



REPORT from:

**A Roundtable Event hosted by Dr. Biljana Borzan MEP
at the European Parliament, Brussels**



Tuesday, 15 October 2013

**'The Role of Radiology/Imaging in Personalised Medicine: How
to provide the right prevention and treatment to the right
patient at the right time?'**

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1. The importance of imaging for the development of personalised medicine

State of play and current challenges

The European Society of Radiology (ESR) and the European Alliance for Personalised Medicine (EAPM) firmly believe that medical imaging is one of the main drivers for the development of personalised medicine. Imaging has always been 'personalised', since it assesses the location and severity of an abnormality in an individual, and it provides several phenotyping biomarkers (morphological, biological, functional, metabolic) in a person-centred approach. It also supports rationalising research processes in healthcare industries, for instance through clinical trials design, it is an essential tool for guiding tissue sampling and target therapy, and imaging facilities are widely accessible throughout the European Union.

Even though in the past imaging was often omitted from personalised medicine, a concept developed with a focus on 'omics', the ESR and the EAPM are convinced that it should be regarded as an integral part in the development of personalised medicine. This point was echoed by ESR President Prof. Guy Frija, when he explained that one of the aims of the roundtable was to convince non-doctors of the importance of imaging, especially since it should be considered on a par with 'omics' given its role in patient profiling and preventive and predictive medicine.

According to MEPs Dr. Biljana Borzan (host), Prof. Maria Da Graça Carvalho (one of the Rapporteurs of Horizon 2020) and Petru Luhan, imaging and its crucial role for the development of personalised medicine is often undervalued by policy makers but clearly marks a new era for a more patient-centred and therefore cost-effective approach.

Dr. Borzan even went as far as to say that personalised medicine was the fourth big step in radiology, after the discovery of x-rays, the development of CT and the introduction of ultrasound and MRI.



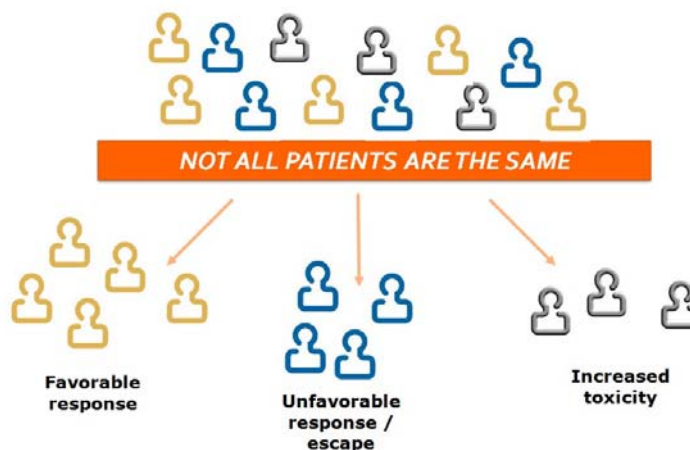
ESR President Prof. Guy Frija and Croatian MEP Dr. Biljana Borzan hosted the event. (Picture kindly provided by AuntMinnie.com)

From the institutional side, Tapani Piha of the European Commission (EC) informed that the Directorate-General for Health & Consumers (DG Sanco) is already addressing personalised medicine, as it was in the process of finalising a working paper on personalised medicine that has been in the pipeline for one year.

Imaging biomarkers – essential in the detection and treatment of disease as well as drug development

Imaging already plays an important part in every stage of cancer treatment, according to ESR expert Dr. Laure Fournier. Besides screening, detection, and staging of disease, imaging is used to predict and evaluate individual patient’s responsiveness to therapies in every stage of cancer treatment. This crucial role for imaging biomarkers in cancer treatment is reflected in the fact that, already, more than 90 percent of cancer patients are evaluated by imaging. This means that without imaging, personalised treatment of cancer and other diseases is impossible.

