company in Denmark and the UK with responsibility for formulation and implementation of regulatory strategies as well as supporting European submissions and post-marketing activities mainly in the Critical Care and CNS areas.

Mr Stefan Führing, European Commission, Directorate-General Health and Consumers

Working in the "pharmaceuticals" unit of the European Commission. Legal background. Lately working in particular on the legislative proposal of the Commission on 'falsified medicines', which is part of the 'pharmaceutical package' adopted in December 2008. Another main responsibility is the regulatory framework of clinical trials in the Union. In the unit Mr. Führing is also in charge of general/procedural matters of the Commission decision-making procedures for authorization of medicines.

Ms Candice Hilder, Health Canada

Candice obtained her Bachelor of Science (Cell Biology and Genetics) from the University of British Columbia, in Vancouver, Canada, and has worked in federal regulation for the past 10 years. Candice began her career in the Public Service as a food microbiologist, prior to joining Health Canada in 2005, where she has worked in with the Medical Device, Drug Investigation, and Good Clinical Practices programmes as a regional inspector. Currently, Candice is the national Coordinator of the Good Clinical Practices compliance program, where her role is to manage and facilitate the delivery of a national inspection, compliance verification, and investigation program for clinical trials of drugs for human use.

MD DrPH Núria Homedes, Red Latinoamericana de Etica y Medicamentos (Latin American Network of Ethics and Medicines)

Received her medical training in internal and preventive medicine at the University of Barcelona. Her doctorate in public health is from the University of Texas-Houston where she is an associate professor. She is an editorial board member of Health Policy, Salud Colectiva (Argentina) and co-editor of Boletín Fármacos since 1998

Dr Ian Hudson, Medicines and Healthcare products Regulatory Agency

Ian Hudson is a physician, who practiced as a paediatrician with a research interest in neonatal haematology. He then worked in clinical research and development in the pharmaceutical industry for 11 years. Since 2001 he has been the Director of the Licensing Division (Medicines) at the MHRA. He has also been the UK delegate to the CHMP since 2002.

Prof (MD, PhD) Juhana E. Idänpään-Heikkilä, CIOMS

Clinical Pharmacologist, worked for 20 years at Finnish Drug Regulatory Agency in Helsinki as a Senior Medical Officer, Visiting Scientist at US FDA in Washington DC, Senior Adviser at United Nations in Vienna. For 10 years Director of Pharmaceutical Policies at WHO, Geneva and General Secretary to WHO Ethics Committee. Subsequently for 9 years as Secretary-General, CIOMS, Geneva

Ms Li Jinju, SFDA China

Madam Li Jinju, born in 1964 in China, PhD in Pharmacology, now assumes Division Director, Division of Drug Research Supervision, Department of Drug Registration, State Food & Drug Administration of the People's Republic of China, mainly engaged in GLP & GCP regulation and supervision.

Dr (PhD) Ock-Joo Kim, Korean Associations of Institutional Review Boards (KAIRB)

Trained in biomedical ethics, Dr. Kim chairs the ethics committee of the national research centers; has played a key role in establishing a national network of the IRBs; and serves as the ethical advisor of Korean Food and Drug Administration, Korea National Enterprise for Clinical Trial, Ministry of Health, and Ministry of Science, Korea.

Dr Otmar Kloiber, World Medical Association

Dr. Otmar Kloiber is the Secretary General of the World Medical Association since 2005. Working in international medicine for 20 years he has focussed on medical ethics, health policy, government affairs, relationships with patients' and professional organizations, manufactures and other stakeholders.

Dr Patrick Le Courtois, European Medicines Agency

Qualified medical doctor from the University of Paris (France), post graduate in Public Health from the University of Bordeaux (France).

After a career in Clinics and Public Health, he joined the French Regulatory Authorities in 1990, in charge of the European Procedures; he has been a CPMP member.

In 1997 he joined the EMEA were he had responsibilities as Head of Sector for Chemicals and for Sector Orphan Drugs and Scientific Advice.

