Oncopolicy Forum

2012 Report

An ECCO initiative because every cancer patient deserves the best

ECCO European CanCer Organisation

www.ecco-org.eu

The European CanCer Organisation (ECCO) Oncopolicy Forum is an annual multidisciplinary and multi-stakeholder platform to harness the expertise and experience of the entire oncology community to bridge the gap between science and policy. It maximises the potential for achieving real change through tackling questions of common concern and looking collectively for answers that will help achieve the best possible outcome for cancer patients.

In October 2012, over one hundred and twenty leaders in European cancer policy gathered together for the fourth edition of ECCO's Oncopolicy Forum at the Bibliothèque Solvay in Brussels, to address the scientific, ethical, financial and practical challenges of making personalised cancer medicine a reality.

All Oncopolicy Forum 2012 speaker presentations have been filmed and are available online in the 'Public Affairs' section of the ECCO website, along with photos and interviews: www.ecco-org.eu

The Oncopolicy Forum - an ECCO initiative because every cancer patient deserves the best.

Introduction

By Professor Cornelis van de Velde, ECCO President

Cancer is one of the pioneering disease areas in the field of personalised medicine.
As such, experiences gained and lessons learned may help pave the way for future strategies not only in cancer but in healthcare more generally. This is why ECCO- the European CanCer Organisation, as a federation of 24 member organisations spanning the entire oncology domain in Europe, brought together a multi-stakeholder audience at its Oncopolicy Forum 2012 to discuss the future of personalised cancer medicine in Europe.

The field of personalised medicine is vastly complex, with many players and disciplines, and offering many promises. Yet there are unanswered questions, and the real prospects for reducing the burden of cancer remain unclear. However, the tantalising prospects and promises of better patient outcomes from continued collaboration in this field provide an immense opportunity.

At ECCO we firmly believe that it is through a multidisciplinary approach that such questions can be answered, in order to truly benefit patients and citizens. ECCO exists to integrate the expertise and insight of the different professions and stakeholders that constitute the oncology community to achieve the best possible patient outcomes, taking into consideration the trends that impact on cancer, the complexity of the disease and the specificity of each cancer patient.

Indeed, we aim to create an environment in which the oncology community network is optimised for each cancer patient. This is of utmost importance at a time when new knowledge is being acquired on a daily basis and governments are trying to find effective, cost-efficient and equitable healthcare solutions.

During the Oncopolicy Forum 2012, we aimed to chart the progress made to date in personalised cancer medicine and to fill the knowledge gaps, so as to gain a good grounding on which the oncology community may build in order to reach the true potential and promise of this exciting area of medicine. What was most apparent from the discussions was the need for improved cooperation, be it in enhancing co-ordination of research, improving public-private collaboration and patient-professional partnerships, or encouraging information exchange to reduce inequalities, address reimbursement decisions and enhance the training of professionals.

As part of our focus on optimising the cancer network to improve both patient involvement and outcomes in the cancer value chain, ECCO is committed to collaborative partnerships and is proud to take a leading role in several multidisciplinary, multi-stakeholder initiatives at EU level, such as the European Partnership for Action Against Cancer, the Alliance for Biomedical Research in Europe and the European Chronic Disease Alliance.

ECCO will continue to encourage multidisciplinary co-operation and collaboration in personalised cancer medicine. The next Oncopolicy Forum takes place on 30 September and 1 October 2013 within the biennial European Cancer Congress. This unique meeting emphasises the multidisciplinary and multi-professional approach to cancer research, treatment and care as the best means to ensure optimal patient outcomes. This report will provide the foundation for the next stage of the debate on the same topic. I do hope you can join us in the wonderful city of Amsterdam to help us define evidence-based multidisciplinary cancer strategies and policy in Europe.

Welcome Letter

by Alojz Peterle,
Member of the European Parliament

Dear fighters against cancer, dear friends,

I would like to express my support for the fourth Oncopolicy Forum organised by ECCO – the European CanCer Organisation, which was dedicated to the future of personalised cancer medicine in Europe.

As a survivor of cancer myself, I know from personal experience how hard cancer is to live with - both for those directly affected and for those close to them. Since I have been elected to the European Parliament, I have committed myself to support people across the European Union in their struggle against the disease. As President of an all-party informal group in the European Parliament, MEPs Against Cancer (MAC), and together with many fellow colleagues, we are committed to promoting action on cancer as an EU priority and harnessing European health policy to that end. As the most cost-effective long-term strategy for the control of cancer, MAC has been focusing mainly on prevention, but has been of course also involved in other cancer areas including research, information and healthcare when relevant opportunities arise.

Through quarterly roundtable discussions between MEPs, other policy makers and invited guests, the MAC group aims to generate the political will needed to fight cancer in Europe.

The health agenda is full of urgent issues, but this disease has been with us for a long time. We need determination, continuity and solidarity in our approach. Many cancers are now preventable and the treatments are there which allow patients to survive. We must put those capabilities to good and immediate use.

As far as personalised cancer medicine is concerned, I am sure this can have a great potential for cancer patients by improving healthcare systems, but at the same time we need wider co-ordination on research, with better access to information for researchers, doctors, pharmacists and patients and multidisciplinary training for healthcare professionals.

Welcome Letter

by Máire Geoghegan-Quinn,
EU Commissioner for Research and Innovation

Cancer is everybody's business. In 2012 alone, 3.2 million people in Europe will be diagnosed for the first time with cancer, about 13 million people will be affected and 1.2 million will die from this disease. For this reason, cancer research and innovation are a priority for the European Union. Since 2007, the 7th Framework Programme for Research (FP7) has allocated some €1.1 billion to this field.

The European Union policy on cancer research is first and foremost at the service of the cancer patient. None of us are supporting or carrying out research simply to acquire more knowledge, but to improve patients' chances of living longer and living well. Thanks to concerted efforts worldwide, many more cancer patients survive compared to 30 years ago as we have developed better diagnosis, better drugs, and better prevention policies based on the best available evidence.

But despite these improvements, more needs to be done. Treatments are not selective enough and inequalities of access continue to exist. Innovative cancer research is needed to underpin and pave the way to better and personalised cancer therapies with a greater impact on every patient and on our society. And we need all this at a reasonable cost.

Personalised cancer medicine requires major changes and unprecedented levels of co-operation along the healthcare innovation chain. From researchers who identify and describe diseases and mechanisms, to those who exploit this knowledge by developing new biomarkers, diagnostics and medicines, and on to the regulators and health ministries who evaluate, approve and implement them and well-informed patients.