Personalising patient therapy



Graphic kindly provided by Dr. L. Fournier, ESR Expert

How can imaging biomarkers, which are essential for assessment of individual risk in healthy people and in patients, be developed? Population imaging is one of the solutions presented by Prof. Aad van der Lugt, Chairperson of the ESR Working Group on personalised medicine. Through the large-scale acquisition and analysis of medical images in controlled population cohorts, radiologists are able to evaluate

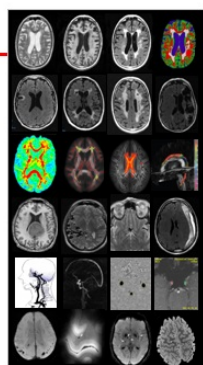
Population Imaging

for disease prediction and prevention



Determinants

- Genetic
- Environmental
- Life-style
- Smoking
- Alcohol
- Diabetes
- Hypertension
-



Outcomes

- Cognitive decline
- Dementia
- Stroke
- Myocardial infarction
- Osteoarthritis

imaging biomarkers by linking determinants to imaging biomarkers and imaging biomarkers to health outcomes, thereby enabling the prediction and prevention of diseases. This raises the issues of standardisation, validation and quality assurance of imaging biomarkers, which are important aspects for their development in a technically valid, robust and reproducible way. Their acquisition must be standardised and quality controlled regardless of the technique used. Some

Population Imaging: large-scale acquisition and analysis of medical images in controlled population cohorts → Imaging Biomarkers

Image kindly provided by Prof. Aad van der Lugt, Chairperson of the ESR Working Group on Personalised Medicine

quantitative imaging biomarkers are currently being developed and proposed for clinical application, but their reproducibility has not yet been well established. Regulatory issues related to imaging biomarkers also need to be clarified.

Therefore, the involvement of academia, industry and regulators is considered essential in tackling these challenges. The required technical tasks are very specific to imaging and would involve a dedicated imaging industry, active and well represented in Europe.

Imaging biobanks to complement 'omics' databases

What is needed are investments in establishing and expanding imaging biobanks that are then referenced with existing 'omics'-biobanks. A further challenge in this regard is the standardisation of imaging biomarkers.

The ESR and the EAPM have criticised that imaging data is currently not included in the landscape of European biobanks, despite an urgent need to do so. Imaging biobanks should be developed and integrated into other biobanks to facilitate exchange of information and data to improve individualised treatments. The ESR and EAPM therefore support the establishment of a European programme to develop an imaging biobank network, as imaging biobanks have very specific requirements due to the type and amount of data to be handled.

Radiogenomics – a promising field

The development and integration of imaging biobanks is an important condition for progress in the promising field of radiogenomics, which involves the correlation of radiological information to genomic data. The establishment of a European programme on radiogenomics as an integrated approach under the auspices of several Directorates-General of the European Commission is something that ESR and EAPM strongly encourage.

Needs

- Development and validation of imaging biomarkers
- Standardisation and quality assurance of imaging biomarkers
- Standardisation of image data acquisition and analysis
- Integration of imaging in current biobank initiatives
- Developing and integrating imaging biobanks
- Clarification of regulatory issues related to imaging biomarkers
- Fostering radiogenomics research

2. Collaboration with industry

Importance of public-private partnerships

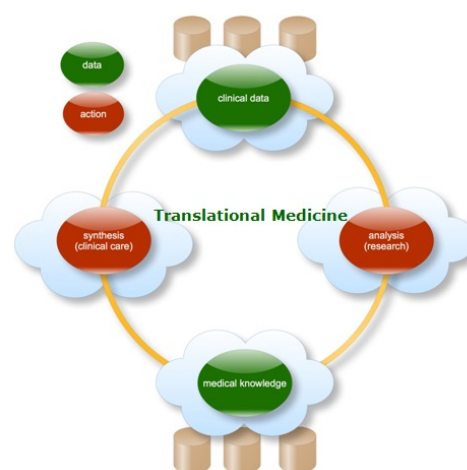
The roundtable discussion's motto 'the right treatment for the right patient at the right time' is only possible if the key enablers such as recognised international standards, common strategies and appropriate funding regimes are put in place to facilitate research and development in PM.

A holistic multi-stakeholder collaboration between large industry, SMEs, regulatory bodies and academia is essential and therefore the support of public-private partnerships (PPPs) needs to be considered under Horizon 2020.