He has been responsible for the implementation of the European Orphan Drug legislation for the Agency and he has been ICH Co-ordinator for the Agency for several years.

He has been Head of Human Pre-authorisation Unit since 2001 and Head of Human Medicines Development and Evaluation since 2009.

Dr David A. Lepay, U.S. Food and Drug Administration

As Senior Advisor for Clinical Science, Dr Lepay advises on GCP policy and initiatives at FDA, on the coordination of FDA's Bioresearch Monitoring program of GCP inspections for human clinical trials, and on international GCP and human subject protection activities. He joined FDA in 1992 and has held previous position as Director of the Division of Scientific Investigations and Director of Good Clinical Practice Programs.

Dr Virginia Alejandra LLera, GEISER Foundation, EURORDIS member

Psychiatry. Elected President of ICORD (International Conference of Rare Diseases and Orphan Drugs). Founder of GEISER the first non profit patient organization to improve welfare for people living with Rare Diseases in LA&C. Founder of SLADIMER the first Latin American Research Society for Rare Diseases. Co author of laws projects, and advisor for Latin American countries about are diseases field.

Thomas Lönngren, MSc (Pharm), PhD h.c., European Medicines Agency

Dr Thomas Lönngren has been Executive Director of the European Medicines Agency since 1 January 2001.

He qualified as a pharmacist from the Faculty of Pharmacy, University of Uppsala, Sweden, in 1976, and holds an MSc in social and regulatory pharmacy. From 1976 to 1978 he was a lecturer at the University of Uppsala. He also holds a diploma in health economics from the Stockholm School of Economics.

He served with the Swedish National Board of Health and Welfare, Department of Drugs, from 1978 to 1990, with responsibilities for herbal medicines, cosmetics, medical devices, narcotics and contraceptives. From 1982 to 1992, he acted as senior pharmaceutical consultant for the Swedish International Development Agency's health-cooperation programme in Vietnam.

In 1990, he was appointed Director of Operations for pre- and post-authorisation of medicines at the newly formed Swedish Medical Products Agency (MPA, formerly the Pharmaceutical Division of the Swedish National Board of Health and Welfare), of which he later became Deputy Director-General.

He was elected an Honorary Member of the Royal Pharmaceutical Society of Great Britain in 2003, and was made an Honorary Fellow of the Royal College of Physicians in 2004. He was granted an Honorary Doctorate from the University of Uppsala in January 2008, and received the Drug Information Association's Distinguished Career Award in March 2008.

Dr Laurence Lwoff, Council of Europe

Mrs Laurence LWOFF holds a MSc. in reproductive physiology from the University of Paris VI – Jussieu (France) and a PhD in Molecular biology. She joined the Council of Europe in 1991 where she was entrusted with activities related to research. She is currently Head of the Bioethics Division and Secretary of the Steering Committee on Bioethics.

Dr Elizabeth Madichie, PPD

Elizabeth has worked in Regulatory Affairs since 1996 in a number of organisations including SmithKlineBeecham/GlaxoSmithKline, Elan and Taro Pharmaceuticals. Her roles have involved strategic and operational activities across all aspects of drug product development. In PPD, Elizabeth is responsible for leading the Regulatory Affairs function in EMEA & Asia Pacific, delivering international regulatory activities to a broad range of clients.

Elizabeth is currently the PPD representative and 2010 Chair of the Association of Clinical Research Organisations (ACRO) EU Scientific and Regulatory Committee.

Prof Charles Stephen Mgone, European and Developing Countries Clinical Trials Partnership-EDCTP

Professor Charles Mgone is the Executive Director of the European & Developing Countries Clinical Trials Partnership (EDCTP). Prof. Mgone is a paediatrician by training and holds a PhD in Medical and Molecular Genetics. He has worked in Africa, Europe and the Pacific where he has served as advisor at international and national levels. He has considerable experience in research, health research ethics, research administration, capacity development and training, particularly in sexually transmitted infections, HIV/AIDS, malaria and other tropical diseases. Before joining EDCTP, Prof. Mgone was the Network Director of the African Malaria Network Trust (AMANET) responsible for coordinating capacity development and networking in accelerating the development and assessment of malaria vaccines and other interventions. Prior to that he was the Deputy Director of the Papua New Guinea Institute of Medical Research and adjunct professor of Health Research of University of Papua New Guinea, and professor of Paediatrics and Child Health at the University of Dar es salaam, Tanzania.

