THE GOVERNMENT
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Ministry of Health

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High-level Conference

"Making Access to Personalised Medicine a Reality for Patients"

8 July 2015

Luxembourg, Cercle Cité

Conference report

GRAND DUCHY OF
Presidency of the Council of the European Union . luxembourg

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Foreword by Lydia Mutsch, Minister of Health, Luxembourg

I would like to first extend a warm thank you to the chairs, the panelists, the moderator and, of course, the audience who all this Conference an enriching and mind-opening experience. Let me also thank all of you who have expressed their gratitude to the Luxembourg Presidency for having chosen Personalised Medicine and the Patient as political priority.

This event was unique in that it gave patients, decision makers, regulators and various stakeholder associations the opportunity to address the issue of the integration of Personalised Medicine into clinical practice from a public health perspective. Synergies between the different sessions were numerous and showed that there is common ground of understanding on many issues.

I believe that the Conference lived up to its primary aim of inspiring future policy making while placing the patient at the center of discussions, in full adequacy with the general theme of the Luxembourg Presidency “A Union for Citizens”.

The first session, dedicated to the patients’ voice, set the tone: it is urgent to act and patients should be an integral part of this action because they can help taking things forward! There has been wide agreement among all the participants to say that putting Personalised Medicine high on the healthcare agenda is timely and necessary and that this agenda needs to be implemented by all the actors concerned. Personalised Medicine calls for a cross-sectoral approach.

We learned what possible ways there are to overcome obstacles while hearing about good practices and how best to implement them to bring Personalised Medicine closer to our patients, be it on the basis of existing tools or on the grounds of new and innovative methods. The discussions of various concrete examples already implemented with success in some Member States allowed us to take discussions beyond abstract reflections.

Moreover, I was delighted to hear the Commissioner Dr. Vytenis Andriukaitis himself and the various speakers from the Commission make clear statements concerning their willingness to drive the issue of access to Personalised Medicine forward.

Participants recognised the political momentum that has been created by the Conference.

It is now up to all of us to make things happen.

Many thanks again to all

Sincerely

Lydia Mutsch

Executive summary

Only a few years ago, Personalised Medicine was not well known or only partially understood by public health decision makers. This is changing slowly but surely, with various initiatives and organisations putting Personalised Medicine higher up the political agenda – as has this Conference attended by a wide variety of Member States' representatives, stakeholders and experts covering virtually every aspect of today's medical disciplines.

Personalised medicine, while exciting and with the potential to maintain and improve the quality of life for the EU's citizens, is currently not properly integrated into clinical practice, although it has gained considerable ground during the past decade, particularly in cancer treatment.

Discussions have shown that there is clearly a need for a specific EU agenda driving forward the access of EU citizens to Personalised Medicine.

Participants agreed that many obstacles exist to integrating Personalised Medicine into day-to-day healthcare, but good practices in several Member States have shown that these hurdles can be overcome.

All the sessions shared one common conclusion: a patient-centered approach ensuring involvement of patients right through the translational chain is a key element, just as is enhanced cooperation and collaboration between disciplines, between Member States as well as between the national and the EU level.

Traditional ways of thinking will no longer suffice. Decision makers need to show significant determination to move on and explore innovative options based on cross-sectoral approaches, leaving silo thinking behind.

Many of the decisions ahead will not be easy, but for the benefit of all Europe's patients, now and in the future, they must be taken soon.

Full Proceedings

Welcome session

Lydia Mutsch, Minister of Health, Luxembourg "A patient-centered concept of innovation tailored to specific individual needs"

Health Minister Lydia Mutsch stressed: "*Personalised Medicine is all about the patient and innovation. Personalised Medicine starts with the patient. It features big potential for improving the health of many patients and ensuring better outcomes of health systems' efficiency and transparency. The focus of today's discussions will be on the public health dimension of Personalised Medicine and on the patient*."

Moreover, in times of budgetary constraints, facilitating better-targeted and more cost-efficient treatment - to a potential 500 million patients in 28 EU Member States - is in line with the Europe 2020 Strategy and the aims of the Juncker Commission.

"*The challenge to be addressed is to put into place a framework which allows to deliver the right treatment to the right patient at the right moment, in accordance with the principle of universal access to high quality healthcare*" said Lydia Mutsch. Yet, its integration into clinical practice

and daily care is proving difficult given the many barriers and challenges to timely access to targeted healthcare that still exist as of today.

The Luxembourg Presidency has made Personalised Medicine one of its health policy priorities. By taking stock of where we are in Europe in terms of access to Personalised Medicine and by highlighting opportunities to accelerate progress, the scene for further action can be set.

Vytenis Andriukaitis, Commissioner in charge of Public Health and Food Safety: "The right balance needs to be struck."

For Commissioner Dr. Vytenis Andriukaitis, Personalised Medicine holds the potential to offer more effective and safer treatments for patients, with better outcomes raising many hopes. However it also creates many challenges.

« *Personalisation will change prevention programmes for obesity or cancer and other complex chronic conditions – we need to find out how*", stressed Andriukaitis. Cooperation between Member States is crucial in order to make access to Personalised Medicine a reality for patients. Personalised Medicine raises several questions: "*Are we able to show that the costs of 'personalised medicine' could be compensated by efficiency gains?" "How will we create adequate mechanisms to maintain solidarity based health protection systems in the EU*?"

According to the Commissioner, answers can be found in different activities on which the Commission is working or will work in a near future, such as for instance the Joint Action on Cancer Control, the incentives provided for under the EU pharmaceutical legislation, cooperation under the European Network on Health Technology Assessment, the work on patient access to innovative medicines by the Expert Group on Safe and Timely Access to Medicines for Patients and, last but not least, the forthcoming revision of the legislation on in vitro diagnostics.

Most importantly, it will be important to "*ensure equitable access to high-quality medicines keeping expenditures within budget; provide space for innovation and long-term investment in innovative medicines; and ensure sustainability and pricing*."

Maggie de Block, Minister of Health, Belgium: "Personalised Medicine: Panacea or Pandora's box?"

The Health Minister of Belgium, Dr. Maggie de Block, underlined that fostering access to Personalised Medicine is not only a challenge for scientists and innovators but also a call for action addressed to creative policymakers. It is not just about treatment, it is also about predictions and prevention.

«*For some people these evolutions are a panacea, for others they look like Pandora's box.*" In Belgium an action plan has been elaborated, together with all stakeholders involved. One of its commitments is to set up a national focal point on Personalised Medicine, fostering and

coordinating the actions by the Belgian public authorities in close collaboration with the research community and private companies. "*It is obvious that this can only be successful if we find the necessary alignment and cooperation at the European level*".

For Minister de Block, reflections need to be articulated around three building blocks: the development process, market access procedures and the use of Personalised Medicine in real practice.

Maggie de Block furthermore stressed the need for a flexible method that evaluates the added value and monitors the evidence for clinical utility. Given the complexity of this issue and the scarcity of high expertise, collaborative platforms at European level need to be set up.

Mary Baker, European Brain Council: "We have to adapt to put it together."