This view was corroborated by the industry representatives in the roundtable discussion. Magda Chlebus, representing the pharmaceutical industry (EFPIA), emphasised that the challenge the health sector is facing cannot be solved by any one stakeholder alone; what is required is multidisciplinary and multi-sector collaboration. For the realisation of personalised medicine, Ms. Chlebus argued that it is necessary to translate scientific discoveries into regulatory and medicinal practice. For this, adequate EU instruments are required that facilitate and foster public-private partnerships as networks where all stakeholders can work together. One such instrument is the Innovative Medicines Initiative (IMI), where cooperation between the imaging and pharmaceuticals sectors has brought great results. Currently, consultations on the strategic research agenda for the successor programme IMI 2 are open, for which Ms. Chlebus invited input for radiology research to be submitted.

Imaging industry representative Nicole Denjoy (COCIR) highlighted the importance of innovation in the medical devices sector in three dimensions: diagnostics, biotech & genomics and IT & bioengineering. COCIR favours a combined approach for achieving personalised medicine, which could improve efficiency of current treatments. COCIR also called for funding mechanisms for medical imaging and health ICT to be simplified in order to promote innovative healthcare and to translate innovation into clinical practice.

Connecting clinical care and medical research



Graphic kindly provided by COCIR

Needs

- More research collaboration between industry and academia
- More research collaboration between pharmaceutical and diagnostic manufacturers
- A robust framework of PPPs to satisfy commercial concerns on data-sharing that makes possible broad exploitation of results in general research and regulatory practice while satisfying the interests of all parties.

3. Patient involvement and empowerment

Patient involvement is vital for successfully developing personalised medicine

Since personalised medicine implies improving the quality of care each individual patient receives, it is very important to recognise patients as full partners in the development of personalised medicine – after all, they benefit most from more personalised healthcare services. Beyond the fact that patients are directly affected by medical



Picture kindly provided by the European Parliament

treatments, they are also key stakeholders in issues pertaining to clinical trials, where ethical standards need to be considered, or the availability of data for research.

The ESR and EAPM call for patients to be included along the entire innovation chain and for their interests in terms of data protection, requirements for informed consent for clinical trials and the quality of treatments to be respected in all facets of personalised medicine.

A multi-professional approach with the interests of the patient at the core was called for by patient representative Dr. Erik Briers of Europa Uomo – the European Prostate Cancer Coalition. He also defined what the primary interests of patients are: not only survival, but living longer with a high quality of life. This can be achieved by providing better information to patients and increased funding of research in this field. As patients have the biggest stake in personalised medicine, he called on all stakeholders to ensure the involvement of patient representatives in all relevant committees and discussions.

Needs

- Patient education, empowerment and involvement in both research and policy making
- Increased research funding to the benefit of Europe's patients
- Respecting patients' rights as regards privacy of personal data including their right to allow use of their personal data in the interest of medical research even after their death

4. Regulatory and legislative challenges

All stakeholders agreed that a regulatory framework addressing the challenge of balancing patient safety and facilitating research and innovation is needed and called on the policy makers to establish a regulatory framework that considers in particular the following issues.

4.1 Market access for imaging biomarkers

It is considered important to incorporate imaging biomarkers in the drug and device approval processes. Imaging biomarkers could be used to select patients for clinical trials or to evaluate the effect of drugs in clinical trials (surrogate endpoints). However, at this stage, the regulatory processes for qualification of imaging biomarkers are very complex.

4.2 Clinical trials

Using imaging biomarkers to streamline drug discovery represents a huge advancement in healthcare. Imaging biomarkers play a key role in particular in new drug development, as advancements in quantitative medical imaging have offered the opportunity of using imaging biomarkers as surrogate endpoints which speeds up the evaluation of new drugs.

However, there are several bottlenecks that currently prevent imaging from unfolding its full potential in the contribution to PM.

Imaging biomarkers have to be clinically validated. This implies access to large cohorts, which is very difficult to be achieved in stand-alone imaging studies. Thus, the use of imaging biomarkers in clinical trials and during drug assessment studies would be very helpful in the development of the validation step of imaging biomarkers. Awareness should be raised among clinical scientists dealing with large cohorts as well as among regulators. Although not limited to imaging biomarkers, this critical step requires also specific consideration, as established protocols could be modified accordingly.

4.3 Data management, standardisation, access and protection

Medical imaging is crucial not only as a final tool in diagnosis but also as a tool that can provide biomarkers for early prediction of disease and personalised medicine. Besides structural information from organs to the cellular-molecular level, imaging can also provide physiological information. Progress in image analysis has resulted in quantitative imaging biomarkers.