Horizon 2020, the new Framework Programme for Research and Innovation that begins in 2014, aims at stimulating and supporting this new approach. Indeed, its major objective is to improve the link between research and innovation, funding every stage of the innovation ecosystem 'from research to retail, from laboratory bench to bedside'. Personalised medicine will be at the core of the research and innovation activities supported under the 'Health, demographic change and wellbeing' societal challenge.

Horizon 2020 will help European researchers take decisive steps towards the development of a comprehensive and co-ordinated effort on cancer research in Europe, based on initiatives implemented by the European Union and its Member States. It will link the public and private sectors and encourage the development of treatments with a molecular, rather than just a symptomatic understanding of cancer. All this will contribute to make a significant move towards more accurate diagnosis and tailored treatments, minimising harmful side effects and improving cure rates. Personalised medicine represents one of the most promising avenues for the future of medical research and health care, and nowhere is this more true than in cancer.

Executive summary

The future of cancer treatment and care in Europe looks promising. With scientific advances paving the way for a more pre-emptive approach to managing the many diseases that together we term cancer, opportunities for personalised approaches to prevention, diagnosis and treatment are an exciting prospect.

However, it is clear that if these opportunities are to come to fruition, a clear vision and strategy will be required to underpin infrastructural, organisational and policy changes for the safe, effective and cost-efficient advancement of personalised cancer medicine.

The Oncopolicy Forum aimed to identify the challenges Europe faces in making personalised cancer medicine a reality in day-to-day practice, what and who is needed to address the challenges, and the extent of multidisciplinary collaboration and networking that is on-going between key stakeholders to bring the full potential of personalised cancer medicine to fruition.

The present summary aims to integrate in a coherent and logical way the main messages stemming from the presentations and discussions.

Databases and information-sharing

Data collection, storage and use are central to personalised cancer medicine, and major databases are needed in order to study prevention, treatment and care. Technology will need to evolve rapidly as well as the education and training of researchers using these databases. Currently, lack of expertise, the high cost of biomolecular characterisation and lack of appropriate quality control programmes are hindering the full exploitation of potential technologies. European collaboration is needed in setting sensitivity and specificity standards to enable comparisons to be made between laboratories using different 'omics' technologies as well as for quality assurance of biomarkers. Finally, different stances on ethical issues between countries surrounding collection, storage and use of patient tissues and data create a complex situation for the sharing of information and cross-border research undertakings.

Molecular screening and diagnostics

Molecular screening and diagnostics hold enormous promise for cancer medicine compared to traditional diagnostic tests, but certain limitations exist regarding their development and use. As there is currently no clear path for reimbursement of molecular diagnostics, there is little incentive for companies to develop them. Use of diagnostic tests requires strict quality control, an issue which could potentially be co-ordinated through a European central authority. While some countries can boast well-developed molecular platforms for the rolling out of national programmes, others could learn from such examples. Indeed, a European platform inspired by existing national initiatives could be a consideration for the future.

Evidence-based development of targeted therapies

Current cancer treatment is not selective enough and is often characterised by significant wasted resources, over-treatment and subsequent unnecessary side-effects for little gain in some patients. Further research is needed to assess how best to use the therapies already in existence, including chemotherapy, radiation therapy and surgical oncology. While personalised cancer medicine offers the opportunity to deliver more targeted treatments, commitment from funders is needed for investment in practice-changing trials to understand who benefits from a given treatment and who does not. Quality-of-life is an important consideration in any assessment of therapy outcomes and measures should incorporate aspects considered of most importance to patients themselves; thus a true definition must be formulated with the patient at the centre. Common databases for treatment patterns and outcomes are needed as well as follow-up studies to verify predictions from models based on information from clinical trials.

Assessment of cost-effectiveness of current and new treatments

Economic aspects of personalised cancer medicine as well as conventional treatments guide treatment modalities and reimbursement decisions, and as such robust cost-effectiveness studies and accurate information on cancer treatment expenditure are needed. More detailed economic information should be sought during the drug development phase and before the treatment appears on the market. While the European Medicines Agency is already starting to approve targeted drugs in small populations at quite an early stage, differences in health technology assessment methodologies mean that inequalities exist in access to treatments within and between countries. Increased collaboration is recommended between regulatory bodies and health technology assessment organisations as well as between health technology organisations themselves.

Innovative and sustainable approaches to research

More innovative, collaborative and sustainable approaches to research are essential for the advancement of personalised cancer medicine in Europe. It is clear that no single country or institute will be able to cover all the research needed for identifying biomarkers, overcoming drug resistance and many other issues besides. Improvements are needed in co-operation and co-ordination of research, and in encouraging private sector capability in order to deal with stratified patient populations and designing appropriate clinical trials. Intellectual property rights are a contentious issue and discussions should be facilitated between researchers and pharmaceutical companies in order for agreements to be reached.

The EU has a clear role to play in fostering co-operation and co-ordination of research and in providing a coherent European strategy based on scientific state-of-the-art. Horizon 2020, the successor to FP7, aims to build on the genomics revolution for a more finely-tuned approach to cancer medicine and a shortening of the innovation cycle.

Multidisciplinarity and patients as key partners

Underpinning the advancement of personalised cancer medicine is the need for multidisciplinarity and multiprofessionality in all aspects of cancer control. The arrival of new technologies means that biologists, nuclear medicine specialists and pathologists need to work together. Pathologists have a vital role to play but are underrepresented, along with nurses, psychologists, physicists and biostatisticians. An understanding of each other's respective roles is crucial, as is inter-professional education and discussion.

The patient also has a central role in the advancement of personalised cancer medicine. Being able to drive forward research and the adoption of results in clinical practice, as well as providing advice on aspects such as quality of life and adherence, personalised cancer medicine will only deliver on its potential with patients as partners. ECCO is afforded direct insight into the issues and challenges faced by cancer patients through its Patient Advisory Committee, and delivers on the philosophy that every cancer patient deserves the best by putting the patient firmly at the core of all ECCO activities and educational programmes.

Multi-stakeholder partnerships and networks

Multidisciplinary and multi-stakeholder partnerships and networks at European level can help pave the way for collaborative and co-ordinated initiatives needed to help advance personalised cancer medicine for the benefit of patients. ECCO is proud to take a leading role in the European Partnership for Action Against Cancer, the Alliance for Biomedical Research in Europe and the European Chronic Disease Alliance, initiatives bringing stakeholders together to structure policy for improved health outcomes. And through the support of excellence led initiatives such as the European Academy of Cancer Sciences and the organisation of multidisciplinary fora such as the Oncopolicy Forum, ECCO believes that collectively, we can devise and implement strategies to win the war on cancer.