Mary Baker from European Brain Council highlighted the role of prevention in ensuring sustainable healthcare systems against the background of a rapidly ageing society where "*longer lives also mean longer chronic diseases*."

"Mankind is basically paleolithic. The institutions are basically medieval. Communication is now space age. We have to adapt to put it together."

For Mary Baker, Prediction, Prevention and Participation are crucial, and so is the ability to make informed choices. Media tend to depict Personalised Medicine as a "*solution for the rich*", although it should be accessible for everyone.

If we want to provide good evidence, the main challenges to be addressed are the collection of data, their measurement, the setting up of collaborative structures and adequate investment in health.

The Conference also provided the opportunity to officially launch the Luxembourg Brain Council, an emanation of the European Brain Council, in the presence of a great number of patient organisations.

The Brain Council brings together researchers and health professionals in brain diseases, representatives of biotech industries dealing with brain disorders and representatives of persons living with brain diseases.

Fostering the exchange 'from bench to bedside', such interdisciplinary approaches will ultimately contribute to faster and better patient care. Luxembourg is now part of nearly 30 countries that have been or are in the process of forming National Brain Councils.

Session 1: The voice of the patients – A patient oriented healthcare

Patients' concerns, their expectations and priorities with regard to Personalised Medicine were at the heart of the discussion of this panel.

Speakers reaffirmed the urgency to act and to identify the corner stones for better information and empowerment of patients. They stressed that patient organisations should engage with specialists, experts, healthcare providers, centers of excellence and scientists to build up partnerships. Attention was drawn to the EU mapping study "EMPATHiE" (Empowering Patients in their Health Management in Europe) and the launch of the Patient Empowerment Campaign in Brussels on 20 -21 May 2015, as important recent steps to foster this approach. The European Patients' Academy on Therapeutic Innovation (EUPATI) project and the work by the European Patients' Forum (EPF) on patient empowerment and health literacy have been singled out as valuable approaches. Patient empowerment goes hand in hand with the acknowledgement of the right to autonomy and self-determination. Some mentioned the necessity to provide access to tailored treatment for patients of small Member States, where

the critical mass of patients is lacking to build up the competence in certain diseases, and the possible role of the crossborder healthcare Directive.

Conclusions on necessary measures to ensure patient oriented healthcare:

1) *Patient empowerment: ensure better information and foster shared decision making*

- Empowerment is a system issue. Health systems should allow and encourage active and participatory involvement of patients in the design of new care models across the entire development process, on the basis of a shift from a disease- to a patient centered-approach.
- Public health campaigning needs to be intensified to broaden awareness of the importance of patient involvement and thus contribute to enhanced access to Personalised Medicine. The role of patient organisations is crucial.
- All stakeholders must work on better patient involvement: decision makers, clinicians, researchers. Doctors must be ready to learn and communicate with researchers and patients about Personalised Medicine and to accept a new distribution of power. Efficient information management and communication pathways must be established, supported by enhanced health literacy, enabling patients to understand the concepts of health risks and prediction medicine. Health literacy is also beneficial for research in terms of data source improvement.

2) *Data sharing – Data protection: create incentives and facilitate data sharing within an adequate data protection setting*

- The right balance between the circulation and sharing of personal health data on the one hand and the respect of individual rights to data privacy on the other hand must be ensured. Above all, the patient himself must be granted access to his own data.
- Patients are willing to share their data if they know that they can contribute to better outcomes in the whole value chain.
- The up-coming EU legislation on personal data processing in medical research should ease access and consent and allow for re-use and secondary use. Data quality and interoperability are crucial.

3) *Informed consent and communication: enable informed choices*

- Informed consent of patients must be ensured through health systems enabling the provision of the right information to the right patient at the right moment. ICT can help putting in place interesting models.
- Current practice in patient consent and in waivers to their consent must be examined and a common understanding on adequate mechanisms to protect privacy should be reached. Example: the Dutch national consent form to allow data donation for research.
- Better patient involvement in clinical trial modelling is needed.

4) *Patient focused care*

- Health professionals and decision makers should ensure better involvement of patients and patient organisations in the discussion on how care should/could be more patient focused; they should allow higher engagement of patients in planning and managing their treatment.
- Patient preferences in designing tailored prevention and treatment should be taken into consideration, thus avoiding medical errors and reducing adverse reactions to medicine and recognise increased responsibility of patients in monitoring their own treatment.
- Incentives at EU level could create the conditions for equal access to specific treatment.

Session 2: Addressing known obstacles to integrating Personalised Medicine into health systems

Concentrating on the discussion of concrete solutions to address and overcome known obstacles to the integration of Personalised Medicine into our health systems, this session went beyond the mere description of those hurdles.

Speakers stressed that one should not only focus on treatments, but also on facilitating predictions and prevention as well as on research into multi-morbidity. The "fast-moving and very dynamic character" of Personalised Medicine was highlighted. Personalised Medicine needs a multi-sectoral approach where many different issues have to be put together such as standardisation, access to data and ethics. The wider outcome needs to be considered, especially when it comes to paying for Personalised Medicine. Rare diseases should be looked at in a less isolated manner, to get away from silo thinking - and the bigger diseases should be broken down into smaller clusters.

Conclusions on measures to address obstacles to integrating Personalised Medicine into health systems:

1) *Adjustment of Health Technology Assessment methods to the value of Personalised Medicine*

- Define mechanisms to tailor existing assessment methodologies to the specificities of Personalised Medicine, exploring possible synergies between HTA and regulatory issues.
- Recognise the role and importance of the integration of overall patient perspective and value based assessment (quality of life gained, side effects avoided) as compared to scientifically based assessment in the development of new methodologies of evidence. The 3rd EUnetHTA Joint Action (2016-2019) could address this, also on the basis of the experience gained by the European Medicines Agency (EMA).
- Promote the role of the EUnetHTA Network in fostering enhanced cooperation of HTA bodies under the crossborder healthcare Directive.

2) *Definition and fostering of adaptive pathways*

- Accept new settings of evidence gathering: move away from randomised large trials to an adaptive approach where the balance risk-benefit remains unchanged.
- Engage into planning ahead together with all the stakeholders involved: regulators, ethical committees, patients, industry.
- Involve patients right at the beginning of the planning, during real life reassessment and during the decision making process.

3) *Ensuring continuous professional development of healthcare professionals*

- Develop a structured approach to allow adequate update of skills and capabilities for all concerned healthcare professionals, including students, and create the conditions to allow equal access of all concerned professionals to this training (role of e-learning platforms, summer schools).
- Put in place, by 2020, an EU education programme on Personalised Medicine and develop an inter-sectoral curriculum on Personalised Medicine.
- Encourage a cross-sectoral approach between healthcare professionals: go beyond the traditional boundaries of individual specialties and interact with various professionals involved in the treatment.

4) *Acknowledgement of the pivotal role of biobanks*

- Create the conditions for increasing awareness of biobanks throughout the EU and for optimal interoperability between biobanks, either via trusted networks or via larger infrastructures (BBMRI).
- Standardise the data collection methods by means of guidelines; ensure quality assurance (certified biobanks and annotation of samples); achieve the right balance between data protection and data availability for their best use by researchers.
- Encourage "European Reference Networks" on rare cancers to promote the role of biobanks.