The availability of open, high-quality and large scale imaging biobanks and processing facilities in terms of data, services and resources will radically simplify access to knowledge, improve interoperability and standardisation of image data acquisition and analysis, and will even help consolidate the medical imaging research community and foster multi-disciplinary collaboration at the European level.

It is essential to strike a balance between ensuring unimpeded medical and scientific network collaboration while maintaining a high level of information security in order to ensure scientific advances and competitiveness in the research arena in Europe.

In the future, biomedical imaging will become one of the major data producers, and people working in this area will have to face the burden of data management and analysis within shared imaging biobanks. There is a clear need to develop harmonised software throughout Europe to send and exchange imaging data and related information to facilitate research and synergies.

In the era of big data, adequate rules are required to balance the needs of researchers, who need access to data for innovations, with patients' right to privacy. The ESR and EAPM call for robust data protection rules that also ensure access to data for the purposes of innovative scientific research.

Needs

- A more effective clinical trials regime considering imaging biomarkers in clinical trials and drug approval processes whenever possible
- New solutions to collecting, integrating and analysing imaging data
- Standardisation and quality assurance of imaging data
- A harmonised EU regulatory framework on data protection balancing patient safety with access to innovation

5. Funding for imaging research

Needs and perspectives for Horizon 2020 and IMI2

Participants of the roundtable discussion agreed that policy makers need to ensure adequate framework conditions in order to facilitate the effective collaboration of all relevant stakeholders. An important aspect of such a framework are the programmes through which funding is made available for scientific research.

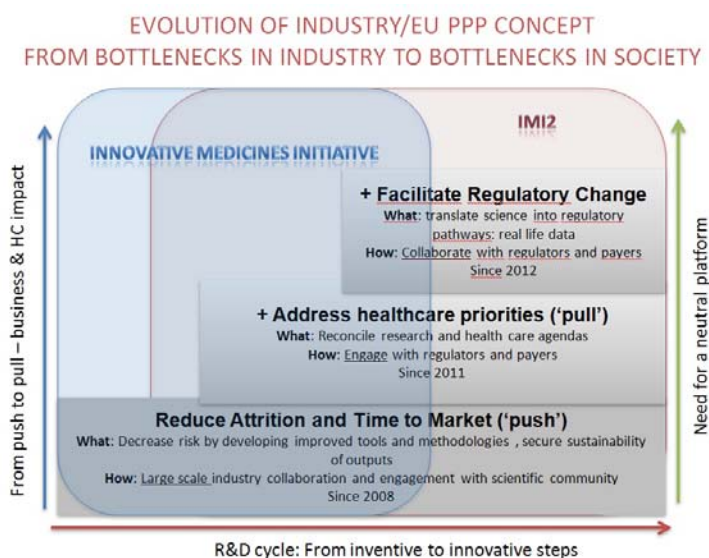
Horizon 2020 is an evolutionary step in the EU's research efforts, as it combines various programmes under one roof. What is important in this respect is that this consolidation leads to genuine interdisciplinarity in innovative research. The sheer complexity of contemporary issues in medicine and medical technology means that coordinating the research conducted in a variety of disciplines is necessary to achieve practical outcomes and sustainable solutions. Working towards this end is at the very core of the EAPM's agenda, as it seeks to channel research towards personalised medicine through an alliance of different stakeholders.

The ESR and the EAPM therefore support the inclusion of imaging as an integral part of many of the research priorities in Horizon 2020. Prof. Aad van der Lugt, Chairperson of the ESR Working Group on personalised medicine, has already identified a number of planned activities within the Health, Demographic Change and Wellbeing section of Horizon 2020 where imaging and personalised medicine can play an important role.

By fostering collaboration between the public and private sectors, IMI2 provides a successful model for bringing together a variety of stakeholders for the purpose of translating scientific research into marketable outcomes and finding the right balance between safety, efficacy and effectiveness.

EFPIA invited ESR and EAPM members to submit proposals of projects and programmes which would support both, the imaging sector objectives and those of the Strategic Research Agenda for IMI2.

The EAPM and the ESR welcome the fact that decision makers in the EU institutions have acknowledged the importance of their role in ensuring conducive framework conditions for research in Europe.