Ms Isabelle Moulon, European Medicines Agency

Isabelle worked as a clinical endocrinologist in hospital until 1987 and then joined the Directorate of Pharmacy at the French Ministry of Health. She worked for the pharmaceutical industry from 1992 to 1995 before joining the European Medicines Agency (EMA) in July 1995. She was responsible for Scientific Advice until December 2000. She was appointed Head of Sector for Safety and Efficacy of Medicines in January 2001. Since September 2005 she has taken up new responsibilities as Head of Medical Information. She co-chairs the EMA Patients' and Consumers' Working Party (PCWP), which is a permanent forum for the EMA to interact with patients and consumers, ensuring that there is ongoing dialogue on the issues that affect them the most.

Dr Pieter Neels, Clinical Assessor

1985: boarded general practitioner (University of Antwerp)

1986-1994: active general practitioner in Antwerp

1994: responsible for the clinical trials performed in Belgium by the headquarters at Byk Belga (now Altana Pharma, taken over by Nycomed)

1997: senior evaluator at Belgian Ministry of Public Health

2001-2002: CPMP member (now CHMP member, Committee for Human Medicinal Products): Rapporteur (today of more than 15 vaccines). After 5 years: Vice-chair of CHMP Vaccine Working Party.

Co-ordinator for spearhead domain: vaccinology at Belgian Agency.

2010:Member of The Immunization Practices Advisory Committer (IPAC) at the WHO.

Priv Doz Dr Detlef Niese, Novartis Pharma A.G.

Dr.Detlef Niese is a licensed pharmacist and internist and heads External Affairs at Novartis Pharma Development responsible for policy and ethical issues in R&D. Before joining industry in 1992 he headed the department of Clinical Immunology at the Medical School in Bonn Germany

He is member of the Faculty of Medicine of the university of Bonn, and the Executive Board of the Pharma Center, university of Basel.

Dr Clarice Petramale, National Health Surveillance Agency, Brazil

Dr Clarice Petramale is a graduate in medicine, post graduate in infectious diseases and public health.

The last ten years she has worked at ANVISA - National Health Surveillance Agency, linked to Ministry of Health of Brazil. She has developed a well established strategy of post marketing surveillance applied to medicines and health products. Now, during the last year she has been working regulating clinical research in Brazil.

Ms Raffaella Ravinetto, Institute of Tropical Medicine Prince Leopold, Antwerp (Belgium)

Raffaella Ravinetto, pharmacist and holder of a post-graduate diploma in Tropical Medicine, has extensive experience in clinical research, as Clinical Research Scientist in the pharmaceutical industry,

as well as in the context of developing countries (mainly with Médecins Sans Frontières). She's the head of the Clinical Trials Unit at the Antwerp Tropical Medicine Institute.

Dr Ana Rodriguez, European Medicines Agency

Dr Ana Rodriguez qualified in Pharmacy in 1990 and received her PhD in molecular microbiology in 1995 at Universidad Complutense of Madrid (Spain). Her background apart of six years of academic research includes seven years of experience in the pharmaceutical industry in the field of clinical trials until she joined EMEA in September 2003 as Scientific Administrator with responsibilities for the co-ordination of Good Clinical Practice (GCP) and Pharmacovigilance inspections, the secretariat of the GCP Inspectors Working Group and the more recently created Pharmacovigilance Inspectors Working Group and in the development of the European Clinical Trial Database (EudraCT). In September 2009 she was appointed as Head of the clinical and non-clinical compliance section as part of the new reorganization of the European Medicines Agency.