5) *Identification of financial mechanisms to pay Personalised Medicine*

- In the absence of a specific reimbursement scheme for Personalised Medicine, explore innovative value based payer models taking into acount patient relevant outcomes (quality-adjusted life year "QALY") and added value offered by Personalised Medicine, rather than overall healthcare spending.
- Analyse the potential of managed entry agreements / risk-sharing agreements between the manufacturer and the payer in addressing the obstacle caused by the financial impact of Personalised Medicine
- Against the background of increasing costly drug spending, especially in the field of cancer and rare diseases, and strains on healthcare budgets, the sustainability of healthcare systems should be pursued as an overall objective.

Session 3: Best practices: Learning and Sharing

The third session put previous reflections into the perspective of initiatives successfully running in some Member States.

It allowed highlighting examples of concrete and innovative projects that aim to or have succeeded in bringing Personalised Medicine closer to Europe's patients and thus contribute to enhance the principle of equal and universal access to high quality healthcare.

Examples of best practices in several Member States:

1) *France: nationwide molecular diagnostic testing free of charge*

- Since 2006: national database of clinical and genomics information, involving 28 regional oncology centers, aiming to guarantee a full sequence analysis of approx. 50.000 patients per year, free of charge, and using algorithms.
- Multi-sectoral approach: the centers are partnerships between laboratories, universities, hospitals, regional organizations and foster cooperation between pathologists, biologists and medical doctors. A central role is exercised by the National Cancer Institute (INCa)
- Added value: This project has resulted in a large increase in the numbers of testing and thus contributes to the development of targeted therapies and immunotherapies An important part of this costly initiative is the funding, with the French Ministry of Health investing 30 million euros per year.

2) *United Kingdom: enhanced genomic knowledge, cost-effective strategies and education*

- In the UK, Personalised Medicine has been on the political agenda since 2000. Since the White Paper (2003), substantial investments (50 million pounds) have been made to develop genetic and genomic knowledge and the creation of regional genetic knowledge parks. These multidisciplinary fora aimed at integrating new genetics and

genomics into existing scientific knowledge in order to develop new treatments and services.

- More recent initiatives revolve around four key areas:

- Funding for basic and translational research: 100.000 Genomes Project by genomics England: development of interest communities around genomic sequencing.
- Robust methods to generate an evidence base and understand clinical and cost effectiveness of strategies: Medical Research Council Stratified medicines program.
- Education of service providers: development of education packages for genetics and non-genetics healthcare professionals, involving nine universities across the UK.
- Engagement with patients and the public: communication of the importance of genomics and genetics.

3) Luxembourg: building multidisciplinary alliances in a small country

The manageable structure of Luxembourg (one university, three research centers, one biobank, five hospitals) facilitates the building of alliances and working in a consensual way. Two structures can be considered as the backbone of Personalised Medicine in Luxembourg:

- The Personalised Medicine Consortium (PMC), based on a ten year joint strategy and on three components:
    - a basic medical research center (LBSC)
    - a biobank (International Biobank of Luxembourg, IBBL)
    - a pilot project focusing on cancer, diabetes and cardio-vascular diseases, neuro-degenerative diseases.
- The National Center for Excellence and Research for Parkinson's disease:
  The institution fosters bottom-up research that is program-oriented and focuses on Parkinson's early diagnosis and stratification. It is driven by partners of different institutions and financed by the National Research Fund.

4) Belgium: SPECTA - innovative access schemes to clinical trials

- The SPECTA collaborative molecular screening platform, launched by the European Organisation for Research and Treatment of Cancer (EORTC), addresses the shortcomings of classical randomized clinical trials in the case of Personalised Medicine by offering more flexible access schemes enabling rapid identification of patients with

specific genotypes, efficient patient sorting and integrated drug/biomarker/drug development solutions.

- Such platforms are necessary to efficiently promote supranational standardisation and interoperability, benchmarking quality for drug and assays, adaptive licensing/combination of drugs, real world validation and knowledge development for researchers. There is also a need for platforms at EU level fostering multi-stakeholder consultation and the interoperability of all existing fora.
- Biological material should not be stored by commercial companies, but by independent platforms with high quality and transparent ways of decision making. If the patient is put into the center of Personalised Medicine, scientific research will develop faster, the quality of trials will improve and market access will increase.

Session 4: The value of Personalised Medicine for Public Health, its impact on EU Health Policy and its global dimension

This final session aimed to put Personalised Medical into the wider context of public health policies at EU and international level, research and outcome centered approaches as well as to give an insight into the European Commission's further plans in the field of Personalised Medicine.

The interventions focused on the different ways to close the gap between research and public health policy and on the place of the patient in those areas which often appear to be moving far away from individual considerations. The panel also gave the European Commission an interesting opportunity to explain in detail which ongoing and future projects can be used in bringing the agenda of Personalised Medicine closer to EU citizens, thus avoiding fragmentation of efforts at national level. The contribution of the representative of the USA, where Personalised Medicine was recently boosted by the Obama precision medicine initiative, provided valuable inspiration for future work at EU level public health policy making, and showed how patients can drive a political agenda.

<u>Conclusions on how Personalised Medicine can be taken forward in national, EU and international research and public health policies:</u>

1) *<u>Personalised Medicine and Public Health Research</u>*
   - Research needs to be structured to emphasize the key position of patient in Personalised Medicine. Research needs to span over the entire translational chain. Healthcare professionals need to be able to translate research into clinical practice and bring it forward to public health decision makers.
   - Need for a cross-sectoral research involving pre-clinical and clinical work, academia, industry and patients, to be completed by real world data. Communication across the continuum of research is requested.
   - Patients have to be involved right from the start of research projects.

2) *<u>Personalised Medicine and Public Health Policy</u>*
   - Build on the recommendations contained in the 2012 report of the Public Health Genomics European Network "European best practice guidelines for quality assurance, provision and use of genome-based information and technologies" to improve public health by using this information.
   - Think of the human body as a system: take into account all the factors and data. In case of multi-morbidity, consider the interconnections of the different

diseases coexisting in one patient and integrate all the -omics data to generate and implement meaningful interventions at the individual level.

- Recognize the interest of rare diseases for public health decisions in Personalised Medicine. They can tell us a lot about which regulatory framework and which drug to choose from. It is important to bring together complex and rare diseases.

3) *Personalised Medicine and EU Health Policy (Commission perspective)*

- Cooperation within Member States in support of EU projects: The Commission works together with Member states to take forward the work ongoing under the crossborder healthcare Directive, namely as regards the eHealth Network (sharing of (Big) Data) and EUnetHTA (assessment). Public private partnerships like the Innovative Medicines Initiative (IMI) offer great perspectives in moving research towards regulatory science and merging data form industry and academia. The Commission's working group STAMP analyses what legal instruments to use to make innovative medicine available to patients.
- Cooperation with the European Medicines Agency: the pilot project 'adaptive licensing' on which the STAMP working group reports on a regular basis; the work of the EMA "patients and consumers working party" (PCWP), composed of patients organisations, provides recommendations to the EMA and its human scientific committees on all matters of interest to patients in relation to medicinal products.
- Cooperation within the Commission: inter-service group DG SANTE, CNECT, RTD, GROW and the Joint Research Center (JRC).
- Cooperation with international actors: The Commission is actively exchanging with the US authorities, including the FDA, on Personalised Medicine.