Graphic kindly provided by EFPIA

MEP Maria da Graça Carvalho, one of the Horizon 2020 rapporteurs, emphasised that the EP had fought hard to ensure adequate funding for research within the next multiannual financial framework (MFF) 2014-2020. Despite an overall decrease in the EU budget, Horizon 2020 will have a higher monetary allocation than the 7th Framework Programme (FP7). MEP Petru Luhan added that at the European level, there was more interest in health than any other topic, particularly from an economic perspective. He highlighted the importance of increasing the effectiveness in bringing research results to bear in the marketplace, which is an important aspect of achieving intelligent growth. Stakeholders should work together to improve the translation of scientific research into tangible outcomes and products.

DG Sanco's Tapani Piha, who also spoke on behalf of DG Research, explained that the EU was focused on the opportunities that personalised medicine offers as a patient-centred, sustainable approach. According to Piha, the EU is already the largest funding source for collaborative medical research, citing a figure of €1 billion for personalised medicine in the widest sense within the 7th Framework Programme, of which 40 projects worth some €200 million are still ongoing. Compared to FP7, Piha declared that Horizon 2020 would have less red tape and describe challenges for researchers to tackle instead of prescribing what should be researched, meaning that Horizon 2020 funding calls would differ considerably.

Needs

- Ensure interdisciplinarity in research activities
- Adequate funding levels for research related to personalised medicine
- European institutions and funding bodies to recognise the importance of imaging in the development of personalised medicine

6. Conclusions

The first and foremost conclusion to be drawn from the roundtable discussion is that imaging must be recognised as an integral part of personalised medicine.

A joint effort of academia, industry and regulators is needed to boost at the European level the development and use of qualified imaging biomarkers to support diagnosis, treatment assessment and medicine development. Moreover,

research and education about the development, standardisation, validation and qualification of imaging biomarkers are needed at the European level in order to allow new promising fields in this area to fully develop their potential and to find their way into clinical practice. Harmonisation with other medical device regulations would be beneficial, however, attention needs to be paid to the fact that medical imaging requires very specific technological and organisational approaches and involves an important Europe-based industry network.



Picture kindly provided by the European Parliament

ESR President Prof. Guy Frija defined two takeaways from the roundtable discussion: first, he re-emphasised that a joint effort was required to drive forward personalised medicine. And, second, that a “Google of health data” was needed which should encompass all biobanks and ensure that everybody speaks the same language and operates within the same taxonomy. This would reinforce the commonality of the efforts undertaken by the various stakeholders involved.

Europe needs

- Wider recognition for medical imaging and its role in personalised medicine
- Focused, transparent development pathways for imaging biomarkers in a framework of clear, harmonised rules applied across the European Union
- Standardisation of imaging biomarkers
- Increase of imaging in cohort studies, which are integrated in imaging biobanks
- Investments in establishing and expanding biobanks, and interoperability between ‘omics’ biobanks and imaging databases

- Greater incentives and allocation of time and resources to developing diagnostics, and coordination of reimbursement for medicines and companion diagnostics
- Closer research collaboration between industry and academia, and between pharmaceutical and diagnostic manufacturers
- A clinical trials regime that can allow for late-stage biomarker research, such as with adaptations of informed consent to allow re-use of samples
- A harmonised EU regulatory framework balancing patient safety with access to innovation
- Patient education and involvement

7. Annex

7.1 About ESR

The European Society of Radiology (ESR) is an apolitical, non-profit organisation, dedicated to promoting and coordinating the scientific, philanthropic, intellectual and professional activities of Radiology in all European countries. The Society's mission at all times is to serve the health care needs of the general public through the support of science, teaching and research and the quality of service in the field of radiology.

The ESR is the European body representing the radiology profession with over 58,000 individual members and acts as the umbrella organisation of all national radiological societies in Europe as well as Europe's subspecialty organisations in the field of radiology.

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7.2 About EAPM

EAPM brings together a range of stakeholders from distinct sectors. They are groups or organisations that can contribute to the actions or aims of the Alliance, and include representatives of patients, medical and healthcare professionals, healthcare planners, industry, and the scientific community. The principle of operation is 'working together in partnership'. Its principal policy-setting body is the Alliance Committee, composed of the heads of member organisations.

This is assisted by an Advisory Committee, which includes five major stakeholders, and which provides advice to the EAPM Office. The EAPM Office provides operational leadership in coordination, communication, financial management, and work planning. EAPM is co-chaired by David Byrne, former EU Commissioner for Health, and Prof. Helmut Brand, president European Health Forum Gastein.