In conclusion, the Oncopolicy Forum 2012 has helped identify and bring to light many of the challenges Europe faces in making personalised cancer medicine a reality in day-to-day practice. The next step is to actively address such challenges, while ensuring that multidisciplinary collaboration and networking is optimised between key stakeholders to bring the full potential of personalised cancer medicine to fruition. That is why the next Oncopolicy Forum will once again concentrate on personalised medicine, as a Track during the European Cancer Congress, 27 September to 1 October 2013, at Amsterdam. ECCO is looking forward to being an active partner in the definition and implementation of a European vision and strategy for personalised cancer medicine, and invite all interested parties to join in the discussions.

Opening Session: Setting the Scene

Introducing the day's events, ECCO President Cornelis van de Velde, explained that the aim of the Oncopolicy Forum is to bridge the gap between science and policy by harnessing the expertise of the entire cancer community and promoting multidisciplinarity.

Patient-centred in its approach, ECCO promotes multidisciplinarity to ensure that all cancer patients get timely access to expert advice, treatment and care from oncology professionals with the most relevant specialist knowledge and skills.

Cornelis van de Velde hoped that the day's proceedings would identify the challenges inherent in achieving personalised cancer medicine for all patients, and indicate where we are today in addressing the challenges, what is needed, who are the stakeholders involved and to what extent they are co-operating in a multidisciplinary way to address the challenges.

Julio Celis, Chair of the ECCO Policy Committee, said that, although the potential of personalised medicine has not yet been fully realised, many oncology professionals firmly believe that it will be an integral part of everyday clinical practice within the next five to ten years, and that its arrival could change the entire landscape of European oncology. The development of individualised therapies has implications for all disciplines, from detection, diagnosis, treatment and care, and personalised prevention is expected to become the gold standard.

EU cancer research policy priorities

In a video address, Máire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science, congratulated ECCO for organising this multi-stakeholder meeting. Cancer is everybody's business, she said, and cancer research and innovation is an important EU priority. Under the EU-funded Seventh Framework Programme for Research (FP7), which is coming to an end in 2013, €1.1bn had been allocated to cancer.

> ***"Cancer is everybody's business"***
>
> (Máire Geoghegan-Quinn, EU Commissioner for Research and Innovation)

The Commissioner pointed out that EU policy on cancer research first and foremost aims to benefit patients, helping them to live longer and live well. Thanks to concerted efforts worldwide, many more patients now survive compared to 30 years ago, but despite improvements much more needs to be done. Treatments are not selective enough and inequalities still exist in Europe. More innovative cancer research will be needed to bring the benefits of personalised medicine to cancer patients and to society – and all this at a reasonable cost, she said.

The Commissioner introduced Horizon 2020, the next Framework Programme for Research which will begin in 2014, and which will fund excellent collaborative research. There will be improvements on previous programmes – for example, it will bring simplification, with one set of rules for the whole programme; cutting through red tape will mean quicker results and easier navigation, leading to faster access to funding; and it will improve collaboration in the entire innovation 'eco-system' all the way from bench to bedside. Building on the genomics revolution, a more finely-tuned approach to cancer medicine should be developed. Personalised cancer medicine requires major changes, and unprecedented levels of co-operation all along the chain, from researchers through to regulators. Cancer research has a major role to play, but so too do patients and primary care physicians. We need to learn from the success of investigator-driven trials in areas such as paediatrics and rare cancers - areas that require collaborative research at a pan-European level. And in order to be able to use innovative approaches we are making dedicated efforts to engage SMEs in cancer research through the Horizon 2020 programme, she said.

Horizon 2020 will help European researchers take decisive steps towards comprehensive and co-ordinated cancer research in Europe, including linking the public and private sectors and running transnational clinical trials. Commissioner Geoghegan-Quinn concluded by saying that she believes Horizon 2020 will help improve the lives of millions of people.

Maria-José Vidal-Ragout, from the European Commission's DG Research and Innovation, said that European cancer research should be concentrated in areas where it will be valuable and useful. It should shorten the innovation life cycle in order to build evidence-based solutions to clinical challenges. For example, the MAMMI project aimed to speed up innovation in molecular imaging and radio tracers against breast cancer, and the CancerDip project was looking at prognostic markers in colon cancer in order to improve treatment. Another example of EU co-operation in cancer research is in childhood cancers, where research has integrated resources and developed results. Moreover, public-private partnerships such as the Innovative Medicines Initiative have also improved co-operation in cancer research at European level.

> ***"We need a new model of collaboration, (…) we need independent evaluation, a more integrated, comprehensive approach, intervening with key players who are out of the game at the moment, i.e. insurance, healthcare providers, payers (…) we need to identify new models to identify where to allocate budgets"***
>
> (Francoise Meunier, Director General, EORTC)

However, personalised medicine presents many challenges – challenges of cost and of increased pressure on European healthcare systems, and technical challenges such as identifying biomarkers, dealing with stratified patient populations, the appropriate design of clinical trials, and how to overcome drug resistance. Improvements are still needed in the co-operation and co-ordination of publicly funded research, in harnessing and encouraging private sector capability, and in adapting to an ageing population, she concluded.

Personalised Cancer Medicine: Defining the concept

Alexander M.M. Eggermont, President of the European Academy of Cancer Sciences and Director of the Institut Gustave Roussy, discussed the conceptual, organisational and financial challenges related to personalised medicine. He began by underlining the importance of distinguishing individualised cancer care from personalised cancer medicine. Molecular biology has meant that oncology has moved from the microscopic examination of cells to a much more developed picture, which means that you can define types of tumour cells by looking at genes. In breast cancer, for example, it is now possible to divide tumours into at least ten types, if not more. In lung cancer too it is now possible to define various targets that may be 'druggable'.

In the future, almost all drug development will be done in Phase 1 and 2 trials and there will be fewer and smaller Phase 3 trials. But the approach still has limitations, with diverse responses to treatment being seen – some patients have a striking response and others much less so. And then there is the 'only 30%' problem, he said, where a targeted drug only has an effect in 30% of any group of patients. What can be done for the 70% who are currently without a personalised treatment, and who have to receive older, standard therapies? A biopsy of the tumour and organ of origin in order to have an accurate genomic profile could lead to the development of an algorithm to pick the drug with the highest probability of effect in those patients.