Dr (PhD) Evgeny Rogov, Federal Service on Surveillance in Healthcare and Social Development of Russia (Roszdravnadzor)

2000 – 2009 - Head of Department of Innovation of Russian State Medical University (RSMU)

2001 – 2009 - Secretary and Board member of Ethic Committee of RSMU

2007 – 2010 - Member of Ethic Committee by Federal service on surveillance in healthcare and social development of Russia (Roszdravnadzor)

2009 - present time - Deputy of Head of Clinical Trials Department of Roszdravnadzor

Dr Agnès Saint Raymond, European Medicines Agency

Dr Agnès Saint Raymond is a qualified Paediatrician. She worked in a teaching Hospital in Paris (Necker-Enfants-Malades Hospital), France, as a Chef de Clinique in Paediatrics. After 5 years in various pharmaceutical Companies she joined the French Medicines Agency as Head of a Pharmaco-toxico-clinical Assessment Unit in 1995. In January 2000 she joined the European Medicines Evaluation Agency in London. In the Pre-Authorisation Unit, she was the Head of Sector for Scientific Advice and Orphan Drugs, and in charge of the implementation of the Paediatric Regulation.

She is now Head of the Sector Human Medicines Special Areas, covering Scientific Advice, Orphan Medicines, Paediatric Medicines, Small & Medium Sized Enterprises Office, and Scientific Support & Project, within the Unit for Human Medicines Development & Evaluation.

Dr Patrick Salmon, Irish Medicines Board

After qualifying as a physician and spending several years in clinical medicine, Dr Salmon moved into clinical research and worked for Contract Research Organisations in Ireland and the UK, organising phase 1, 2 and 3 studies. After a short period working with a pharmaceutical company, he joined the Irish regulatory agency in 1994 and has worked there since then, assessing medical aspects of all types of applications.

In the EMA, he has been a CHMP member since 2000 and Irish COMP delegate since December 2004. Other interests include Product Information and he is Chair of the CHMP ad hoc group on the SmPC and the CMD(h) Sub-group on harmonisation of the SmPC.

Irene Schipper, MSc, SOMO – Centre for Research on Multinational Corporations

Irene Schipper, Senior Researcher, working for SOMO since 1993. Corporate accountability, supply chain responsibility, promoting sustainable development and fighting negative consequences of globalisation are key words in her researches. In recent years she published about ethics for drug testing in low and middle income countries and how to protect clinical trial participants in developing countries against unethical practices.

Dr Amit Sengupta, Centre for Technology and Development, New Delhi, India

Trained in medicine and works on issues related to public health, pharmaceutical policy, medical ethics and Intellectual Property Rights. Has lectured and written extensively on these issues, including in journals, newspaper and magazines. Led several research programmes on public policy issues in collaboration with public agencies in India and with international agencies.

Dr (MD, PhD) Gunilla Sjölin-Forsberg, CIOMS

Medical doctor trained in clinical pharmacology and dermatology

Teaching of medical students for several years parallel to research in experimental and clinical skin pharmacology. PhD degree in 1995

Associate attending physician and consultant in dermatology up 1995-2001 at the University Hospital, Uppsala, Sweden,

Regulatory medicine in the late nineties and between 2003 to 2010 Head of Department of Drug Safety at the Medical Products Agency (MPA) in Sweden

Delegate of the Pharmacovigilance working party (PhVWP) at EMA, London 2008-2010 and member of the WHO Advisory Committee on Safety of Medicinal Products since 2005

Position as Secretary General of CIOMS since April 2010.

Ms Lucky S. Slamet, The National Agency of Drug and Narcotics, Psychotropic and Addictive Food Control (NA – DFC), The Rep. of Indonesia

Her responsibility in the NADFC: pre-market evaluation on efficacy, safety and quality of drug and biological as well as their post-market control (i.e: enforcement of GMP, GDP, inspection on production facilities and distribution channel, and Adverse Drug Reaction Monitoring) and Clinical Trial Authorization and GCP Inspection.