EAPM works in full transparency with funding partners, and remains independent. These partners provide unrestricted sustainable funding to contribute to EAPM's operations. At the same time, open dialogue and exchange continually takes place between EAPM and these partners, without compromising either party.

All financial information relating to EAPM is available.

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7.3 Speakers Biographies



Biljana Borzan, MEP

Biljana Borzan obtained her degree at Osijek Medical Studies, University of Zagreb School of Medicine. She specialised in Occupational and Sports Medicine. Since 1997, she has been working as Doctor of Medicine at the Osijek Community Health Centre. She has been a Member of the Croatian Parliament for two terms. From 2011-2013 she was president of the Health and Social Policy Committee in the Croatian Parliament. She was Deputy Mayor of her home town Osijek. After the Croatian accession to the EU, she became a Member of the European Parliament, Committee on Environment, Public Health and Food Safety.



Helmut Brand, EAPM Co-Chair and President of the European Health Forum Gastein (EHFG)

Helmut Brand is Jean Monnet Professor of European Public Health and head of the Department of International Health at Maastricht University, The Netherlands. He studied Medicine in Düsseldorf and Zürich and earned a Master in Community Medicine from London School of Hygiene and Tropical Medicine and London School of Economics. Prof. Brand is a specialist in Public Health Medicine.

After working in several Health Authorities and Ministries of Health in Germany he was director of the Public Health Institute of North Rhine Westphalia. Since then European Integration in Health is the main topic of his work. He is president of the Association of Schools of Public Health in the European region (ASPHER) and president of the European Health Forum Gastein (EHFG). As policy advisor he serves on the European Advisory Committee on Health Research (EACHR) of WHO Europe and on the Expert Panel on "Investing in Health" for the European Commission.



Erik Briers, Secretary of Europa Uomo

Erik A.M. Briers is secretary of EUROPA UOMO, a non-profit association also known as The European Prostate Cancer Coalition and CEO of Beta Ventures.

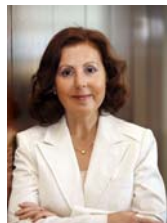
Doctor Briers holds a doctorate in Chemistry from the University of Leuven, Belgium. Since his promotion in 1979 he has been involved in laboratory medicine. After teaching chemistry and physics, Briers served from 1979 until 1980 as the Head of the department for biochemistry, new technologies and quality assurance at the Central Clinical Laboratory in Antwerp, Belgium.

Following his job as the Head of scientific services bioMérieux in the Benelux, managing its scientific affairs from 1980 until 1982, Briers spent his next eight years as the founder and CEO of the diagnostic company Eco-Bio diagnostics.

Since 1990 Briers is CEO of Beta Ventures, a company founded by him to serve the medical devices industry as a consultant and publisher of specialised media. At the same time he is chief editor and founder of the magazine "Focus Diagnostica", which is specialised in laboratory medicine. Besides, Briers has been a guest lecturer for the subject "Applied immunology" within the Master study programme Biochemical Engineering at Leuven University College since 2009.

Doctor Briers strong social involvement within patient organisations began after his own prostate cancer diagnosis in 2011 and successful radical prostatectomy treatment with no signs of recurrences.

He joined the Belgian patient support group "Us Too Belgium" and acted as representative of this group as one of the founders of the European umbrella organisation EUROPA UOMO. Today he is the Secretary of EUROPA UOMO and board member of "Us Too Belgium". For this organisation he is also the editor of the magazine "PROSTAAInfo". Before he became secretary of EUROPA UOMO, he was the Executive Director of the European Cancer Patient Coalition organisation (ECPC).



Maria Da Graça Carvalho, MEP

Maria da Graça Carvalho is a member of the European Parliament in the PPE group since 14 July 2009 (member of the ITRE-Industry, Research and Energy Committee, substitute member of the Budgets Committee and member of the ACP-UE Joint Parliamentary Assembly). She was elected co- President of the Economic Development, Finance and Trade Committee of ACP-UE Joint Parliamentary Assembly. She has been Principal Adviser of President Barroso in the areas of Science, Higher Education, Innovation, Research Policy, Energy, Environment and Climate Change from 2006 to 2009.