> ***"Personalised cancer medicine poses really different questions now and requires different infrastructures compared to what we were used to"***
>
> (Alexander Eggermont, President, European Academy of Cancer Sciences)

One of the problems with molecular medicine, Eggermont noted, is that it is creating vast amounts of data which are impossible for doctors to follow and digest. This is not simply due to tumour heterogeneity but also to patient heterogeneity. It will be important to manipulate the immune system in such a way that cures are created, rather than just working with target agents.

Providing personalised medicine approaches to patients will involve huge costs, and this is yet another hurdle to overcome. Eggermont used the analogy of Disneyland: should society pay for an expensive trip to Disneyland in their final year of life? Should society pay for everyone to acquire expensive personalised treatment to prolong their life, even for only a few months? With the increasing financial pressure on national health systems, this debate needs to take place, he said.

A big impact in small, well-defined populations and in newly-defined diseases will decide drug development processes in the future, he said, and no single institute or country will be able to do all the research that is needed. To avoid duplication of effort and fragmentation of research, consortia and networking at European level is crucial.

We can definitely make an impact with targeted drugs and we will only get cures if we involve the immune system, Eggermont said. But we cannot create huge expectations and we must deliver on our side, he concluded.

Session 1 - Key Issues in Personalised Cancer Medicine

Chair of the session, Gordon McVie, from the European Institute of Oncology, said that the time had come to take decisions on strategy. The term 'personalised medicine' can be confusing for patients who already consider that their doctors treat them as individuals. It is important to keep patients informed of changes in medical practice and what the benefits to them will be.

"Multidisciplinarity allows you to personalise your treatment choices. However, it is still a challenge in our everyday professional lives, in our hospitals, it's a challenge in Europe, it's a challenge everywhere...we need to work on this"

(Paolo Casali, Executive Board Member, ESMO)

Addressing harmonised standards

Peter Lichter, an expert in molecular genetics at the German Cancer Research Centre (DKFZ), said that next generation sequencing has meant that it is now possible not just to look at the DNA of cancer patients, but also to include scrutiny of, for example, their genome, epigenome and proteome. It means that, for example, the identification of germline tumours in some cancers, that have implications for treatment, is now possible.

The era of personalised cancer medicine poses challenges to overcome and Lichter provided examples of several areas that need further discussion and proposed several solutions. As sequencing research advances, ethics is a burning issue, he said. Furthermore, current informed consent does not sufficiently take into account the extent of the use of data in personalised medicine research.

And how should additional findings from this data be handled? There is currently no clarity on how to deal with non-medical researchers who can have access to data which is not protected. Clear ethical guidelines for these researchers are needed, he explained. How could such data be published and still maintain anonymity? A working group, at least on the national level but preferably Europe-wide, on the ethical aspects of personalised medicine, could be the answer, he suggested.

Many different 'omics' technologies are being used at present in different ways which leads to differing depths of analysis. Lichter underlined the importance of sensitivity and specificity standards achieved through inter-laboratory comparison of identified genomic alterations in defined cell populations, which can help overcome this.

Data storage is another major issue. This requires huge resources and researchers need to learn which data is sufficient to extract so that all data does not have to be stored.

New standards for clinical trials will be important as patient cohorts get smaller and smaller. And there is the difficult question of co-ordination of pharmaceutical industry partners. Lichter concluded by suggesting that a round table moderated at European level would be a useful first step in moving forward on this issue.

Towards a faster uptake in clinical practice

We are now in an era of stratified oncology, said Martine Piccart, ECCO President-elect, and it would be important to address the issues involved in moving from stratification to personalisation. While a lot has been accomplished, there are many issues that still need to be addressed, and Europe must ensure it doesn't fall behind.

"In Europe we don't pay enough attention to the importance of diagnostics and there cannot be precision medicine without powerful diagnostic tests"

(Martine Piccart, President-Elect, ECCO)

Taking the example of early breast cancer, she said that currently women with the disease are offered drugs to prevent metastases. But this means that some women are over-treated and some under-treated, and there are huge economic costs incurred, as well as serious consequences for the patient. It is impossible to provide precision medicine without precision diagnosis, but there is currently very little incentive for small companies to develop new diagnostic tests because there is no clear path towards their reimbursement. Experts have high hopes for gene expression signatures to identify individual risks but there is far higher take-up of such tests in the US than in Europe at the present time.

Pathologists have a vital role to play in bringing personalised medicine to fruition but they are disappearing fast, she said. Pathology should be made more attractive and supported – currently we depend on the pharmaceutical industry for biobanking.

M. Piccart

Limitations to the traditional diagnostic tests need to be recognised and molecular diagnostics taken seriously. There needs to be a commitment by funders to invest in practice-changing trials to understand who benefits and who does not; otherwise we will have to continue to use expensive drugs on people who will not benefit from them. The pharmaceutical industry cannot be expected to pay for this, she explained. To move from stratified to personalised oncology would need molecular diagnostics to be taken seriously by all those involved and for the EU and governments to support practice-changing trials. Quality control measures for diagnostic tests are also needed and better co-ordination of this entire domain could be more efficiently run through a European central authority. The ultimate dream solution to encourage the acceleration of personalised medicine in Europe would be the foundation of a genome cancer medicine centre, she concluded.

Regulatory clarity

Jonas Bergh, Vice Chair of the European Medicines Agency's (EMA) Scientific Advisory Group on Oncology and based at the Karolinska Institute, said that in his opinion, the drug approval process in Europe, co-ordinated by EMA is working well. Drug approval is voted on by the competent authorities in the 27 EU Member States and approval is made by a simple majority of voting countries. An issue that needs to be addressed in the approval of the drug is the quality-of-life of the patient, and more pre-defined points on quality-of-life need to be considered.

Health technology assessment (HTA) in Europe, however, is rather messy. There are far too many stakeholders and the role of the 96 evaluation agencies varies from country to country, with almost no collaboration. There are also major differences in reimbursement Europe-wide, and once again little or no co-ordination in place. This heterogeneous framework and the excessive hurdles that are slowing down research should be tackled at a pan-European level.