4) *Putting PM into perspective: the USA Precision Medicine Initiative*

- Generating data: The integration of precision medicine into clinical practice will be enabled in the US through scientific evidence generated by multiple data.
- Patient empowerment: experiences in the US have shown that people need to be given incentives to work together. Personalised Medicine needs to be not only patient-centered, but also patient-*driven* ("*care for and by the people*"), with the patient as an enabled partner.
- Setting of goals: goals need to be concrete and achievable. Strong partnerships between industry and existing patient cohorts, willing to share their data on a voluntary basis, will make a difference.

General conclusions and close of conference

- By Lydia Mutsch, Minister of Health of Luxembourg and chairs of sessions -

For **Lydia Mutsch**, one of the major take-home messages of this Conference is the acknowledgment that obstacles to the integration of Personalised Medicine into clinical practice can indeed be overcome.

The fact that the Conference was attended by such a large and diversified audience is a clear sign just how important it is to have all concerned stakeholders on board if we want to address the uptake of Personalised in an efficient and comprehensive way.

"*What we need is a patient centered approach involving EU decision makers and regulators in the area of public health, to enable EU and Member States to contribute to this endeavor of making Personalised Medicine a Reality*."

Many examples on how to overcome obstacles have been elucidated. Several good practice examples could serve as valuable inspiration for implementation in a different setting – to bring Personalised Medicine closer to patients.

The Conference enabled participants to listen to the expectations of patients and to their description of unmet needs. Health Minister Lydia Mutsch: "*We need to fully consider the voice of the patient. Personalised Medicine is, and should be, all about the patients. It offers the opportunity for them to be seen not merely as passive recipients of care but as participants, partners and even guides in their own health care.*"

In order to acknowledge the right of patients to self-determination, it will be necessary to overcome the traditional way of thinking. To some extent, courage to accept paradigm shifts will be needed; in other cases, it will be possible to build on existing tools, as shown by the Conference. The Commission gave the necessary assurances that they are willing to drive this agenda forward.

Minister Lydia Mutsch concluded by stressing that the Conference has significantly contributed in raising the profile of Personalised Medicine and has allowed to gather most interesting input for the Council conclusions on Personalised Medicine which will be submitted to Health ministers at the Council in December for adoption.

The chairs joined the concluding remarks by Minister Lydia Mutsch by briefly stressing the following issues:

Anna Chioti (chair of session 1) welcomed that the Conference put the accent on the voice of the patient whereas, in previous conferences, the patient was addressed only in a timid way. She also highlighted the importance of actions on patient empowerment, as done by the European Patients' Forum, and the need for a new EU strategy to really involve the patients, "*so that we don't do things to the patients, but with the patients.*"

Emmanuelle Benzimra (chair of session 2) acknowledged that one of the major obstacles a few years ago was that Personalised Medicine was not well known by the European decision makers. Today this is no longer the case thanks to initiatives putting it high on the political agenda.

For **Mary Baker (chair of session 3)** too, this event has contributed to the profiling of Personalised Medicine. Future developments should be governed by mutual respect, trust and a cross-sectoral approach of all concerned disciplines coming together. Science must be underpinned by ethics and humanity, "*Science is always about the HOW. We sometimes need to ask for the WHY*."

John Bowis (chair of session 4) retained above all the determination of the participants to move on and look at the different hurdles in a constructive way, while making use of best practices in the EU and elsewhere in the world. The momentum is there and it's now urgent to make the necessary choices in order to progress. Some of these choices might be difficult ones, but they will be in the interest of patients.

Annexes

Conference Program

8:15-9:00: registration, coffee, networking

09:00-9:45: Welcoming address by Lydia Mutsch, Minister of Health, Luxembourg

Opening address by commissioner Dr. Vytenis Andriukaitis

Opening address by Dr. Maggie de Block, Minster of Health, Belgium

Opening address by Dr. Mary Baker, European Brain Council

Presentation of the sessions by the moderator

9:45: official launching of the Luxembourg Brain Council followed by a press conference

Conference moderator: Prof. Helmut Brand, head of the Department of International Health at Maastricht University

10:00-11:15: **Session 1: The voice of the patients - A patient oriented healthcare**

For Personalised Medicine to succeed and for healthcare innovations to fulfill their true potential, an informed, engaged and empowered patient is crucial. Personalised Medicine often calls for an enhanced need of information and advice. This session looks at patients concerns, expectations and priorities with regard to Personalised Medicine.

- Patient empowerment
- Shared decision making
- Informed consent – communication
- Patient focused care
- Data sharing – data protection

Chair: Dr. Anna Chioti, Luxembourg Institute of Health, Director

Panelists: Kaisa Immonen-Charalambous (European Patients' Forum); Joseph Even (ALAN), Pascal Niemeyer (EUPATI Luxembourg), Dr. h.c. Peter Kapitein (Inspire2Live, a cancer patient advocacy group).

Followed by Q&A.

11:15 – 12:30: **Session 2: Addressing known obstacles to integrating PM into health systems**

Following a short overview of obstacles identified as of today to the integration of PM into clinical practice, this session will focus on the way forward and possible solutions at EU and national level.

- Adjusting Health Technology Assessment / HTA methods to the value of Personalised Medicine
- Adaptive pathways
- Training of healthcare professionals : continuous professional development
- No Personalised Medicine without biobanks
- Paying for Personalised Medicine

Chair: Emmanuelle Benzimra, EPEMED, Luxembourg, General Delegate

Panelists: Tapani Piha (DG SANTE), Prof. Guido Rasi (EMA), Prof. Christine Chomienne **(**European Haematalogy Association), Dr. Catherine Larue (IBBL), Valérie Paris (OECD)

Followed by Q&A.

12:30 – 14:00: lunch break and poster session

14:00-15:15: **Session 3: Best practices: Learning and Sharing**

The objective of this session is to highlight examples of projects that aim to or have succeeded in bringing Personalized Medicine closer to Europe's patients and which furthered the principle of equal and universal access to high quality healthcare.

5) Innovative model of diagnostics, France
6) New initiative « personalized medicine », United Kingdom
7) Interdisciplinary PM research in cancer, diabetes and Parkinson: the Personalized Medicine Consortium (PMC), Luxembourg
8) Access to clinical trials: The SPECTA programme, Belgium

Chair: Dr. Mary Baker, European Brain Council

Panelists: Prof. François Sigaux (INCA), Prof. Katherine Payne (Uni Manchester), Prof. Rudi Balling, (LCSB), Dr. Denis Lacombe (EORTC).

Followed by Q&A.

15:15 -15:45: coffee break

15:45-17:00: **Session 4: The value of PM for Public Health, its impact on EU Health Policy and its global dimension**

This session aims to put Personalised Medical into the wider context of public health policies and outcome centered approaches as well as to give an insight into the Commission's further plans in this field.