She is a Full Professor at Instituto Superior Técnico (Technical University of Lisbon) and she has a 30 years research experience in the areas of energy, environment and climate change. In 1983 she obtained her Ph.D. at the Imperial College in London in the area of energy intensive industries. She was the founder of a research group of 50 people at Instituto Superior Técnico (Technical University of Lisbon) in the Energy, Environment and Climate Change fields.

She has been Minister of Science and Higher Education of the XV Constitutional Government of Portugal and Minister of Science, Innovation and Higher Education of the XVI Constitutional Government, Director-General of GRICES-Office for International Relations in Science and Higher Education and Deputy President of the Portuguese Association of Engineers. She has been member of the Board of Directors and President of the Scientific Board of Instituto Superior Técnico (Technical University of Lisbon). She is a member of 22 national and international scientific associations and fellow of AIAA-American Institute of Aeronautics and Astronautics, of AAAS-American Association for the Advancement of Science, of the WAAS – World Academy of Art and Science and of the Portuguese Academy of Science.

She published 115 articles in international scientific journals and more than 300 articles in international books and proceedings of conferences. She is author of 2 books and editor of 14 books and special editions of international scientific journals. Her main area of research is Energy, Climate Change and optimization of energy intensive industries. She was decorated by the President of Portugal with the designation "Great Official of the Order of Public Instruction" within the scope of International Women Day Programme (8 March 2002) and by the Chancellery of the International Order of Merit of the Discoverer of Brazil with the high honour of the Great Cross (26 April 2005).



Magda Chlebus, Director of Science Policy of the European Federation of Pharmaceutical Industries and Associations (EFPIA)

Magda Chlebus, Director of Science Policy at the European Federation of Pharmaceutical Industries and Associations, is in charge of policy and legislative debates which shape the research environment in Europe. This includes public-private collaborations (including the Innovative Medicines Initiative) and enabling and sensitive technologies. She joined EFPIA in 1995.

Her experience covers public and government affairs, including designing and implementing advocacy campaigns on EU legislation and policies, as well as implementation of pharmaceutical legislation in new Member States.



Nicole Denjoy, Secretary General of the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)

Nicole Denjoy is the COCIR Secretary General since Oct. 2005:

Leading the COCIR Office in Brussels and COCIR Office in China, raising COCIR profile in EU and internationally, building high level relationships with key stakeholders including decision-makers with COCIR members as well as with the European institutions and other regulatory bodies inside and outside Europe (includes USA, Japan, Canada and China),

Articulating strategies on specific activities with COCIR members on economic, regulatory, technical, business aspects as well as promoting active contribution of COCIR in the sustainability of healthcare systems.

Nicole's overall experience is:

27 years experience in the field of Regulatory Affairs, Vigilance and Quality Assurance working with known international healthcare industries, including L'air Liquide, Ohmeda, Boston Scientific and Baxter.

17 years experience in International & European Standardization.

Nicole has a Master in Organisation and Change Management.

Nicole is representing COCIR in a variety of influential fora such as the Health Policy Forum, European Partnership Against Cancer, EUnetHTA Industry Stakeholder Forum, coordinated by DG Sanco. Nicole is also representing industry stakeholder group in eHealth activities such as i2010 sub-group and is actively participating in Joint Action on Governance on eHealth under close relationship with DG INFSO and DG Sanco.

Nicole since 2008 is representing COCIR, as one of the European Healthcare Industry Organisation in Global Harmonization Task Force (GHTF) Steering Committee and became the Standards Rapporteur in May 2010.

Nicole became as of May 2010 the chair of the BIAC Task Force on Health Care Policy representing the business branch in front of the OECD Health Committee.



Laure Fournier, Member of the ESR Working Group on Personalised Medicine

Laure Fournier works as an Associate Professor at the Hôpital Européen Georges Pompidou, in Paris, France. Her time is divided between clinical work, specialising in urological and gynaecological cancers, and imaging research in the Laboratoire de Recherche en Imagerie (INSERM U970).

She is pursuing work on techniques of functional computed tomography (CT) and magnetic resonance imaging (MRI) in patients, to extract quantitative parameters from images reflecting tumour physiology and biology. Her main field of interest is defining response to therapy, in particular for targeted therapies which require development of new response criteria.