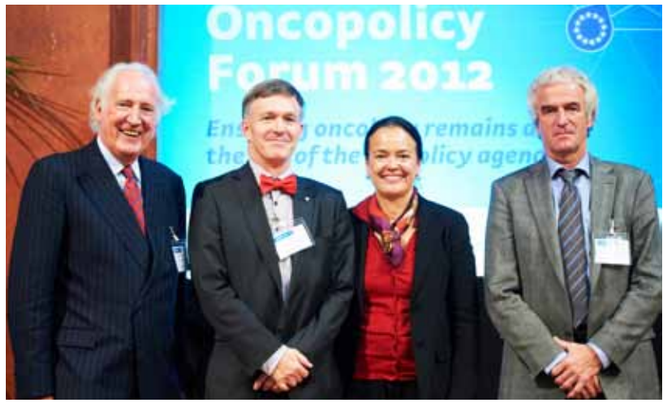
"It's a very exciting time but the finances are limited. We need to prioritise and only such interactions can help us in discussing, negotiating and prioritising"

(Riccardo Audisio, President-Elect, ESSO)

Quality assurance of diagnostic tests and imaging procedures is needed. The old strategy of measuring the size of the tumour is not good enough, Bergh said. There is a need to know what is happening at cellular level using advanced methods, particularly during tumour progress. The approval process for new treatments is working well, with the EMA starting to approve targeted drugs in small populations at quite an early stage, but HTA procedures are not; there is a need for European collaboration and guidelines in biobanking and also in quality assurance of biomarkers.

In a discussion with the audience, a number of issues were raised. It is important to focus efforts on subgroups of patients where there is no existing treatment, and to establish new guidelines for personalised medicine clinical trials with a defined process that is appropriate for the whole of Europe, speakers said. This can hopefully address the major lack of co-ordination amongst different research groups in Europe, as currently developments are being taken at both national and European level, with little oversight. This process should be transparent.

The role of pharmaceutical companies and in particular their attitudes to intellectual property received a lot of attention. New biomarkers are urgently needed in oncology to identify whether particular tumours respond to a treatment or not but this has led to endless contract negotiations about intellectual property, which meant losing valuable time. There has been very little progress over the last few years because of this. A platform facilitating discussions between researchers and large pharmaceutical companies on ownership issues should be discussed as current negotiations are lengthy and inefficient.



From left to right: G. McVie, J. Bergh, M. Piccart, P. Lichter

The role of patients and in particular their enthusiasm to help researchers accelerate in this field through the use of their tissues was discussed. Politicians currently do not seem to take into account the opinions of the patients themselves on their information and as the EU Directive on Data Protection is currently being discussed, patients and professionals should work together to voice their concern about the direction the legislation is taking. This issue is further complicated by the fact that ethics is dealt with at the national level with no strategic European approach in place.

The importance of imaging techniques in precision diagnosis was emphasised, together with the need to work together with nuclear medicine specialists to design trials so that whether or not a treatment works can be shown at an early stage – in some cases, after only two weeks. But it is difficult to get enough funding to be able to recruit sufficient patients for a reliable result, and quality control studies would also be needed. In Europe there is no European validation and no oversight of medical devices before they are put into laboratories; so for the same molecule one can have different results at different sites. A laboratory accreditation system is urgently needed, speakers said.
Questions related to inequalities in reimbursement across Europe and how to deal with personalised medicine in the context of an ever-increasing older population were also raised by the audience.

Summary

Winding up the session, Session Chair Gordon McVie outlined several recommendations. Ethical issues related to personalised medicine need to be debated and addressed urgently. Issues related to personal health data in the proposed EU Data Protection Regulation which is currently being reviewedalso needs to be assessed and the necessary action taken. Standardisation in quality assurance and speed in adopting diagnostic tests are needed and technology in cancer centres should be checked between cancer centres. Finally, a policy on health technology assessment needs to be developed quickly.

A. Eggermont

Participants at the Oncopolicy Forum

Session 2 – Key Issues in Personalised Cancer Medicine

Richard Sullivan, from King's College, London, and Kings Health Partners Integrated Cancer Centre, Guy's Hospital, chaired this session.

Health economics and personalised cancer medicine

Bengt Jönsson, from the Stockholm School of Economics, introduced his presentation by explaining that currently we know little about how we are spending our resources on cancer. Personalised medicine has great potential but healthcare systems have to understand which treatments provide the best value. This requires a lot of additional information – part of which needs to be available during drug development and before the treatment arrives on the market. The use of particular drugs in different countries also depends on their national economies and reimbursement policies. Relative effectiveness may thus vary between countries. Personalised medicine holds great potential for pharmaceutical innovation, but innovation needs to be more efficient, i.e. less costly and/or providing better outcomes, he said. Cost effectiveness analyses would be an important tool for optimising the use of personalised treatments.

> ***"There are some priorities that are related to health, education and knowledge that are above political priorities (...) We need more than ever to emphasise there are issues that can be the symbol of Europe"***
>
> (Federico Mayor-Zaragoza, Former Director-General, UNESCO)

Jönsson called for an evidence-based approach for the introduction, uptake and use of new cancer medicines. Common databases should also be developed, allowing the sharing of treatment patterns and outcomes, and follow-up studies should be carried out to verify predictions from models based on information from clinical trials. Finally, there is a need for improved collaboration between regulatory bodies and Health Technology Assessment organisations.

Training of healthcare professionals

Angelo Paradiso, from the Giovanni Paolo II National Cancer Institute (Italy), discussed what was needed in terms of training of healthcare professionals in order for them to optimise the use of personalised cancer treatments. The arrival of new technologies means delays in moving from standard to new practices, particularly since people with different expertise and competencies – biologists, nuclear medicine specialists, pathologists et cetera – need to work together.

There are delays in the availability of technology caused by the cost of biomolecular characterisation, the lack of appropriate quality control programmes for assays, and lack of specific expertise. Scientific societies provide high-quality education in new technologies, but some specific cancers are still not included in education activities. It is often difficult for professionals to work together, with problems of competition, a lack of understanding of their respective roles, a lack of consensus about technology, and a lack of training in specific medical areas. Nurses, psychologists, physicists and biostatisticians are particularly underrepresented in such activities. Discussion and debate is needed between all the professionals involved, focusing on clinical case studies, and with the development of specific inter-professional education, he said.

In conclusion, Paradiso recommended improved co-ordination of educational action at EU level to cover all multidisciplinary needs in personalised cancer medicine. All stakeholders, including patients, should be involved in training. Finally, he said that inter-professional educational doctoral training in all areas affected by personalised medicine should be encouraged.