Dr Aaron Glyn Sosola, Pharmacy, Medicines and Poisons Board (NRA) of Malawi

Pharmacist as well as Public Health Specialist by Profession; Worked with Central Medical Stores of Malawi from 1997-2005 as Chief Pharmacist; and has worked for Pharmacy, Medicines and Poisons

Board (NRA) as Deputy Chief Executive from 2005-2008 and for the same as Chief Executive from 2008 to date.

Dr (PhD) James A Southern, Medicines Control Council of South Africa

Dr Southern has worked in all aspects of vaccine development, production and control between 1968 and 2000; Currently consultant to the biotechnology industry, advisor to the National Regulatory Agency and temporary evaluator for WHO Prequalification of vaccines; Chair of the Developing Countries Vaccine Regulators' Network.

Fergus Sweeney, PhD, European Medicines Agency

Current Responsibilities

Fergus Sweeney is Head of the Compliance and Inspection Sector at the European Medicines Agency.

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.

Prof (PhD) Cristina E. Torres, Forum for Ethical Review Committees in Asia and the Western Pacific

FERCAP Coordinator, WHO-TDR Clinical Coordination and Training Center, Thailand

Social Science Professor, University of the Philippines Manila and Thammasat University Thailand

Consultant, Philippine Department of Health and National Institutes of Health of the Philippines.

Mr Kin Ping Tsang, Alliance for Patients' Mutual Help Organizations, Hong Kong, China

Mr. Kin Ping Tsang, patient of Retinitis Pigmentosa, has been volunteering in patients' groups in Hong Kong since 1995. He was elected to the Board and Chairman of Alliance for Patients' Mutual Help Organizations (APMHO) in 2003 and 2009respectively. He was elected to Governing Board of IAPO in 2008, and Secretary in 2009.

Dr (PhD) Antonio Ugalde, Salud y Fármacos

Antonio Ugalde received his PhD from Stanford University. He is an Emeritus Professor (University of Texas-Austin) and president of Salud y Fármacos-USA and co-editor of Boletín Fármacos. He has been a consultant for UNDP, WHO, and other international agencies. He has authored more than 100 professional articles and several volumes.

Ms Chao-Yi Wang, Taiwan Food and Drug Administration

Ms Chao-Yi Wang has worked at Taiwan Department of Health for over 10 years and is the section chief of biologics and new biotechnology products currently. She used to be the section chief of Clinical Trial, New Drug Application, and Post Marketing Surveillance before Taiwan Food and Drug Administration inauguration. Taiwan has implemented GCP inspection for more than 10 years; it is a good opportunity for her to share Taiwan experience with all participants in clinical trial review, GCP inspection.

Dr. Colin Wilsher, Pfizer

Colin Wilsher is a member of the Ethics Committee Workgroup of EFGCP (European Forum for Good Clinical Practice).

He qualified as a Chartered Psychologist in the late 1970's and went on to do a PhD in Neuropsychopharmacology at Aston University, UK. For four years he worked for a Belgium pharmaceutical company (UCB Pharma Inc) in the USA, as a Clinical Development Coordinator running Phase III studies across the USA. Following this, for 16, years he went on to work, in the UK, for UCB Pharma Ltd. In 2002 he joined Pfizer clinical audit group and is currently the Regularity Intelligence Lead and an Associate Director in Quality Assurance at Pfizer Medical.

He joined BARQA (British Association for Research Quality Assurance) as a member in 1994 and was made a Fellow of Research Quality Assurance (FRQA). He has been an active member of the GCP Committee for many years and is currently serving his second term as Chairman of the GCP Committee. He is on the editorial board of the Quality Assurance Journal (QAJ) and is a senior correspondent of the CQAdvisor.

Also he holds an honorary faculty position in the School of Psychology at the University of Wales, Bangor, UK.

Mr Peter Walton, GlaxoSmithKline

Peter worked originally as a bench scientist in pathology, initially for the UK NHS and then for Schering, in Agrochemical Research. While at Schering he became an auditor, first in GLP QA then SmithKline Beecham in Clinical QA. Now Director, Clinical Quality Assurance - Europe, Middle East and Africa at GSK.