9) PM and Public Health Research
10) PM and Public Health Policy
11) PM and EU Health Policy
12) Putting PM into perspective: the USA precision medicine initiative

Chair: John Bowis, former UK Health minister and MEP

Panelists: Dr. Ulrike Busshoff (PerMed), Prof. Angela Brand (Maastricht Uni, Institute for Public Health Genomics), Dr. Andrzej Rys (DG SANTE), Dr. Stephen Friend (Sage Bionetworks, USA).

Followed by Q&A.

17:00-17:30 – **Conclusions and close of conference**: Lydia Mutsch, Minister of Health, Luxembourg and chairs of sessions.

List of Participants

First Name(s)	Surname	Function
Ain	Aaviksoo	Deputy Secretary General for E-services and Innovation, Ministry of Health Estonia
Laura	Alexandrescu	Council of the European Union - Political Administrator - Health and Foodstuffs
Helena	Alexandrou Panayiotoullou	Pharmacist
Vytenis	Andriukaitis	European Commissioner for Health and Food Safety
Lieven	Annemans	Professor of Health Economics, Ghent University, Brussels University
Sabine	Atzor	EFPIA
Mary	Baker	Immediate Past President, European Brain Council
Rudi	Balling	Director, Luxembourg Centre for Systems Biomedicine
Sina	Bartz	Gemeinsamer Bundesausschuss, Germany
Laura	Batchelor	Director, FIPRA
Marie-Laure	Bellengier	Chargée de mission, Santé-Europe, Ministry of Social Affaires, Health and Women's Rights, France
Christina	Benedetti	Federal Office of Public Health, Division Biomedicine, Switzerland
Emmanuelle	Benzimra	General Delegate, EPEMED
Guy	Berchem	Medical Oncologist, Centre Hospitalier Luxembourg, Luxembourg
Chiara	Bernini	Junior Policy Officer, EAPM
Françoise	Berthet	Head of Curative Medicine Department, Health Directorate, Ministry of Health, Luxembourg
Claire	Biot	Office Chief, Ministry of Health, France
Alexandre	Bisdorff	President, Luxembourg Brain Council
Kris	Boers	Health Attaché, Permanent Representation of Belgium to the EU
Georges	Bourscheid	Chairmann of the Steering Committee, Luxembourg institute of science and technology (LIST)

John	Bowis	Special Adviser for Health and Environmental Policy, FIPRA
Angela	Brand	Professor, Maastricht University, Netherlands
Helmut	Brand	Head of Department of International Health, University of Maastricht
Almuth	Bredimus	ALAN–Rares Diseases Luxembourg
Ulrike	Bußhoff	Senior scientific officer, PerMed, Germany
Anne	Calteux	First Counsellor to the Government, EU Coordinator, Ministry of Health, Luxembourg
Anna	Chioti	Head of Clinical and Epidemiological Investigation Center, Luxembourg Institute of Health
Christine	Chomienne	Immediate Past President, European Haematalogy Association
Teresa	Cody	Principal Officer, Primary Care, Department of Health, Ireland
Constance	Colin	Policy advisor, CPME
Anders	Colver	Project Officer, DG RTD, European Commission,
Arnaud	d'Agostini	Marketing & Communication, IBBL, Luxembourg
Maggie	De Block	Health Minister, Belgium
Johan	De Cock	CEO NIHDI, Belgium
Guillaume	de Luxembourg	Prince
Regine	Deniel-Ihlen	Lung Cancer Europe
Thomas	Dentzer	Head of Life Sciences Sector, Luxinnovation, Luxembourg
Vincent	Depret	Business Area Manager, Astrazeneca
Nilsy	Desaint	Public Policy and Communications Manager, Merck
Frederic	Destrebecq	Executive Director, European Brain Council
Mars	Di Bartolomeo	President, Luxembourg Parliament
Thomas	Dominique	First Counsellor to the Government, Ministry of Social Security, Luxembourg
Diego	du Monceau	Chariman, EORTC Cancer research Fund, Belgium
Steve	Ehmann	Patiente Vertriedung, Luxembourg

Mogens	Ekelund-Jorgensen	President, Lung Cancer Europe
Josiane	Entringer	Deputy Advisor to the Directorate, Ministry of Higher Education and Research
Joseph	Even	Vice-president, ALAN Rare Diseases Luxembourg
Marie Helene	Fandel	Senior Manager, Amgen
Stephen	Fawbert	MHRA Policy, United Kingdom
Antonio	Federici	Medical Officer, Directorate General of Health Prevention, Ministry of Health, Italy
Shirley	Feider-Rohen	President, ALAN –Rares Diseases Luxembourg
Barbara	Freischem	Executive Director, EBE
Claude	Frieden	National Health Insurance Funds (CNS), Luxembourg
Stephen	Friend	President and Founder, Sage Bionetworks, USA
Dagmar	Friese	Federal Ministry of Health Germany
Pascal	Garel	Chief Executive, HOPE
Miriam	Gargesi	Director, Healthcare Biotechnology, EuropaBio
Marius	Geanta	Co-founder, Center for Innovation in Medicine, Romania
Patricia	Gehrlein	Policy Advisor, Siemens Healthcare, Belgium
Claude	Geimer	Member of the Steering Committee, National Health Insurance Funds, Luxembourg
Alessandro	Ghirardini	Senior medical officer, Head of Unit III, Directorate General for the Health Planning, Ministry of Health, Italy
Frank	Glod	Head of Unit - Strategic Research Programmes, FNR Luxembourg
Aldo	Golja	Senior Policy Advisor Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sports, Netherlands
Marc	Graas	General Director, CHNP - Centre Hospitalier Neuropsychiatrique, Luxembourg
Elke	Grooten	European Public Affairs, Novartis
Ans	Heirman	MSD - Market Access, Policy and Communications Lead, Merck

Elisabeth	Heisbourg	Acting Director, Health Directorate, Ministry of Health, Luxembourg
Juliane	Hernekamp	EU Presidency Team, Ministry of Health, Luxembourg
Isabelle	Hinkel	BioHealth Cluster project officer, Luxinnovation, Luxembourg
Gérard	Holbach	Medical Director (Contrôle médical de la sécurité sociale), Ministry of Social Security, Luxembourg
Denis	Horgan	Executive Director, EUAPM
Michael	Hübel	Head of Unit "Programme management and diseases", DG SANTE, European Commission
Joseph	Huggard	Managing Director, Huggard Consulting
Frank	Hulstaert	Senior Researcher, Governement Belgium
Kaisa	Immonen-Charalambous	Senior Policy Adviser, European Patients' Forum
Rebecca	Jungwirth	Vice-Chair, EBE Personalised Medicine WG
Peter	Kapitein	Board member and Patient Advocate, Inspire2Life
Tim	Kievits	Director of Healthcare Innovation, Vitromics
Dorothee	Knauf-Hübel	Head of Unit Curative Medicine, Health Directorate, Ministry of Health, Luxembourg
Suzette	Kox	Scientific Director, Egagenerics
Hendrik	Kühne	General Secretary, APL, Luxembourg
Elizabeth	Kuiper	Director European Affairs, EFPIA
Denis	Lacombe	Director General, EORTC
Eero	Lahtinen	Ministerial Advisor, Ministry of Social and Health Affairs, Finland
Catherine	Larue	CEO, Integrated Biobank, Luxembourg
Jean-Pol	Leblon	Managing Director, Pfizer
Viktória	Ludányi	Biomedical assessor, Government, Hungary
Jan	Marounek	Director of the Health Services Department, Ministry of Health, Czech Republic
Agnès	Mathieu	Legal Officer, DG SANTE, European Commissoin