Educating patients as partners in personalised medicine

Jan Geissler, from the ECCO Patient Advisory Committee, raised the issue of biomarker medicine as having the potential to create new access barriers. Imagine a scenario where they are used to exclude patients rather than to target patients, he suggested.

Personalised medicine might only be available in centres of excellence and accessible to those who are sufficiently informed to seek these centres, leading to inequalities in access to care. To deliver the promise of personalised medicine, patients need to play an increased role in driving forward research for new therapies and their adoption in daily practice. This means ensuring that empowered patients understand the process of personalised medicine, that

informed consent procedures are improved, that trial results are made known more widely, and that patients provide valuable insights to researchers, including information on issues like quality-of-life and adherence, he said.

The European Patients' Academy on Therapeutic Innovation (EUPATI) launched in February 2012 and funded by the Innovative Medicines Initiative (IMI), will educate patients and build competencies and expertise. A better non-centralised model for patient information in Europe is urgently needed. Personalised medicine, if applied correctly, will be a blessing, he concluded. But it should become truly personalised and multidisciplinary, and not more exclusive, and it will only work with patients as partners. As a recommendation, he called for a revival of the debate on a better "information to patients" policy that really meets today's patients' needs, something that is urgently required by patients for the adoption of personalised cancer care.

In a discussion with the audience, the issue of equal access to personalised medicine was raised. There are already major inequalities of access to new treatments across Europe, speakers said, and healthcare spending in European countries is already expensive: it is now rated at around 10% of the annual budget and may go up to 15%, with the next decade probably seeing a rapid expansion of resources spent on cancer. In some countries new drugs have been approved but national reimbursement decisions meant it was impossible to use them. Biomarkers are still evaluated in terms of incremental cost, and not of cost saving, though this should change over the next ten years or so. Incorporating health economics at an early stage of drug development should become policy, and the same applied to guidelines – once two or three countries have developed them, others could follow without needing further validation. Health technology assessment methodologies that have proven successful in various countries could be identified and promoted.

"We are in a hurry. We don't have years to wait for ponderous research programmes. We need information now and we need better treatments now"

(Kathy Oliver, Co-Director, International Brain Tumour Alliance)

New therapy assessments need to take the patient perspective into account and particularly the impact on their social lives – for example, does giving a patient a particular treatment mean that he or she can go back to work?

Applying molecular screening in everyday diagnosis will become crucial as cancer becomes the number one cause of mortality in Europe. Major databases will be needed in which prevention, treatment and care can be studied in order to harness new technologies for the benefit of patients. ECCO could take a co-ordinating role in harmonising European guidelines, said Cornelis van de Velde. Furthermore, there should be a common platform for guidelines that could be individualised for each European country.

From left to right: B. Jönsson, J. Geissler, A. Paradiso

Regarding the issue of equity and social justice, in some respects, personalised medicine can be understood as having the potential to exacerbate inequalities since different health technology assessment methodologies in different countries lead to varying levels of access to targeted therapies. The EU Directive on Cross-Border Healthcare may, on the other hand, address inequalities by encouraging the exchange of knowledge and expertise.

"Personalised medicine comes with an obligation to empower patients to increase their health literacy and to make more information available to patients"

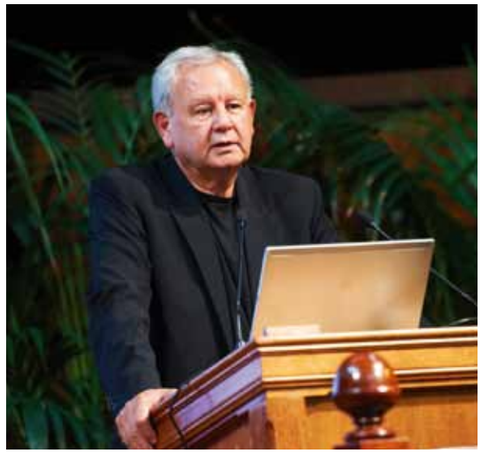
(Jan Geissler, Vice President and Managing Director, Leukemia Patient Advocates Foundation)

Regarding cost of new treatments, Bengt Jönsson explained that comparison with conventional treatments is very difficult, since we do not actually know how much we are spending currently. Information is needed on how much is spent on cancer treatment as a whole, and not just on drugs. Estimates suggest that around 20-30% of healthcare expenditure is wasted. This waste needs to be weeded out and used on treatments with proven benefits. Health technology assessment can be seen as a way of delivering equity, as it helps provide arguments and justifications for where to spend resources.

One member of the audience suggested that since the French model of molecular testing has proven to be extremely cost-effective, it should be used all over Europe. Indeed, ECCO is working together with France's Institut National du Cancer (INCa) through the European Partnership for Action Against Cancer (EPAAC) Joint Action, to evaluate the expansion of this model at European level.

Summary

In conclusion, it was stated that there needs to be proof that personalised medicine can generate cures. A holistic approach that addresses research, diagnosis, treatment and prevention through the combined efforts of researchers, clinicians, patients and advocates is the way the oncology community should pursue personalised cancer medicine. A key strength of ECCO lies in the fact that it is able to organise multidisciplinary meetings such as the Oncopolicy Forum, covering a broad spectrum of issues, and together with ECCO Member Societies and the European Academy of Cancer Sciences, the European oncology community should be able to win not only the battle against cancer, but also the war.



J. Celis

W. van Harten

Session 3 – Oncopolicy 2020 – Personalised Cancer Medicine: The way forward

This session focused on showcasing current and future examples of multidisciplinary partnerships and pilot projects in personalised cancer medicine.

Session Chair, Ian Banks, from the ECCO Patient Advisory Committee, introduced this session by saying that patient advocacy had made great strides in the last ten years. It is to ECCO's credit that they recognise the integral value of patient advice, he said.

> ***"This is hugely exciting (...) But it is applying (personalised cancer medicine) in the real world that really matters, including consideration of the human elements such as questions of quality-of-life when life is prolonged"***
>
> (Ian Banks, President, European Men's Health Forum)

The European Alliance for Personalised Medicine (EAPM)

Bernard Malavaud, from the European Alliance for Personalised Medicine, described personalised medicine as getting the right treatment to the right person at the right time. It is urgently needed because current healthcare systems are unsustainable in terms of cost. Avoiding unnecessary treatment and increasing efficacy is the first priority. Many studies have shown that personalised medicine could reduce costs, and it is indeed now the standard of care in haematology.