Guy Frija, President of the European Society of Radiology (ESR)

Prof. Guy Frija is currently Head of the Imaging Department at Hôpital Européen Georges Pompidou. Opened in 2000, H.E.G.P. is the most advanced hospital in France in the field of IT. The Imaging Department has 5 professors, 2 assistant professors, 5 fellows, 10 full time consultants and 14 residents. Its structure is organ-based with oriented activities in oncology, cardiac and emergency imaging.

His professional orientations are in chest imaging, contrast agents and IT. He has also developed clinical and fundamental research within these areas presented in several relevant publications.

During the past fifteen years, he served in various positions in national and international societies, such as:

- Chairman of the SFR for 12 years
- General Secretary of EAR and then elected as member of the Executive Council of ESR (2007)
- President of the International Society for Strategic Studies in Radiology (2007)
- President of the European Society of Radiology (2013-2014)



Petru Luhan, MEP

Petru Luhan is Romanian Member of the European Parliament. He earned a bachelor's degree from the Institute of Economic Studies Osnabrück from Germany and an MBA degree in International Economics and Global Management and Finance at the same university.

His professional experience began as Finance controller at the Continental Automotive Systems in Frankfurt a.M., which led to other managerial positions in big companies in Romania. Before he became MEP, he was the public administrator of Duceava county, Romania. He won the MEP of the Year award in 2013.



Ciarán Nicholl, Head of Unit Public Health Policy Support (JRC)

Ciarán Nicholl is Head of the newly created Public Health Policy Support unit in the Joint Research Centre's Institute for Health and Consumer Protection (JRC-IHCP). His background is scientific research in public health and he completed his MSc at Kings College Hospital (England) and his PhD in skin cancer research at Heidelberg University (Germany).

The JRC is the European Commission's in-house science service and it provides independent scientific and technical support to EU policies. Ciarán is convinced that the JRC, with over 55 years experience in standardisation and harmonisation, will play a pivotal role in improving health information in the EU. Harmonised, high-quality health information is the key to improving policy interventions to enhance health care in the EU. The areas which the JRC's new unit is addressing include health information (cancer and rare diseases), cancer care quality, nutrition, behavioural sciences and medical devices.



Tapani Piha, Head of Unit e-Health and Health Technology Assessment (DG SANCO)

Tapani Piha works as Head of Unit in the European Commission since 2004. First he managed the Health Law and International Unit, then the Human Resources Unit from 2009, and moved to the eHealth & Health Technology Assessment Unit in

September 2012. The Unit works on expert advice for EU health systems, on health research and nano policies, Health Technology Assessment, eHealth and data protection issues.

A physician and specialist in community medicine and public health by training, he started his career in epidemiological and intervention research on health behaviours and cardiovascular disease. He held positions at the Finnish Ministry of Health working on health promotion and tobacco control. He coordinated Finland's EU policies in health in 1995-2001, based first in Helsinki and later in Brussels.

He joined the WHO Regional Office for Europe, in Copenhagen, for 5 years in 1989-1994 and was responsible for the Action Plan for a Tobacco-free Europe.

He is particularly interested in European integration as a unique process; the impact and effectiveness of health and other interventions; health and economy. His interest in information and communication technologies started in the 1970s.



Aad van der Lugt, Chairman of the ESR Working Group on Personalised Medicine

Aad van der Lugt is a professor of Neuroradiology and Head/Neck Radiology at the Erasmus MC in Rotterdam. He is responsible for the neuroradiological research programme, which is focused on neurovascular, neurodegenerative and neuro-oncological diseases. His own research focuses on vascular imaging (CTA/MRA) with emphasis on the visualisation of atherosclerotic disease in the carotid artery with ultrasound, CT and MRI. The main goal is to find imaging parameters, which are related to increased risk of ischemic stroke.

More recently, he expanded his interest to imaging biomarkers in large population-based studies. He was responsible for the imaging infrastructure in the "Rotterdam Study", a prospective population based cohort study aimed at investigating determinants of chronic and disabling diseases in the elderly. Both neurovascular and neurodegenerative disorders are key topics in this study.

He is director of the Hands-On teaching program of the European Society of Magnetic Resonance in Medicine and Biology (ESMRMB) and as such Board Member of the ESMRMB.

He is member of the research committee of the European Society of Radiology (ESR) and chairman of the ESR Working Group on Personalised Medicine.