Jelena	Matuzović	Senior Drugs Inspector, Creation Health Insurance Funds
Martine	Mergen	CHL, Luxembourg
François	Meyer	Advisor to the President, International Affairs, HAS France
Stephen	Mifsud	Health attaché, Permanent Representation of Malta to the EU
Fredrik	Moen	Director of European Government Affairs, AstraZeneca
Antoni	Montserrat	Policy Officer, DG SANTE, European Commission
Sabine	Mosch	Head of Communication, Luxembourg Centre for Systems Biomedicine
Martine	Neyen	Director, Fondation Cancer Luxembourg
Anna Skat	Nielsen	Danish Ministry of Health
Pascal	Niemeyer	Member, EUPATI, Luxembourg
Elmar	Nimmesgern	Deputy Head of Unit, DG RTD, European Commission
Annika	Nowak	Member of Cabinet of Commissioner Andriukaitis, DG SANTE, European Commission
Wolfgang	Oertel	Coordinator, EAN Sub Committee European Affairs
Valérie	Paris	Health Division, OECD
Katherine	Payne	Professor of Health Economics, University of Manchester, UK
Łukasz	Pera	Chief Specialist, Ministry of Health, Poland
Carlos	Pereira	Member of the Executive Board, OGBL, Luxembourg
Marie-Claire	Pickaert	Deputy Director General, EFPIA
Tapani	Piha	Head of Unit eHealth and Health Technologie Assessment, DG SANTE, European Commission
Krishna	Prasad	MHRA, United Kindom
Guido	Rasi	Principal Advisor, EMA
Nils Olav	Refsdal	Norwegian Directorate of Health
Peter	Reiner	Ministry of Health of the Slovak Republic
Alexander	Roediger	Chair, Healthcare Committee, AmCham EU
Gisele	Roesems	Deputy Head of Unit Health and Well-being, DG CNECT, European Commission

Florence	Romano	Chargée de direction de la cellule d'expertise médicale, IGSS, Luxembourg
John	Ryan	Acting Director, DG Public Health, DG SANTE, European Commission
Andrzej	Rys	Director Health Systems and Products, DG SANTE, European Commission
Claudia	Scharl	Policy Officer, EUCOPE
Marc	Schiltz	Fonds National de la Recherche, Luxembourg
Ludmilla	Schlageter	Vice-President, Siemens Healthcare, Belgium
Ingrid	Schmidt	Senior Advisor, Ministry of Health and social affairs, Sweden
Beate	Schmidt	RAPS European Liaison
Alain	Schmit	President, AMMD, Luxembourg
Paul	Schmit	President, CNS, Luxembourg
Claude	Schummer	Secretary general, AMMD, Luxembourg
Mike	Schwebag	Service national d'information et de médiation santé, Luxembourg
Lynn	Settinger	OGBL, Luxembourg
François	Sigaux	Director of Research and Innovation programmes, Cancer Institute INCa, France
Emőke	Soós	Health Care Counsellor, Government, Hungary
Wouter	Spek	Director, EuroBioForum Foundation, Netherlands
Holger	Stenzhorn	Saarland University - Faculty of Medicine, Germany
Gert-Jan	Sterckx	Policy Advisor on International Relations, Ministry of Health, Belgium
Tairi	Täht	Counsellor for health affairs, Ministry of Health, Estonia
Sabine	Tejpar	Digestive Oncology Unit, University of Gasthuisberg, Leuven, Belgium
Tomáš	Tesař	Ministry of Health, the Slovak Republic
Inga	Tharun	Trainee, Ministry of Health, Welfare and Sport, Netherlands
Antoine	Thomas	Ambassador of Belgium, Luxembourg

André	Valentin	Patientenvertriedung, Luxembourg
Laura	Valli	Health Attachée, Permanent Representation of Luxembourg to the EU
Johan	Van Calster	Administrator, Clivan bvba
Brieuc	Van Damme	Deputy Chief of Staff, Ministry of Health, Belgium
Ann	van Gysel	EPEMED
Evert Jan	Van Lente	ESIP
Jean-Marie	Vlassembrouck	EORTC
Rainer	Voelksen	Swiss Federal Office of Public Health Project Manager
Liisa-Maria	Voipio-Pulkki	Director, Ministry of Social and Health Affairs, Finland
Anouk	Waeytens	NIHDI expert pharmaceuticals, Belgium
Raymond	Wagener	Director, IGSS, Luxembourg
Yolande	Wagener	Head of School Medicine Division, Health Directorate, Ministry of Health, Luxembourg
Jaroslaw	Waligora	Policy Officer, DG SANTE, European Commission
Michèle	Wennmacher	Patientevertriedung
Paul	Wirtgen	Directeur Général, Hôpitaux Robert Schuman, Luxembourg
Audrey	Wolf	Public Affairs Manager, EBE
John Peter Mary	Wubbe	Secretary General, EPPOSI
Karina	Zālīte	Health Counsellor, Ministry of Health, Latvia
Solvita	Zvidriņa	State Secretary of the Ministry of Health, Latvia

Biographies of Speakers

OPENING SESSION

Lydia Mutsch

Following the legislative elections of 20 October 2013, Lydia Mutsch joined the government as Minister of Health, Minister for Equal Opportunities on 4 December 2013. A member of the LSAP since 1987, Lydia Mutsch became a municipal councillor in Esch-sur-Alzette in 1988. In 2000, she was appointed mayor, an office she held until her appointment to the government in December 2013. Lydia Mutsch was elected to Parliament for the first time in 1989 at the age of 27 while standing for the LSAP in the constituency of the South. She was re-elected in 1994, 1999, 2004, 2009 and 2013. From 2009 to 2013, Lydia Mutsch assumed the role of vice-president of Parliament. As a member of Parliament, she assumed among others the role of chairwoman of the Committee for Health and Social Security from 2004 to 2013.

Vytenis Povilas Andriukaitis

Vytenis Povilas Andriukaitis is the European Commissioner for Health and Food Safety (2014-2019). His main responsibilities include building up knowledge on the performance of national health systems to shape national and EU policies, and helping address the challenge of increased calls on national health services at a time of intense pressure on public finances. Vytenis Andriukaitis served as a Member of the Lithuanian Parliament during several years and was the Minister of Health from 2012 to 2014. He worked as a cardiac surgeon, and is the co-author of 44 books and author of 616 press articles on the history of medicine, surgery, political science a.o.. He also received the Award of the WHO for his merits in tobacco control (2014).