Rare diseases should be studied at European level with novel trial designs, he said, and it is important to include a quality-of-life element in trials. Multidisciplinary research, treatment and care, support from regulators, and appropriate education of all involved will be needed if such trials are to succeed, he said.

From left to right: I. Banks, J. Celis, C. van de Velde, O. Wiestler, P. Casali

Public-private partnerships to stimulate drug development through academic clinical research

The work package on research co-ordination of the European Partnership for Action against Cancer (EPAAC) aims to promote a Europe-wide approach to all aspects of cancer research, said Fabien Calvo, of the Institut National du Cancer (France), co-leader of the work package together with ECCO. The EU should support the discovery and development of better medicines, and the benefits of European co-operation in this respect are considerable.

> ***"Research in many fields will not be possible without the participation and proximity of patients"***
>
> (José Mariano Gago, Former Minister for Science, Technology and Higher Education, Portugal)

Describing the situation in France, he said that a network of 16 early phase trial centres and 28 regional platforms have been in existence since 2008. High-quality molecular testing for patients is available all over the country and collaboration with industry has led to the discovery of five innovative molecules.

Cancer drug costs in France are €1bn, about 13% of total drug costs, and diagnostic tests cost €10m in 2011. The total cost of cancer is €12bn, or 6.6% of total national health expenses.

European collaboration means that time could be gained, especially in trials of treatments for rare cancers, he concluded. It would improve the quality and scientific level in early phase trials and molecular biology tests, give access to additional sources of funding, and have a beneficial health impact for all.

The German Consortium for Translational Cancer Research

Otmar D. Wiestler, from the German Cancer Centre (DKFZ), said that there were big challenges ahead for his country. Interdisciplinary expertise and complex infrastructures are needed. A project to develop long-term partnerships between Heidelberg and centres of excellence at seven sites in universities is underway.

A clinical communication platform has been set up and data from patients recruited goes to a central biobank. Patients participate in trials, in particular trials of personalised therapies. This might serve as a model at European level and in other EU countries in the future.

Rare Cancers: a case study

Rare cancers are not so rare – they make up at least 20% of new cancer cases, said Paolo Casali from the Istituto Nazionale Tumori (Italy), who explained that a European network for rare cancers has been created.

> ***"What we need is a change of culture(...) We need to get people to work together and devise new ways to evaluate the impact of work on life, not just on impact factors in journals"***
>
> (Julio Celis, Past President, EACR)

One of the continuing problems of trials of personalised medicine, he said, is that the statistics used do not deal with probabilities, which means that a higher degree of uncertainty in trial results needs to be accepted by regulators. If efficacy for subgroups of patients increases, cost effectiveness increases too. In rare cancers it is more likely that regulators will allow the testing of new options because the cancers are rare and there are no other alternatives – and we may well find that the solutions we find for rare cancers are useful in more common ones too.

Scientific-led strategic action in future European health research

Julio Celis, speaking as Vice-President of the Alliance for Biomedical Research in Europe (BioMed Alliance), said that current challenges in health research could only be met by increased knowledge and by developing a coherent European strategy. There are many obstacles to be overcome, and a change of culture to facilitate working together across borders is urgently needed. The EU's Horizon 2020 programme provides this opportunity. For the first time, 20 health research organisations representing around 250,000 biomedical research scientists from across Europe, have come together to form the BioMed Alliance. This consortium of medical societies has proposed the creation of

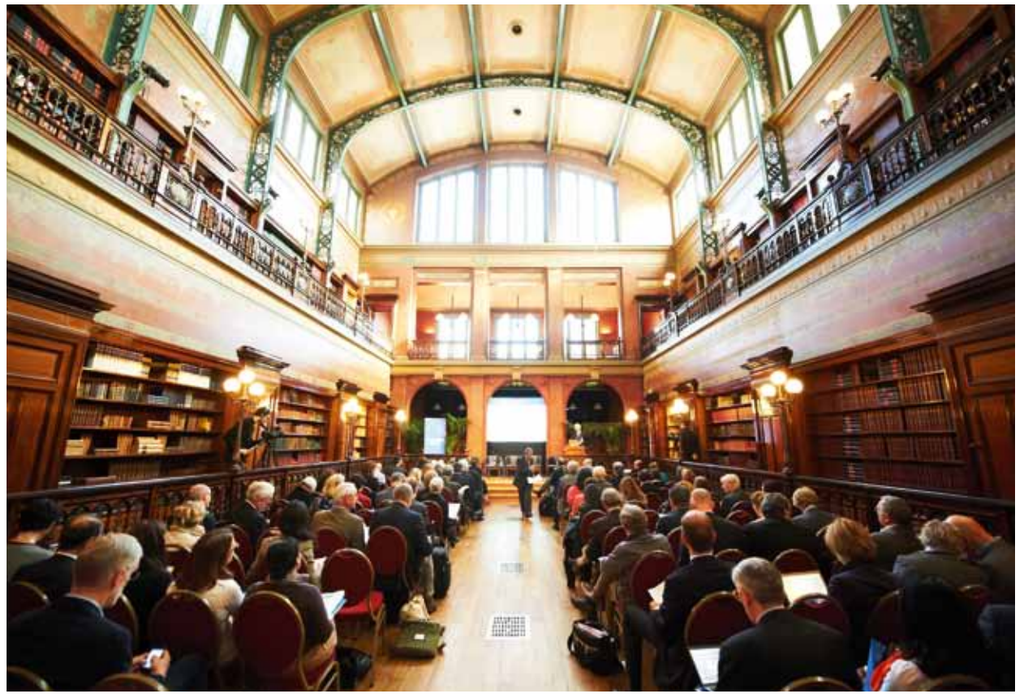
a 'European Council for Health Research', with a bottom-up structure led by top-level scientists, and incorporating all stakeholders, including patients to boost health research in Europe. This steering body should define research programmes to meet unmet medical needs and seek better co-ordination and strategic planning of research across Europe.
It is proposed that this can be achieved by jointly working with the European Commission and Member States through the 'Programme Committees', as well as encouraging the contribution of other science and technological fields to stimulate cross-talk and innovation, promote long-term collaborative initiatives, and ensure that advances in one clinical area benefit others.

It is hoped that a European Council for Health Research will be created under Horizon 2020, which is currently being reviewed by the national ministries and the European Parliament. Members of the European Parliament are favourable to the BioMed Alliance proposal: their amendments to the European Commission's proposal for Horizon 2020 advocate the need for a scientific-led steering board for health to foster co-ordination on health research.