Maggie De Block

Maggie De Block is a Belgian politician and holds currently the portfolio of Minister of Social Affairs and Public Health in the Michel Government. She studied medicine at the Vrije Universiteit Brussel (VUB) after which she became a general practitioner. The main stages of her political career include having been a Member of the Belgian Chamber of Representatives for the electoral district Brussels-Halle-Vilvoorde from 1999 to 2011.

In December 2011 she became the Secretary of State for Asylum, Immigration and Social Integration in the Di Rupo Government, before being appointed as Minister of Justice charged with Asylum, Immigration, Social Integration and Poverty Reduction in July 2014.

Mary Baker (chair)

Mary Baker, is immediate past President of the European Brain Council and President of their 'Year of the Brain' project. She is consultant to the World Health Organisation (WHO), Chair of the Working Group on Parkinson's Disease and a member of the Commission's CONNECT Advisory Forum. Academic appointments include Associate Membership of the Health Services Research Unit, University of Oxford and Visiting Fellow within the London School of Economics (LSE) Health Centre. In 2009, Dr Baker received the prestigious British Neuroscience Association Award for Outstanding Contribution to British Neuroscience and for Public Service, and in 2014, she received the Dana/EDAB Lifetime Achievement Award for Outreach on Behalf of Brain Research.

Helmut Brand (moderator)

Helmut Brand is Jean Monnet Professor of European Public Health and Head of the Department of International Health at Maastricht University. He is a specialist in public health medicine and worked in several health authorities and Ministries of Health in Germany before he became Director of the Public Health Institute of North Rhine Westphalia. Since then, European integration in health is the main topic of his work. Brand is also President of the European Health Forum Gastein (EHFG) and co-chair of the European Alliance for Personalised Medicine (EAPM). As policy advisor he serves e.g. 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.

SESSION 1: The voice of patients: a patient oriented healthcare

Anna Chioti (chair)

Anna Chioti is Head of Unit, Clinical and Epidemiological Investigation Center at the Luxembourg Institute of Health (LIH). Since 2012, she is the chair of the ECRIN Network Committee and Board Member of EFGCP. After her studies at Université Catholique de Louvain, Belgium, she worked as a medical doctor until 2003 after which she held various positions with the industry before joining the LIH. In 2014, she received both the Award for Advancing Public Awareness in Clinical Research from the Association of Clinical Research Professionals (ACRP), Texas, USA as well as the Outstanding Contribution to Luxembourg Healthcare and Life Sciences Community, Luxembourg. She has also been active as Chair at The European Society for Translational Medicine (EUSTM).

Kaisa Immonen-Charalambous

Kaisa Immonen-Charalambous has a Master's degree in International Relations and is Senior Policy Adviser at the European Patients' Forum (EPF) since 2010. She is responsible for the overall lead of EPF's policy and advocacy work at EU level, including policy analysis, liaising with the EU institutions and stakeholders. Specific areas of responsibility include patient empowerment and patient-centred chronic disease care; quality and safety of healthcare; health literacy; clinical trials; pharmaceuticals regulation; and cross-border healthcare. Kaisa is a member of the European Commission's Expert Group on Patient Safety and Quality of Care, the European Medicines Agency's Working Party with Patients and Consumers, and the PISCE Platform of Experts on Self-Care.

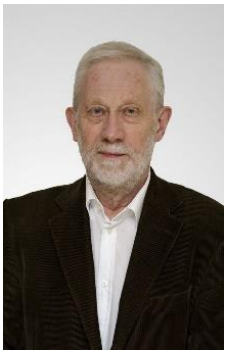
Pascal Niemeyer

Pascal Niemeyer is a member of the EUPATI (European Patients' Academy on Therapeutic Innovation) Luxembourg national liaison team. The aim of EUPATI is to provide scientifically reliable, objective, comprehensive information to patients on medicines research and development in order to promote patient's empowerment. Furthermore, Pascal is the Director of the European Gaucher Alliance (EGA), President of the executive board of the Gaucher Gesellschaft Deutschland e.V., and member of the Luxembourgish umbrella patient organisation for patients with rare and neuromuscular diseases, called ALAN.

Peter Kapitein

Peter Kapitein is a board member and Patient Advocate of Inspire2Live, an international patient advocacy organization. As a Patient Advocate he connects patients, researchers and clinicians to further research, treatments and care. His tasks include organizing congresses, lobbying the matrix of public authorities, health care organizations, insurance companies as well as health research institutes, and deliver lectures and talks. Peter is also co-founder of the annual cycling event on Alp d'Huez fundraising for cancer. He works at the Central Bank of the Netherlands as a program manager and advisor. In October 2012, Peter was honoured with a doctorate at the Free University of Amsterdam.

Joseph Even



Joseph Even holds a number of medical degrees and postgraduate training a.o. in molecular biology, microbiology and immunology. Between 1985 and 2004 he held permanent positions at CNRS (National Center for Scientific Research) and was a staff member (group leader or assistant group leader) in different Inserm (National Institute for Medical Research) units in Paris. He occupied the position of Joint Head Microbiology and Head Virology and Serology at the National health Laboratory, Luxembourg between 2005 and 2012 when he retired. He has been Vice-President of ALAN Rare Diseases, Luxembourg since 2013.

SESSION 2: Addressing known obstacles to integrating PM into health systems

Emmanuelle Benzimra (chair)

Emmanuelle Benzimra was appointed in 2012 General Delegate of EPEMED, the European PErsonalised MEDicine association, a pioneer organisation based in Luxembourg and acting to make personalised medicine and diagnostics a reality for European patients. She is also board member of PM Connective, an international non-profit in the making aimed at generating a new collaborative model that maximizes the value of personalised medicine for all involved. Before that she collaborated with different non-profit start-ups, supporting them from creation, to business development and general management, more especially, Bench2Cures, a foundation dedicated to support biomedical research in Luxembourg.

Tapani Piha

Tapani Piha works as Head of Unit in the European Commission since 2004. His current Unit on eHealth & Health Technology Assessment deals also with data handling and protection in healthcare. 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. At the WHO Regional Office for Europe, Copenhagen, in 1989-94 he was responsible for the Action Plan for a Tobacco-free Europe.

Guido Rasi

Guido Rasi is Principal Adviser in Charge of Strategy at the European Medicines Agency (EMA) after having been his Executive Director (2011-2014) and a member of its Management Board. He was Director-General of the Italian Medicines from 2008 to 2011 and member of the Management Board from 2004 and 2008. He was made full professor of microbiology at the University of Rome 'Tor Vergata' in 2008. From 2005 to 2008, he was Director of the Institute of Molecular Medicine of the National Research Council in Rome. Professor Rasi holds a degree in medicine and surgery, with specialisations in internal medicine, allergology and clinical immunology from the University of Rome. From 1978 to 1990, he worked as a physician in hospital, research and private practice. He is author of more than 100 scientific publications.

Christine Chomienne

Dr Christine Chomienne is Professor of Cellular Biology at the University Paris Diderot and Head of the Cell Biology Department at the Hôpital Saint Louis in Paris. She is also Director of the University Inserm Research Laboratory at the Institut Universitaire d'Hématologie. She was a pioneer researcher in differentiation therapy and translated ATRA therapy in APL in 1987 and coordinated the European Biomed I network on APL from 1991 to 1995. Dr Chomienne has since devoted her time in translational research in myeloid malignancies and coordinating internal conferences and networks for dissemination and training in novel concepts and technologies in France and Europe. She was President of the European Hematology Association from 2013 to 2015. Furthermore, she is author/co-author of more than 250 peer- reviewed publications and has received several scientific awards.