What is needed to ensure that initiatives really make an impact in personalised medicine? Who should drive the personalised medicine agenda? These are all questions that still need to be answered and the conversation can continue through such a body, he concluded.

Summary

It was concluded that there is a high value in multidisciplinary and multi-stakeholder partnerships and networks at European level in helping pave the way for collaborative and co-ordinated initiatives to advance personalised cancer medicine for the benefit of patients. Long-term, structured initiatives both within and between countries can lead to time-saving as well as improved quality and outcomes of activities. An interesting consideration is the extension of existing successful national initiatives at European level.



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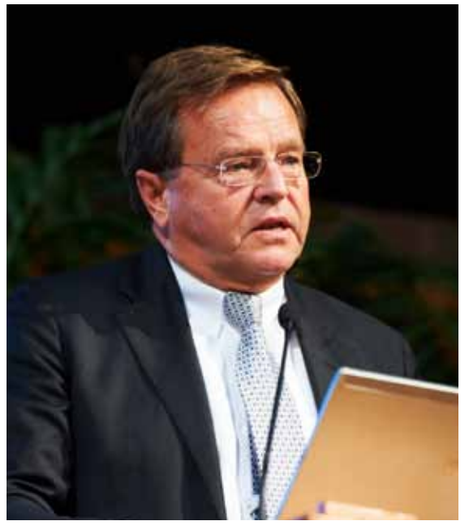
Closing Session



C. van de Velde

Concluding the day, Cornelis van de Velde said that many useful and relevant recommendations for accelerating the path towards personalised cancer medicine had been put forward.

There needs to be more discussion on the definition of the term 'personalised medicine' to ensure that everyone is clear as to its meaning. Collaboration with all stakeholders involved in personalised medicine needs to be promoted; better co-ordination with industry is needed, and patients should be partners; empowered and informed patients can make important partners to be relied on and are for sure essential in the further development of new treatments.

Ethical issues were discussed throughout the Forum, and it was clear that data protection and tissue storage issues need to be urgently addressed in order to accelerate progress on personalised medicine.

Furthermore, speakers pointed to the need for more attention to quality assurance in the implementation of new diagnostic tests in order to improve care. Multidisciplinary education will play an essential role as we move forward in this field and training of healthcare professionals should be prioritised.

In terms of investment, it was strongly recommended that public funding should be used to conduct the optimisation studies required to see how best to use therapies already in existence. Indeed, investment in this domain should not consider only drug trials but funding should also be allocated to radiation therapy and surgical oncology.

> ***"We must never forget that it is the patients we are here for"***
>
> (Birgitte Grube, President, EONS)

Finally, policymakers have a crucial role to play in ensuring that personalised medicine can fulfil its promise to patients and not only at the EU level: for truly practice-changing trials, both European and national government support is required.

Progress on all these issues will be discussed at the next multidisciplinary European Cancer Congress in Amsterdam, 27 September – 1 October 2013.

Programme

The Future of Personalised Cancer Medicine in Europe

8:30-9:00	Registration & Welcome Coffee
9:00 – 10:00	**OPENING SESSION**
9:00-9:10	***Welcome address*** Chairs: Cornelis J.H. van de Velde, ECCO President Julio E. Celis, Chair of ECCO Policy Committee
9:10-9:30	***Opening Speech*** Video address: Máire Geoghegan-Quinn European Commissioner for Research, Innovation and Science Speaker: Maria-Jose Vidal-Ragout, Head of Unit, Medical Research, DG Research and Innovation, European Commission
9:30-9:50	***Opening Lecture***: "Personalised Cancer Medicine – Defining the concept and state-of-the-art" Speaker: Alexander M.M. Eggermont, President, European Academy of Cancer Sciences and Director, Institut Gustave Roussy
9:50-10:00	*Questions and Answers*
10:00-10:30	**Networking Coffee Break**
10:30 – 12:30	**SESSION 1 – Key Issues in Personalised Cancer Medicine**
	Chair: Gordon McVie
10:30-10:50	***Towards Common Standards (Omics technology, bioinformatics, system biology, imaging, infrastructures)*** Speaker: Peter Lichter, Head of Department, Molecular Genetics, Cancer Research Centre (DKFZ), Heidelberg, Germany
10:50-11:10	***Towards a Faster Uptake in Clinical Practice*** Speaker: Martine Piccart, ECCO President-elect
11:10-11:30	***Regulatory Issues*** Speaker: Jonas Bergh, Karolinska Institute, Sweden
11:30-12:30	*Discussion*
12:30-13:30	**Networking Lunch**

13:30-15:30	**SESSION 2 – Key Issues in Personalised Cancer Medicine**
	Chair: Richard Sullivan
13:30-13:50	***Health Economics Issues*** Speaker: Bengt Jönsson, Professor in Health Economics, Stockholm School of Economics, Sweden
13:50-14:10	***Training of Healthcare Professionals*** Speaker: Angelo Paradiso, Giovanni Paolo II National Cancer Institute, Bari, Italy
14:10-14:30	***Educating Patients as Partners in Personalised Medicine*** Speaker: Jan Geissler, ECCO Patient Advisory Committee
14:30-15:30	*Discussion*
15:30 -15:45	**Networking Coffee Break**
15:45-17:00	**SESSION 3 – Oncopolicy 2020 - Personalised Cancer Medicine: The Way Forward**
	Chair: Ian Banks, ECCO Patient Advisory Committee
15:45-15:55	***EPAAC WP8: Towards Co-ordination of Cancer Research in Europe Public and Private Partnerships to Stimulate Drug Development Through Academic Clinical Resarch. From a National to a European Dimension*** Speaker: F. Calvo, Deputy General Director, INCa
15:55-16:05	***The German Consortium for Translational Cancer Research*** Speaker: Otmar D. Wiestler, Director, German Cancer research Centre (DKFZ), Heidelberg, Germany
16:05-16:15	***Rare Cancers Europe - A Case Study*** Speaker: Paolo Casali, Istituto Nazionale Tumori, Milan, Italy
16:15-16:25	***European Alliance for Personalised Medicine (EAPM)*** Speaker: Bernard Malavaud, EAPM
16:25-16:35	***Accelerating Europe's Health Research and Innovation Through Strategic, Scientific-Led Actions: The European Council for Health Research*** Speaker: Julio E. Celis, Vice-President, Alliance for Biomedical Research in Europe
16:35-17:00	*Discussion*
17:00-17:15	**CONCLUSIONS**

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