Catherine Larue

Catherine Larue is CEO of Integrated Biobank of Luxembourg (IBBL), a not-for-profit and independent biobank designed to facilitate medical research in Luxembourg. Her main expertise relies in the cardiovascular and diabetes areas. She participated in the discovery of several innovative biomarkers and in the market launch of dozens of diagnostic products. In her most recent position at Genfit, she led the biomarkers branch (strategy and discovery) in order to answer personalised medicine needs within a translational approach. Catherine Larue is an author of 85 publications and filed 13 patents. She holds a Ph.D. in Experimental Biology (Rouen University), a University degree in Clinical Cancer Biology (Paris VI University), and an Executive MBA (St. John's Univ, NY).

Valérie Paris

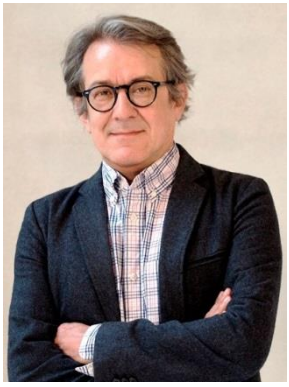
Valérie Paris works as an Economist at the Health Divison of the Organisation for Economic Co-operation and Development (OECD). Valérie joined the OECD Secretariat in September 2005 and since then, she has contributed to several projects on health systems' characteristics and performance and on pharmaceutical policies. Previously, she was researcher at the French Institute of Research and Information on Health Economics (IRDES), a non-profit organization. She participated in research projects on pharmaceutical policies, physicians' payment schemes, health accounts and comparative analysis of health systems. Valérie holds a master's degree in Economics, statistics and econometrics from the University of Paris 1-Sorbonne.

SESSION 3: Best practices: Learning and Sharing

Mary Baker (chair)

Mary Baker, is immediate past President of the European Brain Council and President of their 'Year of the Brain' project. She is consultant to the World Health Organisation (WHO), Chair of the Working Group on Parkinson's Disease and a member of the Commission's CONNECT Advisory Forum. Academic appointments include Associate Membership of the Health Services Research Unit, University of Oxford and Visiting Fellow within the London School of Economics (LSE) Health Centre. In 2009, Dr Baker received the prestigious British Neuroscience Association Award for Outstanding Contribution to British Neuroscience and for Public Service, and in 2014, she received the Dana/EDAB Lifetime Achievement Award for Outreach on Behalf of Brain Research.

François Sigaux



François Sigaux has been appointed Director of the "Cancer" Multi-Organisation Thematic Institute (ITMO) which brings together all research teams working on this disease. A university professor and hospital practitioner (PU-PH) at Université Paris Diderot, François is Head of the Department of Biological Haematology at Saint Louis Hospital. A former President of the French Society of Haematology, he has directed the Doctoral School of Biology and Biotechnology, and occupied the positions of Director of the University Institute of Haematology, Inserm Unit Director, Vice-President of the Institut Curie and President of the Cancéropôle Île-de-France. He is also Director of Research and Innovation at the French National Cancer Institute (INCa).

Katherine Payne

Katherine Payne was awarded a personal Chair in Health Economics at the University of Manchester in 2010. Between 1990 and 1993, she also worked as a hospital pharmacist and has since maintained links with the pharmacy profession to understand the training needs in health economics, in general, and the evaluation of genomic technologies specifically. She has extensive experience working as an academic health economist with different clinical research groups. In 2007, she was awarded an RCUK Academic Fellowship to focus on the evaluation and valuation of genomic technologies including genomic-based diagnostics and pharmacogenetic tests. Based in the Manchester Centre for Health Economics, established in

2012, she is now leading a research group that focuses on the evaluation and valuation of genomic technologies and stratified medicine.

Rudi Balling

Rudi Balling is Director of the Luxembourg Centre for Systems Biomedicine (LCSB) since 2009.

His research topics include systems biomedicine, pathophysiology of Parkinson, bioinformatics, metabolomics, systems biology, comparative genomics and gene regulation. Balling holds a PhD in Reproductive Biology from the University of Aachen. After his habilitation in 1991, he carried out research in the Mount Sinai Research Hospital, Toronto, and in the Max Planck Institutes.. In 2001, he took over the position as Scientific Director of the Helmholtz Center in Braunschweig. January-July 2009, Prof. Balling was a guest professor at the Broad Institute of MIT/Harvard University.

Denis Lacombe

Dr Denis Lacombe is the Director General of the European Organisation for Research and Treatment of Cancer (EORTC). He has worked as a Clinical Research Advisor in charge of the development of a new drug in oncology in the pharmaceutical industry before joining the EORTC in 1993 as a research fellow. In his current position, Denis Lacombe is involved in the coordination and administration of all EORTC activities in order to promote the EORTC as a major European organization in Cancer Clinical and Translational Research and is responsible for the organization of scientific activities, public relations and medium term strategies as well as for internal and external communications.

SESSION 4: The value of PM for Public Health, its impact on EU Health Policy and its global dimension

John Bowis (chair)

John Bowis joined Finsbury International Policy & Regulatory Advisers (FIPRA), as Special Adviser for Health and Environmental Policy in June 2009. John is a former MEP (1999-09) and Member of British Parliament (1987-97). He served two terms in the UK Government as Minister for Health (1992-1996) and Minister for Transport (1996-1997), after which he worked as international policy adviser for the WHO, before being elected to the European Parliament. In the EP, he was spokesman for the EPP Group on the environment and health, and led for the Parliament on a range of reports, including establishing the ECDC, neglected diseases, food safety, mental health and cross border healthcare, and for his Group on the environmental issues of climate change, chemicals and cosmetics.

Ulrike Bußhoff

Ulrike Bußhoff is a senior scientific officer at the Project Management Agency at German Aerospace Centre (PT DLR), which is a service organisation engaging in the promotion of research, education and science, and supporting the Federal Ministry of Education and Research with the implementation of research programmes. Bußhoff is also responsible for the coordination of the Coordination & Support Action (CSA) PerMed, an initiative to step up coordination efforts between European key stakeholders in the area of Personalized Medicine.

Angela Brand

Angela Brand is Founding Director and Full Professor of the Institute for Public Health Genomics (IPHG) at Maastricht University, as well as Dr. T.M.Pai Endowed Chair on Public Health Genomics and Adjunct Professor at the Manipal Life Sciences Centre of Manipal University, India. She is a paediatrician and specialist in public health medicine. She has been the pioneer of public health genomics in Europe and established successfully this field in more than 15 European Member States within the last years. Among others, Prof. Brand is a coordinator of the Public Health Genomics European Network, full partner of the FP7 CSA PerMed on Personalised Healthcare and serves as expert for the WHO or the European Commission.

This report has been elaborated by the Ministry of Health Luxembourg and facilitated by the European Alliance for Personalised Medicine .

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